United States
Environmental Protection
Agency

Pesticides and
Toxic Substances
Enforcement Division

Washington, DC
20460

EPA

Federal Insecticide, Fungicide, and Rodenticide Act

Compliance/Enforcement Guidance Manual

Policy Compendium

Volume 3: FIFRA Compliance Monitoring Strategies

Table of Contents

Volume 3 of the FIFRA Compliance Enforcement Guidance Manual Policy Compendium contains the enforcement strategies issued by the Office of Compliance Monitoring that are currently in effect. The Table of Contents of the remaining volumes, FIFRA miscellaneous sources, and a list of obsolete documents are contained in the Appendices.

Any questions or comments concerning these documents should be addressed to:

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Volume 3: Enforcement Strategies (continued)

Volume 3: Enforcement Strategies (continued)

Volume 3: Enforcement Strategies (continued)

ENFORCEMENT FACTS AND STRATEGY

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COMPLIANCE MONITORING PROCEDURES

WATER PURIFICATION DEVICES

October 1980

Pesticides & Toxic Substances
Enforcement Division
Office of Enforcement
U. S. Environmental Protection Agency
Washington, D. C. 20460

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Strategy Overview

Water purifiers are products which are intended to render [illegible]ter safe to drink by removing pests (microorganisms) through [illegible] chemical or physical means. Water purification devices eliminate pests (microorganisms) from water by using a physical method such as ultraviolet light, filtration, or other non-chemical means. To qualify as a "purifier", the product must remove all disease causing microorganisms from the water, including bacteria, viruses, and cysts. Since devices are not subject to the registration requirements under FIFRA, regulation of them falls entirely on the Office of Enforcement, which must determine if they comply with the other requirements of the Federal Insecticide, Fungicide, and Rodenticide Act to which they are subject. The key to the compliance determination will be verification of label claims through a program of product testing.

The testing program will examine the purifier claim used by many products. If a product claims to be a purifier but it does not remove test organisms in the efficacy test, the product is deemed to be misbranded and subject to enforcement action under FIFRA, including Stop Sale Orders to remove the product from the marketplace. The testing scheme designed for this program consists of two phases. Phase I tests the ability of the products to remove environmental coliforms. Phase II tests specific bacterial, viral and protozoan pathogens likely to be found in water such as Pseudomonas aerogenosa, Poliovirus and Giardia lamblia. To substantiate a purifier claim, a product must pass both phases. Thus, if it fails Phase I, enforcement actions will be taken, [illegible]t spending time and money on the Phase II tests.

The goal of the program is to remove from the market those products which do not purify water to protect the health of persons who might rely on the products for safe drinking water.

Background

Water purifiers are a class of products which are intended to render unprocessed water safe for drinking. They may be used in homes which obtain water from wells, by backpackers to treat lake and stream water, by persons whose community water supply may be temporarily contaminated, and by vacationers who may encounter water of questionable quality. Consequently, failure of a product to adequately purify water may present a serious public health hazard.

Because purification of water involves the killing of microorganisms, which are defined as pests in Section 2 of FIFRA, these products are regulated by the Environmental Protection Agency. There are two kinds of water purifiers: Those which employ a chemical means to purify water, and those which use a physical method. While both types are subject to the provisions of FIFRA, including but not limited to, Sections 7, 8, and 12 as well as Section 2(p) and (q), only purifiers utilizing a chemical must obtain product registration as prescribed by Section 3 of the Act. Under Section 25(c)(4) of FIFRA the Administrator is authorized to declare a device subject to the Act. Water Purification devices are among those devices subject to the Act (see Fed. Reg. Vol. 41, No. 225, page 51065, November 19, 1976).

The registration process for chemical purifiers is central to the Agency's ability to evaluate the risks and benefits presented by the product. If data submitted to the Agency does not support the label claims made for the chemical purifier, the Agency will not register the product. Enforcement of the labeling and misbranding provisions of FIFRA is very straightforward for chemical-based water purifiers. If a manufacturer makes claims on a label that do not appear on the label accepted by the Agency at the time of registration, then the manufacturer has violated FIFRA by "making claims in excess of those accepted at the time of registration," which is a misbranding violation.

Water purifiers which use a physical means of microorganism elimination are devices, and are therefore subject to the same requirements of FIFRA as the chemical water purifiers except that they are exempt from product registration requirements. Consequently, since a premarket label review based on test data was not performed, products may appear on the market with label claims which falsely exaggerate the capabilities of the product. If the claims are found to be "false or misleading," the product is misbranded as defined in FIFRA Section 2(q) and subject to enforcement action.

The EPA cannot require the manufacturer to substantiate the claims made for the product, so to evaluate the performance of such devices, EPA must sample and test the devices. The results of laboratory analysis will document or call into question claims made on the labeling. The test results will also form the basis for enforcement actions brought against a manufacturer making false or misleading claims.

Regulated Industry

Water purification device producers are generally small businesses, although a few large companies are also in the market. There are approximately 50 purification devices now on the market. Producers must register their establishments, but there may be some producers who have not done this.

Almost any available physical method that might kill a microorganism is employed in at least one product. The most popular are ultraviolet (UV) light, micropore filtration, chlorine generators, and ozone generators. Ultrasound, reverse osmosis, electrolysis, and distillation are other known methods used by purification devices (See Appendix I). These types of devices are called "point-of-use" treatment products, since the water is treated immediately before use. "Small systems" treatment products treat water intended for use in small communities -- generally several taps and a distribution network are part of the system. "Small systems" treatment units are also regulated under FIFRA but the quality of the water produced is regulated by the Safe Drinking Water Act. Since the public is protected under another Act and the resources of the Office of Enforcement are limited, these products will not be tested as part of this program. However, if such products are found to be ineffective, they may be subject to enforcement actions under FIFRA.

Application of FIFRA

FIFRA and its implementing regulations clearly apply to devices. The requirements of those regulations are outlined below. State laws are often ambiguous where devices are concerned.

Since it is desirable that Stop Sale Use or Removal Orders have nation-wide applicability, this policy is to be administered as a federal program. State inspectors who may collect evidence will turn that evidence over to the appropriate Regional office for enforcement actions.

Requirements of FIFRA

Producers of water purification devices are regulated under FIFRA, the applicable sections include but are not limited to §2(p) and (q), 7, 8 and 12 of FIFRA (see 40 CFR 162.10 and 41 Federal Register 51065, November 19, 1976). Based on these sections, the water purification devices are subject to the following requirements.

- Establishment Registration (Section 7)
  - Registration of all producer establishments; establishment registration number on all products
  - Annual reporting of products

- Books and Records (Section 8)
  - Must keep records of brand name of device
  - Must keep records of production data
  - Must keep records of distribution
  - Must allow an authorized Inspector to examine these records

- Product must be properly labeled (Section 2 (p); 40 CFR 162.10)
  - Must bear the Establishment Registration Number
  - Must include warning and caution statements
  - Must not be an imitation of other products

- Product must not be misbranded (Section 2(q)). A product may be misbranded if its label:
  - Lacks adequate directions for use
  - Lacks adequate warning or caution statements
  - Bears a statement which is false or misleading in any particular
  - Bears a false or misleading statement concerning the effectiveness of a product
  - Bears a statement which directly or indirectly implies that the device is recommended or endorsed by any agency of the Federal Government

For greater detail, consult 41 Federal Register 51065, November 19, 1976. All requirements of device producers described in that document apply to producers of water purification devices.

FIFRA Enforcement Authorities

Failure to adhere to any of the above requirements of FIFRA may be an unlawful act under §12 of FIFRA as follows:

- Failure to register the establishment [Section 12(a)(2)(K)]
- Failure to keep books and records or to permit inspection of books and records [Section 12 (a)(2)(B)]
- Misbranding [Section 12 (a)(1)(F)]
- Failure to file production reports [Section 12 (a)(1)(N)]

Remedies

General

FIFRA provides several remedies for violations of its provisions. If the purifier efficacy claims are found to be false, a serious public health hazard can exist, and a Stop Sale, Use, or Removal Order will be issued immediately to limit the availability of the product. Penalties for other violations are to be determined through application of the general FIFRA penalty policy and matrix (39 Federal Register 2771, July 31, 1974). Civil penalties for misbranding violations, which are applied in addition to Stop Sale Orders, are to be determined by consulting the penalty matrix for Ineffective Water Purifiers, below. If there are severely misleading claims, particularly in advertising material, the case may be referred to the Federal Trade Commission through headquarters.

Misbranding Purifier Claims

Water Purification Devices which fail the purifier efficacy test are misbranded. A Stop Sale, Use or Removal Order will be issued to the manufacturer of any product which fails the efficacy test. The Stop Sale is issued because of the health hazard presented by the continued sale or use of the product, and will not be lifted until the product comes into compliance with the Act.

In addition to the Stop Sale Order, a civil penalty will be assessed as described below. The Civil Penalty must be assessed within fourteen days of the Stop Sale Order. 1/

(This is consistent with the penalties for similar violations in the current FIFRA Penalty Matrix.)

Ineffective Water Purifiers

	I	II	III	IV	V
1. Category A	5000	5000	5000	5000	5000
2. Category B	1000	1750	2500	3200	4500

1/ See A. E. Conroy's Memorandum of September 12, 1980, "Interim Final Regulation Section 13, FIFRA."

Category A - Products in this category failed Phase I of the testing protocol (see Strategy Overview page 1). Phase I tests the ability of the product to remove a known group of pathogens which commonly occur in water, so products which fail are presenting the consumer with a potentially severe health hazard.

Category B - Products in this category passed Phase I but failed Phase II. Since viruses and cysts are pathogens as well as bacteria, a health hazard is also presented by these products, although the hazard is somewhat reduced by the removal of the coliform bacteria.

Some products in this category nearly passed the efficacy test. It may be that a slight change to either the label instructions or the product itself would bring the product into compliance with the Act. 2/ A Stop Sale Order would be issued in such cases, but it may be lifted when the manufacturer agrees that he will immediately incorporate those changes which appear to have a reasonable likelihood of remedying the problem. The "modified" device is, of course, subject to testing.

Recall

Another remedy that is used either as an alternative to a civil proceeding or in addition to one is a recall action. Recalls may be voluntary or compulsory. If this remedy is employed, the guidance in Section 12 of the Case Proceeding Manual should be followed.

2/ For example, UV light kills viruses and bacteria but may permit G. lamblia cysts to persist in water. Since the cysts are relatively large, a pre-filter on the system could predictably remove them. Another example would be a chlorine generator whose directions do not explicitly indicate the concentration and contact time that are necessary for chlorine to effectively disinfect water.

Other Violations of FIFRA

As described in the section on the Application of FIFRA, the Agency has authority to take enforcement action when provisions of FIFRA are violated. Violations which do not involve the purification claim (e.g. violation of Sections 2(p) and (q), 7 and 8) are also to be handled in the regions according to current enforcement policy.

If enforcement actions based on violations of FIFRA which do not include the efficacy of the product are taken before the efficacy tests are complete, the complaint or warning should clearly state that additional action may be taken if the results of the efficacy test should prove to be unsatisfactory. We recommend that all civil actions be initiated at the same time.

Criminal Citations

Willful violations of FIFRA may justify the filing of criminal charges against a manufacturer. PTSED concurrence would be required for criminal actions.

Given below are procedures for the compliance monitoring aspects of the program with description of responsibilities and data flow

I. Guidelines for Selection of Devices To Be Tested

- CMB-PTSD will select the devices to be tested and determine the order of testing based on criteria noted below.
- Only "point-of-use" devices will be tested. These devices consist of those intended for use in a single family household, camper, boat, etc.
- Two categories will be established to help determine the order of testing.
  - The first category, which will be given the highest priority, will contain those products for which there is reason to believe that a violation has occured. This will be determined by consumer or competitor complaints, scientific judgement based on the study of product design, and failure of the device in similar tests.
  - The second category will contain all other products. The order of testing for this category will be determined by such neutral criteria as the number produced and distributed, and the availability of testing space. If production data is not available for all devices, the order of testing will be determined by random selection.
- CMB-PTSD will prepare the sample request forms and forward them to the appropriate Region for collection.

II. Inspection

- At the opening conference:
  - The inspector should request efficacy data from the manufacturer pertaining to his/her device(s). The manufacturer cannot however, be required to submit this data.
  - The inspector should advise the manufacturer that his/her product is not being singled out for attention. The collection of his/her device is part of a nationwide effort to test water purification devices.

- Inspection of books and records will be performed in accordance with the Pesticides Inspection Manual for the purpose of determining compliance with the record keeping requirements (§8).

- An official sample of the device will be collected at the producer establishment according to the Pesticides Inspection Manual. The official sample will include labeling (including instructions for installation) and all other documentation as required (Notice of Inspection, Receipt for Samples, etc.).

  - "Optional Equipment", such as a pre-filter, which is required for the quality of water the laboratory will be using should also be collected. Specific guidance will be provided on the sample request form.

  - Because many of these devices are very expensive, the inspector should make an attempt to have the manufacturer donate the device. Many manufacturers have already indicated a desire to have their devices tested, and a willingness to donate them for this purpose.

  - If the manufacturer refuses to donate the device, the inspector should offer to purchase it.

  - Two samples of the device will be collected unless the cost of the device exceeds $700.

- If the manufacturer requests to install the device himself, arrangements with the testing laboratory should be made through CMB-PTSED.

- If entry is denied:

  - The inspector should follow established procedures for denied entry. 3/

  - If a distributor of the product can be located through reviewing the advertising or contacting a local trade association, then a marketplace sample can be obtained.

3/ Barlow's Decision: Guidance to Regional Personnel: Conduct of Inspections after the Barlow's Decision (April 11, 1979)

- If a product sample obtained from the marketplace fails the efficacy tests, a warrant to conduct an in-depth books and records inspection may be obtained. This will be necessary if production and distribution data is needed.

III. Post Inspection

- When the requested sample has been collected, the "PRD Acknowledgment" copy of the sample request form will be forwarded to CMB-PTSED with the "Sample Identification" section completed.

- All non-confidential information obtained by the inspector will be placed in the enforcement jacket and forwarded to the testing laboratory along with the device(s).

  - A second copy of the device's labeling is to be assembled by the inspector and forwarded to CMB-PTSED for contract management purposes.

IV. Testing

- Efficacy testing will be performed by the State of New York, Department of Health, Division of Laboratories and Research.

- Each device will be examined when received by the laboratory for any possible defects resulting from shipment.

- Chain of custody procedures will be followed for all official samples.

- The device will be subjected to a series of microbial challenges until it fails or exhausts the series.

  - All failures will be confirmed by a second test

- A second device will be tested if the first one fails.

  - Enforcement action will not be initiated unless both samples fail

- The testing laboratory will be subjected to a Quality Assurance (QA) Performance Audit and a QA Systems Audit. These audits will be initiated by PTSED.

- The testing laboratory will submit to CMB-PTSED a QA Program and Project Plan.

- CMB-PTSED is to be kept informed of the testing status of the device. This information is to include:

  - date the official sample was received

  - date testing was initiated and completed

- When testing is completed, the laboratory will review the test results and determine if the device has failed efficacy testing. All test results will be placed in the device's enforcement jacket.

  - All enforcement jackets will go directly to the appropriate Region from the testing laboratory for review to determine violations, and to initiate enforcement action.

  - A copy of the test results will be forwarded to CMB-PTSED from the testing laboratory to monitor the contract.

- The testing laboratory will retain all devices for which violations exist until enforcement action is completed or the case is placed in permanent abeyance.

V. Pesticide Enforcement Management System (PEMS)

The Regions will keep PTSED informed as to the enforcement status of the device by entering relevant information, such as the date they issued a particular order or penalty, the results of the enforcement action, etc. to the PEMS Computer system.

VI. Outreach

Many manufacturers of water purification devices do not appear to be aware of Section 7 establishment registration requirements. To help notify industry of these requirements, a letter to potential manufacturers and their trade associations has been prepared (Appendix III-B)

The responses from this letter will allow the Agency to compile an accurate list of manufacturers, their products, and production and distribution data.

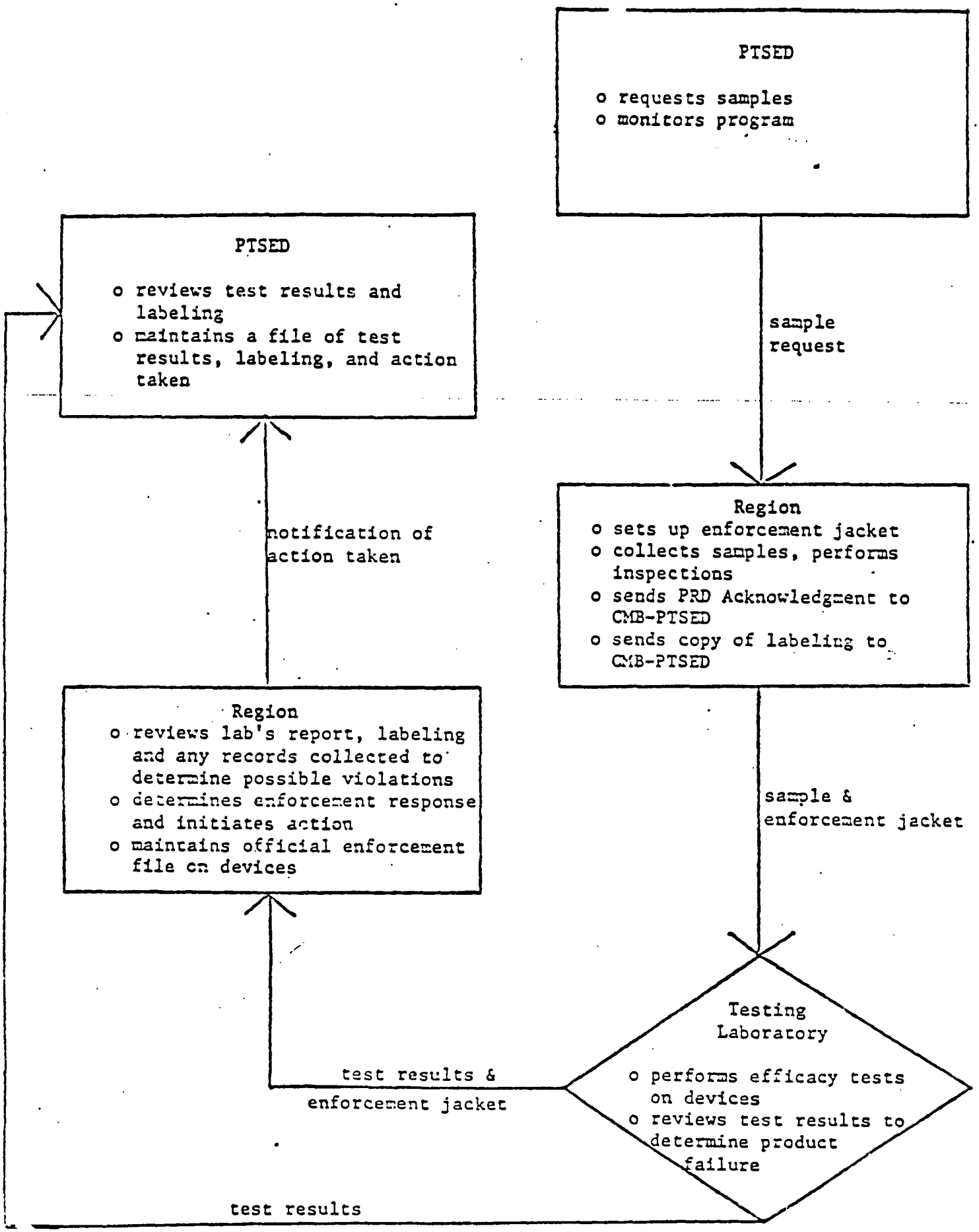
A press release has also been prepared announcing the program to the public and notifying industry of the establishment registration requirements (Appendix III-A)

As a result of this outreach program, it is anticipated that the public and the industry will report the existence of various companies which they suspect are not in compliance with the Act (establishments not registered, products are ineffective, etc.). All information obtained by the Regions should be forwarded to CMB-PTSED, Compliance Monitoring Coordinator.

Microbiological data generated by this program will be submitted to the Journal of Applied and Environmental Microbiology for publication after the enforcement cases are completed. The results of the tests may also be presented at the 1982 Annual Meetings of the American Society for Microbiology.

The results of this program are also of interest to the National Sanitation Foundation and D-19, Committee on Water Microbiology of the American Society for Testing Materials. It is possible that presentations will be made to these groups.

Regions may release information concerning individual cases in the same manner that such information is handled in other civil proceedings.


PTSED
o requests samples
o monitors program
sample request
Region
o sets up enforcement jacket
o collects samples, performs inspections
o sends PRD Acknowledgment to CMB-PTSED
o sends copy of labeling to CMB-PTSED
sample & enforcement jacket
Testing Laboratory
o performs efficacy tests on devices
o reviews test results to determine product failure
test results & enforcement jacket
Region
o reviews lab's report, labeling and any records collected to determine possible violations
o determines enforcement response and initiates action
o maintains official enforcement file on devices
notification of action taken
PTSED
o reviews test results and labeling
o maintains a file of test results, labeling, and action taken
test results

CASE DEVELOPMENT

Case development will proceed in accordance with the Case Proceedings Manual. The Regions are advised to avail themselves of the option of Enforcement Review through headquarters. The label review will be done by the Registration Division using the product performance criteria developed for evaluating both chemical and physical water purifiers and the data on product performance from the efficacy test.

Please note that a civil complaint should be issued along with the Stop Sale, Use or Removal Order when the product fails the efficacy tests.

ALLOCATION OF RESPONSIBILITIES

This chart is a guide to the responsibilities for the different tasks in the water purification device enforcement program.

Headquarters (PTSED)	Regions
1. Identification of Purifier Devices • Information sources: ERSS, consumer queries, competitor complaints, advertising, other.	1. Identification of Purifier Devices • Regions submit information on new products they become aware of to Compliance Monitoring Branch
2. Selection of Devices to be Tested • Compliance Monitoring Branch updates list of known devices and selects devices. • Policy & Strategy Branch will evaluate Neutral Inspection Scheme. All known devices will be tested.	
Allocation of Inspections • Compliance Monitoring Branch determines names and locations of device producer establishments; assigns inspections to appropriate Regions; prepares sample request forms and sends them to Regions.	
	4. Inspections and Sample Collection • Regions assign inspectors to conduct establishment and/or books and records inspections and product sample and documentary material collection. (Inspections may be made by Federal or State inspectors.) • Inspector performs inspection according to FIFRA procedures and guidance; special instructions may appear on the sample request form.

Headquarters (PTSED)	Region
	• Inspector ships sample(s) and one set of documentary material to testing laboratory; sends copy of documentary sample to headquarters.
5. Testing of Devices • Laboratory (Environmental Health Center, State of New York, Department of Health, Albany, N.Y.) performs efficacy test according to PTSED approved protocol; furnishes results etc. to PTSED and the Region. (See N.B. below.) The lab will keep the device until litigation is completed.	
6. Determination of Violations • The testing laboratory indicates whether the product passed or failed the efficacy test.	6. Determination of Violations • Region reviews inspection data and its set of documentary material to determine existence of violations under FIFRA Sections 7, 8, or 12 as well as well as Section 2(q) misbranding violations. • The regions are strongly advised, particularly early in the program to send the jacket to headquarters for a pesticide Enforcement Review. The reviewers compare testing results against label and advertising claims to determine if purifier claims are false and misleading (misbranding violation). N.B. The enforcement jacket accompanies the sample to the laboratory. The laboratory inserts the data from the testing program and forwards the jacket to Regions which may forward them to headquarters for Enforcement Review; the jacket and the review will then be sent back to the appropriate Region.

Headquarters (PTSED)	Regions
	• Based on the laboratory's determination, the Regions may initiate action on the purifier claim. This should not preclude discussion of the case with headquarters.
7. Determination of Appropriate Enforcement Response • If misbranding violation based on the purifier claim has occurred, headquarters may provide additional information based on historical files. Appropriate records and recommendations will be forwarded to the Regions. If advertising is seriously misleading, a referral to the Federal Trade Commission will also be made.	7. Determination of Appropriate Enforcement Response • A Stop Sale, Use or Removal Order (SSURO) will be issued for all products which fail efficacy test. A civil penalty is also assessed. • Region applies general FIFRA civil penalty policy and matrix to determine appropriate level of actions for all violations.
8. Enforcement Actions, Litigation, Settlement • PTSED may, under exceptional circumstances, initiate enforcement actions. • Sections of the agreements which involve label or product improvements to bring the product into compliance are to be sent to PTSED for concurrence.	8. Enforcement Actions, Litigation, Settlement • Regions will initiate enforcement actions (warning letters, civil complaints, SSURO's). • Region may obtain expert testimony from headquarters reviewers or laboratory scientists.
9. Completed Case Files • PTSED will maintain a file of all test data results and copies of Final Orders for use in documenting the possible need for regulatory or legislative changes.	9. Completed Case Files • The Region should retain completed case files, including all relevant documents. • A copy of the Final Order should be sent to PTSED.

Headquarters (PTSED)	Regions
10. Publicity • Start of Program - Press Release - Letters to manufacturers and trade associations. • Release of data generated by testing program. (Laboratory and Compliance Monitoring Branch) - Publication of Scientific data in appropriate journals - Presentation in proper forums. • Consumer Information determined as a result of the whole program. - number distributed - type of use/risk factor - conclusion to be drawn from the program.	10. Publicity • Release of information about individual cases in the same manner as other pesticide civil cases.

Enforcement Facts and Strategy

TYPES OF PURIFIER PRODUCTS

Water purification devices employ a variety of techniques to purify water. The most common techniques are:

- Ultraviolet light - Light of wavelengths around 260nm damages the DNA of exposed organisms. If the exposure time is sufficient, the organisms are no longer viable. Light may also be absorbed by the bonds of certain complex organic molecules which could result in photolysis of those molecules. Efficacy of this method depends heavily on the engineering of the whole system. The protocols used by the Canadians are the basis of the screening phase of the US EPA Water Purification Device Testing Protocol. Duplicative verification of results on the same types of products used to develop the protocol is useful to the U.S. and Canadian Enforcement Programs.

- Submicron Filtration - Some products filter water through "sieves" whose pores are about 0.4 micron. Since a typical bacterium is 1 micron in diameter, these products frequently make purifier claims. Unfortunately, a very large virus would be only 0.1 micron in diameter and some bacteria are capable of changing shape. The filter would consequently not work.

- Ultrasound - High frequency sound causes pulse waves to form in water. The rapid changes in water pressure result in "shearing forces" which cause bacterial cell walls to break. This technique is used in a research setting to avoid chemical denaturing of macromolecules and cellular organelles. Whether it would be efficent on the scale necessary to purify water is unknown.

- Chlorine generators - These devices electrolyse salt (NaCl) to form chlorine. The chlorine acts as a disinfectant to purify water. These products are devices and not chemical pesticides because the product which enters channels of trade is not a chemical. The consumer generates the pesticide at the site of use for his own use and not for sale or distribution. Unfortunately, since there has been virtually no regulation of these products, the label directions may not be sufficiently explicit to ensure efficacy of the product. Chlorine levels can be tested using a simple test kit and the presence of adequate levels of free chlorine for a minimum contact time would ensure a reasonably pure water.

- Ozone generators - Oxygen from air is electrically ionized to form ozone, a powerful oxidizing agent and disinfectant. Unlike chlorine, ozone does not persist (it rapidly decomposes to oxygen) and cannot be easily measured. It is difficult for consumers to know if the device is actually working or if some minor product failure has resulted in lower levels of ozone production. Installation is complex - often done by the seller - and cheaper products may be unsafe electrically.

- Electric current - Presumably the microorganisms are electrocuted by the passage of an electric current through a water reservoir.

- Distillers - These products condense steam from boiled water.

Microorganisms are killed by boiling. Distillation can concentrate certain organic compounds.

- Reverse Osmosis - High quality organic polymer membranes selectively filter water. This product is similar in principle to a kidney dialysis machine. It is a potentialy workable means of purifying water since the pores of the membrane act as a molecular sieve. Complex organic molecules are prevented from crossing over to the "pure water" side of the membrane. Viruses, bacteria and protozoans would also be retained on the "impure side". Maintenance of these products is important. A damaged membrane would not purify water. There is some indication that old membranes may themselves be colonzied by some forms of bacteria which use the organic polymer as a food source.

Two types of products which are labeled as water purifers will not be tested:

- Potable water "purifers" - These products use the term purifier on their labeling but are clearly intended for use on water that is already potable (i.e., faucet "purifiers" for use on municipally treated water). Manufacturers of these products should be warned that use of the term "purifier" is for products which process untreated water. (See 41 Federal Register 32778, August 5, 1976) Other enforcement actions may also be necessary.

- Large purifiers which treat water for groups of twenty-five persons or more. These products are regulated by FIFRA. However, the quality of the water is requlated by the Safe Drinking Water Act. Since the public is protected by another act and the resources of the Office of Enforcement are limited, these products will not be included in this program. (These are also known as "small systems" purifiers.)

Legal Definitions, "Purifier" and "Device

Since the enforcement strategy and penalty policy rests on the definitions of "water purifer" and "devices," the following material is attached to support the definitions used in this document:

A. Purifier:

1. FTC ruling in the matter of Sibco Products Company Inc., Et Al. (68 FTC (1965) pg. 917).

2. Guidelines for Registering Pesticide Products in the United States Section G: Product Performance Standards for Water Purification Devices.

3. EPA ruling In re Contact Industries, Inc., I.F. & R. Docket No. II-?86 (1978) pg. 6.

B. Devices

Pest Contol Devices and Device Producers: Consolidation and Clarification of Requirements. Federal Register, vol. 41, no. 225 (11/19/1976).

... Excerpts from ... Sibco Products Co., Inc., et al. (Full text available from headquarters.)

IN THE MATTER OF

SIBCO PRODUCTS COMPANY, INC., ET AL.

ORDER, OPINION, ETC., IN REGARD TO THE ALLEGED VIOLATION OF THE FEDERAL TRADE COMMISSION ACT

Docket 8628. Complaint, June 8, 1964—Decision, Nov. 22, 1965

Order requiring a New Jersey manufacturer of water filtrators to cease misrepresenting the effectiveness and capability of its water filtration units and deceptively guaranteeing the performance of such units.

2. Implied Representations Respecting Micro-organisms and Viruses

Complaint counsel charges that by the use of such words as "pure," "purify" and "clean" and the phrase "pure drinking and cooking water are vital to the health of your family * * *" in connection with the unit, respondents are implicitly representing that disease-carrying water will be made safe for drinking through the use of the Sibco "Purifier."

Respondents admit that the unit will not kill micro-organisms but maintain that the words quoted above do not constitute an implicit representation to this effect. Moreover, respondents alleged in their answer that the literature accompanying the unit contains a specific disclaimer that it does not kill bacteria.

We conclude from the evidence that respondents' water purifier does not in fact remove water-borne micro-organisms or viruses capable of causing diseases. Moreover, we hold that the statements in respondents' advertisements and form letters—that their unit will "purify and filter" water, will ensure "clean" water, will correct "bad" water, will give "pure drinking and cooking water" which is "vital to the health of your family" and will filter "impurities" found in the consumer's water supply—constitute representations that respondents' unit will remove bacteria and other disease-causing germs. We find that a potential purchaser who has or believes he has or may have contaminated water could easily be led by statements of the type quoted above to believe that respondents' unit will make his water potable. *Giant Foods, Inc.* v. *F.T.C.* 332 F. 2d 977 (1963).

With respect to the disclaimer used by respondents in one brochure, we have no way of knowing from the evidence whether all of respondents' prospective customers actually received this pamphlet. Furthermore, this disclaimer was not inserted until respondents' precomplaint negotiations with complaint counsel. Finally, the presence of this disclaimer in one of respondents' brochures does not negate the contrary impression in the affirmative representations contained in their advertisements and sales literature as to the purifying qualities of their unit.

elements: representative levels of organic and inorganic soil contamination; various water temperatures; the specific dosage and exposure period recommended for the proposed product; a variety of test microorganisms representative of the target pests to be controlled; and quantitative determination of the level of microbial contamination of the water before and after treatment.

(ii) Performance standard. The treatment must eliminate all test microorganisms from the water.

(3) Water treatment units. (i) Water purifier units. Any unit intended for the treatment of raw water to eliminate the potential health hazard posed by microorganisms is identified as a water purifier. The unit may rely on physical filtration (pesticidal device), or chemical treatment (pesticide), or a combination thereof, to achieve the intended purpose of purifying microbiologically non-potable water by eliminating water-borne pathogens in the water itself. Those units, such as submicron membranes and absolute filters, which rely solely on a physical means for removal of microorganisms from water, are identified under the Act as devices, and are subject to regulation but not registration. The test requirements indicated below are for the units containing an antimicrobial agent.

(A) Test standard. Controlled simulated-use studies for the water purifier unit must be conducted under conditions representing actual use employing a defined raw water source containing a high level of microbiological pollution. The test design will vary

with different types of units and patterns of use, but must include such basic elements as: representative levels of organic and inorganic soil contamination; various water temperatures; documentation of the antimicrobial concentration found in the test system; and quantitative determinations of the microbial contamination level of the water before and after passage through the unit. The duration of effectiveness or effective capacity of the unit before a replacement is necessary must be documented.

(B) Performance standard. The treatment must eliminate the microbial pollution in the raw water.

(ii) Potable water treatment unit. Any unit intended for physical and/or chemical treatment of microbiologically potable water from a municipal treatment facility to remove undesirable tastes odors, chemicals, or other aesthetically objectionable properties is identified as a potable water treatment unit. A substrate such as activated charcoal (with or without a bacteriostatic agent) is incorporated into the unit for this terminal processing treatment of potable water prior to consumption. Since the requirements of the Safe Drinking Water Act do permit municipally-treated drinking water to contain a limited number of harmless "saprophytic" bacteria which are commonly recognized contaminants of water, an antimicrobial agent is sometimes incorporated in a potable water treatment unit to provide bacteriostatic activity against these contaminants. Only potable water treatment units containing a bacteriostatic agent are under the purview of the Act.

Exerpt from In re Contact Industries, Inc. (pg. 6-8). (Full text of document available from headquarters.)

ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE REGIONAL ADMINISTRATOR

In re	)	
	)	
Contact Industries, Inc.,	)	I.F. & R. Docket No. II-186C
	)	
Respondent	)	Initial Decision

The term purifier connotes a product which eliminates impurities and polluting matter. We are in agreement with the conclusion of Complainant's expert witness that the "word purifier is sufficiently broad to include ridding the air of objectionables, including micro-organisms as they would exist." An air purifier would therefore cleanse the air of air-borne bacteria, virus, and fungi particles. If Respondent had intended for the product to be understood to be merely an air freshener or deodorizer, the label could have contained the term air freshener (cf. Respondent's Ex. 7) or been limited to the claim that the product was an industrial odor absorbent and not also a glycolized air purifier. In fact, the latter phrase would be somewhat redundant in the context in which it is employed on the label if all that was intended thereby was to inform the consumer that the product functions as an air freshener. As indicated by Complainant's expert witness, the term air purifier especially when

taken together with the word "Sanicide" on the label would indicate that the product is intended to rid the air of germs, that is, bacteria or viruses.

"Sanicide" is printed in bold-face, conspicuous type on the front of the label. The word also appears at the top of the back of the label in type which is in larger and bolder print than all other words on that side of the label. It is clear that the word "Sanicide" is meant to provide the most conspicuous reference to the product.

"Sanicide" implies both a sanitizing and a killing action or, at the least, a killing action. Sanitize means to free from dirt, germs, etc., as by cleaning or sterilizing. The suffix -cide means killer or killing. See Webster's Third New International Dictionary (1966). A consumer would, we believe, recognize the meaning of the suffix -cide as is evidenced by the common usage of words such as homicide, pesticide, and insecticide.

In interpreting broad remedial legislation, the consumer is not assumed to be an expert or one possessing special knowledge or ability, and includes "the ignorant, the unthinking, and the credulous." United States v. An Article. . .Consisting of 216 Cartoned Bottles, supra at p. 740 and cases cited therein; United States v. An Article of Drug. . .47 Shipping Cartons. . ., 331 F.Supp. 912, 917 (D. Md. 1971). Nor can we assume that the buying public will exercise great selectivity and caution in what they choose to believe of what they

read. United States v. Articles of Drug, Etc., 263 F.Supp. 212 (D. Neb. 1967). Cf. Helbros Watch Company v. Federal Trade Commission, 310 F.2d 868, , 869 (D.C. Cir. 1962), cert. denied 372 U.S. 976 (1962), rehearing denied 374 U.S. 857 (1963), and cases cited therein. A consumer would be justified in believing that the product he purchased had the capability of both cleansing the area sprayed (sanitizing) and killing microorganisms present in the area sprayed. This is especially so when the term "Sanicide" is read in conjunction with representations that the product is an air purifier or a glycolized air purifier. Certainly, the use of the prefix sani- with the suffix -cide has greater significance than the use of that prefix in other contexts disclosed in the record.

Antimicrobial agents are specifically included as one of the classes of sanitizers or pesticides subject to registration under the act. (See section 162.3(ff) of the regulations (40 CFR 162.3(ff))). The claim that the product Superior Sanicide Air Purifier is an air purifier when read in conjunction with the word "Sanicide" would indicate that the product is indeed an antimicrobial agent "intended to reduce the number of living bacteria or viable virus particles on inanimate surfaces, in water, or in air", in this case. See 40 CFR 162.3(ff)(2)(i)(B) (Emphasis supplied).[1/] Thus, representations made

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1/ Microorganisms, including but not limited to algae, fungi, and bacteria, and viruses have been declared by the Administrator to be pests when they exist under circumstances that make them deleterious to man or the environment (See 40 CFR 162.14(b)(4) and (5)).

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

JUN 8 1981

OFFICE OF ENFORCEMENT

MEMORANDUM

SUBJECT: Child Resistant Packaging Requirements for Pesticides - Enforcement Strategy and Penalty Policy

TO: Enforcement Division Directors
Pesticide Branch Chiefs

On March 9, 1979, the Agency published a final rule which requires certain pesticides labeled for residential use to be packaged in Child Resistant Packaging (CRP) if released for shipment on or after March 9, 1981.

The CRP enforcement strategy document, which is attached, stipulates that states operating under grants will be responsible for conducting inspections to determine compliance with the CRP requirements. This activity should be incorporated into their routine establishment inspection program. The regions will be responsible for coordinating the program and initiating enforcement actions for CRP violations with PTSED's concurrence. The reasons for this are: 1) violations of the CRP requirements are not violations of pesticide statutes in many states, and 2) a need for close coordination with the Office of Pesticide Programs during the initial stages of the program.

The strategy document should be distributed to states with a cover letter from the appropriate office within your region explaining the specifics of the program.

If you have comments or questions on the strategy document, please contact Phyllis Flaherty (755-0970) of my staff.

I am also attaching an amendment to the Guidelines for Assessing Civil Penalties pursuant to FIFRA. This amendment adds violations of the CRP regulation to the Civil Penalty Matrix and provides guidance on appropriate enforcement actions for CRP violations.

Comments or questions on the amendment should be addressed to Patricia Mott (755-9404) of my staff.

Also attached are copies of the applicable Federal Register notices.

A. E. Conroy II

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

Attachments

STRATEGY FOR THE ENFORCEMENT OF THE CHILD RESISTANT PACKAGING REGULATION UNDER FIFRA

OVERVIEW

REQUIREMENTS OF THE RULE

- Applicability
- Exceptions
- Exemptions
- Specific Requirements

REGULATED INDUSTRY

ENFORCEMENT

- Objectives
- Voluntary Compliance
- Violations
- Inspection Scheme
- Violation Detection Priorities

ADMINISTRATIVE CONSIDERATIONS

- Program Management and Allocation of Responsibilities
- Program Integration

Strategy for the Enforcement of the Child Resistant Packaging Regulation Under FIFRA

Overview

On March 9, 1979, the Environmental Protection Agency published a final rule at 44 Federal Register 13019 (40 CFR 162.16) which requires child resistant packaging (CRP) of certain pesticides labeled for residential use. The intent of the rule is to reduce the number of accidental exposures by children to pesticides.

The regulation requires child resistant packaging for any pesticide product released for shipment after March 9, 1981, if (1) its labeling allows for residential use, (2) it has not been classified for restricted use, and (3) it meets certain toxicity criteria. Exemptions may be granted for products for which special packaging is not technically feasible or where the toxicity criteria are not indicative of hazard to humans.

The rule also requires affected registrants to submit applications for amended registration and maintain records on child resistant test data.

Possible violations include misbranding, failure to keep records, failure to file reports, and falsification of data.

It is anticipated that states operating under grants will have major responsibility for conducting inspections concerning the CRP requirements. The Regions will handle the casework since these types of violations would not be in violation of many State statutes. Concurrence from PTSED is required for enforcement actions resulting from violations of the CRP regulation. Headquarters support will be available for data review and to answer questions on whether or not a product meets the criteria that trigger the requirement for child resistant packaging. In addition, PTSED will provide inspection targeting information.

Requirements of the Rule

Applicability

As indicated in the overview, child resistant packaging is required for any pesticide product released for shipment after March 9, 1981, if (1) its labeling allows for residential use,

(2) it has not been classified for restricted use, and (3) it meets certain toxicity criteria. In addition, registrants with products subject to the rule must amend their registrations to reflect changes in packaging and certify that the packaging complies with the CRP regulation.

For your information certain terms used in the Strategy have been defined below:

- "Released for shipment" is defined as that point in time when it is the intent of the producer to introduce the product into commerce. Intent exists in any of the following situations:

  (1) a producer asserts that what is being sampled is representative of what is actually sold;

  (2) a product is stored in an area where finished products are held for shipment in the ordinary course of business (warehouses, loading docks, etc.);

  (3) the custom of the pesticide chemical industry indicates that similarly situated products are intended for release; or

  (4) the custom of the particular producer indicates that similarly situated products have been intended for release in the past.

- "Residential use" - A pesticide meets this criterion if it is applied (other than by a commercial applicator) directly to humans or pets or is applied in, on or around all structures, vehicles, or areas associated with the household or homelife or noncommercial areas where children spend time, including, but not limited to gardens, houses, yards, patios, mobile homes, campers and recreational vehicles, noncommercial campsites, home swimming pools, educational, lounging, and recreational areas of preschools, nurseries, and day camps, etc. Furthermore, residential use is determined by whether a product has a use on the label which is within the meaning of residential use. A registrant may have a product that is not really intended for residential use, but the labeling is either vague concerning use areas, or use areas are actually omitted. Such a product is subject to the child resistant requirements unless its registration and label are amended to indicate a strictly non-residential or agricultural application.

- "Toxicity criteria" are defined in 44 Federal Register 13019 (March 9, 1979) and at 40 CFR 162.16(C)(2).

Exceptions to CRP

- "Dormant" Product Registration

  A dormant product registration is defined as a product which is not currently in production but retains valid EPA registration. For a product not in production and which is not scheduled to be released for shipment on or after March 9, 1981, an amended registration, special packaging certification and other related forms need not be submitted at this time. However, at any time after March 9, 1981, if the product is put back into production, an amended registration, child resistant certification, etc., must be submitted before the product is released for shipment if it meets the criteria for special packaging.

- Toxicity Data

  If the toxicity of a product is not known to the level of specificity necessary to determine whether or not the toxicity criteria are met (e.g., the information on file with EPA is extrapolated data), the registrant may perform additional testing. If testing indicates that the toxicity criteria are not met, the product is not required to have child resistant packaging. However, if the registrant does not conduct further testing when the toxicity is not known to the necessary level of specificity, child resistant packaging is required.

- Products for Residential Use by a Serviceperson

  The Agency has decided to remove from the scope of CRP requirements certain products which meet the criteria for special packaging but are not normally stored in areas where children could likely have access to them. Examples include products used by janitors in nurseries or daycare centers and products used by exterminators or lawncare servicepersons. To accomplish this, EPA will allow products such as those listed above to be sold and distributed without child resistant packaging if such products bear a statement restricting the sale, use, and storage to servicepersons.

This provision has been communicated to producers through a Federal Register Notice issued March 3, 1981; it will also appear in proposed revisions to Section 3 Registration regulations. Until it appears in final regulations, EPA will use prosecutorial discretion and not take enforcement action if a subject product is not specially packaged but is labeled or sticker-labeled with a statement restricting the product's sale, use, and storage to servicepersons, e.g., "Only for Sale to, Use, and Storage by Servicepersons." The statement must appear in type size at least as large as the child hazard warning statement. Labels need not be submitted to the Agency for approval but must be submitted for the official label file used to determine compliance with FIFRA.

- A registrant may amend his/her registration so that the new label does not allow for residential uses. In such a case the product bearing the new approved label would no longer be subject to the special packaging requirement.

Exemptions to CRP

Exemptions may be granted by the Director of the Registration Division for products for which special packaging is not technically feasible or where the toxicity criteria are not indicative of hazard to humans.

Note that only the Agency may grant an exemption. It is not up to the registrant to decide if he or she is exempt or not, based on the two factors listed in the above paragraph.

Specific Requirements for Registrants of Products Subject to the Special Packaging Requirement

- Develop and test special packaging

  "Special packaging" refers to packaging that is designed and constructed to be significantly difficult for children under five years old to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time. In addition, it should not be difficult for normal adults to use properly. Effectiveness testing procedures which must be used are those specified by the Consumer Product Safety Commission (CPSC) at 16 CFR 1700.20(a), (b), and (c). Effectiveness specifications and standards for special packaging are delineated in 40 CFR 162.16.

- Amend registration - Certification

  Prior to changing a product's packaging, the registrant must submit an application for an amended registration and have it approved by EPA. Instead of submitting

detailed information demonstrating that the packaging meets the requirements, the registrant shall include with his application a certification that the package meets the standards of §162.16(d). An applicant for a new registration shall also submit a certification statement that the package meets the standards.

° Utilize special packaging

Products subject to the requirement must be in child resistant packaging if released for shipment after March 9, 1981.

° Recordkeeping

Certain records must be retained by the applicant or registrant for as long as the registration is valid. These records shall be available, upon request, for inspection and copying purposes or for submission to EPA. The records which must be kept are:

(1) A full description of the package including:

(i) A full description of the container including:

(A) Its dimensions, and
(B) Its composition; and

(ii) A full description of the closure or special package, if appropriate, including:

(A) The name of its manufacturer,

(B) The manufacturer's designation (title) for the special packaging closure or the physical working of the special packaging mechanism, and

(C) The explicit directions for proper use of the closure or special packaging and the placement of these directions on the package;

(2) A complete copy of the data resulting from the tests conducted in accordance with §162.16(d); and

(3) Data demonstrating the compatibility of the pesticide formulation with the entire package to determine that the chemical and physical characteristics of the substance will not interfere with the safety and efficacy of the pesticide and functioning of the special package.

- Note: The registrant may not have actual data on file if the company did not perform the testing but, instead, relied on verification from others such as the company which produces the packaging. The registrant should have a letter or literature verifying that the packaging has been tested and met the CRP standards.

Regulated Industry

The regulated community consists of registrants of those products subject to these regulations. Estimates suggest that approximately 9000 products may be involved.

The Registration Division of EPA has prepared a preliminary list of types of products which are expected to be covered by the CRP regulations if used and stored in and around residential areas. (See attachment.) A second, more complete list will be developed and forwarded as soon as it is available.

A company may remove its product from these requirements by amending the label to remove residential uses, stickering or amending the label so that sale, use and storage is restricted to a serviceperson, or by receiving an exemption.

Enforcement

Objectives

The objective is to assure compliance with this regulation so as to minimize or eliminate accidental exposures to highly poisonous pesticides used in and around residential areas.

Outreach

Registrants should be aware of the regulation through its publication in the Federal Register. In addition, the Glass Packaging Institute prepared and distributed, with EPA's concurrence, a pamphlet entitled, "Pesticides and Protective Packaging." Personnel in the Registration Division are generally available to answer any questions and clarify the requirements for registrants.

Violations

- Misbranding - §12(a)(1)(E) of FIFRA

  As defined in §2(q)(1)(B) of FIFRA, a pesticide is misbranded if "it is contained in a package or other container or wrapping which does not conform to the standards established by the Administrator pursuant

to §25(c)(3)." Failure to have special packaging for those products released for shipment after March 9, 1981, would make the product misbranded if it is subject to the special packaging requirement.

There are three variations of this violation:

(1) No special packaging, although required.

(2) Company's new toxicity test data indicate that such packaging is not required, but the Agency does not agree that the toxicity data support their conclusion (e.g., improperly conducted toxicity tests or incorrect toxicity tests utilized).

(3) Company changes packaging, but it does not meet the child resistant requirements because tests were incorrectly done or the tests were conducted on the incorrect container size.

° Failure to File Reports Required - §12(a)(2)(N) of FIFRA

It is unlawful for a person who is a registrant to fail to file reports required by this Act. Prior to changing a pesticide's packaging, the registrant must submit an application for amended registration to EPA. Failure to do so prior to distributing the product in new packaging would be in violation of this section.

In addition, the registrant is required to submit a certification statement with the amended registration application.

° Failure to Maintain Reports Required - §12(a)(2)(B) of FIFRA

It is unlawful for a registrant to fail to maintain reports required by FIFRA. The regulation requires the registrant to submit a certification that the product is in compliance as opposed to detailed data supporting this. However, it is required that the detailed data be maintained and be subject to Agency inspection or request for submission. The registrant is not required to have such data on file if the firm relied on testing conducted by others such as the package supplier. In lieu of such data he or she must have some verification on file that the product is in compliance.

In some cases, the company may claim that the parent company/company headquarters has the data. This should be noted on the inspection report and sent to the appropriate region. The regional office should forward this to PTSED so that a request for the data can be sent to the company's headquarters by OPP.

° Falsification of Application/Report or of Records Maintained or of Exemption Request - §12(a)(2)(M) of FIFRA or Title 18 of the U.S. Code.

It is unlawful to falsify all or part of any application for registration, any records required to be maintained pursuant to §8, or any report filed under this Act. Thus, falsification of an application for amended registration, the certification, or data such as test protocol and results would be in violation of FIFRA. Title 18 of the U.S. Code also makes this type of activity illegal.

INSPECTION SCHEME

Inspections to determine compliance with these special packaging requirements should be incorporated into a state/region's existing inspection program, which should be based on a Neutral Administrative Inspection Scheme. Generally, only producer establishments will be inspected for compliance with the CRP regulation. Prior to inspecting a pesticide producing establishment, the appropriate personnel (inspector or whomever is designated to do this) should determine if the company produces any of the products on the attached list prepared by the Registration Division. If so, the inspector should check for compliance with the child resistant requirements.

Reports from inspections involving possible violations of these requirements should be forwarded to the regional office for case review and appropriate enforcement action.

Violation Detection Priorities

During an inspection, it is helpful to establish priorities for detecting violations. The following table gives the general priority ranking for violation detection. The following is meant only as a guide to decision making and is not a rigid OE policy.

Priority 1 - Misbranding

Failure to utilize Child Resistant Packaging where required. This will probably be the most common violation found initially.

Priority 2 - Failure to Maintain Records

Such records may be necessary to verify compliance with the regulations. This includes test data which either (a) show the package meets the child resistant requirement (CPSC test results) or (b) show the product's actual toxicity does not meet the criteria.

Priority 3 - Failure to File Reports

This refers to a company's failure to amend the registration prior to a packaging change. This should not be a frequent violation but is easy to determine.

Priority 4 - Falsification of Data

While this is one of the most serious violations, it should not be encountered frequently. Child Resistant Tests are expensive (approximately $8000) and may be conducted under contract if a company's test results are suspect.

ADMINISTRATIVE CONSIDERATIONS

PROGRAM MANAGEMENT AND ALLOCATION OF RESPONSIBILITIES

State and regional personnel if appropriate will be responsible for conducting inspections and documenting cases.

With regard to actual casework, issuing penalties, notices of warning, etc., the regions will have primary responsibility but must request and receive concurrence from PTSED. This is necessary for 3 reasons:

1) A violation of the child resistant requirement is not a violation of many state laws.

2) Some companies may have received exemptions or the product may not be subject based on toxicity data on file with EPA.

3) The Registration Division may consider cancellation action for those products which remain in violation.

PTSED's Case Development and Legal Branch will be responsible for resolving questionable cases, i.e., those for which there is some doubt or question as to the product's

status or the validity of the data, and reviewing concurrence requests.

Program Integration

The Case Development and Legal Branch, PTSED, will coordinate with the Regions and the Registration Division to resolve any questions regarding the child resistant packaging requirement and the status of products covered.

The Regions will coordinate with the States regarding the enforcement of the special packaging requirements.

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

FEB 26 '93

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Enforcement Strategy Concerning Child-Resistant Packaging of Pesticide Products.

TO: Jack Neylan
Pesticide Toxic Substances
Enforcement Division (EN-342)

As a follow-up to our recent meeting concerning an enforcement strategy on compliance with CRP regulations we are providing to you a list of generic products for which an unqualified assumption can be made that they need to be in CRP if used and stored in the household. This is considered phase I of the strategy. Phase II will consist of a more refined list which will be based on the actual CRP amendments we receive.

X 1. Disinfectants

Product	Concentration	Use
1. Calcium hypochlorite	65%	swimming pool
2. Lithium hyprochlorite	35%	" "
3. Sodium dichloro s- triazine trione and Trichloro-s triazine trione	98-100%	" "
4. Mono (Trichloro tetra (monopotassium dichloro) penta-s-triazinetrione	99%	Swimming pool
5. Hydrochloric acid	8%	Toilet bowl
6. Phosphroric acid	17%	" "
7. Chlorophenolics	6%	Disinfectant
8. Sulfamic Acid	20%	Toilet bowl
9. Quaternary Ammonium Compounds	10%	General disinfectant
10. Parafomaldehyde	95%	" "
11. Formaldehyde	37%	" "

2. Insecticide and Rodenticide

Pesticide Chemical	% At and Above Requiring CRP	Remarks
1. Carbophenothion	1.4	Some lawn use products
2. Chlordane	28.0	Termite control products
3. Chlorpyrifos (Dursban)	9.0	Sprays for outdoor Ornamentals
4. Cryolite	15.0	Plant dusts
5. Diazinon	7.0	Many plants and garden sprays; encapsulated diazinon does not require CRP
6. Dimethoate (Cygon)	17.0	
7. Disulfoton (Disystox)	0.4	Systemic insecticides for indoor and outdoors plants
8. Dyfonate	1.2	
9. Ethion	3.5	Some combinations with lawn fertilizer
10. Imidan	10.0	
11. Lindane	6.5	Borer sprays, dog dips
12. Metaldenyde	20.0	Slug and snail control
13. Mexacarbate (Zectran)	2.0	Insect, slug and Snail control
14. Naled	18.0	
15. Propoxur (Baygon)	6.2	
16. Phosphorus (white)	1.1	Rodenticide

3. Herbicides and Fungicides

Chemical	Formulation / % A.I.	Use
Bis (tributyltin) oxide	Above 0.5%	Wood Presenvative
Paraquat	any %	Homeowner herbicide
Pentachlorophenol	above 88%	Wood preservative
Chlorothalonil	above 40%	Homeowner fungicide
Copper-8-quinolinolate	above 5%	Wood preservative

Reto Engler, Chief
Disinfectants Branch
Registration Division (TS-767)

cc: D. Campt
R. Gross
J. Jenkins
H. Harrison
J. Akerman

General Compliance Strategy for Products Subject to the FIFRA Label Improvement Program

Overview

On June 5, 1980 EPA published in the Federal Register (45 FR 37884) a notice initiating a program to improve pesticide labeling. The Label Improvement Program (LIP) was initiated to upgrade product labeling in an attempt to better protect health and the environment as well as further defining legal use of a product. This program was designed to work in conjunction with currently existing registration programs and to respond rapidly to labeling needs identified by the Agency. To date, four major label improvement program notices have been issued and are in effect. Two additional label improvement program notices have been recently issued but are not yet in effect.

Regulated Industry

Some label improvement rules affect all registrants, while others affect only registrants of certain products.

Requirements of the Rule

Submission of Applications

The Office of Pesticide Programs (OPP), Registration Division (RD) will notify each registrant of an affected product by certified letter or a certified mail copy of a PR Notice that his product is subject to specific requirements under that label improvement program revision. For each affected product, the registrant is required to submit the following to EPA:

1) An application for amended registration (EPA Form 8570-11).

2) Five copies of draft labeling incorporating required changes.

3) If necessary, a Statement of Confidential Formula (EPA Form 8570-4).

Registrants must normally submit applications within 60 calendar days of receipt of the LIP Notice. The Agency will state any deviation from this deadline in the LIP Notice.

Products for which the Agency has not received an application for amended registration within the stated deadline will be subject to cancellation. The Agency will issue a Notice of Intent to Cancel for any such product, effective 30 days from its receipt, unless within that time the registrant or an interested party with the consent of the registrant, either applies for amended registration or requests a hearing under section 6 of FIFRA.

Exemption from Compensation Requirements

In many cases an amended registration to meet the requirements of a Label Improvement Program Notice will not be subject to compensation requirements. If this is the case, the Offer to Pay or Certification Statement will not be required to be submitted to RD and approval of labeling submitted will not convert registrations to conditional status. Each notice will address the compensation status of applications submitted in response to the LIP Notice.

Processing of Applications

Generally, the Registration Division will review labels for compliance with the requirements of the LIP Notice. A registration amendment submitted in response to a LIP Notice is not complete until the amended labeling is submitted and accepted by RD. If draft labeling is not acceptable, RD will notify the registrant of the deficiencies by letter and give the registrant 75 calendar days to submit amended labeling. Amended labeling

must be limited to changes required by the letter in order to maintain the exemption from compensation requirements.

Combined Application in Response to Multiple Label Improvement Notices

Applicants receiving multiple notices requiring LIP labeling amendments for the same product may combine responses into one application for amended registration provided the relevant LIP Notices are clearly referenced. Applications that are non-compensable under FIFRA section 3(c)(1)(D) may not be combined with applications that are compensable. The submission deadline for combined applications for amended registration is the later of the deadlines established in the LIP Notices.

Time Frames for Compliance

Any product released for shipment 180 calendar days after the registrant receives RD's acceptance of amended labeling must bear that accepted label. Registrants are responsible for compliance by their sub-registrants (distributors).

Products that have been released for shipment and are in retail channels of trade prior to the 180 day deadline may continue to be distributed in commerce, sold and used until supplies are exhausted.

Enforcement Objectives

The objective of LIP compliance program is to ensure that product labeling is in compliance with the requirements of the various Label Improvement Program Notices. This will be accomplished through producer establishment inspections.

Types of Violations

Producers not complying with the requirements of the notices issued under the Label Improvement Program are in violation of of FIFRA section 12(a)(1)(E) in that their products are misbranded under sections 2(q)(1)(F) and (G). Products being sold in violation of a cancellation order are in violation of FIFRA section 12(a)(2)(L) and subject to the penalties thereunder.

Administrative Considerations

The Office of Pesticide Programs has issued four major label improvement notices (See Attachments) which are currently in effect with two more LIP Notices issued but not yet in effect. The four existing LIP Notices are listed below in order of inspectional targetting priority according to their potential hazard.

1) Fumigants - Issued 12-4-80 - This LIP Notice requires registrants of products containing certain active ingredients to add additional precautionary labeling, misuse statements and storage and disposal statements.

2) Termiticides - Issued 11-7-81 - This LIP Notice requires registrants of termiticide products containing one of the active ingredients listed in the LIP Notice to revise use directions of their product, use the appropriate storage and disposal statements, add a misuse statement, and reformat their labels.

3) Antifouling Paints - Issued 3-9-82 - This LIP Notice required registrants of all antifouling paints to make extensive revision of their product's labeling.

4) Salt Water Emesis - Issued 11-30-80 - This LIP Notice requires all registrants to delete salt water emesis statements from their labeling. Since the revision was a simple deletion, registrants were not required to submit amended labeling for review.

Two more LIP Notices have been recently issued dealing with worker reentry intervals and disposal requirements. As they become effective they will be included for targetting in the inspectional program.

Targetting Inspections

The Registration Division, OPP is responsible for compiling lists for each LIP Notice consisting of:

1) The name and address of each registrant affected;
2) The name and registration number of each product affected;
3) The registration status of each product affected, i.e., compliance, pending, or subject to cancellation; and
4) The date of acceptance of the amended labeling if the product is in compliance.

These lists, which the Compliance Monitoring Staff will forward to the Regions, will be a basis for the States' or Regions' inspection targetting.

States should target inspections* based on the priority assigned to each LIP Notice in this document and on the current registration status of products regulated under each Notice. To identify inspection targets, States should first list under each LIP Notice the registrants and the number of their products whose: a) product labels are subject to cancellation for failure

*Only producer establishments should be targetted for inspection under this guidance. Marketplace inspections are not appropriate for determining compliance with this rule. Products in the channels of trade prior to the date when amended final printed labeling must appear on a product may continue to be sold. Therefore, it would not be an effective use of resources to determine the existence of violations based on marketplace samples.

to respond to the LIP Notice; and b) label amendments RD has approved. Inspection priorities will not include registrants whose products have label amendments pending with RD. Priority for inspection should then be assigned on the following basis:

1) Registrants of products subject to cancellation for failure to respond to the LIP Notice. These registrants should be ranked based on the number of their products subject to the LIP Notices in the following order: Fumigants, Termiticides, Antifouling Paints and Salt Water Emesis.

2) Registrants with the most number of products with accepted amended labels subject to any LIP Notices in the following order: Fumigants, Termiticides, Antifouling Paints and Salt Water Emesis.

After determining inspectional priorities for the LIP, the States should integrate these priorities with the criteria listed in the FY 84 Cooperative Agreement Guidance for scheduling producer establishment inspections (past violative history, products subject to Label Improvement Program, products subject to Child Resistant Packaging (CRP) regulations, and Restricted Use Pesticides). The highest priority in scheduling inspections should be given to those producers which meet the largest number of these criteria.

Inspections

Inspectors will examine products released for shipment at the producer establishment to determine compliance with the terms of the LIP Notice. Registrants have 180 calendar days following acceptance of amended labeling to bring the product into compliance. Any product released for shipment after this 180 calendar day period must bear accepted amended labeling.

Registrants with products not in compliance with any LIP Notice will be issued a Stop Sale Use or Removal Order (SSURO) by

the State or EPA in addition to any enforcement action taken by the State or EPA. The SSURO will be removed only after the registrant brings the product into compliance. SSURO's will not be lifted for cancelled products sold in violation of a cancellation order. Issuance of a SSURO is an appropriate response to non-compliance as the LIP is designed to mitigate the risks of handling pesticides through labeling changes and the registrant is given ample time to make and incorporate these changes on the label.

Allocation of Responsibilities

Headquarters Responsibility

a) Provide Regions with a compliance strategy for Label Improvement Program,

b) Provide Regions with copies of each LIP Notice,

c) Provide list of registrants affected by a Notice, status of the products affected and date of acceptance of final printed labeling for each product in compliance.

Regional Responsibility

a) Provide copies of all pertinent materials to the States.

b) Provide guidance and assistance for State enforcement efforts.

c) Assist in issuance of SSURO's.

State Responsibility

a) Schedule and conduct inspections of affected registrants.

b) Issue SSURO's to non-complying registrants.

c) Take enforcement actions where appropriate.

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

NOV 22 1983

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Compliance/Enforcement Strategy for the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

TO: Alvin L. Alm
Deputy Administrator

Attached is the Compliance/Enforcement Strategy for the Federal Insecticide, Fungicide, and Rodenticide Act. The strategy was developed by a work group composed of Headquarters, Regional, and State pesticides personnel, and reflects the views of all participants.

The pesticides program is a well established program that has evolved over the years in which States have a major enforcement role.

The strategy is based on the assumption that adequate resources would be available to support a balanced credible program. Because of actual resource constraints, however, our primary goals through FY85 are 1) to maintain the present monitoring/compliance level in States with cooperative enforcement agreements, 2) to negotiate cooperative agreements with the remaining States, 3) to refine the program management and oversight activities and 4) to further develop and expand the data audit/Good Laboratory Practices inspection program. To meet these goals, we will perform the following activities through FY85:

- Write FY85 Cooperative Agreement Guidance.
- Develop a formal procedure for and provide support to the Office of Pesticide Programs for most new regulations and suspensions/ cancellations to ensure that the documents are enforceable. CMS plans to prepare a draft document on the formal procedure by the end of the second quarter of FY84. Input and agreement from the Office of Pesticide Programs on the procedure is anticipated by the end of the third quarter of FY84 and should be operational immediately thereafter.
- Develop compliance monitoring strategies and enforcement response policies for most new regulations and suspensions, as appropriate.
- Finalize strategy for conducting data audit and Good Laboratory Practices (GLP's) inspections.

- o Finalize enforcement response policy for data audits/GLP inspections.
- o Ensure that all States and Regions conducting Federal enforcement programs have fully implemented the most effective/flexible system for allocating resources to priority pesticide problems.
- o Provide technical and legal support to States.
- o Provide training for State inspectors and chemists.
- o Prepare additional policies for the FIFRA Policy Compendium, as needed.
- o Promulgate a final FIFRA §4 rule requiring dealers to keep records of their restricted use pesticide sales and clarifying where commercial applicators must keep their records on their applications of restricted use pesticides.
- o Conduct Certification Programs in States without approved certification plans.
- o Along with States, ensure that applicators are made aware of changing technology.
- o Along with States, continue to certify new applicators.
- o Prepare guidance to encourage States to address major use problems in Certification and Training materials.
- o Prepare guidance which ensures that State Certification and Training materials meet Federal standards, as appropriate.

As soon as we receive your approval to pursue these activities, they will be incorporated into the Administrator's Management System with projected completion schedules. Due to anticipated resource limitations, we will be unable to undertake the following activities through FY85:

- o Expand FATES data to include State data and ensure that FATES data is complete and current. (CMS plans to request funding to initiate this activity in FY86.)
- o Provide guidance and training to the Regions for data audits/laboratory inspections and case preparation.
- o Support all rulemaking by the Office of Pesticide Programs.
- o Develop compliance monitoring strategies and enforcement response policies for all new regulations.

- o Update the Pesticides Inspection Manual.
- o Consolidate FIFRA Enforcement Response Policies.
- o Revise FIFRA §7 establishment registration rule and reporting form to improve the usefulness of data in the system.
- o Conduct periodic surveys of pesticide use to improve the priority setting system.

Please let me know if you have questions or would like to further discuss our plans for implementing the FIFRA Strategy.

Don R. Clay
Acting Assistant Administrator
for Pesticides and
Toxic Substances

Attachment

FIFRA COMPLIANCE/ENFORCEMENT STRATEGY

FIFRA Compliance/Enforcement Strategy

Introduction

This document contains EPA's strategy for achieving and maintaining compliance with the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended and implementing regulations. The document provides an overview of the FIFRA compliance/enforcement program, a summary of prior strategies, the existing state of compliance, the current goals and priorities of the program, recommended strategies for attaining these goals, a discussion of the roles of the Federal and State governments in implementing strategy elements, a discussion of cross program elements, and a description of the system for program evaluation.

The major elements in this strategy are reflected in existing guidance documents unless otherwise indicated.

It should be noted at the outset that this strategy takes a comprehensive look at the program and indicates a number of actions which should be taken to implement an effective program. Based on resource constraints, the actions which will be taken are limited to those indicated in the priorities for FY85.

FIFRA Compliance Program Overview

Statutory/Regulatory Requirements

FIFRA, as amended, currently has a variety of mechanisms to protect health and the environment from unreasonable risks from pesticides It contains the following requirements:

- Federal registration of pesticides.
- Submission of data to EPA by the registrant/applicant for registration in support of registration, which shows that the product, when used as directed will not injure man, animals, crops, or the environment and will not result in illegal residues on food or feed.
- Federal classification of pesticides for general or restricted use.
- Specific labeling of pesticides, including the product's classification and proper use directions.
- Child Resistant Packaging if a product meets certain toxicity criteria and its label allows for residential use.
- Submission of a Notice of Arrival for all importations of pesticides or devices.
- Certain labeling for all exported pesticides and notification of EPA when unregistered pesticides are exported.
- Establishment by EPA of residue tolerance levels for products used on a food or feed crop.
- Experimental Use Permits (EUP's) for limited field testing prior to registration.
- FIFRA §18 Emergency Use Exemptions by the Administrator upon application from a State if certain criteria are met.

- o FIFRA §24(c) State registration for additional uses of a registered pesticide within a State to meet special local needs.
- o Cancellation/suspension by EPA of pesticides which cause unreasonable adverse effects.
- o Federal registration of pesticide or device producing establishments.
- o Submisson of annual reports to EPA and maintenance of books and records by each registered establisnment.
- o Establishment inspections.
- o Certification and training for users of restricted use pesticides by the States with plans or EPA. (Pesticides classified for restricted use may only be applied by or under the direct supervision of a certified applicator.)
- o Use in accordance with the label.
- o Efficacy requirement for pesticides.
- o Prohibitions of statements or graphic representations on the label which are false or misleading.

Implementation

FIFRA was first enacted as the Federal Insecticide Act in 1910. Since then, it has undergone major revisions which have resulted in changes in the compliance/enforcement program.

Traditionally, primary responsibility for enforcing the requirements of FIFRA has resided with the Federal government. In 1972, however, Congress paved the way to shift responsibility to the States by amending FIFRA to provide for Federal/State cooperative programs governing pesticides enforcement and applicator training and certification. Congress furtner strengtnened tne responsibility of the States in the 1978 FIFRA amendments which establish the presumption that States, under certain circumstances, shall have primary responsibility for bringing enforcement actions against violators of pesticide use requirements (primacy).

Most States who enter into a cooperative enforcement agreement with EPA under §23 automatically obtain primacy as do States which have an approved pesticide applicator certification plan (§4) which also meets the criteria under §26(a) for adequate pesticide use laws and implementing procedures. A State which has neither a cooperative agreement nor an approved plan can also obtain primacy if it has adequate laws and procedures governing pesticide misuse as required by §26(a).

Section 27 of FIFRA provides for: 1) an EPA response to a complaint alleging a significant violation of the pesticide use provisions when a State does not commence appropriate enforcement action within 30 days of a referral from EPA; 2) rescission of primacy if the Administrator determines that a State is not carrying out its enforcement responsibility; and 3) action by EPA during emergency conditions.

The 1972 amendments to FIFRA require the certification of applicators to apply or supervise the application of pesticides classified for restricted use. Congress expected States to certify applicators and authorized funding support. The State Cooperative Extension Services were to be utilized for the training of pesticide applicators with EPA funding support.

As of October 1983, all but 4 States have funded cooperative enforcement agreements; all but 3 States have been granted use enforcement primacy; and all but 2 States have approved certification plans. As these figures indicate, most FIFRA enforcement and certification and training responsibilities rest with the States. EPA activities include oversight of States with agreements, taking enforcement action for cases referred by the States, conducting enforcement and certification and training activities in States without cooperative agreements, and conducting national compliance/enforcement programs in areas where States have limited jurisdiction or capability such as data audits/laboratory inspections, import and export surveillance, and rodenticide/device testing, and regulation development support.

Previous Compliance/ Enforcement Strategies

Pre-1980 Program Reassessment

General Enforcement of FIFRA

While the FIFRA enforcement program was located in the United States Department of Agriculture (USDA), the enforcement program was centralized with all activities, inspections, case preparation and policy development conducted by Headquarters personnel. After EPA was formed, a Regional program was adopted. Inspections and case preparation were conducted by Regional personnel. Concurrence from Headquarters was required for all civil actions. Headquarters provided guidance and made policy decisions regarding the program.

Prior to 1972, the strategy for the Federal program was to enforce product-related violations, i.e., mislabeling, inefficacy, chemical deficiencies, nonregistration. There was no authority to take enforcement action against improper use. Criminal action was the only available response against violators.

The 1972 amendments to FIFRA 1) provided for administrative civil penalties as well as criminal action, 2) made use inconsistent with the label a violation, 3) provided for cooperative enforcement agreements with the States, and 4) required classification of pesticides along with provisions for certification and training (C & T) of pesticide applicators. As a result, the Federal program shifted to include enforcement of the label use directions. The use of civil penalties became the backbone of the enforcement effort. States were responsible for developing C & T programs based on EPA regulations and obtaining approval for these programs from EPA.

In 1974, EPA entered into pilot cooperative agreements with 5 States. Prior to this time, the States and the Federal government had separate programs with little interaction. The initial emphasis of the cooperative program was joint enforcement with continued Federal presence in those States with agreements.

The Federal enforcement program became more decentralized in February 1975 when Headquarters announced a program to waive concurrence for routine civil cases, excluding use cases. By November 1978, all Regions were granted 1) full relaxation of the requirement for Headquarters concurrence in actions related to stop sales and civil cases other than misuse cases, and 2) partial relaxation of Headquarters concurrence in the enforcement of misuse cases.

The 1978 amendments, under certain circumstances, gave primary responsibility for use enforcement (primacy) to States. As more State programs became operational under cooperative agreements and received primacy, Federal activities shifted to enforcement programs in States without cooperative agreements and primacy, program oversight, training of State personnel, disinfectant/device testing, import/export surveillance, and data audits.

Guidance for the cooperative agreement program was issued annually. Until 1980, strategies emphasized a gradual shift from activities related to product compliance to those monitoring use. Guidance documents assigned percentages to various activities including agricultural, nonagricultural and experimental use inspections; producer establishment, marketplace, import, certified applicator records inspections; and restricted use pesticide dealer inspections. The percentages correlated to the amount of total workyears EPA expected the States to spend on the various activities. Percentages were assigned based on prior violation trends and new regulatory requirements.

Federal and State Certification and Training

Prior to FY81, the C & T program was operated by the Office of Pesticide Programs (OPP) independently of the compliance program.

1980 Program Reassessment

In June 1980, the pesticides compliance/enforcement program was reassessed. The resultant strategy document, "Reassessment of the Federal/State Pesticides Enforcement Program", has guided the Federal/State cooperative pesticides program in recent years. The document was the basis for major changes in the compliance/enforcement program and contained the following goals and priorities:

- Improve management of all State and Federal pesticides enforcement program elements by: a) developing a priority setting system; and b) improving program evaluation through a better information retrieval system, uniform evaluation standards, periodic program evaluations, and appropriate program modifications.

- o Ensure that eligible States receive primacy and adequately protect the public. This goal was to be achieved by: a) promulgating an interpretive rule on primacy standards; b) promulgating a regulation governing hearings for rescission of primacy; c) issuing guidance on incentives and sanctions to encourage adequate State programs; and d) evaluating all State use enforcement programs.

- o Ensure effective compliance monitoring and enforcement activities by assessing training programs and revising training materials.

- o Ensure adequacy of the certification and training program by: a) reviewing State plans and certification and recertification procedures and Extension Service program materials; and b) revising training materials as appropriate.

- o Increase public understanding of and participation in pesticides enforcement activities. This goal was to be achieved by preparing materials and sponsoring training activities designed to help users minimize pesticide risks and to help persons exposed to pesticides in documenting misuse violations.

Implementation of Strategies

The Compliance Monitoring Staff designed and began implementing strategies for achieving these goals in 1981. A summary of these strategies follows:

Improve Management

Priority Setting. The largest portion of the Agency's pesticides compliance and enforcement resources are directed at pesticide product and use activities. These resources are used primarily by the States through the cooperative agreement program but also by the Regions in conducting FIFRA compliance programs in Colorado, Nebraska, Wyoming, and Ohio and handling referrals from the States.

In the past, EPA Headquarters directed that resources in both the State and Federal programs be allocated to compliance activities based solely on general national priorities. As a result of the reassessment in 1980, EPA required both the States and the Agency's compliance program to identify priority pesticide problems and to allocate resources to activities which most effectively deal with these problems. To assist the States in this activity, the Compliance Monitoring Staff (CMS), in conjunction with the Office of Planning and Resource Management (OPRM), developed a flexible priority setting model designed to ensure that resources in both Federal and State FIFRA compliance programs would be applied in a manner which would most effectively address major pesticide use problems arising in individual States. This model was included in the FY82 guidance for Cooperative Enforcement Agreements and was referenced in the Guidance for Federal Programs in States without Cooperative Agreements.

Application of the model results in four products:

1. A list of pesticide use problems ranked by their relative contribution to harm from pesticide use/misuse incidents.

2. A listing of pesticides ranked by their relative contribution to harm from pesticide use/misuse incidents.

3. A list of program activities to be carried out to deal with each of the identified problems, including both traditional compliance monitoring and enforcement efforts as well as other activities such as increased education.

4. An allocation of program resources that maximizes potential program effectiveness by considering 1) the relative priority of the use problem addressed; and 2) the likely effectiveness of the proposed activities in dealing with that problem.

All States have begun implementing this model or a related method for identifying priority pesticide use problems and effectively allocating available resources.

The FY82 Cooperative Agreement guidance gave general directions for setting non-use priorities but contained no specific model. Upon request of the States, such a model was developed for the FY84 guidance. Because harm is likely to be greater for use-related activities and the compliance rate is generally high for non-use related activities, the ranking procedure suggests that 25% of available inspection resources be allocated to non-use related activities. Under the ranking procedures suggested for non-use priorities, compliance monitoring priority is assigned in the following order to establishments within a State which produce restricted use pesticides (RUP), pesticides subject to the Label Improvement Program (LIP), and pesticides likely to be subject to the Child Resistant Packaging (CRP) requirements:

1. Violators in the State
   a) Establishments with major violations.
   b) Establishments with multiple violations.
   c) Establishments with minor violations.

2. Establishments not previously inspected.

3. Establishments previously inspected with no violations detected.

Information System. A strategy for improving data storage and retrieval for both the pesticides and toxic substances compliance enforcement programs was initiated in 1979. Prior to 1981, the Compliance Monitoring Staff had two ADP systems: 1) the Pesticide Enforcement Management System (PEMS) which contained inspection, sampling and case development data, and 2) the Establishment Registration Support System (ERSS) which contained FIFRA §7 establishment registration data. In 1979, a strategy was developed for consolidating, expanding, and improving these systems into a new automated data system FATES (FIFRA and TSCA Enforcement System). FATES consists of five subsystems which operate independently with cross reference capabilities:

- o Pesticide establishment registration and production reporting
- o Inspections and sampling
- o Case management
- o Grants information
- o Contract inspections

After a feasibility study in 1979, a system design phase was initiated in 1980. Development and implementation was begun in early 1981, and by October 1981 FATES was operational. Regional system installation and user training was accomplished in 1982, and system validation was completed in 1983. However, major FATES data base system updates and enhancements are required to maintain data for new program activities such as the FIFRA Child Resistant Packaging and Label Improvement programs, and to provide comprehensive information for the Administrator's Management Accountability System. Additional ADP contract resources are required to provide these system enhancements and to maintain the additional data the new programs generate. When fully operational, FATES should facilitate priority setting.

Uniform Standards. In 1982, an evaluation protocol was included in the FY83 cooperative agreement guidance. The protocol was developed 1) to ensure that all State cooperative enforcement and C & T programs would be evaluated annually by the Regions according to uniform standards; and 2) to ensure that appropriate pesticide use problems would be addressed in State pesticide applicator training and certification materials. This protocol was developed for use in FY83 and will be modified as appropriate based on experience with its use.

Information from program evaluation is particularly important, since it is to be used by the States to update priorities for the next year and to determine specific areas needing additional regulation (for example, through OPP's label improvement program). This use of priority setting and evaluation gives the program an element of flexibility which allows resources to be allocated each year to those areas where they are most needed and can be most effectively used.

Primacy

At the request of the States, EPA developed a rule interpreting several key provisions in §26 and §27 of FIFRA. The Interpretive Rule promulgated on January 5, 1983 addressed 1) when a State will be deemed to have adequate pesticide use laws and enforcement procedures, 2) criteria used by EPA to determine whether a State is adequately carrying out primacy, 3) EPA procedures for referring misuse allegations to the State and tracking State responses, 4) the meaning of appropriate enforcement action, and 5) factors constituting an emergency and circumstances under which EPA will defer to the State for enforcement. Generally, the Agency determines whether a State should be granted primacy or whether its use program is adequate based on a review of the State's entire program rather than a case by case review. EPA evaluates a State's primacy program during the end of the year grant review for those States with cooperative enforcement programs.

On May 11, 1981 EPA promulgated a rule (46 FR 26033) governi procedures to be followed by the Administrator in rescinding primacy. Under these procedures, whenever the Administrator makes a determination that a State is not adequately discharging its use enforcement responsibilities, he must send a notice to the State specifying the deficiencies in the State's use enforcement program. If after ninety days from receipt of a notice by a State, the Administrator finds that the State has not corrected the deficiencies set forth in the notice, the Administrator may rescind, in whole or in part, the State's primary enforcement responsibility for pesticide use violations. In practice, if someone complains or deficiencies are discovered during an evaluation, the Regional office will contact the State and try to resolve the problem prior to formal rescission procedures. Generally, few problems have arisen, and those were satisifactorily resolved.

Training/Guidance

Throughout the development of the cooperative agreement program, EPA has placed a major emphasis on training state pesticide inspectors. State inspector training has been accomplished primarily by the Regional offices through formal training sessions and through having experienced EPA pesticide insoectors assist State inspectors in the field. In addition the National Enforcement Investigations Center (NEIC), in cooperation with the Compliance Monitoring Staff (CMS) and the Regions, conducts use/misuse investigation worksnop for State pesticide inspectors. These workshops cover state of the art pesticide drift monitoring techniques and basic use/misuse investigation techniques. The workshops include both classroom and field training. EPA intends to continue both these training programs in the future.

In addition to inspector training, EPA has emphasized the improvement of State pesticide laboratories and training of State chemists to ensure the quality of State pesticide analytical data. Under a Memorandum of Agreement between CMS and NEIC, the NEIC conducts chemists training workshops, provides advice to the States on analytical techniques, conducts on-site reviews of State pesticide laboratories to evaluate sufficiency and recommend improvements, and conducts a check sample quality control program. These activities will continue in the future.

To ensure that compliance/enforcement activities were properly carried out, an inspection manual and case preparation manual including a FIFRA civil penalty policy was issued to the States. Additional strategies and penalty policies were developed for new regulations. In addition, guidance has been issued to the Regions/States governing response to cancellations/suspensions. CMS and the Office of Legal Enforcement Policy recently released a revision of the Pesticide Case Preparation Manual as the FIFRA Compliance/Enforcement Guidance Manual.

Certification and
Training Program

In FY81, OMB transferred the program to the compliance/ enforcement program. This transfer provided an opportunity to better coordinate the two programs.

FIFRA provides that certification of pesticide applicators be accomplished under State Certification Plans approved by EPA with training provided by the State Cooperative Extension Services (SCES's). This objective has been largely accomplished. Only Colorado and Nebraska lack approved certification plans and only the Colorado* SCES fails to provide applicator training. In each of these States, EPA has established programs in the absence of State activity.

Three Federal agencies, the Department of Defense (DOD), the Department of Interior (DOI), and USDA, have established programs to certify their own employees. These programs are authorized by EPA to allow Federal agencies to certify their employees to apply pesticides anywhere in the performance of their official duties. Federal employees can still be certified by States, but their certification has the same geographic limitations as other applicators certified by the State.

Based on operational experience, there has been a need for some changes, and certification plans have been amended in response to these needs.

Certification plans were required to contain a provision keeping applicators abreast of changing technology. This requirement is generally met by recertification either at specified intervals or when deemed appropriate by the State. Most States have completed at least one recertification cycle.

EPA has worked with USDA to develop training material. There is need to periodically update the material in order to incorporate information on new technology. Existing training material is cataloged at the USDA Beltsville library.

Additional Activities - Federal Program

Input into Development of New Regulations

To ensure that new regulations are enforceable, CMS participates and assists in the development of regulations or other regulatory actions such as suspension/cancellation orders for which the Office of Pesticide Programs (OPP) has the lead role.

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*Colorado has indicated an interest in establishing a program, which will initially cover only commercial applicators.

General

As mentioned previously, the Federal role shifted, as more States received grants, to the oversight of the cooperative program, enforcement response for State referrals, enforcement programs in States without cooperative programs or primacy, and a compliance monitoring and enforcement program consisting of data audits, import and export surveillance and efficacy testing. With the exception of the data audit program, which is managed at Headquarters, the Regions have primary responsibility for the Federal Program. CMS provides guidance documents, policy interpretations, technical support, and oversight for Regional activities.

Data Audits

The data audit program for studies submitted in support of pesticide registration was instituted in 1975 after the Food and Drug Administration (FDA) found that studies submitted to it had serious deficiencies. The strategy has been to audit studies at problem laboratories, audit studies of special significance to regulatory decisions, and conduct routine audits at all pesticide laboratories. Under an Interagency Agreement originating in 1978, FDA conducts inspections at laboratories which conduct health effect studies. EPA inspectors primarily conduct audits of environmental studies. EPA scientists participate on audits as appropri[illegible]. A Data Audit Panel within Office of Pesticides and Toxic Substan[illegible] (OPTS) targets inspections, reviews reports, and recommends appropriate actions.

FIFRA Import Surveillance

Compliance monitoring of the import provisions of FIFRA is performed in cooperation with the U.S. Customs Service. Customs inspectors screen imported pesticides and allow only products which are in compliance with FIFRA to enter the United States. If a pesticide appears to be in violation of FIFRA, the Customs inspector stops the entry of the pesticide into the Customs Territory of the United Staes and refers the matter to the appropriate EPA Regional Office for resolution or enforcement action. In addition, a Notice of Arrival form is required to be submitted to EPA for all importations of pesticides and devices. An annual average of 4375 Notices of Arrival have been received and 670 inspections of imported products have been conducted for the past few years.

Efficacy Testing

Disinfectant Testing

The Federal program for disinfectant testing, which is no longer active, involved efficacy testing of hospital disinfectant Such testing is important considering that failure of hospital

disinfectants can contribute to the incidence of infections among vulnerable patients and result in unnecessary and unknowing exposure of hospital staff to pathogenic organisms. OPP's Beltsville laboratory formerly performed efficacy testing on about 200 samples per year. The failure rate ranged from 46% of 111 samples in 1980 to 72% of 40 samples in 1982. The Beltsville laboratory suspended testing of disinfectants, sanitizers, sterilizers, and germicides in October 1982 due to competing higher-priority needs, although the capability to perform such tests remains. CMS proposed an efficacy testing program for FY85; however, it was not included in the priority listing of OPTS programs.

Ultrasonic Device Testing Program

Under an Interagency Agreement between the FDA's Winchester Engineering Analytical Center and EPA's CMS, the FDA tested the acoustical properties of a dozen different ultrasonic pest control devices being manufactured in the United States. This information was used to select "representative" devices for testing the princip of ultrasound on rodent control. The efficacy testing is being conducted under a separate Interagency Agreement with the Denver Wildlife Research Center, Fish and Wildlife Service and CMS. A final report on the first of six devices was recently received, and the other tests and reports will be completed by February 1984. CMS and OPP will use this information in the regulation of ultrasonic device labelling claims which are overstated.

Electromagnetic Device Testing Program

A program similar to the ultrasonic program was conducted for devices which purport to control pests utilizing the principle of electromagnetism. The Bureau of Standards, through an Interagenc Agreement with CMS, conducted the electronic analysis of eighteen different devices. University and USDA personnel conducted efficacy tests on rodents and insects for CMS and determined that electro-magnetic devices were ineffective for these pests. Appropriate regulatory actions were taken by CMS which resulted in the ban of these types of devices from the consumer marketplace.

Rodenticide Efficacy Testing

The Office of Pesticide Programs funded an Interagency Agreement with the Denver Wildlife Research Center in FY83 to conduct a national program to test rodenticides for efficacy. CMS is participating in this program by coordinating the sampling, chemistry testing, efficacy reviews, and enforcement response, if any, for the rodenticides.

Monitoring of Federal Spray Programs

The EPA through the Federal enforcement program or the cooperative State programs routinely monitors spray programs funded by Federal agencies. For instance, applications by for-hire applicators during the Grasshopper Control Program have been monitored by the States of New Mexico, Texas, and Oklahoma, and by EPA in Nebraska and Colorado. The EPA and the States may also conduct use investigations for smaller scale programs including aquatic weed control, forest pest control, and predator control programs.

Present State of Compliance

Regulated Community

The following is a list of known members of the regulated community:

o Number of Registered Establishments	11,000
o Number of Applicators Trained and Certified	
Private	1,500,000
Commercial	496,000
o Number of Laboratories Conducting FIFRA Studies	400
o Number of Notice of Arrivals Received in 1982 (imports)	5,014
o Number of Export Notices received annually (approximate)	75
o Number of Experimental Use Permits Issued in 1982	441
o Number of §18 Exemptions issued in 1982	373
o Number of Restricted Use Pesticide Dealers (This number does not include dealers in Colorado, Montana, or North Dakota. It is estimated that these States have approximately 300 RUP dealers.)	23,706

This list does not include information on the total number of pesticide users or pesticide dealers of unrestricted pesticides. Many users of pesticides only use general use pesticides and therefore are not certified. This is especially true of homeowners who are not commercial applicators or farmers. Although the unknown categories represent a large number of persons, the overall impact of violations by this group which go undetected is much less than the effect of violations by members of the known regulated community. Violations by the known community may involve more highly toxic pesticides or product type violations which impact a large number of people if left undetected. Violations by private users who are uncertified generally affect a more limited population. In addition, violations by users which result in serious harm are likely to be reported to the Agency.

Inspections and Actions

The shift from a Federal to a State program has resulted in an increased number of inspections and increased field presence. A complete data base on enforcement actions which includes State activities only exists for FY81 and FY82. In FY81, a total of 50,104 State inspections was conducted. The percent of inspections resulting in action was 17.4. In FY82, a total of 59,317 State inspections was conducted. The percent inspections resulting in actions was 13.1. Violations figures for specific types of inspections indicate a higher rate of noncompliance for use related requirements than for non-use related requirements.

The number of Federal inspections for FY81 and FY82 was 2254 and 2021 respectively. In FY81, the number of enforcement actions was 756 and in FY82 the number was 1139. These figures include actions based on referrals from the States. A detailed breakdown of the numbers of inspections and actions can be found in Tables I, II, III, and IV. (See Appendix.)

Both EPA and the States are collecting a large body of data related to specific types of violations. The Agency will include this data in the FATES system and then use the system to better define major violations and specific causes of violations if funding is available for system modification.

Goals and Priorities

Long Term Goals

Long term goals for the FIFRA Compliance/Enforcement Program are listed in order of priority below:

- o Expand FATES to include State data and assure completeness of data.
- o Develop a predictive model to set priorities.
- o Ensure that all States participate in cooperative enforcement agreements and the C & T Program.
- o Improve EPA-State communication systems through the use of state of the art technology, e.g., use of electronic mail.
- o Provide guidance and training to the Regions for data audits/ laboratory inspections and case preparation.
- o Conduct periodic surveys of pesticide use to improve priority setting system.
- o Continue refinement of program management for the cooperative enforcement program, the C & T program and Federal program.
- o Improve program evaluation.
- o Ensure the adequacy of the C & T program.
- o Review certification and training materials.
- o Ensure adequacy of Federal Compliance/Enforcement Program.
- o Promote programs to prevent violations of FIFRA.
- o Provide technical and legal support to States.
- o Continue to provide training for State inspectors and chemists.
- o Continue cooperative relationship with States.

- o Develop compliance monitoring strategies and enforcement response policies for new regulations and suspensions cancellations as appropriate.
- o Update the Pesticides Inspection Manual.
- o Consolidate FIFRA enforcement reponse policies.
- o Revise FIFRA §7 establishment registration rule and reporting form to improve the usefulness of data in the system.
- o Expand formal referral systems within the Agency.
- o Expand formal referral systems with other Agencies.
- o Improve referral system between the Regions and States.
- o Expand work with the press and special interest groups.
- o Continue integration of inspections.

Near Term Priorities

Priorities for the FIFRA compliance/enforcement program through FY85 fall into the following management, compliance monitoring enforcement response and certification areas:

Management

- o Write FY85 Cooperative Agreement Guidance.
- o Develop formal procedure for and provide support to OPP for most new regulations, suspensions/cancellations and other actions to ensure that the documents are enforceable. In order to do this effectively, it is mandatory that compliance/enforcement program staff be involved early in the development of such documents. This has been a problem in the past. Therefore, a formal system of communication between OPP, Office of General Counsel, and CMS should be developed.
- o Finalize strategy for conducting data audits and Good Laboratory Practices (GLP) inspections.
- o Finalize enforcement response policy for data audits/GLP inspections.
- o Develop compliance monitoring strategies and enforcement response policies for most new regulations and suspensions, as appropriate.
- o Ensure that all States and Regions conducting Federal enforcement programs have fully implemented the most effective/flexible system for allocating resources to priority pesticide problems.
- o Provide technical and legal support to State.
- o Provide training for State inspectors and chemists.
- o Prepare additional policies for the FIFRA Policy Compendium, as needed.
- o Promulgate final FIFRA §4 rule requiring dealers to keep records of their restricted use pesticide sales and clarifying where commercial applicators must keep their records on their applications of restricted use pesticides.

Compliance Monitoring

Program guidance indicates that generally 75% of inspection resources should be directed at use problems and 25% at product related priority problems. The priority setting guidance is designed to be flexible, allowing a shift in inspection targets from year to year based on shifts in State specific problems and new FIFRA regulations.

In addition, the Federal program will emphasize the data audit/laboratory inspection program.

Enforcement Response

States will set their own enforcement priorities with major emphasis being given to priority use problems which they have agreed upon with EPA.

The Agency attaches the highest priority to responding to the following instances of noncompliance:

- o Violations related to those priority use problems which EPA and the State have agreed to track under primacy and for which the State does not take appropriate action.
- o Violations related to other priority use problems established by the States or EPA.
- o Submission of false data to EPA in conjunction with pesticide registration.
- o Sale of Restricted Use Pesticides to uncertified applicators in States with Federal Programs.
- o Label or formulation violations likely to result in harm to health or the environment.
- o Violations of Child Resistant Packaging regulation.
- o Pesticide enforcement registration and reporting violations.

Certification

- o EPA will conduct Certification Programs in States without approved certification plans.
- o EPA and States will ensure that applicators are made aware of changing technology.
- o EPA and States will continue to certify new applicators.
- o EPA will prepare guidance to encourage States to address major use problems in C & T materials.
- o EPA will prepare guidance which ensures that State C & T materials meet Federal standards, as appropriate.

Plans for Achieving Program Goals

This section discusses the compliance monitoring plan, the compliance promotion plan, plans for responding to noncompliance, certification and training, Headquarters/Regional coordination, Federal/State relationship, and cross program effects.

Compliance Monitoring Plan

Objectives

The basic objectives of the compliance monitoring plan are: 1) to provide a visible enforcement presence which will encourage voluntary compliance; 2) to collect evidence to support enforcement actions; 3) to expand the data base for determining compliance by the regulated community (FATES) and to use this information to identify persons likely to be in noncompliance; and 4) to discover problem areas requiring resolution through regulatory initiatives by OPP.

Compliance Monitoring Tools

Tools available to EPA and the States for monitoring compliance with FIFRA include data review, letters, and on-site inspections.

EPA can determine by reviewing available data whether an establishment has met its §7 reporting requirements or whether there is some questionable registration data.

Letters are used to determine which specific industries are actually subject to FIFRA requirements when a full scale on-site inspection is not cost effective. They are generally used when purposeful noncompliance is not suspected and the likelihood of response is good.

On-site inspections are the major method through which EPA monitors compliance with FIFRA. These inspections are conducted in response to complaints and on the basis of target selection under a neutral administrative inspection scheme (NAIS).

Inspections Based on Referrals/Complaints

Both the Agency and the States place a high priority on response to complaints or referrals regarding violations. Referrals, tips, and complaints are particularly important to EPA compliance monitoring for misuse. This is because FIFRA §9 gives EPA inspectors authority to enter only establishments where pesticides are held for distribution in commerce. It does not clearly give EPA authority to enter places where pesticides are being used. Therefore, the Agency can enter such places only with 1) consent of the owner or his agent, or 2) with a warrant based on probable cause that a violation has occurred, or is occurring. Probable cause can be based upon a detailed allegation from a reliable source linking specific action with a specific misuse.

Some State statutes give their inspectors broader entry authority to detect misuse.

Misuse is difficult to detect unless an inspector is present during actual use or soon after the use of the pesticide. Therefore, use inspections are conducted in response to a complaint referral or during the actual application of the pesticide. Legitimate complaints/referrals regarding pesticide misuse may be ineffective if they are not made and investigated promptly because the evidence, especially in the case of highly toxic organophosphates, will no longer be there at the time of the investigation.

Even if there were no limitations on entry authority, evidence of pesticide misuse may be difficult to detect during a planned use observation. Because inspectors would not generally otherwise know when and where a commercial or private applicator is going to make a pesticide application, they make appointments to conduct the observations. It is, therefore, not as likely that instances of knowing and willful misuse will be detected on a planned inspection, as on an investigation conducted in response to a complaint.

Routine Inspections

EPA and the States can use on-site inspection to determine with relative ease and at reasonable cost whether an establishment has met its establishment registration or reporting requirements, whether a product is appropriately labeled, or whether scientific data submitted in support of a pesticide registration correctly reflects the testing which was conducted and the results.

Since most States have regulations requiring dealers of RUP's to keep records of their sales, it is relatively easy for States to determine whether the requirement is being met. In addition States can follow-up the records and inspect the applicator to determine whether he is certified. Based on records which commercial applicators are required to keep, it is often possible for the States to determine whether the RUP was used in accordance with its label instructions.

EPA does not have regulations requiring dealers in States without cooperative agreements/primacy to keep records regarding their sales of RUP's. As a result, it has been difficult for EPA to determine whether dealers in these States have sold RUP's to uncertified applicators. Although Federal regulations exist requiring commercial applicators to keep records regarding their RUP applications, the regulations were unclear about where these records had to be kept. However, EPA expects to remedy these problems by promulgating a final rule under FIFRA §4 requiring dealers to keep records of their RUP sales and clarifying where certified commercial applicators must keep their records on their applications of RUP's. This rule should appear in the Federal Register early in FY84.

Targetting

As indicated on page 6, EPA and the States use the priority setting system for pesticide use/misuse to determine specific categories of persons who should be targetted for inspection. Selection of specific persons within each category is based on an NAIS. The system is flexible and may vary from year to year based on major existing or anticipated problems. Each neutral scheme includes a set of criteria designed to help the Agency and States achieve the best cost/benefit ratio between the use of compliance monitoring resources and detection of violations. The criteria applied to all facilities under a neutral scheme vary based on individual priorities but generally include the following: violation history, production volume, amount of specific pesticides used, inspection history, and location. Inspection targets are selected at random based on available resources from the facilities identified through application of the NAIS criteria.

The current use/misuse priority setting system is based primarily on data in case files and incident files. It thus yields priorities which are responsive to previously existing problems which posed actual harm. This system should be complemented by one aimed at predicting potential for harm based on trends in the quantities and types of pesticides used. Such a system would require periodic surveys of pesticide use by the States and/or EPA. To date, resource limitations have prevented further exploration of this option.

The priority setting system for product/facility related inspections (see page 7) results in the targetting of specific persons and products for inspection. Again priority is based on a number of factors including violation history, production of products most likely to result in human or environmental harm if violative, and the need to show a government presence for important new regulations. Since States and Regions will use this system for the first time in FY84, EPA may need to make adjustments in FY85.

To assist in targetting use inspections, the Agency needs to encourage the successful generation and transmittal of referrals, tips, and complaints in both misuse and use areas. Therefore, EPA should undertake the following activities:

Expand Formal Referral Systems Within the Agency

A system for data audit/laboratory inspection referrals exists between the Office of Toxic Substances (OTS), OPP, and CMS. Also, OPP provides referrals regarding products not in compliance with the Child Resistant Packaging Regulations. A formal system for referrals for other requirements should be developed. EPA should encourage States to develop similar referral systems within each State.

Expand Referral Systems
With Other Agencies

While the Agency has referral systems for specific types of products or violations with FDA, Consumer Product Safety Commission (CPSC), Occupational Safety and Health Administration (OSHA), and Federal Trade Commission (FTC), it should expand the systems. EPA should encourage States to set up similar systems.

Improve Referral System
Between the Regions and States

FIFRA §27 requires EPA to refer all significant allegations of pesticide misuse to the States. The Interpretive rule provides specific procedures for the referral and tracking of such cases. Although all Regions have implemented informal referral and tracking systems, some systems are better developed than others. All the Regions need to implement a formal system.

Expand Work with the Press
and Special Interest Groups

Both EPA and the States periodically encourage the national and local trade press to write articles on new and existing pesticide control requirements. Knowledge of FIFRA and State pesticide laws have consistently resulted in discovery of violations of both laws. Because evidence of pesticide misuse may rapidly disappear, it is particularly important that EPA and the States expand their efforts to work with such groups as farmworkers to educate them about basic evidentiary requirements and the need to contact the government as soon as possible after occurrence of the alleged misuse. Efforts made in this area continue to be restricted by resource levels. CMS has issued a Complaint Form, which was sent out as an update to the FIFRA Inspection Manual, to facilitate the reporting of complaints or referrals.

Integration of Inspections

To make the most effective use of resources, both EPA and the States currently conduct inspections based in part on geographic proximity of the targets. Both will continue this approach.

EPA will also continue its program of integrating FIFRA and TSCA data audit/laboratory inspections.

Inspection Frequency

In the past EPA and the States were to inspect establishments manufacturing general use pesticides every 5 years and those manufacturing RUP's every 3 years. In practice, this has varied based on the number of establishments existing in a State. EPA has moved

away from requiring a specific frequency in its guidance. Instead, the Agency suggests that frequency be established through the priority setting system. This is true for misuse as well as establishment inspections.

Laboratories are expected to be inspected under the data audit/laboratory inspection program every 2-3 years.

Inspections at device producing establishments should be part of the routine inspections of establishments manufacturing general use pesticides. When the Agency is conducting a major testing program for specific devices, samples are collected at Headquarters' request or in response to complaints. Types of devices for which testing has been/is being conducted are water purifiers and electromagnetic, supersonic, and ultrasonic devices with rodenticide or insecticide claims.

Disinfectants are collected as part of a State's routine inspections. Since the Agency no longer conducts efficacy testing, there is no separate program for disinfectants.

Rodenticides are collected as a result of sample requests prepared by CMS. Samples are requested based on an OPP prepared list of products which OPP believes should be tested.

Follow-up Inspections

Follow-up inspections are conducted when more information is needed for a possible enforcement case or when violations have been found and the Region/State determines that another inspection is necessary in order to assure compliance. The frequency is determined on a case-by-case basis depending on the need for a follow-up inspection to assure compliance.

Inspection Quality

To ensure inspection quality and the evidentiary value of compliance monitoring information collected by the States, EPA will continue to provide training for State pesticide inspectors and State pesticide chemists. The types of training provided by EPA are described under the training section on page 9. Aside from training, basic guidance on the conduct of pesticide inspections is contained in the Pesticides Inspection Manual. This manual will be up-dated and revised if resources for this activity are available in the future.

In addition to providing training and basic guidance, EPA reviews State inspection reports to ensure that inspections are conducted properly, appropriate inspection procedures are followed, and sufficient evidence is collected to support enforcement actions. This review is normally conducted as part of EPA's routine oversight of the cooperative program during mid-year and end-of-year reviews. This review activity will continue.

In accordance with the Agency's Quality Assurance (QA) requirements, States receiving grant money through the cooperative enforcement program must develop QA Plans covering both compliance monitoring and sample analysis. These QA Plans must be submitted to the Regional Quality Assurance Officers annually for review and approval. The Compliance Monitoring Staff, with the approval of the EPA Quality Assurance Management Staff of ORD, has provided guidance to the Regions and States on the development of QA Plans.

Compliance Promotion Plans

Objective

Compliance promotion is an important component of any successful compliance program. The objective of compliance promotion is to ensure that the regulated community is aware of the requirements of FIFRA and related State pesticide laws and understands what it must do to comply.

Since neither EPA nor the States have sufficent resources to inspect every member of the community regulated under FIFRA, both must depend largely on voluntary compliance.

Tools

EPA and the States promote voluntary compliance with FIFRA through the following mechanisms.

Educational Programs

Certification and Training. Perhaps the most widespread compliance promotion tool is the pesticide applicator training and certification program. This program is conducted by EPA in two States and in other States by the States themselves. It ensures that both private (farmers) and commercial applicators (all others) are not only aware of pesticide use requirements and generally competent to apply pesticides but competent in particular to apply restricted use pesticides. Training materials are frequently revised, and EPA will issue further guidance in FY85 directing that information from the priority setting process be incorporated into certification and training materials and examinations as appropriate. Implementation of this guidance will be dependent on available resources.

Other education programs. These programs are designed to promote safe pesticide use. An example is Project SAFE, which is sponsored by the National Aerial Applicators Association and the Extension Service and is supported in part through cooperative agreement funds. During the first phase of project SAFE, trainers were trained to

conduct fly-ins* to teach aerial applicators better calibration techniques to minimize pesticide drift and to obtain optimal pest control with the minimum amount of pesticide. There have been three trainer fly-ins which involved approximately 30 States. During the next phase of the program, these trained specialists, mostly cooperative extension staff, will be conducting fly-ins for aerial applicators in their States to help the applicators calibrate and apply pesticides in the most environmentally effective manner.

Farmworkers Program

Several years ago, the Agency initiated a program to evaluate the specific problems of pesticide misuse related to farmworkers, especially the migrant farmworker.

In 1974, the Agency promulgated 40 CFR 170 Worker Protection Standards, which addressed four basic protections to persons engaged in agricultural hand labor in the field: 1) protection from being sprayed, 2) reentry periods (one general and 12 specific), 3) protective clothing, and 4) warnings. The worker protection rule found in 40 CFR 170 are implemented through the labeling of agricultural pesticides. The regulation is enforced at the registrant level by requiring specific label language. The regulation is enforced at the user label in that it is illegal to use a pesticide in a manner inconsistent with its labeling. A workgroup has been formed to revise the Worker Protection Standards at 40 CFR 170.

Language for use on outdoor agricultural products to meet the standards is being developed under OPP's Label Improvement Program. OPP is also considering a dual language requirement, English and Spanish, for highly toxic products labeled for agricultural use to help assure compliance.

The Agency continues to hold meeting with farmworker groups to discuss farmworker problems and seek solutions. CMS included in the annual cooperative enforcement agreement guidance a request that States consider Farmworker exposure in setting priorities.

Publications

Compliance Policy Compendium. The Agency has developed and will continue to expand its compendium of FIFRA Compliance Policies. These policies interpreting compliance requirements are available to the regulated community as well as the Regions and the States.

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* Fly-ins are programs in which aerial applicators actually fly their airplanes to the training site. They then fly over a designated area and apply water containing a dye. The spray pattern is then analyzed.

Suspended and Cancelled Pesticides Booklet. This booklet was first prepared by OMS in 1977. It was compiled to summarize and clarify Agency actions on pesticides which have been suspended, cancelled, or otherwise restricted. It was designed as a quick reference guide for use by pesticide inspectors but is available to the public.

Publication of Results of Major Testing Programs. In October 1980, OMS issued a publication called The Investigation of Efficacy and Enforcement Activities Relating to Electromagnetic Pest Control Devices. The results of the ultrasonic testing program will also be published in the future. These types of publications are useful to other Federal regulatory agencies, consumer groups, foreign countries, prospective producers of such devices, and to the public.

Notices of Judgment. Under Section 16(d) of FIFRA, EPA publishes enforcement actions taken against violators. It is believed that the Notices of Judgment have some deterrent effect.

Press Releases. These are generally issued when major violations occur or if public attention has been focused on a case.

Personal Contacts

Compliance Inspections. Discussions of regulatory requirements during inspections also provide a system for educating the regulated community concerning specific FIFRA requirements and the need to comply.

Public Presentations. EPA personnel give presentations and participate in panel discussions at industry conferences, seminars, and other public meetings.

Noncompliance Response Plan

The objectives of a program for responding to instances of noncompliance are 1) to ensure that violations and resulting problems are promptly corrected; 2) to quickly and effectively take equitable enforcement action against violators; and 3) to deter similar noncompliance in the future.

A broad range of enforcement responses is available under FIFRA, including advertisement letters (i.e., letters to registrants regarding advertising claims), warning letters, stop sale, use and removal orders, request for voluntary recalls, seizure, injunctions, administrative civil penalties, criminal penalties, suspension or revocation of certification, refusal to accept data from labs refusing inspection, suspension/cancellation of the registration, and revocation of the establishment number.

Detailed guidance for selecting the appropriate response is available to the Regions and States in the 1983 FIFRA Compliance/ Enforcement Guidance Manual and in the Civil Penalty Policies listed on page 25 under the Administrative Civil Actions Section. Inspections will continue to be conducted with increased frequency at those establishments with a violation history.

States also have a broad range of enforcement responses including fines, revocation of licenses and permits. Under EPA's interpretive rule for primacy, EPA considers a State's action to be adequate if the State takes the most stringent action available which is comparable to the available FIFRA response.

A description of the FIFRA enforcement responses follows:

Advertising letters

An advertising letter is a letter issued by EPA as notice to the company that collateral literature concerning a product (i.e., literature or advertising that does not accompany the product) bears unacceptable pesticide statements or pesticide or device claims. The letter may be issued on receipt of or knowledge of such literature. The letter requests a written response from the recipient informing the Agency of what action the company plans to take to correct the situation. Receipt of an advertising letter does not mean the recipient has been found in violation.

Notices of Warning - FIFRA §9(c)(3) or §14(a)(2)

For minor violations, a written Notice of Warning may be issued. Also, Notices of Warning are issued for first time violators which are private applicators or other persons not covered by Section 14(a)(1). Section 14(a)(1) covers registrants, commercial applicators, for hire applicators, wholesalers, dealers, retailers, and other distributors.

Notices of Detention - FIFRA §17

Section 17 authorizes EPA to refuse admission of a pesticide or device being imported into the United States if EPA determines that such pesticide or device violates any provisions of the Act. This refusal is known as a Notice of Detention and Hearing.

Stop Sale, Use, or Removal Order - FIFRA §13

The Administrator may issue a Stop Sale, Use, or Removal Order (SSURO) when: 1) based on inspection or tests, there is reason to believe that a pesticide or device is in violation of the Act or will be sold or distributed in violation of the Act, or 2) the registration of a pesticide has been cancelled or suspended.

Request for Voluntary Recall

No explict authority exists in FIFRA for the recall of products. The effectiveness of a recall action depends on the cooperation of the involved company. Recalls are considered for products which are likely to result in adverse effects to the user or environment, physical or economic injury due to ineffectiveness or presence of residues. There are two types of recalls formal and informal. The level of recall also varies, i.e., wholesale point of distribution, retail, or user level. The scope may also vary, e.g., one batch or all of the product.

Seizure - FIFRA §13

Section 13(b) gives EPA the authority to initiate in rem condemnation proceedings in district court. Seizure is generally used if a Stop Sale, Use, or Removal Order is not being obeyed, or for extremely hazardous pesticides that require removal from the marketplace or place of use, or if a company does not comply with a Recall Request, or to dispose of products being held under a Stop Sale, Use, or Removal Order, if appropriate.

Injunctions - FIFRA §16(a)

EPA has the authority to initiate injunctive actions before district courts. This is to be used 1) when all other remedies would be inadequate to restrain a violation or to prevent unreasonable risk, 2) all other remedies have been used but the violation continues, or 3) irreparable injury, loss, or damage will result if relief is not granted.

Penalties - FIFRA §14(a) and (b)

Any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who violates any provision of the Act may be assessed a civil penalty of up to $5,000 per offense. Should any of the above-mentioned parties knowingly or willfully violate the Act, a criminal penalty of up to $25,000 and/or imprisonment for up to one year may be imposed. A private applicator or other person not included above who violates the Act after receiving a warning letter or citation for a prior violation may receive a $1,000 civil penalty for each subsequent offense. "For hire" applicators may be fined $500 for the first offense and $1,000 for each subsequent offense. Criminal penalties for private applicators and "for hire" applicators may be a fine of up to $1,000, 30 days' imprisonment, or both.

Civil Penalties are issued by the Agency and criminal cases are handled by the Department of Justice.

Civil Administrative Penalties - FIFRA §14(a)

A civil penalty, as authorized by FIFRA §14(a), is the remedy of choice for most violations. Figure 1 in the Appendix contains a flow chart for FIFRA cases. A civil penalty should be proposed where the violation presents (a real but not an extreme and unreasonable) risk to humans or the environment; is likely to be an isolated occurrence; was apparently committed as a result of ordinary negligence, inadvertence, or mistake; and either:

- o Involves a first offense under the Act by any registrant, commercial applicator, "for hire" applicator, wholesaler, dealer, retailer, or other distributor (no prior warning is required by FIFRA for violators in this category); or

- o Involves a private applicator or other person, other than any party specified in the first category, who has received a prior warning or citation for a violation of FIFRA. (The prior warning or citation may have been for the same or a different FIFRA violation.)

Under FIFRA §14, the Agency may issue administrative civil complaints to persons who violate FIFRA §12. The Agency must establish by proper evidence each element of the violation charged. Generally, the Region issues the Civil Complaint. (The Regional Administrator is delegated the authority to issue administrative complaints and negotiate and sign consent agreements).

The following factors are used to determine the penalty amount: 1) the size of the business of the person charged, 2) the effect on the defendant's ability to continue in business, and 3) the gravity of the violation. The penalty assessment system initially determines a penalty amount based on the nature and extent of violation and then adjusts this amount in consideration of mitigating or exacerbating factors. The guidelines for assessing civil penalties are provided in the following documents:

- o Guidelines for Assessing Civil Penalties Under Section 14(a) and Citation Charges for Violations of FIFRA (published July 31, 1974 at 39 FR 27711).
- o Memorandum (22 April 1975) - Interim - Deviation from Civil Penalty Assessment Schedule.
- o Guidelines for Enforcing the Child-Resistant Packaging Regulation (June 1981)
- o Memorandum (11 June 1981) — FIFRA Enforcement Policy; Interim Penalty Guidelines.

Note: All the above documents are found in the 1983 FIFRA Compliance/Enforcement Guidance Manual prepared by CMS and the Office of Legal and Enforcement Policy. Also, the Consolidated Rules of Practice (CROP, prepared by CMS and promulgated on April 9, 1980, 45 FR 24360, codified at 40 CFR §22) governs all adjudicatory proceedings for the assessment of civil penalties under FIFRA.

After a complaint is issued, a respondent is given a Notice of Opportunity for an Informal Settlement Conference with Regional personnel. The respondent has a right to request a hearing concerning any fact in the complaint or on the appropriateness of the assessed penalty. Such a hearing will be held before an EPA Administrative Law Judge. A respondent may appeal the decision of the Agency's Judicial Officer. The respondent can then appeal the Judicial Officer's decision to the Administrator. He may then appeal the Administrator's decision to a United States Court of Appeals. Finally, he may appeal the decision to the Supreme Court.

Criminal Proceedings - FIFRA 614(b)

The Agency may initiate criminal proceedings in every case in which EPA can meet the stringent requirements of evidence and proof leading to a conviction. However, Agency policy, as well as pragmatic resource considerations, argue against the use of criminal sanctions in any but the most serious instances of environmental misconduct, as determined by the nature of the violation, the history of compliance on the part of the responsible person, or the seriousness of the environmental consequences.

Criminal action is appropriate for knowing and willful violations which actually or potentially result in serious harm to health or the environment. EPA will follow the guidance contained in the Criminal Enforcement Priorities for the Agency set forth in Robert E. Perry's memorandum of October 12, 1982. EPA will identify cases for criminal action as early in the case development process as possible to ensure that the potential defendant's rights are protected and to ensure the integrity of the criminal enforcement process. When a Region receives information indicating potential criminal activity, it will refer the matter to the Criminal Enforcement Division at Headquarters for further investigation and prosecution.

Use of Criminal Proceedings

The Agency has identified a number of specific situations for which criminal prosecution is particularly appropriate. To list these situations, however, should not be viewed as precluding criminal prosecution in circumstances not included below:

- o Failure to report information on the unreasonable adverse effects of a registered pesticide;
- o Falsification of records;
- o Violation of an order suspending or cancelling a product registration;
- o Violation of an SSURO;
- o Unlawful uses of pesticides; and
- o Illegal distribution of unregistered pesticides.

Denials, Suspensions, Modifications, or Revocations of Applicator Certification

The regulations relating to the certification of pesticide applicators (40 CFR Part 171) authorize EPA to deny, suspend, modify, or revoke Federally issued applicator certifications if the certificate holder violates FIFRA or its regulations. EPA considers this a strong measure, to be taken only when public health, interest or welfare warrants immediate action. Therefore, EPA will deny, suspend, modify, or revoke a certification only in response to serious violations or against persons with a history of noncompliance.

Refusal to Accept Data from Laboratories Refusing Inspections

This policy is stated in the final FIFRA Good Laboratory Practice Regulations (GLP's) which are to be promulgated in FY84.

Suspension/Cancellation of Registration

This is an action which may be considered if the statement of compliance or noncompliance with the GLP's that is to be submitted along with any data under FIFRA §3 is falsified. This action is discussed in the final FIFRA GLP's.

Termination of Establishment Registration

The regulations on the registration of pesticide-producing establishments (40 CFR §167.3) state than an establishment registration will remain in effect so long as the establishment continues to submit annual pesticides reports. If an establishment does not submit an annual pesticides report within 20 days after receipt of a Notice of Warning or civil penalty for failure to submit the report, EPA will initiate procedures to terminate the establishment registration.

Federal Facilities

Generally, if Federal Agencies are found in violation of FIFRA the EPA does not issue penalties. This is in accordance with Executive Order 12088, Federal Compliance With Pollution Control Standards, which established a government wide program for ensuring Federal facility compliance with pollution control requirements. Instead of assessing penalties, EPA tries to resolve the problem. First, a Notice of Warning is issued to notify facility managers of violations, and the EPA works with the violative agency to establish a remedial plan. If the problem cannot be resolved between agencies, the matter is referred to OMB.

With regard to criminal action, the Department of Justice has indicated it would not allow EPA to file suit against another Executive Agency. In FY 1983, EPA issued a warning letter to the Fish and Wildlife Service for failure to comply with the provisions of an EUP.

The EPA Office of Federal Activities has developed a Federal Facilities Compliance Program Strategy which outlines how EPA Headquarters and Regional offices will handle Federal facility compliance activities. This strategy covers:

- o Technical Assistance - to ensure cost effective and timely compliance.
- o Compliance Monitoring - to monitor actual compliance.
- o Fiscal Planning Assistance - to assist OMB in evaluating budget requests for funds to comply with pollution control requirements and monitor use of funds.

- o Resolution of Non-Compliance Disputes - to notify facility managers of violations and establish remedial plans.

- o Exemptions - to advise the President, through OMB, on Federal Agency recommendations for exemptions.

Headquarters/Regional Coordination

To ensure implementation of the national FIFRA compliance/enforcement strategy, Headquarters and the Regions will communicate through the following mechanisms:

- o Policy and Guidance documents
- o Reporting and tracking through FATES
- o Technical assistance and review for inspections and casework
- o Evaluation of State and Regional Programs

The following is a brief discussion of each of these mechanisms.

Policy and Guidance Documents

Policy and guidance documents currently exist for all phases of the program. These documents will be revised and supplemented as necessary. Plans for revisions and new guidance are discussed on page 37. Both Regions and States will continue to be included in the review of all major policy and guidance documents.

Reporting and Tracking

The FATES system described previously is an integral tool for inspection targetting program evaluation, responses to the Hill, OMB, and budget development. Headquarters plans to revise the FIFRA §7 establishment registration rule and report form to improve the usefulness of data in the system.

Technical Assistance

Headquarters will continue to provide the Regions guidance in performing inspections and developing cases. CMS will also continue to coordinate technical assistance for the Regions through NEIC.

Evaluation

Headquarters will continue to advise the Regions regarding the effectiveness of their Federal programs and oversight of State programs through the Regional Reviews and through written and verbal communication with the CMS.

Federal/State Relationship

Most States now have entered into cooperative agreements with EPA for compliance/enforcement and C & T programs. However, EPA still retains distinct responsibilities under both programs. The relationship under the C & T program is discussed on page 32.

Cooperative Enforcement Program

As the cooperative enforcement program has evolved, the States with agreements have accepted increasing responsibility and now share fully in all phases of the program with EPA.

Compliance/Enforcement Activities

The States with cooperative agreements conduct all FIFRA compliance monitoring activities related to pesticide production sale and use. Federal inspections are limited to those related to data audit, imports, and assistance upon State request in major spray programs in the State. (These major spray programs are usually funded by Federal agencies.) In addition, EPA through NEIC provides technical assistance including:

- o pesticide use investigation workshops
- o state-of-the-art techniques for monitoring pesticide drift
- o conducting state chemists training courses
- o evaluating State pesticide laboratories and providing check sample analyses

Under the terms of the cooperative agreements, States will take all enforcement actions on violations of only State law and will refer all violations of only Federal law product and establishment registration requirements to EPA for enforcement action. Where there is a violation of both State and Federal law, a State may take enforcement action itself or refer the case to EPA if it is unwilling or unable to do so.

All States with cooperative agreements also have primary use enforcement responsibility (primacy). Under the terms of FIFRA §§26 and 27 and the final rule interpreting these sections, EPA may not take enforcement action on a significant case referred to the State unless the State does not take adequate and timely enforcement action.

State Program Oversight

EPA has primary responsibility for cooperative enforcement programs oversight; however, the States are closely involved in this process.

Program Guidance and Compliance/Enforcement Priorities

The States through SFIREG (State FIFRA Issues, Research and Evaluation Group) participate in the development of annual program guidance. Although the guidance contains national priorities, these are only for consideration by the States as they develop

their own annual program priorities. Specific outputs for compliance/ enforcement activities are negotiated on the basis of the State priorities and productivity factors in the guidance.

Program Evaluation

Major elements of the Regional evaluation of State programs include:

- o Semiannual reports by the States of their accomplishments compared to the types and numbers of inspections projected in the grant agreement.
- o Midyear and end of year on-site evaluation based on a uniform evaluation protocol which contains both quantitative and qualitative evaluation factors. The States are given an opportunity to review evaluation reports before they become final.
- o Training and close informal review of the quality of State activities.

The effectiveness of a State program is judged primarily on the quality of its priority setting system, its adherence to negotiated number of outputs, the quality of its inspections and the adequacy of its enforcement responses.

Federal Program in Non-Cooperative Agreement States

In Colorado, Nebraska, and Wyoming, EPA conducts the entire Federal enforcement program. The Regions use the same priority setting mechanism used by States with cooperative agreements to allocate resources, conduct all inspections and take enforcement actions.

EPA will continue its efforts to persuade these States to participate in the Cooperative Program.

Cooperative Certification and Training Program

Certification and Training Activities

Currently all States but two have approved and operating State pesticide applicator certification plans. All States with the exception of Colorado have applicator training programs administered by their State Cooperative Extension Service in accordance with FIFRA §23. Ten Indian tribes have received EPA funds to develop Certification Programs. Under the C & T program, over 1.6 million private applicators and 496,000 commercial applicators have been certified and trained. As of September 1982, there were over 600,000 private applicators and over 266,000 commercial applicators recertified.

EPA will continue to conduct certification programs in States without certification plans. Both EPA and States update training material and information to ensure that applicators are aware of changing technology. EPA and States will continue to certify new applicators.

Program Guidance and C & T Priorities

In the past priorities for the C & T program have been the approval and, when necessary, the amendment of State certification plans along with the maintenance of training programs. Two studies of national scope were performed. One involved pre and post testing of applicators in North Carolina; the other consisted of a comprehensive telephone survey of attitudes and practices of private applicators in five States. On-site evaluation of State program effectiveness has been performed by Regional personnel without specific guidance from Headquarters. Headquarters personnel accompanied by Regional personnel have visited States and reviewed certification files. However, there has been no requirement that EPA monitor certification and training sessions and evaluate content, presentation, and effectiveness. A recent GAO study found in two States that enforcement misuse information was not incorporated in C & T sessions and that commercial applicators were not fully tested against the EPA standards of competency.

In response to the recent GAO report, EPA intends: 1) to ensure that enforcement problems identified in the priority setting process are addressed as appropriate in certification and training materials; 2) to ensure that State programs require applicators to meet Federal standards of competency; and 3) to review and revise training materials as appropriate.

Program Evaluation

Major elements of the Regional evaluation of State programs include:

- Semiannual reports by the States of their accomplishments compared to the types and numbers of activities projected in the grant agreement.

- Midyear and end of year evaluations based on uniform evaluation protocol which contains both quantitative and qualitative evaluation factors.

Coordination with Enforcement

Stronger emphasis will be placed on transferring information from the enforcement priority setting process to the certification and training program for inclusion in training and certification materials. To accomplish this, EPA will include in its annual Cooperative Agreement Guidance a request that States establish a management mechanism which will assure that information on priority pesticide problems are included in the State's certification and training programs, as appropriate.

Update of Materials

The core manual and various category manuals were recently updated to reflect changing needs and technology. Copies of the manuals will be printed by the State Cooperative Extension Services (SCES). These and other training materials will be cataloged at the USDA Beltsville library using EPA funding. The problem continues to be future availability of copies. Neither the Government Printing Office or the Department of Commerce will maintain copies of these publications for distribution and sale. Therefore, while copies can be reviewed at the Beltsville library, a user can only print his own copies from a camera ready copy, or if the timing is correct, order from a SCES which is about to make a printing run. SCES's do not usually maintain an inventory of copies for sale. Therefore, the problem is not so much updating training material, but making it available when requested to groups other than the SCES's.

Indian Tribes

Ten Indian tribes have received EPA funding assistance to develop certification plans and some draft Indian plans are now being reviewed. Therefore, while some tribes will probably have approved plans, others will not. EPA must then urge these tribes to enter into an arrangement with States to perform certification on the reservations or EPA must establish Indian certification programs. There is also the possibility of some split options, such as, States issuing certificates and EPA enforcing misuse and denial, suspension or revocation of certification.

Review Plans

A more complex and long-term proposal is the review of all existing certification plans for adherence to current standards. Currently limited resources preclude such an evaluation.

Colorado and Nebraska

Efforts will continue to be made to have these States develop and submit certification plans. Colorado has recently indicated its interest in developing a program which will initially address only commercial applicators. The Nebraska State Cooperative Extension Service has provided training since the program began, and this should prove an asset in the effort to have the Nebraska Department of Agriculture develop a certification program.

Federal Facilities

Federal agencies can have their employees certified under State or EPA administered certification programs. Most Federal agencies chose this option, even though it imposes geographic limitations on where the applicator can apply pesticides, i.e., the State issuing the certificate or States with reciprocal agreements. However, because some Federal applicators must work in several States, often on short notice, EPA allows Federal

agencies to develop certification plans for their employees. Applicators certified under Federal agency plans can apply pesticides anywhere, but this certification is limited to official duty functions. To date, three Federal agencies, DOD, USDA and DOI, have approved Federal agency certification plans.

Cross Program Elements

The pesticide program impacts regulations and enforcement of other State and Federal environmental statutes. There is a need to 1) establish a better and more formal referral program, and 2) to develop a mechanism to educate inspectors on the various program requirements in order for them to effectively make referrals to other programs.

IntraAgency

Toxic Substances Control Act (TSCA)

Since CMS is responsible for both FIFRA and TSCA compliance/enforcement, activities under both programs are closely coordinated.

PCB's (Polychlorinated Biphenyls) in Pesticides. Use of oil containing any PCB's as a pesticide carrier has been prohibited under TSCA. Additional TSCA regulation of chemicals may have a similar impact on pesticide registration and use which require monitoring under both Acts.

Pesticide Precursors and Intermediates. Hazardous pesticide precursors, and intermediates which are not directly regulated under FIFRA are regulated under TSCA.

Pesticide Wastes. The TSCA §6 Dioxin Rule regulates waste from the manufacture of 2,4,5-Trichlorophenol and its pesticide derivatives. TSCA Dioxin Rule inspection targets were derived primarily from information collected under FIFRA Section 7.

Data Audit/Laboratory Inspections. The FIFRA Data Audit Laboratory Inspection program directly complements the TSCA program in that information is shared and inspections under FIFRA and TSCA are coordinated and conducted in conjunction with one another whenever possible. The programs are formally coordinated through an OPTS Data Audit Panel which has representatives from OPP, OTS, and CMS. The Panel deals with targetting inspections, case evaluation, and enforcement or regulatory responses.

Hazardous Waste Program

Pesticides are a major constituent of the wastes at a large number of hazardous waste sites and information on registrants and producers is needed for clean-up cost recovery and associated enforcement actions. Information on pesticide manufacturers has been provided to the Office of Waste Programs Enforcement as part of the Agency's dioxin monitoring program.

For pesticides listed as hazardous wastes under Resource Conservation and Recovery Act (RCRA), disposal of the pesticide and/or empty container is directly regulated under RCRA. Investigations and cases involving illegal disposal of RCRA regulated pesticides identified under FIFRA or associated State enforcement programs requires close cooperation with State and Federal RCRA personnel. Pesticide investigations may also provide information on disposal practices which point to the need for regulation under RCRA.

Water Program

Use of pesticides resulting in drift into water is primarily a FIFRA and State pesticide enforcement function having a direct interface with Water Quality Criteria established by the Water Programs. Pesticide contamination of groundwater resulting from pesticide use also requires coordination between the pesticides and water programs.

InterAgency

Data Audits/Good Laboratory Practice Inspections

As discussed on page 10, FDA conducts inspections for EPA at laboratories which conduct health effects studies.

Spray Programs

As discussed on page 28 under Federal Facilities, EPA/States have monitored spray programs conducted by USDA and the DOI.

Efficacy Testing

As discussed on page 11, EPA has coordinated with FDA, USDA, DOI, and the Bureau of Standards to have testing conducted on ultrasonic devices, electromagnetic devices, and rodenticides.

C & T

EPA works with other Federal Agencies at their request in the development and implementation of C & T programs. Currently DOD, USDA, and DOI's Bureau of Land Management have approved C & T programs.

Food Contamination

USDA and FDA monitor pesticide residues in food. Both agencies forward reports on food contamination by pesticides to EPA for followup investigation, if appropriate.

Referrals and Information Exchange

EPA coordinates with USDA, FDA, DOI, FTC, CPSC, and the U.S. Postal Service on several specific types of products/devices that are of mutual interest.

Program Evaluation

A system for evaluating the effectiveness of the FIFRA compliance/enforcement program must define specific areas for evaluatio measures of program success and mechanisms for performing the evaluation. The Agency can best measure its success in achieving compliance when it has developed 1) an adequate data base for identifying members of the regulated community and 2) predictive models designed to select those members most likely to be in violati At that stage, the Agency can consider its program a success if only 13% of those persons inspected under a neutral scheme are violators of FIFRA.

Evaluation Areas

Areas for evaluation include 1) adherence by EPA and the States to quantitative and qualitative performance commitments; and 2) the extent of compliance with FIFRA by the regulated community.

Measures of Success

Adherence to Commitment

The adherence by EPA and the States to performance commitments can be measured by the following factors:

- o Implementation of a priority setting scheme.
- o Adherence to output commitments as measured by the Administrator's Management Accountability System.
- o Adherence to inspection procedures required in guidance.
- o Number, promptness, success and adequacy of enforcement actions
- o Accuracy and timeliness of compliance data entry and retrieval

These factors will allow a quantitative and qualitative evaluation of the system.

Compliance by the Regulated Community

The extent of compliance for the regulated community may be measured to a limited degree by the following factors:

- o Number of applicators trained and certified.
- o Proportionate number of establishments known to be in compliance.
- o Proportionate number of applicators known to be in compliance.
- o Proportionate number of laboratories known to be in compliance.
- o Trends in major types of violations.

Evaluation Mechanisms

The major mechanisms to be used in program evaluation are the following:

- o FATES. The FIFRA and TSCA Enforcement System contains data on inspections and sampling, case development, grants and contract inspections. This data will be analyzed to determine whether program commitments were met. The FATES system should be modified to include State data and to generate descriptive information which could be used to better target inspection areas based on an analysis of major types of violations and violation trends. However such a modification cannot be implemented without additional resources. In FY86, CMS plans to request funding to incorporate State data into FATES.

- o Mid-year and end of year State program reviews. As discussed on page 31, these reviews/evaluations are based on a uniform evaluation protocol which contains both quantitative and qualitative evaluation factors.

- o Regional Reviews. A team of Headquarters and Regional personnel visits each Region every two years to conduct a thorough program review. The review concentrates on Regional program organization; performance of outputs; adherence to national guidance in the performance of inspections and development of cases; and the need for improved/expanded Headquarters support of Regional activities in specific areas.

  Approximately four weeks after the on-site review, Headquarters submits a written report to the Region covering all program elements that were part of the review. The report notes both positive and negative aspects of the Region's pesticides compliance/enforcement program and includes recommendations for changes to be implemented by the Region and Headquarters. The Director of the Compliance Monitoring Staff conducts a follow-up visit with the Regional Administrator to go over any issues raised by the review which require further discussion.

- o Periodic review of overall program based on review of FATES data and State and Regional reviews. In order to effectively evaluate the program, it is necessary to review the program in its entirety.

Program Modification

EPA uses data from FATES, State Program Reviews, Regional reviews and the overall program review, to modify the compliance/enforcement program as necesary and to give input to OPP concerning regulatory changes necessary to facilitate compliance monitoring, enforcement, or compliance.

Future Guidance

The following is a list of guidance documents currently under development or consideration.*

- o FY85 Cooperative Agreement Guidance. This document will modify C & T allocations, specific instructions on transferring enforcement priorities to the C & T programs, evaluation of the C & T program plans and training materials, and improved productivity factors for negotiating grant outputs.

- o FIFRA Compliance Program Policy Compendium further defines the requirements of FIFRA regulations. Currently there are twenty such policies in the compendium and three under review by the Regions, the States (through SFIREG), and the program office.

- o FIFRA Inspection Manual provides information on conducting inspections, collecting samples, chain-of-custody procedures, preparing support documents, and other information necessary to conduct FIFRA inspections. This document should be revised if resources are available.

- o FIFRA Enforcement Response Policy. Several additions to the original penalty policy have been developed over the years to reflect amendments to the law. These will all be combined into one comprehensive document.

- o FIFRA Compliance Strategies. The FIFRA Compliance Strategies are developed for all rules promulgated under FIFRA. A compliance strategy identifies the (a) requirements of the regulation, (b) the type of actions which are appropriate for the violation, (c) the inspection scheme (from which the regulated community is targetted), and (d) allocation of responsibilities between Headquarters and the Regions.

- o Quality Assurance Plan Development Guidance When manuals are updated, and as resources are available, CMS will coordinate with the Office of Research and Development's Quality Assurance Management Staff and the NEIC in developing a model Quality Assurance Plan for use by the States in developing individual Quality Assurance Plans. States receiving Federal funds for compliance monitoring must submit Quality Assurance Plans to EPA annually.

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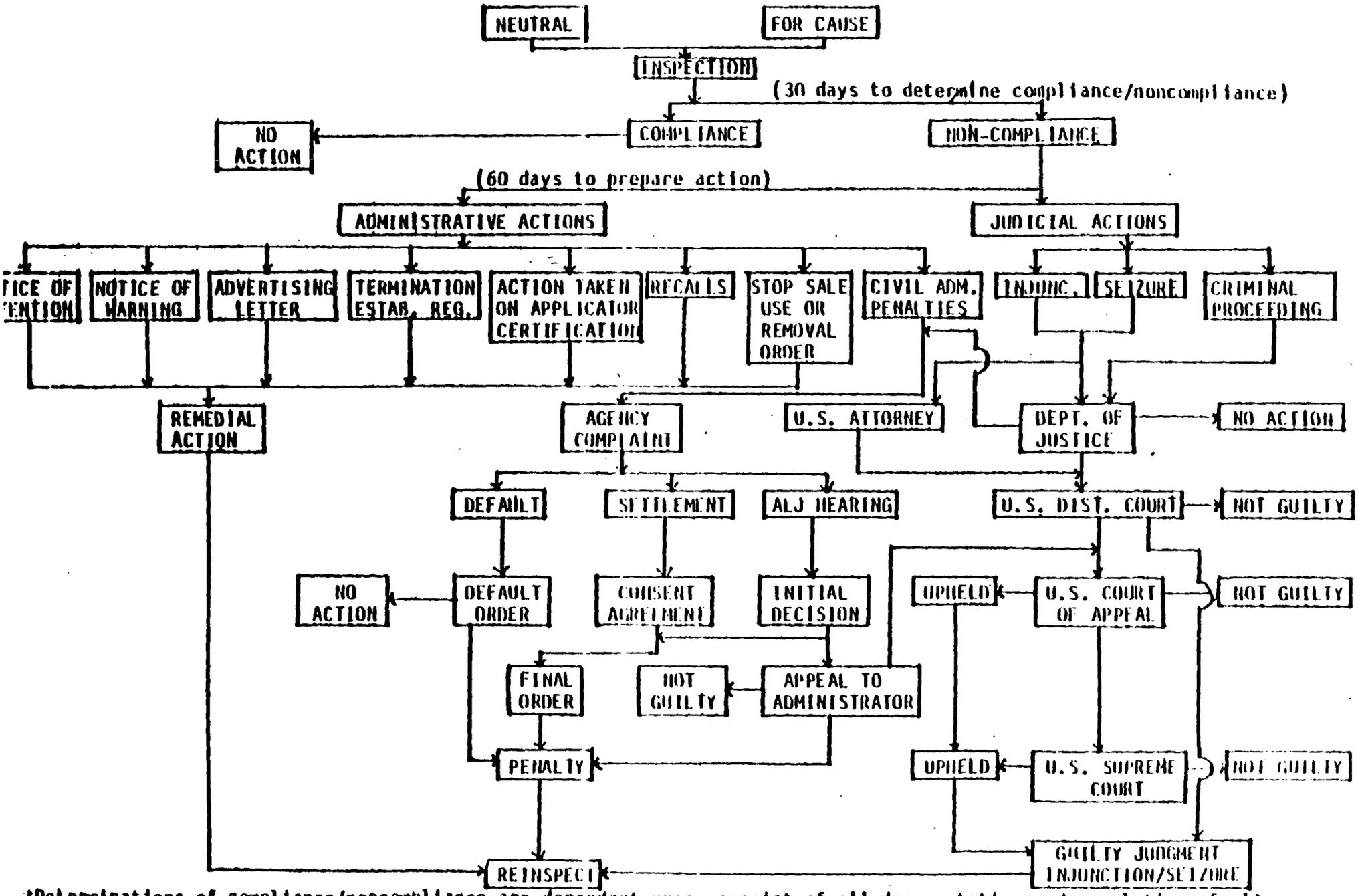
* A comprehensive list of existing compliance/enforcement guidance documents is included in the Appendix of the FIFRA Compliance/Enforcement Guidance.

APPENDIX

Figure I

FIFRA CASE FLOW



*Determinations of compliance/noncompliance are dependent upon receipt of all documentation and completion of all sample analyses. Action preparation is dependent upon resolution of any new policy issues presented by the case. The timeframes are based on the ideal situation.

[redacted] E

ENFORCEMENT ACTIONS RESULTING FROM GRANT INSPECTIONS
FY81 ACCOMPLISHMENTS
REGION National

ENFORCEMENT ACCOMPLISHMENTS	AGRICULTURAL Use	AGRICULTURAL Misuse	NONAGRICULTURAL Use	NONAGRICULTURAL Misuse	EXP USE INSP	PRODUCE ESTAB	MARKET-PLACE	IM-PORTS	CERTIFIED APPLICR RECORDS	RESTRICTED USE PEST DEALERS	TOTAL
Inspections	2,923	3,675	4,631	1,807	384	2,653	12,522	523	11,175	9,811	50,104
Civil Actions	19	70	7	160	20	30	142	6	159	44	665
Criminal Actions	2	47	20	77	0	5	1	0	90	0	242
Administrative Hearings	16	76	21	65	0	25	57	2	67	14	343
License/Certificate Suspension	1	33	11	13	0	0	3	0	502	2	565
License/Certificate Revocation	14	126	10	6	0	3	0	0	26	1	186
License/Certificate Conditioning or Modification	8	17	24	2	0	2	3	0		0	57
Number of Cases Issued Warnings	366	366	694	412	16	402	620	1	706	219	3802
Stop-Sale, Seizure, Quarantine or Embargo	24	17	62	21	3	77	1032	0		50	1301
Cases Forwarded to EPA for Action	11	22	4	29	3	119	163	0	7	0	354
Other Enforcement Actions	0	43	25	51	0	87	970	10	2	9	1197
Total Number of Actionable Inspections	451	817	878	846	42	750	2991	19	1561	347	8712
Percent of Inspections Resulting in Action	15.4	22.2	18.9	46.8	10.9	28.3	23.9	3.6	13.9	3.5	17.4
Percent of Total Actions (8712)	5.2	9.4	10.1	9.7	0.5	8.6	34.4	0.2	17.9	4.0	100
Number of Cases Assessed Fines	12	59	9	93	14	30	136	15	26	22	424

TABLE 11

ENFORCEMENT ACTIONS RESULTING FROM GRANT INSPECTIONS

FY82 ACCOMPLISHMENTS

NATIONAL

ENFORCEMENT ACCOMPLISHMENTS	AGRICULTURAL Use	AGRICULTURAL Misuse	NONAGR Use	CUTURAL Misuse	EXP USE INSP	PRODUCE STAB	MARKET-PLACE	IM-PORTS	CERTIFIED APPLICR RECORDS	RESTRICTED USE PEST DEALERS	OTHER *	TOTAL
Inspections	4,841	2,401	4,962	1,792	313	2,339	15,932	174	14,708	11,779	76	59,317
Civil Actions	22	26	20	27		2	10		7	5	1	120
Criminal Actions	2	15	41	152		1	5		5			221
Administrative Hearings	20	59	43	175		14	57		27	11		406
License/Certificate Suspension		29	7	21					148	11		216
License/Certificate Revocation	1	5	18	35					1			60
License/Certificate Conditioning or Modification	8	13	3	3			1		2			30
Number of Cases Issued Warnings	123	471	666	406	1	237	585	3	742	218	17	3,469
Stop-Sale, Seizure, Quarantine or Embargo	18	12	38	54		136	1,024	1	5	119	124	1,531
Cases Forwarded to EPA for Action	9	10	10	5	30	69	84	4	2		1	224
Other Enforcement Actions	51	17	173	52		14	940		102	127	3	1,479
Total Number of Actionable Inspections	254	657	1,027	930	31	473	2,706	8	1,041	491	146	7,764
Percent of Inspections Resulting in Action	5.2	27.4	20.7	51.9	9.9	20.2	17.0	4.6	7.1	4.2	-	13.1
Percent of Total Actions (7764)	3.3	8.5	13.2	12.0	0.4	6.1	34.8	0.1	13.4	6.3	1.9	100
Number of Cases Assessed Fines	10	25	5	105		2	6	0	25	11		190

* Includes 76 other Inspections and one Civil Action in Region 11 and 145 enforcement actions reported by

TABLE III

FEDERAL PESTICIDE COMPLIANCE INSPECTIONS

	FY79	FY80	FY81	FY82	FY83 [1]
Producer Establishment Inspections	448	284	287	286	161
Use Investigations	482	559	485	414	124
Marketplace Inspections	1115	320	291	283	210
Import Inspections	382	494	241	306	301
Dealer Inspections	359	956	946	719	0
Laboratory Audits/ Inspections	17	8	4	13	25
TOTALS	2803	2621	2254	2021	821

[1] 2nd Quarter FY83 Totals

FEDERAL PESTICIDE ENFORCEMENT ACTIONS

	FY79	FY80	FY81	FY82	FY83
Civil Complaints Initiated	253	176	151	176	221
Criminal Referrals Initiated	2	4	0	2	1
Stop Sale, Use, Removal Orders	479 2/	113	105	50	42
Notices of Warning	507	831	429	856	1270
Import Detentions	91	70	71	53	11
TOTALS	1332	1194	756	1137	1545

1/ Second Quarter FY83 Totals
2/ An additional 24,000 Stop Sale Orders were issued to firms that held suspended 2,4,5-T and Silvex products.

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

JAN 15 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Final GLP Compliance Strategy

FROM: A. E. Conroy II, Director
Office of Compliance Monitoring (EN-342)

TO: Addressees

Attached for your information is the final compliance strategy for the Good Laboratory Practice (GLP) regulations (also attached) published on November 29, 1983 (48 FR 53922). The rules became effective on December 29, 1983 for the Toxic Substances Control Act (TSCA) and on May 2, 1984 for the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Office of Compliance Monitoring (OCM) is now evaluating comments on the TSCA GLP enforcement response policy (ERP) and the final ERP is expected to be completed during the second quarter of FY 85.

We appreciate the time and effort spent by the various program offices and regions in reviewing this document. OCM received several editorial comments regarding the compliance strategy which has helped to clarify portions of the final policy. While all the comments received were reviewed, all comments were not incorporated into the final policy. Responses to the most significant comments are provided below.

Comment 1- For large commercial laboratories and/or complex studies, two days notice prior to inspection is unrealistic. Recommend two weeks. Without adequate notice... personnel and key data... (may not be) readily available.

Response- The GLP regulations have provided adequate notice to all persons, in the section for storage and retrieval of records and data, that there shall be archives for orderly storage and expedient retrieval of all raw data and documentation. Persons will be in violation of the GLP regulations when not complying with this provision. Two days has generally been accepted as adequate notification by the other commentors and OCM staff.

Comment 2- OTS has noted that "some data submitted with PMNs have stated that studies were done according to GLPs (usually OECD GLPs). However, protocols are often missing, test substances are inadequately defined, and there are other deviations from any known GLPs. OTS recommends that claims that data were in accordance with GLPs not be allowed unless the data reports are sufficiently detailed to support the claim. As a GLP compliance issue, this recommendation should be considered by OCM."

Response- OCM does not have the authority to restrict persons from making claims such as described above. OTS could remedy this by amending the PMN rule requiring submitters to 1) provide statements with PMNs indicating whether the submitted studies adhere to the GLPs and 2) support such claims with sufficiently detailed reports. When OTS has concerns with specific data and compliance with the GLPs, OTS should provide OCM a list of studies supporting PMNs and the names of the labs. OCM can then schedule inspections/audits at the laboratory.

Comment 3- OPP recommends that the "quality assurance unit establish written procedures which it would follow in conducting inspections." OPP justifies this request by stating that section 160.35(d) of the FIFRA GLP regulations does not clearly identify who is responsible for writing the procedures.

Response- OCM agrees that such language is needed. However, OCM does not have the authority to require this in the GLP strategy unless it first appears in the GLP regulation. OCM suggests that OPP propose an amendment to the regulation regarding this subject.

Comment 4- OPP recommends that the GLP strategy indicate that management communicate deviations from the regulations "in writing" to EPA because the GLP regulations do not specify the means of communication.

Response- Same response as for comment 3.

If you have any questions concerning this memorandum, please call Richard Green of my staff at (202) 382-7845.

Attachments

Addressees

Marcia Williams	Air and Waste Management Division Directors
Don Clay	Environmental Services Division Directors
Steven Schatzow	Regional Toxics and Pesticides Branch Chiefs
Terrell Hunt	Office of Regional Counsel
Ruth Bell	
Jim McCormick	

Strategy for the Enforcement of the Good Laboratory Practice Regulations Under TSCA and FIFRA

Overview

On November 29, 1983, the Environmental Protection Agency (EPA) published final rules establishing Good Laboratory Practice (GLP) standards for the conduct of laboratory studies that are used to obtain data for hazard evaluations under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Federal Food, Drug, and Cosmetic Act (FFDCA), and the Toxic Substances Control Act (TSCA). The GLP regulations became effective on December 29, 1983 for TSCA and on May 2, 1984 for FIFRA. They were the result of investigations by the Food and Drug Administration (FDA) and EPA which showed that some studies submitted in support of the safety of regulated products and pesticides had not been conducted in accordance with acceptable practice, and that, accordingly, the quality and integrity of such studies were not always adequate. In conjunction with EPA's new data audit efforts, the regulations are intended to ensure the high quality of laboratory test data required to evaluate the health and environmental effects of regulated chemical substances and pesticides.

The Assistant Administrator for Pesticides and Toxic Substances has established a Laboratory Data Integrity Program (LDIP) within the Office of Compliance Monitoring (OCM) which combines the GLP inspection program with EPA's data audit program. OCM, the Office of Pesticide Programs (OPP), and the Office of Toxic Substances (OTS) are charged with cooperating in the development and conduct of an effective laboratory inspection and data audit program.

Requirements of the Rule

Applicability

The GLP regulations apply to any study conducted, initiated, or supported on or after the effective dates of the rules that relate to health effects, environmental effects, and chemical fate testing under TSCA and studies (as defined by section 160.3(m) of the FIFRA GLPs) that support or are intended to support applications for research or marketing permits for pesticide products regulated by EPA. By their terms the rules apply to studies related to TSCA Section 4 Test Rules, under FIFRA to Section 3 (applications for registration), Section 5 (experimental use permits), Section 18 (emergency exemptions), and Section 24(c) (registrations for special local needs), and under FFDCA to Section 408 (tolerances for pesticide residues on raw agricultural commodities) and Section 409 (food additive regulations).

In addition, under TSCA the Agency will require sponsors to utilize the GLP standards when conducting testing under negotiated testing agreements. Agency policy also requires that all data developed as a result of regulations or orders under Section 5 of TSCA must be in accordance with GLP standards. Any failure to adhere to GLP standards in generating data under negotiated testing agreements or under Section 5 of TSCA may result in the Agency's electing to consider such data insufficient to evaluate the health effects, environmental effects, and fate of the chemical.

Specific Requirements of the GLP Regulations

The requirements of the GLP regulations are contained in 40 CFR Part 160 (48 FR 53946, November 29, 1983) and 40 CFR Part 792 (48 FR 53922, November 29, 1983). Generally, the rules contain provisions relating to:

(1) General Provisions;
(2) Organization and Personnel;
(3) Facilities;
(4) Equipment;
(5) Testing Facilities Operation;
(6) Test and Control Substances;
(7) Study Protocols; and
(8) Records and Reports.

(1) General Provisions (Subpart A).

Subpart A contains a number of key provisions that are designed to promote an awareness of GLP requirements on the part of all persons involved in the testing process. First, the rules require that a sponsor must notify of the GLP regulations' applicability any laboratory that performs all or part of a study that is subject to the regulations.

Second, any person who submits data from a study in connection with a TSCA Section 4 test rule or an application for a research or marketing permit must include in the submission a statement signed by the applicant, the sponsor, and the study director, of one of the following types:

(a) A statement that the study was conducted in accordance with the GLP regulations;

(b) A statement describing in detail all differences between the practices used in the study and those required by the GLP regulations; or

(c) A statement that the person was not a sponsor of the study, did not conduct the study, and does not know whether the study was conducted in accordance with the GLP regulations.

Finally, Subpart A details the sanctions available to the Agency that are in addition to the imposition of civil and criminal penalties. For example, EPA may choose not to consider reliable for purposes of showing that a chemical does not present a risk of injury to health or the environment any study which was not conducted in accordance with GLP requirements. Any determination that a study will not be considered reliable will not relieve the sponsor of a required test of the obligation under any applicable statute or regulation to submit the results of the study to EPA. EPA may also require the sponsor of data submitted under a TSCA Section 4 test rule to develop data in accordance with GLP requirements where he or she failed to do so in a previous submission.

(2) Organization and Personnel (Subpart B).

(a) Personnel (Sections 160.29 and 792.29).

While specific qualifications are not required of laboratory personnel, the rules generally require facilities to document that each individual engaged in the conduct of a study has education, training, and experience to enable that individual to perform his or her assigned functions.

Personnel are also required to take necessary personal sanitation and health precautions to avoid contamination of test and control substances and test systems.

(b) Testing Facility Management (Sections 160.31 and 792.31).

For each study, testing facility management is required to designate as study director a scientist or other professional of appropriate education, training, and experience. The study director has overall responsibility for the technical conduct of the study, as well as for the interpretation, analysis, documentation, and reporting of results, and represents the single point of study control.

Testing facility management is required to establish a quality assurance unit responsible for monitoring each study to ensure that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with the GLP regulations. For any given study the quality assurance unit must be entirely separate from and independent of the personnel engaged in the direction and conduct of that study.

Management is also required to ensure that test and control substances have been properly tested for identity, strength,

facilities, equipment, materials and methodologies are available as scheduled. Finally, management must ensure that any deviations from the regulations reported by the quality assurance unit are communicated, preferably in writing, to the study director and that corrective actions are taken and documented.

(3) Facilities (Subpart C).

Each testing facility is required to be of suitable size, construction, and location for the proper conduct of studies. It must be designed so that activities are sufficiently separate to prevent any adverse impacts on the study. More detailed requirements ensure proper facilities for:

(a) Animal care and supplies;
(b) Handling test and control substances;
(c) Laboratory operation;
(d) Specimen and data storage; and
(e) Administration and personnel.

(4) Equipment (Subpart D).

Any automatic, mechanical, or electronic equipment used in the generation, measurement, or assessment of data, and equipment used for facility environmental control is required to be of appropriate design and adequate capacity to function according to the protocol and must be operated, inspected, cleaned, and maintained in a suitable location. Equipment used for the generation, measurement, or assessment of data must be adequately tested, calibrated, and standardized.

(5) Testing Facilities Operation (Subpart E).

A testing facility is required to have standard operating procedures (SOPs) in writing that set forth study methods adequate to ensure the quality and integrity of the data generated in the course of a study. Any deviations must be authorized and documented. SOPs are required for most facets of a study.

(6) Test and Control Substances (Subpart F).

The identity, strength, purity, and composition, and any other characteristics which will appropriately define the test or control substance, must be determined for each batch and be documented before the study is initiated. The sponsor or testing facility must document all methods of synthesis, fabrication, or derivation of the test and control substances and must determine

that they are stable, properly labeled, stored, and handled in such a way as to prevent contamination, deterioration, or damage. The receipt and distribution of each batch must be documented and reserve samples retained.

For each test or control substance that is mixed with a carrier, tests must be conducted to determine the mixture's uniformity, concentration, and stability. The expiration date of any components of the mixture must be shown clearly on the container.

(7) Study Protocol (Subpart G).

Each study is required to be conducted in accordance with an approved protocol that clearly indicates the objectives and all methods for the conduct of the study. Any changes in an approved protocol must be explained, documented, signed and dated by the study director, and maintained with the protocol.

(8) Records and Reports (Subpart J).

A final report must be prepared for each study, signed and dated by the study director, and maintained by the sponsor and the testing facility. In addition, all raw data, documentation, records, protocols, specimens, and final reports generated as a result of a study must be retained and archived for orderly storage and expedient retrieval. This includes correspondence and other documents relating to the conduct, interpretation, and evaluation of data.

(9) Environmental Testing (Subpart L - TSCA only).

The TSCA GLP regulations contain special provisions that adapt the regulations to environmental studies. The FIFRA GLP regulations contain no corresponding subpart.

Regulated Community

The regulated community consists of those who sponsor and submit tests that are subject to the GLP regulations and the laboratories that conduct such tests (see Applicability, above).

Enforcement

Objective

The objective of this strategy is to maximize compliance with the GLP regulations in order to promote the high quality of laboratory test data necessary to evaluate the health and environmental effects of regulated chemical substances under TSCA and pesticides under FIFRA.

Violations

Generally, the failure to comply with any requirement of the GLP regulations is a violation of those regulations (see Specific Requirements of the GLP Regulations, above). However, violations are actionable in a different manner under FIFRA than under TSCA, since, unlike TSCA, FIFRA does not provide that it is unlawful to violate a regulation promulgated under its authority. Accordingly, a violation of the GLP regulations is not necessarily a violation of FIFRA. Exceptions are where falsification is committed knowingly within the meaning of Section 12(a)(2)(m) of FIFRA, and where records are not maintained as required by FIFRA. The FIFRA GLP regulations provide further that EPA may refuse to consider reliable for purposes of supporting an application for a research or marketing permit any data from a study which was not conducted in accordance with the GLP regulations.

In addition, the submission of a false statement under the certification provisions of the GLP regulations may form the basis for cancellation, suspension, or modification of a research or marketing permit, or denial or disapproval of an application for such a permit under Sections 3, 5, 6, 18, or 24 of FIFRA or Sections 408 or 409 of FFDCA, for criminal prosecution under 18 U.S.C. 2 or 1001 or Section 14 of FIFRA, or for imposition of civil penalties under Section 14 of FIFRA.

Similar sanctions are contained in the TSCA GLP regulations, except that the failure to comply with the TSCA GLP regulations is a violation of Section 15 of TSCA. Violations are therefore subject to the sanctions contained in that section.

Inspection Scheme

EPA, with the assistance of the Food and Drug Administration (FDA) and the National Toxicology Program (NTP), will use a Neutral Administrative Inspection Scheme (NAIS) for laboratories that have conducted or are conducting health effects studies

that are subject to the GLP regulations. The responsibilities of FDA and NTP are set forth in two interagency agreements. Laboratories conducting environmental effects studies will be addressed similarly, but only EPA will be involved in these since FDA and NTP do not review studies of this type.

The GLP regulations require testing facilities to permit EPA inspections at reasonable times and in a reasonable manner. EPA believes that the possibility of unannounced inspections motivates compliance and efficiently uses resources. Generally, however, EPA will notify laboratories up to two days before an inspection in order to ensure the availability of appropriate personnel and records. Once EPA notifies a laboratory, it will not change the date of the inspection unless the laboratory demonstrates unusual circumstances and good cause. EPA will coordinate with FDA and NTP to avoid multiple inspections at the same facility.

The NAIS will consist of two major categories of inspections: GLP inspections and data audits. Inspections within both of these categories normally will be conducted on the basis of objective criteria or random selection. However, inspections may be targeted for cause at certain facilities where: 1) major problems were discovered during a previous inspection that might affect the validity of unaudited studies; 2) EPA receives tips (i.e., phone calls and letters from various sources, and information provided by OPP or OTS based on their ongoing reviews which OCM will review for validity and significance to determine the level of priority for enforcement action), complaints, or other information indicating that a particular laboratory is in violation of the GLP regulations; or 3) a particular study is assigned a high priority because it is expected to form the basis for major regulatory action.

GLP inspections are laboratory-oriented and will focus on a facility's compliance with the GLP regulations. They will usually include partial audits of at least two ongoing studies. GLP inspections will be scheduled by OCM and carried out by Regional inspectors and FDA. NTP, at OCM's request, will provide assistance when OCM personnel lack specific expertise.

A data audit is study-oriented and is the process by which EPA verifies that the data from a completed laboratory study are consistent with the final report that was submitted to the Agency. This is accomplished by examining raw data and other records generated during the study and comparing them with results provided in the study report. Data audits will be scheduled and carried out by OCM, with necessary assistance provided by FDA, NTP, Program Offices, and the Regions.

Ideally, EPA should inspect regularly every laboratory that conducts EPA-related studies and should audit every study that has been (or will be) submitted to EPA in support of the safety of regulated substances. However, in the event that EPA's resources do not permit such complete coverage of the regulated community, EPA will apply the following criteria to the conduct of inspections:

GLP Inspections/Partial Study Audits: EPA will assign priority to the estimated 90-100 laboratories that conduct 90 percent of EPA-related testing. EPA plans to conduct inspections on a periodic basis at every laboratory conducting testing under TSCA and FIFRA. Priority will be assigned to testing laboratories with greatest number of studies performed under TSCA and FIFRA and those who initiate testing under TSCA or FIFRA for the first time. The frequency of these inspections will depend upon available resources and will be geared towards visiting labs to inspect the full gamut of studies (acute, subchronic and chronic), if possible.

Data Audits: EPA will assign priority to studies based upon the known need of the specific program to form the basis for major regulatory action. EPA will also assign priority to studies known to be or suspected of being in violation of FIFRA or TSCA. High priority studies often will be the subject of both a GLP inspection/partial study audit while they are ongoing and an audit after completion. Studies that were not required to be conducted in accordance with the GLP regulations normally will be targeted for audit by the Program Offices.

Within both of these categories, EPA will assign the highest priority to responding to tips, complaints, and other information indicating that violations of the GLP regulations exist.

Violation Detection Priorities

The requirements of the GLP regulations may be separated into two categories: (1) those directly related to the actual conduct of a study; and (2) laboratory housekeeping requirements. EPA will assign a higher priority to violations in the former category. However, some overlap between these categories may be expected. Where this occurs, the guiding consideration becomes the degree to which a given violation may compromise the validity of a study. For example, a violation of the recordkeeping requirements would ostensibly fall within the housekeeping category. Nevertheless, the lack of records may prevent EPA from determining that a study's results are valid and would therefore be given a higher priority.

Administrative Considerations

The attached Memorandum of Agreement (MOA) between OCM, OTS, and OPP will govern the administration of LDIP. Generally, the MOA establishes the LDIP Panel which will be chaired by OCM and will include members from OPP and OTS. The Panel will serve as a clearinghouse for the flow of information among participating Offices and will periodically review LDIP policies, procedures, and operations and recommend program changes to the Director, OCM, who has full responsibility for implementing the program. The Panel will serve as a steering committee to ensure that Agency commitments and objectives are fully implemented and met.

OCM will have the lead in directing the program by (1) coordinating all laboratory inspections and data audits with OPP, OTS, and the Regions, and by (2) acting as a liaison with other agencies, such as FDA and NTP, which cooperate with EPA in conducting laboratory inspections and data audits. OCM will be the Agency contact for scheduling FDA and EPA laboratory inspections and study audits, as well as for receiving and disseminating audit and inspection reports to both OPP and OTS. OCM will monitor the status of each inspection and audit.

The Regional Offices will provide support for inspection and enforcement activities as needed. Regional responsibilities will include the conduct of and case development for most GLP inspections.

OTS and OPP will provide the scientific and regulatory review of laboratory GLP inspection reports and data audit reports within their respective program areas. Program Office scientists will recommend studies for audit and will participate in inspections and study audits at laboratories, consistent with resource allocations. They will also serve as expert witnesses in support of Agency litigation efforts.

INTERAGENCY AGREEMENT
BETWEEN
THE U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDES AND TOXIC SUBSTANCES
AND
THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL TOXICOLOGY PROGRAM

1. PURPOSE

This agreement provides for cooperation between the National Toxicology Program (NTP) and the Environmental Protection Agency (EPA) in the areas of inspector training, inspection operations, data audits and information exchange. This cooperation will enhance the EPA's mandated activities designed to determine whether laboratory testing was performed properly and in compliance with Good Laboratory Practice (GLP) regulations and whether the test report can be fully validated through audits of the raw data generated during the testing phase.

The primary purpose of this cooperation is to utlize NTP's experience in conducting and reporting laboratory GLP inspections and data audits to enhance the training and capabilities of EPA personnel in these activities.

2. SCOPE OF WORK

The Environmental Protection Agency (EPA) is responsible for setting tolerances for pesticide residues in or on raw agricultural commodities and processed food under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346 and 348) and for registering pesticides under the Federal Insecticide, Fungicide,

and Rodenticide Act (FIFRA)(7 U.S.C. 136 et sec). In addition, EPA has the mandated task under the Toxic Substances Control Act (TSCA) (15 U.S.C. 2601) to assure that no chemical will present an unreasonable risk of injury to health or the environment. EPA regulatory decisions on such matters are based in part on the results of toxicological testing performed by or for registration applicants, tolerance petitioners, and chemical manufacturers or processors.

This agreement, which provides for cooperation in the training of EPA laboratory inspectors and auditors, in providing specific scientific expertise as required for laboratory inspections and data audit as well as in the sharing of information on laboratory GLP compliance monitoring will enable EPA to determine (1) whether the testing was performed in accordance with specified methodology, (2) whether any reported deviations may have affected the reliability of the test results, (3) whether the test results as reported can be fully supported by the raw data generated during the study and (4) whether the testing was carried out in compliance with EPA's GLP regulations. The authority for FIFRA GLP regulations is 40 CFR Part 160 and for TSCA is 40 CFR 792. For studies conducted prior to this, "GLP regulations" refers to the Food and Drug Administration's GLP Regulations (43 FR 59986).

Laboratories inspected may be facilities in which both EPA and NTP have common interests or they may be facilities carrying out studies applicable only to the EPA but that the EPA finds it cannot inspect due the to the lack of specific expertise.

While EPA may have an interest in an NTP-sponsored study, EPA will not audit an NTP-sponsored study without the express approval of NTP management. Studies to be audited may be either in progress or completed.

3. EXCHANGE OF INFORMATION

Each agency will exchange information concerning active inspections and audits of interest to the other agency.

Each agency will inform the other of legal or administrative action being considered or taken against any laboratory covered under this agreement. This section is concerned with legal or administrative penalties and not with such infractions or deviations as can be corrected easily and judged to have had little or no significant impact on the validity of the study.

4. NTP'S RESPONSIBILITIES

a. Study Audits - NTP will provide EPA's Compliance Monitoring Staff (CMS) with a copy of the final NTP audit report of chemicals of interest to EPA; such chemicals may have been originally nominated or co-nominated by EPA for study or EPA may

have developed an interest in the chemical during the testing phase. NTP will provide CMS on a quarterly basis with the schedule of NTP audits of completed studies to be conducted in the next quarter.

b. GLP Compliance Monitoring - NTP will supply CMS on a quarterly basis with an advance schedule of site visits to be conducted by NTP in the next quarter. At the request of CMS, NTP will provide EPA with a copy of the report of a site visit of interest to CMS. EPA will not institute any enforcement action against an NTP-inspected laboratory based solely on an NTP inspection report.

c. Training - NTP, within constraints of personnel and schedules, will detail experienced NTP personnel who will act as instructors in EPA-sponsored courses or workshops on GLP compliance monitoring, data audits and related topics. Schedules and topics will be worked out cooperatively to ensure adequate time for course preparation and review. Such details of personnel will be at no expense to NTP other than salary.

d. Expert Inspections - NTP, at the request of CMS, and within the constraints of personnel and schedules, will detail expert personnel to accompany a CMS inspector or EPA audit team when EPA is unable to inspect a testing laboratory or complete a data audit because of the lack of specific expertise. CMS will provide the requested scheduling in advance to NTP along with all non-confidential information on the laboratory and study(ies) necessary to prepare for a compliance inspection.

NTP personnel in this situation will be advisory to the CMS inspector who has the responsibility for conducting the inspection or audit and preparing the report of the inspection or audit. The NTP personnel's advisory report of findings will be incorporated into the EPA inspector's report. Wherever possible such inspections will be at no cost to NTP other than salary.

e. Confidentiality - Under various provisions of FIFRA and TSCA, toxicology data submitted to EPA may be considered trade secrets entitled to protection from unauthorized public disclosure. Such information will not be furnished to NTP personnel in advance of a laboratory inspection or a study audit. Any requests for further disclosure of such information received by the NTP under the Freedom of Information Act will be referred to the EPA for processing. NTP personnel will not prepare any reports utilizing data which may be confidential.

5. EPA'S RESPONSIBILITIES

a. List of Laboratories for Coverage - EPA will provide NTP with a quarterly listing of labortories to be visited. This listing is to be provided to NTP at least 30 days in advance of a given quarter and will include the name(s) of the facility(ies) to be inspected, the dates of the inspections and the EPA scientific personnel who will participate in the inspection or audit. This information will be classified as "For Official Use Only" and should not be disclosed except on a need-to-know basis.

EPA will identify for NTP those inspections where assistance is requested from NTP and provide NTP with a clear definition of the assistance needed.

In advance of a laboratory inspection EPA will provide NTP with a list of EPA studies in progress as well as test protocols, EPA test guidelines as available and FDA test guidelines as appropriate.

b. Reporting Format - A mutually agreed format will be used by NTP in reporting its advisory portions of EPA inspections.

c. Studies to be Audited - EPA will provide NTP with copies of the test protocol, guidelines and toxicology test reports including any special instructions which might be appropriate to the study to be audited. None of the material so provided will be classified as Confidential Business Information.

d. Confidentiality - EPA is required, under both FIFRA and TSCA, to maintain confidentiality of certain test-related information. EPA will not provide NTP any material classified as FIFRA or TSCA "Confidential Business Information." EPA may furnish NTP with material classified as "For Official Use Only" which is not to be disclosed by recipient NTP personnel to others except on a need-to-know basis.

e. NTP Requests - EPA will respond to all requests for information received by NTP under the Freedom of Information Act which relate to visits performed for EPA by NTP.

f. Delegation of Authority - As necessary EPA will provide to NTP personnel a letter containing appropriate delegation of authority. This letter will then be furnished to the management of the laboratory at the beginning of the visit.

g. Notification of Sponsor - Contracts may exist between laboratory and sponsor prohibiting disclosure of raw data by the laboratory without the permission of the sponsor. In order to ensure that raw data are available to EPA and NTP personnel conducting a data audit, EPA's Compliance Monitoring Staff will notify the sponsor of the study of the intent to audit one or two working days preceding the scheduled visit. CMS will exercise its own discretion regarding advance notification to the laboratory of the scheduled visit.

h. Evaluation of Reports - EPA will determine whether discrepancies listed in the compliance inspection reports submitted by NTP personnel or study audit reports impact on the validity of studies. Any administrative or regulatory actions resulting from these reports will be the responsibility of EPA.

i. Training Schedules - CMS will consult with NTP on the content and scheduling of training courses and workshops and will jointly determine the faculty for such courses and workshops. Both EPA and NTP staff will be invited to attend such courses and workships as appropriate.

6. DURATION OF AGREEMENT

This agreement will become effective on the date of the last signature and shall continue in effect until September 30, 1984, unless modified by mutual written consent of both parties or terminated by either party upon a ninety (90) day advance written notice to the other. This agreement may be reviewed by written consent of both parties on a fiscal year basis.

7. PROJECT OFFICERS

For EPA: Dr. Dexter S. Goldman (EN 342)
Head, Laboratory Data Integrity Program
Compliance Monitoring Staff
Environmental Protection Agency
401 M Street, S. W.
Washington, DC 20460

For NTP: Dr. Bernard A. Schwetz
Chief, Systemic Toxicology Branch
National Toxicology Program
National Institute of Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, NC 27709

8. FUNDING

No transfer of funds is necessary under this agreement. Each agency will fund its part of cooperative actions. EPA will fund travel and travel associated expenses of NTP personnel requested to participate in EPA activities described above.

9. AUTHORITY

APPROVED AND ACCEPTED FOR THE ENVIRONMENTAL PROTECTION AGENCY

BY: _____

John A. Moore, DVM

TITLE: Assistant Administrator for Pesticides and Toxic Substances

DATE: 9-28-84

APPROVED AND ACCEPTED FOR THE NATIONAL TOXICOLOGY PROGRAM

BY: _____

David P. Rall, MD, Ph.D.

TITLE: Director

DATE: 8-16-84

MEMORANDUM OF AGREEMENT

BETWEEN

THE COMPLIANCE MONITORING STAFF

THE OFFICE OF TOXIC SUBSTANCES AND

THE OFFICE OF PESTICIDE PROGRAMS

IN THE OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

FOR A MANAGEMENT FRAMEWORK

FOR THE CONDUCT OF

LABORATORY INSPECTIONS AND DATA AUDITS

1. PURPOSE AND PRINCIPLES

A Laboratory Data Integrity Program (LDIP) has been established within the Compliance Monitoring Staff (CMS) of the Office of Pesticides and Toxic Substances (OPTS). LDIP is specifically charged with developing and conducting laboratory inspection and data audit programs to assure the reliability and validity of data reported to EPA under both the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA) Sections 4 and 5. This Agreement establishes the matrix management framework under which CMS, the Office of Pesticide Programs (OPP) and the Office of Toxic Substances (OTS) will work cooperatively to assure an effective laboratory inspection and data audit program.

2. PROGRAM ABSTRACT

CMS will establish and chair the Laboratory Data Integrity Program Panel (the Panel) which will also include members from OPP and OTS. The Panel will serve as the conduit for the flow of information between participating Offices and will periodically review LDIP policies, procedures, and operations and advise the Director, CMS, who has full responsibility for implementing the program, of recommended program improvement and changes. The Panel will serve as a steering committee to ensure that Agency commitments and objectives of the LDIP are fully implemented and met.

The CMS will have the lead in directing the program by (1) coordinating all FIFRA- and TSCA-related laboratory inspections and study audit activities with OPP and OTS as well as by (2) liaison with other agencies, such as the Food and Drug Administration (FDA) and the National Toxicology Program (NTP), which cooperate with the EPA in laboratory inspections and data auditing. LDIP will be the Agency contact for scheduling FDA and EPA laboratory inspections and study audit activities, as well as for receiving and disseminating audit and inspection reports to both OPP and OTS. LDIP will monitor the status of each inspection and audit.

It is the goal of LDIP to (1) ensure full compliance with FIFRA and TSCA Good Laboratory Practice (GLP) regulations, as applicable, at all testing facilities performing studies to be presented to the EPA to meet requirements of both FIFRA and TSCA and (2) to audit fully all data supporting the results of

these studies. Both the CMS and the OPTS Program Offices are responsible for recommending studies for audit and laboratories for inspection.

The OPTS Program Offices will provide the scientific review of laboratory GLP inspection reports and data audit reports of studies within their respective program areas to LDIP. Program Office scientists will participate in inspections and study audits at laboratories, as appropriate and as resources permit.

A detailed description of the responsibilities of CMS, LDIP, OPP, OTS and the Panel is given in Section 3 of this document.

A detailed definition of terms used in this document is given in Section 5 of this document.

3. DIVISION OF RESPONSIBILITIES

a. Compliance Monitoring Staff

(1) Appoints the Chairperson of the Panel.

(2) Establishes inspection procedures and specific audit procedures, with necessary technical input and review from OPP and OTS.

(3) Establishes neutral administrative inspection schemes for routine selection of laboratories for inspection and, based on recommendations from OPP and OTS, specific criteria for "for cause" and follow-up inspections, where necessary.

(4) In conjunction with the Regional Offices, supports appropriate enforcement actions based on the information provided in reports, audits, reviews and impact assessments. Notifies OPP and OTS of the progress and disposition of compliance procedings.

(5) Responds to FOIA requests for information on and availability of completed compliance inspection reports (GLP inspections or data audits).

(6) Reports program activities to the Assistant Administrator for Pesticides and Toxic Substances and to the Administrator through the Management Accountability System.

b. Laboratory Data Integrity Program

(1) Closely coordinates activities with FDA and NTP to avoid duplicative efforts and to achieve maximum efficiency in auditing studies used for government decision making.

(2) Trains EPA inspectors and auditors in the conduct of laboratory inspections and audits with technical assistance from OPP, OTS, FDA, NTP and contractors as needed.

(3) Establishes and maintains an accessible data file of studies submitted to or required by the EPA under TSCA Section 4 Test Rule or Negotiated Testing Agreement, TSCA Section 5 Significant New Use Rule, Section 5(e) Order, FIFRA Sections 3, 5, 8, 18 and 24(c) as well as FFDCA Sections 408 and 409. This data file will be maintained and updated by LDIP staff and will permit the tracking of both CMS-directed activities on studies as well as OPP- or OTS-negotiated study milestone dates starting with the date of agreement between OPP or OTS and Sponsor and ending with the final study data audit report.

(4) Receives copies of notices of deliverables sent by test Sponsors to EPA Product Managers and enters dates of deliverables into the data file. The deliverables themselves are directed to OPP or OTS by the Sponsor.

(5) Notifies OPP or OTS Product Managers of schedule deviations and refers to CMS evaluations by OPP or OTS scientists of deviations as well as recommendations for action.

(6) Receives notices of sponsor-requested protocol changes and refers these requests to the OPP or OTS Product Manager for evaluation and recommendations. Refers these evaluations and recommendations to CMS for communication to the Sponsor.

(7) Maintains security as needed on all reports, schedules and data files under its control.

(8) Within the constraints of available resources selects laboratories for inspection and studies for audit based on the neutral administrative schemes and selection criteria of CMS along with target lists and selection criteria supplied by OPP and OTS.

(9) Schedules data audits and laboratory GLP inspections for health effects, for ecological effects and chemical fate studies. Coordinates the audit and inspection schedule with FDA, EPA Regional Offices and with OPP or OTS scientific support staff as necessary.

(10) Receives inspection and audit reports from FDA and EPA inspectors after the audit or inspection is completed.

(11) Develops and utilizes procedures for clarifying questions and resolving conflicts raised in data audit reports with the testing laboratory and/or the test sponsor prior to issuing a final report of a data audit to ensure that the audit can be properly evaluated.

(12) Prepares GLP compliance reports and final data integrity statements based on inspection reports as well as reviews

of the raw data and final study report.

c. Office of Toxic Substances and the Office of Pesticide Programs

(1) Appoint a representative to the Panel. This representative will also be the focal point for all information exchange between OPP, OTS and CMS and will serve as technical program representative.

(2) Provide LDIP with information needed to track studies submitted to or required by the EPA under TSCA Section 4 Test Rule or Negotiated Testing Agreement, TSCA Section 5 Significant New Use Rule, Section 5(e) Order, FIFRA Sections 3, 5, 8, 18 and 24(c) as well as FFDCA Sections 408 and 409.

(3) Maintain a current awareness of LDIP-set laboratory GLP inspection and study audit schedules from the LDIP data file. Recommend to LDIP changes in these schedules when problems are noted that may jeopardize a study. Such requests will contain an assessment of the need for the inspection or audit based on OPP or OTS review, pending regulatory decisions and other established criteria.

(4) Provide LDIP with copies of the study protocols and revisions , FIFRA or TSCA testing guidelines for each type of test, available EPA scientific reviews, and all study interim and/or final reports as well as other pertinent test information from both the sponsor and the testing laboratory before inspections and audits are undertaken.

(5) Within resource constraints designate appropriate scientific staff to accompany FDA and EPA inspectors on GLP inspections and study audits as requested by LDIP. Staff scientists may participate in routine inspections and audits as recommended by LDIP, and will participate in inspections and audits where violations are suspected by CMS.

(6) Provide LDIP in a timely fashion with review and assessment of Sponsor-initiated protocol changes, test laboratory schedule changes and any other study-related information from either the Sponsor or the testing laboratory.

(7) Provide LDIP in a timely fashion with regulatory significance reviews of GLP inspection and data or study audit reports including an assessment of the impact of inspectional or audit findings on the study itself.

(8) Recommend, to CMS and LDIP, specific criteria for "for-cause" or "priority" GLP inspections or study data audits.

(9) Regulatory decisions (registrations, cancellation, suspension, rule-making, etc.) are the responsibilities of the program offices; enforcement responses (stop-sale, civil complaints, etc.) are the responsibility of CMS.

d. <u>The Laboratory Data Integrity Panel</u>:

(1) Serves as a steering committee to ensure that EPA committments and objectives on LDIP are implemented and met.

(2) Serves as a steering committee to oversee the manner in which LDIP tracks studies under FIFRA and under TSCA Sections 4 and 5.

(3) Assists CMS in evaluating the effectiveness of the

audit and inspection programs through periodic program reviews.

(4) Advises the Assistant Administrator for Pesticides and Toxic Substances through the Director, CMS, of recommended improvements and changes in LDIP.

(5) Reviews, at the request of LDIP, criteria for laboratory inspection and study audit priorities to ensure that needed changes in inspection or audit schedules are made promptly and in a manner consistent with OTS requirements.

4. IMPLEMENTATION

The Director, OTS and the Director, OPP shall select that Office's representative for the Panel within 30 days of concurrence in this Memorandum of Agreement by the Assistant Administrator. The Panel members' names shall be provided to the Director, CMS.

5. DEFINITIONS

a. Data Audit - The data audit is the process by which the Agency determines the validity of the results of any ongoing or completed laboratory study. Validation is accomplished by examining raw data and other records generated during the study with results provided in the study report. A data audit is not a scientific review of the conclusions of the study. Data audits may be partial or full.

(1) Partial data audits are associated with:

(a) In-life studies where data are still being generated and the audit provides confidence that the data in general are being generated according to protocol requirements and time frames and properly recorded.

(b) Completed studies where selective percentages of available data are examined.

(2) Full data audits are those audits where, insofar as possible, all raw data from all segments of a completed study are audited. Full data audits are usually associated with rule or regulation processes where full prior validation of the results is considered necessary.

b. Study Audit - A study audit compares the actual conduct of a study with the approved study protocol. A study audit contains elements of a data audit and a Good Laboratory Practices inspection and may be partial or full.

c. Good Laboratory Practices (GLP) Inspection - The authority for GLP inspections is contained in 40 CFR Part 792 (TSCA) and 40 CFR Part 160 (FIFRA). A GLP inspection is an inspection of a test facility or laboratory where EPA-related test data are generated. The purpose of such an inspection is to ensure full compliance with GLP's (as regulations). GLP inspections may be carried out by EPA inspectors or by inspectors or other designees of other government agencies under interagency agreements. At present such an interagency agreement exists between EPA and FDA.

Other definitions pertaining to studies and to GLP are contained within the GLP regulations.

6. CONCURRENCES

John A. Moore, D.V.M. Assistant Administrator for Pesticides and Toxic Substances	1 May 84 Date
Don R. Clay, Director Office of Toxic Substances	4/16/84 Date
Edwin L. Johnson, Director Office of Pesticide Programs	20 Apr 84 Date
A. E. Conroy II, Director Compliance Monitoring Staff Office of Pesticides and Toxic Substances	30 April 84 Date

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

SEP 3 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Compliance Strategy for FIFRA §3(c)(2)(B) Suspensions

FROM: A. E. Conroy II, Director
Office of Compliance Monitoring

TO: Addressees

Attached is the Compliance Strategy for FIFRA Section 3(c)(2)(B) Suspensions. This strategy sets forth the responsibilities of the Office of Pesticide Programs (OPP), OCM and the Regions in implementing a program to assure compliance with suspensions issued under section 3(c)(2)(B) of FIFRA.

Section 3(c)(2)(B) of FIFRA authorizes the Administrator to require registrants to develop and submit data to fill gaps in the data base for registered pesticides. Failure to respond to a section 3(c)(2)(B) data call-in or to properly develop data results in suspension of the product for which the data was requested.

Comments on the draft compliance strategy and OCM's responses are as follows:

- One Region requested that the three month period for conducting inspections for compliance with the Stop Sale, Use or Removal Order (SSURO) not begin until the States receive the information on the issuance of the SSURO. The strategy has been amended to reflect this comment.

- One Region noted that each time a State is requested to conduct a Section 3(c)(2)(B) inspection, the grant will have to be renegotiated and outputs will have to be adjusted. An amendment to the FIFRA Enforcement Grant Guidance was issued on July 31, 1985 to address this problem.

- Several Regions questioned the need to search FATES to provide a list of inspection targets to the States. The list provided by OCM lists only the registrants affected. The FATES data will provide the States with any establishments that may have produced the suspended products.

- One Region commented on the fact that the policy does not address contract manufacturers or supplemental registrants who may have produced suspended products. By the Regions providing States with information from FATES on those establishments which have in the past produced suspended products, the States should be able to reach those distributors who have produced a product which has been suspended. In the case of contract manufacturing, the registrant should immediately instruct the contract manufacturer to cease production. The SSURO sent to registrants covers those products produced under contract as well as products supplementally registered. States can confirm that distribution has been halted by visiting those establishments.

- One Region commented that the Regional offices needed the certified receipt cards for the NOITS and SSURO to support enforcement cases. OCM will not routinely send the certified receipt cards to the Regions. Please note that OCM may have one green card, verifying that the registrant received the SSURO, which applies to several establishments located in different Regions. If a Region needs a certified receipt to support a specific enforcement action, OCM will provide it on request.

- The Office of Pesticide Programs suggested that OCM include a copy of the OPP Standard Operating Procedure Number 3049.1 - Suspension of Pesticide Registrations in the package. OCM has attached the SOP to this package.

Thank you for your cooperation in reviewing the draft strategy. If you or your staff have questions, please contact David Stangel of my staff at FTS 382-7845.

Attachments

SEP 3 1985

COMPLIANCE STRATEGY FOR FIFRA §3(c)(2)(B) SUSPENSIONS

OVERVIEW

Section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes the Administrator to require registrants to develop and submit data to fill in gaps in the data base for registered pesticides. Failure to respond to a FIFRA §3(c)(2)(B) data call-in appropriately or failure to develop data as agreed to in the FIFRA §3(c)(2)(B) response will result in suspension of the product for which the data was requested. In those cases the Office of Pesticide Programs (OPP) will issue a Notice of Intent to Suspend (NOITS). The suspension becomes effective thirty days after its receipt unless the company complies with the requirements of the data call-in notice, requests a hearing, or requests a voluntary cancellation. Generally, there will be no existing stocks provisions for products in the registrant's possession unless registrants request a voluntary cancellation.

In order to enforce a suspension under FIFRA §3(c)(2)(B), it is necessary to issue a Stop Sale, Use, or Removal Order (SSURO) and to conduct followup inspections. A registrant whose product is suspended under FIFRA §3(c)(2)(B) may comply with the data call-in requirements at any time. OPP will lift the suspension and OCM the SSURO provided all FIFRA §3(c)(2)(B) data requirements have been met for that product.

REGULATED INDUSTRY

The regulated industry consists of all registrants which receive a FIFRA §3(c)(2)(B) data call-in notice. There are several types of data gaps for which data call-in notices may be issued:

- chronic toxicological data gaps,
- registration standards data gaps,
- special review data gaps, and
- others such as product chemistry data gaps, confidential statements of formula, or ground water data gaps.

REQUIREMENTS

Section 3(c)(2)(B) of FIFRA:

- Authorizes the Administrator to require additional data on a chemical to further evaluate the chemical and to support existing registrations.

- Requires each registrant to provide evidence within ninety days after notification that he is taking appropriate steps to secure the additional data.

- Grants EPA the authority to issue a Notice of Intent to Suspend if a registrant fails to take steps to secure the required data. (This includes failing to respond to the data call-in notice, responding inadequately such as maintaining that testing is not necessary, or failing to submit data in the timeframe to which the registrant committed or which OPP established.)

- Allows a registrant and other parties adversely affected by the NOITS to request a hearing within thirty days of receipt of the NOITS by the registrant regarding whether: (1) the registrant diligently took one of the listed steps to develop the data, or whether (2) the Agency's decision on the disposition of existing stocks is consistent with the Act. If a registrant requests a hearing, the suspension on his product does not take effect until after the conclusion of the hearing.

Each registrant originally is given the following options for complying with the data request:

- develop or supply the required data himself or jointly with other registrants;

- certify that the product is exempt, e.g., because it is an end-use product formulated from a registered, non-suspended manufacturing use product and was therefore not subject to the data call-in for safety data;

- delete uses that require the data requested;

- request and receive a waiver of some or all of the data requirements; or

- voluntarily request cancellation.

Failure to exercise one of these options within certain specified time periods will result in the suspension of the registrant's product. When a product is suspended under FIFRA §3(c)(2)(B), there will generally be no existing stocks provisions for products in the registrant's possession. More information on how OPP suspends a product and the conditions of the suspension can be found in OPP's Standard Operating Procedure for FIFRA §3(c)(2)(B) Suspensions.

ENFORCEMENT OBJECTIVES

The aim of the compliance strategy is to enforce the FIFRA §3(c)(2)(B) suspension via a SSURO.

TYPES OF VIOLATIONS

Section 12(a)(2)(J) of the Act prohibits the violation of a suspension order under FIFRA §6. There is, however, no specific unlawful act under section 12 for the violation of a section 3(c)(2)(B) suspension order. Under section 13 of FIFRA, the Administrator may issue a SSURO when a product is suspended. By issuing a SSURO, EPA is able to enforce the suspension. Any person violating a SSURO would be in violation of section 12(a)(2)(I) and would be subject to the penalties thereunder. It is essential that each registrant of a suspended product be issued a SSURO in order for the section 3(c)(2)(B) suspension to have the force of law.

NEUTRAL ADMINISTRATIVE INSPECTION SCHEME

The Regions should work with the States to schedule inspections of producing establishments of suspended products within three months after the State receives notification of the SSURO. Once it is determined that a producing establishment is in compliance, no additional special targetting is necessary. However, continued compliance should be checked during the next routine inspection.

ADMINISTRATIVE CONSIDERATIONS

Program Management

OPP is responsible for tracking data requests up until the point at which a commitment to test is made. At that point, the Office of Compliance Monitoring (OCM) is responsible for tracking the test schedule. OPP is responsible for issuing the NOITS and tracking the registrants' responses. When a product is suspended (thirty days after receipt of the NOITS unless the registrant requests a hearing or complies with the data request), OPP notifies OCM and forwards a copy of the NOITS to OCM. At that time, OCM will issue a SSURO to the registrant of the suspended product. Previously, OPP had allowed a specified amount of time for continued production of the product and sale of all existing stocks. The current OPP Standard Operating Procedure indicates that there will be no distribution of stocks by the registrant allowed after the effective date of the suspension, i.e., thirty days after receipt by the registrant. If there are any existing stocks provisions allowed, OPP will forward this information to OCM at the same time OPP notifies OCM of the effective suspension. Normally, there will be no prohibition on sale of suspended products in the channels of trade.

At the time that OCM issues the SSURO, it will send a sample copy of the SSURO, a sample NOITS, a list of registrants to whom SSURO's were issued and products affected, and any other relevant supporting documents to the Regions. The Regions will notify States of the suspension and the SSURO and provide them with copies of all the information which the Region has received from OCM. The SSURO may only be vacated by OCM. This will only be done when OPP is lifting the suspension because the company has come into compliance with the data call-in request. The Regions will be notified immediately that OPP has lifted the suspension and OCM has vacated the SSURO. Regions and States may issue SSURO's for any products which have been distributed in violation of a SSURO issued by OCM.

ALLOCATION OF RESPONSIBILITIES

OPP

Issues data call-in notices and tracks responses.

Issues NOITS as appropriate and tracks responses.

Notifies OCM of products suspended and provides copies of NOITS at that time along with other relevant documents.

Lifts suspensions when registrant fully complies.

Prepares letters lifting the suspensions and the SSURO's for OPP and OCM signature.

OCM

Tracks testing once commitment to test is made and notifies OPP of failures by registrants to meet commitments.

Issues a SSURO to the registrant after being notified that a suspension is effective.

Sends the Regions a list of registration numbers for suspended products and the names and addresses of registrants which received SSURO's within 5 days of mailing the SSURO's. OCM will also send a sample SSURO and NOITS. Upon request by a Region, OCM will provide the actual SSURO and NOITS for a specific product as well as the certified receipt.

Vacates a SSURO at the same time OPP lifts the suspension for a registrant, which fully complies with the data call-in, and sends the Region information on the vacation of the SSURO.

Is working with OPP to develop and implement a system for tracking suspensions and SSURO's.

Regions

Regions forward information on the suspensions and SSURO's to the States within a week of receipt and work with the States in monitoring compliance. The Regions will provide to the States a list of producing establishments which have produced the products subject to the suspension and SSURO. This information should be obtained from FATES.

In those States without State Cooperative Enforcement Agreements, the Regions monitor compliance with the SSURO's within three months of their receipt of the information on the issuance of the SSURO.

Regions negotiate with the States to assure that States conduct inspections at producing establishments to verify compliance within three months of the date the State receives the information on the SSURO and that States check for compliance during future routine producing establishment inspections.

Regions will handle any cases arising from violations of the SSURO's issued by OCM.

States

States will conduct follow-up inspections to ensure compliance with the SSURO's and forward results of the inspections to the Regions. For situations involving a violation of the SSURO, the State will forward the case file to the Region for appropriate enforcement action.

PENALTIES

Violation of a SSURO is a violation under section 12(a)(2)(I) and subject to the penalties found under section 14(a)(1) and section 14(b)(1). Violation of a SSURO will generally result in an administrative civil complaint. The FIFRA penalty policy provides guidance on calculating the administrative civil penalty for this violation. Repeated or continued violations of SSURO's will be considered for criminal referral.

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCE

MEMORANDUM

SUBJECT: Compliance Monitoring Strategy for Pesticide Registration Cancellations Due to Nonpayment of Fees

FROM: John J. Neylan III, Director
Policy and Grants Division
Office of Compliance Monitoring

TO: Addressees

Attached is: (1) the Compliance Strategy for Pesticide Registration Cancellations Due to Nonpayment of Fees; and (2) the Notice of Cancellation which was published in the Federal Register on October 18, 1989 (54 FR 42936). Thank you for your comments on the February 12, 1990 draft. A summary of those comments and our responses is also attached.

The effective date of cancellation for the first fee period was October 10, 1989, the date of the letter informing registrants of the Cancellation Order. However, registrants could continue to sell and distribute existing stocks until March 1, 1990. The attached Strategy calls for routine producer establishment inspections to ensure that the 20,000 pesticide products are not sold in violation of FIFRA. Last October, the Office of Pesticide Programs (OPP) sent the States and Regions copies of the list of approximately 20,000 products, which were cancelled for nonpayment of fees under FIFRA section 3 and section 24(c). On March 9, 1990, the Office of Compliance Monitoring (OCM) sent the Regions a list of the registrants and producing establishments, which have produced since 1984 any of the pesticide products cancelled for nonpayment of fees.

Please provide copies to the State pesticide control officials in your Region as soon as possible. If you have any questions regarding the Strategy, please contact Beverly Updike of my staff at FTS 475-9438 (EN-342).

Attachments

ADDRESSEES

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Air, Pest. & Toxics Mangt. Div.

II Barbara Metzger, Director
Environmental Services Div.

III Thomas J. Maslany, Director
Air, Toxics and Radiation Mangt. Div.

IV Winston A. Smith, Director
Air, Pest. & Toxics Mangt. Div.

V William H. Sanders III, Director
Environmental Services Div.

VI Bob Hanneschlager, Acting Director
Air, Pesticides & Toxic Div.

VII William A. Spratlin, Director
Air and Toxics Div.

VIII Irwin L. Dickstein, Director
Air and Toxics Div.

IX David P. Howekamp, Director
Air Management Div.

X Lynn McKee, Acting Director
Air and Toxics Div.

cc: Valerie Jewett (TS-788)

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Anne Lindsay	(TS-767C)
Steve Johnson	(H-7506C)
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Connie Musgrove	"
David Dull	"
Mike Wood	"
Phyllis Flaherty	"
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IX Davis Bernstein, Chief
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X Kenneth Feigner, chief
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RESPONSE TO COMMENTS ON PESTICIDE CANCELLATION STRATEGY

All of the following comments submitted by the Regions are appreciated and have been considered. The Compliance Strategy incorporates many of these comments.

Existing Stocks

COMMENT 1

One commenter wanted the following language used in the Strategy to be added to the Summary:

> Due to the face that the Cancellation Order allows stocks at the dealer and user level to be used until exhausted, inspections beyond those at producing establishments are not being requested.

RESPONSE 1

We have incorporated that statement into the Summary.

COMMENT 2

A commenter reported that the proposed existing stocks provision presents a problem for those States in which pesticide products must have a current EPA registration to be offered for sale.

RESPONSE 2

State inspectors should take their direction from the State laws in those States which have more stringent laws regarding the distribution and sale of existing stocks of pesticide products no longer registered by the EPA.

Enforcement Response

COMMENT 3

One commenter asked what would be the appropriate enforcement action if the inspectors discovered pesticides on the cancellation list in the marketplace.

RESPONSE 3

If an inspector finds existing stocks at the user and dealer level which have been produced, packaged or labeled after October 10, 1989 (effective date of cancellation), those stocks are in violation of the Cancellation Order. Registrants had until March 1, 1990, to dispose of existing stocks of cancelled products. A Stop Sale, Use or Removal Order (SSURO) should be issued for violative acts and penalties assessed as needed.

Cancellation Information

COMMENT 4

One commenter requested that the list of registrants and producer establishments which produced since 1984 any of those pesticide products included among the 20,000 cancellations be sorted by registrants with product names.

RESPONSE 4

The information was developed in this format and mailed out by OCM.

COMMENT 5

One commenter cited a need for a list of current cancellations and SSUROs.

RESPONSE 5

This Strategy deals only with the cancellations related to nonpayment of the registration maintenance fees. OCM will send out periodic updates amending the list of products cancelled for nonpayment of the fees. In addition, in April, the Compliance Division of OCM published a booklet, "Suspended, Cancelled, and Restricted Pesticides", which summarizes the Agency's actions on such pesticides.

SUMMARY

COMPLIANCE MONITORING STRATEGY FOR PESTICIDE REGISTRATION CANCELLATIONS DUE TO NONPAYMENT OF FEES

- The due date for the EPA required payment of the maintenance fee to maintain registration was March 1, 1989.

- On October 10, 1989, EPA notified registrants of 20,000 products by letter that their registrations were being cancelled due to nonpayment of maintenance fees. A Notice of Cancellation was published in the Federal Register on October 18, 1989. The effective date of cancellation was October 10, 1989, the date of the letter informing registrants of the Cancellation Order.

- Registrants could continue to sell and distribute existing stocks until March 1, 1990. Existing stocks are defined as those stocks produced, packaged and labeled on or before the effective date of cancellation.

- Compliance inspections to assure compliance with these cancellations will be conducted by States and EPA (where there is no Cooperative Enforcement Agreement) as part of their routine pesticide producing establishment inspections. Due to the fact that the cancellation order allows stocks at the dealer and user level to be used until they are exhausted, inspections beyond those at producing establishments are not needed.

- All imports are to be checked against the cancellation list prior to Regions signing off on the Notice of Arrival.

- Exports are subject to FIFRA section 17(a) after October 10, 1989 and should be checked as part of routine inspections.

COMPLIANCE STRATEGY FOR PESTICIDE REGISTRATION CANCELLATIONS DUE TO NONPAYMENT OF FEES

OVERVIEW

Section 4(i)(5) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) requires the payment of annual pesticide registration maintenance fees by March 1 of each year to keep registrations in effect. During the first fee collection period ending March 1, 1989, there were approximately 20,000 registered products for which registrants did not pay the required fee. Section 4(i)(5)(D) of FIFRA states that the Administrator may cancel the unpaid registrations without a hearing. Accordingly, Cancellation Orders were issued to cancel the majority of the unpaid registrations. This group includes approximately 13,500 products registered under section 3 of FIFRA and about 6,000 under section 24(c) of FIFRA. The Notice of Cancellation was published in the Federal Register on October 18, 1989 (54 FR 42936). However, the effective date of cancellation was October 10, 1989, the date of the cancellation letter. As new cancellations go into effect for subsequent fee periods, OCM will provide an amendment to Appendix II which will inform the Regions of the products cancelled, the date of the cancellation, and any existing stock provisions.

The Federal Register Notice of October 18, 1989, deferred for 30 days the cancellations of 189 pesticide products (containing 77 different active ingredients) for which the registration maintenance fee was not paid. These were products which have been in production at least one year since 1984. Additionally, unlike the majority of the other cancelled registrations, the records for these 189 products show that there are no other registered products containing these active ingredients. The deferral period allowed potentially affected users of these pesticides an opportunity to develop strategies to maintain the continued registration of any products important to their needs. Only four of the registrants producing the 189 pesticide products have now complied with the provisions of the maintenance fee requirements. See Appendix I for the list of product registration numbers and names of the registrants.

This Compliance Monitoring Strategy provides for compliance checks during routine producer establishment inspections to assure compliance with the Cancellation Orders issued for nonpayment of maintenance fees and to assure compliance with FIFRA section 17 export requirements. Note that registrants of cancelled products for the first fee period could continue to sell and distribute existing stocks until March 1, 1990. Due to the fact that the Cancellation Order allows stocks at the dealer and user level to be used until they are exhausted, inspections

beyond those at producing establishments are not needed. As the Strategy is amended for future cancellations, Appendix II will be updated to include Federal Register information on existing stocks, dates of effective cancellation, etc.

REQUIREMENTS

The Cancellation Order of October 18, 1989, allowed registrants to continue to sell and distribute existing stocks of the cancelled products until March 1, 1990, the due date for the next annual registration fee. Existing stocks are defined as those stocks produced, packaged, and labeled on or before the effective date of cancellation. Existing stocks already in the hands of dealers or users can be sold and used until they are exhausted. The exceptions to these provisions are cases where more stringent restrictions on sale, distribution, or use of the products have already been imposed through separate Agency actions. Dates regarding existing stocks provisions for products cancelled after subsequent fee periods can be found in Appendix II.

Exports

In the case of exports, any products exported after the effective date of cancellation must comply with section 17 of FIFRA, which includes citations for other applicable FIFRA requirements. Under section 17, prior to export, a foreign purchaser must sign a purchaser acknowledgement statement and a copy of that statement must be submitted by the exporter to EPA. In addition, note that unregistered pesticides intended for export must conform with labeling requirements pursuant to section 17, including section 2(q)(1)(H) (i.e., the label must say in a conspicuous manner "Not Registered for Use in the United States of America").

COMPLIANCE MONITORING

Compliance inspections are to be conducted by the States and EPA (in States without Cooperative Enforcement Agreements) during routine producer establishment inspections to monitor compliance with the cancellations and the section 17 export provisions for such products. If inspectors find cancelled products at the producing establishment after March 1, 1990, Stop Sale, Use or Removal Orders (SSUROs) should be issued. Prior to establishment inspections, States should check the list of producing establishments to determine if an establishment has produced one or more of the products since 1984. Appropriate enforcement is also to be taken for violative products.

ALLOCATION OF RESPONSIBILITIES

The following is a summary of the allocation of responsibilities between OPP, OCM, Regions and the States.

Office of Pesticide Programs (OPP)

Will provide the Regions and States with a hard copy and disks of the list of products and registrants cancelled because of nonpayment of maintenance fees for section 3 and section 24(c) registrations.

Will provide periodic updates of deletions or additions to the cancellation list will be provided to OCM.

Office of Compliance Monitoring (OCM)

Will provide the Regions with a list of registrants and producer establishments which have recently produced (since 1984) any of those pesticide products included among the approximately 20,000 cancelled for nonpayment of maintenance fees.

Will prepare the Compliance Monitoring Strategy for Pesticide Cancellations Due to Nonpayment of Maintenance Fees and will send periodic updates of additional cancellations or deletions to the cancellation lists.

As new cancellations go into effect for other maintenance fee periods, OCM will update the Compliance Strategy to include information on the number and type of product cancellations. Appendix II will be updated to include Federal Register information on existing stocks, dates of effective cancellations, etc.

Regions

Will provide the States with the Strategy.

Will conduct compliance inspections as part of routine producer establishment inspections in States without Cooperative Enforcement Agreements to assure compliance with the October 18, 1989 Cancellation Order and section 17 export requirements.

Will distribute the list of cancelled products; the names of registrants whose products have been cancelled; and information on producing establishments to the States, including updates on newly cancelled products or products whose cancellations have been rescinded.

Will check all Notices of Arrival for imports against the list of cancelled products before releasing such products.

Will take enforcement action and issue Stop Sale, Use or Removal Orders (SSUROs), as appropriate.

States

Will conduct compliance inspections as part of routine establishment inspections to assure compliance with the October 10, 1989 Cancellation Order and export requirements.

Will take enforcement action and issue Stop Sale, Use or Removal Orders (SSUROs), as appropriate.

APPENDIX I

The following registrants for the pesticide products listed below, which were previously included among the 189 deferred products, are now in compliance with the 1989 maintenance fee requirements of FIFRA.

Reg.No.	Registrant & Product No.	Product Name
#47319	Savanah Co.	
	047319-00001	Sevana Bird Repellent
	047319-00002	Sevana Bird Repellent
	047319-00004	Agrigard Insect Repellent
#11275	Guth Corp.	
	011275-00002	Lithate 2,4 D - Broadleaf Weed Killer Non-Volatile
#01457	Hexcel Corp.	
	001457-00015	Bromat
#08730	Hercon Environmental Co.	
	008730-00035	Lure N Kill Roach and Ant Killer Insecticidal Baits With Sex Lure

APPENDIX II

SUMMARY OF CANCELLATIONS

FEDERAL REGISTER NOTICE	MAINTENANCE FEE PERIOD, MARCH 1	NUMBER OF PRODUCTS CANCELLED	EFFECTIVE DATE OF CANCELLATION	EXISTING STOCKS AT REGISTRANT, DEALER & USER LEVEL
10-18-89	88-89	13,500 sec. 3 6,000 sec. 24(c)	10-10-89	Registrant can continue to sell and distribute stocks until 3-1-90. Dealer and user can use existing stocks until exhausted. Existing stocks are defined as those products produced, packaged or labeled by 10-10-89.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 30 1990

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Strategy for Aldicarb

FROM: John J. Neylan III, Director
Policy and Grants Division
Office of Compliance Monitoring (EN-342)

Phyllis Flaherty for JJ Neylan III

TO: Addressees

Attached is the Compliance Monitoring Strategy for the Voluntary Action by Rhone-Poulenc for Aldicarb.

On April 11, 1990 Rhone-Poulenc announced that it would voluntarily stop sale aldicarb labeled for potato use and recall stocks of aldicarb in areas where potatoes are grown, for modification of the labels. In addition the Environmental Protection Agency, Food and Drug Administration and the U.S. Department of Agriculture also issued a statement on this action. This is a voluntary action by the company while further studies are completed. Rhone-Poulenc has not amended its registration to delete use on potatoes, and they have not voluntarily cancelled the use.

No specific inspections need to be targeted as a result of the voluntary action by Rhone-Poulenc. In keeping with the voluntary stop sale by Rhone-Poulenc for these pesticides, the attached strategy calls for Regions and states to notify distributors/dealers/retailers of the action if aldicarb stocks are found during routine inspections and to monitor compliance with the revised label as part of any routine or for-cause inspections.

Please transmit the strategy to the States within your Region. If you have any questions on the attached aldicarb strategy, please contact Virginia Lathrop at FTS 475-8418.

Attachments

Addresses:

Douglas Campt (TS-766C)
Edwin F. Tinsworth (TS-767C)
Anne Lindsay (TS-767C)
Fredrick Stiel (LE-134A)
Mark Greenwood (LE-132A)
A.E. Conroy II (EN-342)
Connie Musgrove "
David Dull "
Mike Wood "
Jerry Stubbs "
Maureen Lydon "
Ken Kanagalingam "
Bob Zisa "
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Region IV

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Environmental Sciences Division, Region V

Bob Hanneschlager, Acting Director
Air, Pesticides and Toxics Division, Region VI

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Air and Toxics Division, Region VII

Irwin L Diskstein, Director
Air and Toxics Division, Region VIII

David P. Howekamp, Director
Air and Toxics Division, Region IX

Gary O'Neal, Director
Air and Toxics Division, Region X

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Pesticides & Toxic Substances Branch
Region I

Ernest Regna, Chief
Pesticides & Toxic Substances Branch
Region II

Larry Miller, Chief
Toxic & Pesticides Branch
Region III

Richard Stonebraker, Chief
Pesticides & Toxic Substances Branch
Region IV

Phyllis Reed, Chief
Pesticides & Toxic Substances Branch
Region V

Robert Murphy, Chief
Pesticides & Toxic Substances Branch
Region VI

Leo Alderman, Chief
Pesticides & Toxic Substances Branch
Region VII

Alvin Yorke, Chief
Toxic Substances Branch
Region VIII

Davis Bernstein, Chief
Pesticides & Toxic Substances Branch
Region IX

Kenneth Feigner, Chief
Pesticides & Toxic Substances Branch
Region X

Attachment

ALDICARB COMPLIANCE MONITORING STRATEGY

BACKGROUND

On Wednesday, April 11, 1990, Rhone-Poulenc announced that it would voluntarily stop the sale of aldicarb for potato use and recall the stocks of aldicarb labeled for use on potatoes in areas where potatoes are grown. The recalled stocks will be relabeled to delete the potato use. This is a voluntary action by the company while further studies are completed. Rhone-Poulenc has not amended its registration to delete use on potatoes nor has the Company voluntarily cancelled the use.

COMPLIANCE ACTIVITIES

Given that this is a voluntary action by the registrant, sale, distribution and use of Rhone-Poulenc aldicarb for use on potatoes remains legal. However, once a user has a product with the potato use deleted, he may not use the product for potatoes.

Although no inspections are being specifically targeted, routine or for-cause pesticide inspections may involve aldicarb. During these inspections, two actions should be taken:

- When aldicarb products are found at the distributor/ retailer/user level in States where potatoes are grown, the inspector should inform the distributer/retailer/ user of the voluntary stop sale and recommend that the person contact Rhone-Poulenc at 1-800-334-9745. It may be useful to provide copies of the attached statement when aldicarb stocks are found (See Attachment).

- If a user applies aldicarb bearing a label which no longer has potatoes on it, appropriate enforcement action should be taken for use inconsistent with the label.

AFFECTED PRODUCTS

Aldicarb products with potato use on label:

EPA Registration No.	Brand Name
264-319	Temik Brand TSX Granular Aldicarb Pesticide (1)
264-417	Temik Brand 15G Aldicarb Pesticide (2)
264-331	Temik Brand 10% Granular Aldicarb Pesticide (3)

(1) This is the most common aldicarb product sold in 1986 to 1988.

(2) Sold primarily in 1988.

(3) Only sold for export in 1987.

EPA Environmental News

(~~THURSDAY~~ WEDNESDAY, APRIL 11, 1990)

The following joint statement is being issued as the result of action taken yesterday by Rhone-Poulenc Ag Co. to voluntarily stop sales and recall the stocks of the pesticide aldicarb for use on potatoes. The Company has informed EPA that it found the allowable residue level of aldicarb was exceeded on a few potatoes in one field among 26 fields tested. Aldicarb has been registered since 1970 to control insects, mites and nematodes. Since aldicarb was registered, there have been no reported illnesses from eating potatoes. For more information, contact Al Heier at (202) 382-4374.

JOINT SATEMENT BY

ENVIRONMENTAL PROTECTION AGENCY

FOOD AND DRUG ADMINISTRATION
AND
U.S. DEPARTMENT OF AGRICULTURE

The Environmental Protection Agency (EPA), the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) commend Rhone-Poulenc Ag Company for voluntarily ceasing the sale and recalling the stocks of the pesticide aldicarb for use on potatoes due to recent data which indicate that the allowable residue level was exceeded on potatoes in isolated cases. The action taken yesterday is a cautious measure to ensure the safety of our food supply.

Consumers should not be alarmed and they should continue their normal consumption of potatoes. The company is taking this action after recently finding that the allowable residue level was exceeded in ten individual potatoes among approximately three hundred that were tested following a request for data from the EPA.

In the seventeen years aldicarb has been used, there are no reports of illness from eating aldicarb-treated potatoes. At the highest levels found in a few potatoes, aldicarb could cause flu-like symptoms such as nausea, headache and blurred vision which disappear quickly.

EPA will continue to review and monitor this situation and take any further action if necessary.

# # #

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

JAN 10 1975

To: Regional Administrators

From: Assistant Administrator for Water and Hazardous Materials (WH-556)

Assistant Administrator for Enforcement and General Counsel (EG-329)

Subject: Continuing State Registration of Products Containing Aldrin and Dieldrin for Which Uses Have Been Suspended

Late in December, 1974, the Agency became aware of the existence of activity in the above referenced matter, first in the State of California, and subsequently in several other States in other Regions. Preliminary investigation into the magnitude of the problem suggests that there may be significant continuing activity on a national scale, that there is confusion as to the extent of Federal jurisdiction over such activity by States, and that the economic, political and regulatory considerations involved require additional action by the Agency.

Accordingly, our joint staffs are preparing a Federal Register notice, which, upon publication, will formally assert Federal jurisdiction over non-Federally registered products containing Aldrin and Dieldrin by implementing Section 3 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136 et seq.). Attached is a strategy paper which explains the background of this matter in greater detail and provides an explanation of how these Aldrin and Dieldrin products should be treated upon the activation of Section 3. In addition, proposed enforcement activities by the Agency, anticipated in cooperation with involved States, is discussed.

We shall expedite publication of this notice in the Federal Register. Pending formal publication, you should proceed with confidence in the proposed substance of the notice as outlined above and in the attached paper to inform affected States in your Region of these developments. Further, we trust you will encourage their support and cooperation in our effort to achieve orderly and equitable disposition of existing State-registered products together with even-handed and comprehensive enforcement of the Aldrin-Dieldrin cancellation and suspension orders. The Enforcement Division of each region will be contacted by the Pesticides Enforcement Division in Washington which will provide additional details and support, where needed, to achieve Federal-State cooperation in providing notice of these developments and in proceeding with enforcement of the Administrator's orders relating to cancellation and suspension of Aldrin and Dieldrin.

Enclosure:

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

Strategy Paper:

State Registration of Products Containing Aldrin and Dieldrin for Which Uses Have Been Suspended

Background:

Late in December, 1974 Headquarters was informed by Region IX and the State of California that products containing Aldrin and Dieldrin were being registered by the State in possible contravention of the intent of the Administrator's Order of December 7, 1972 (37 F.R. 26463, 26465). That order provided that henceforth all technical Aldrin and Dieldrin must bear the label restriction: "For use only in formulating products bearing EPA-approved FIFRA registrations." It was thought that such a restriction on use of the technical material, which is available only through import and therefore subject to Federal jurisdiction, would preclude further formulation of finished products for State registration and thereby provide de facto Federal control of all products containing Aldrin or Dieldrin. Investigations by California and Region IX (confirmed now by several other Regions and States) have revealed that many State-registered Aldrin-Dieldrin products were: 1) formulated from technical material held prior to December 7, 1972 and therefore not subject to the restrictive labeling requirement, 2) formulated from so-called "end-use" or finished Aldrin-Dieldrin products bearing State or Federal registrations and lacking any stated restrictions concerning reformulation, 3) formulated from technical meterial sold after December 2, 1972 which failed to bear the required restriction, 4) formulated from technical material restrictively labeled and ignored by the formulator. States, having lately become aware, of the intent of the December, 1972 order, are faced with a dilemma: pressure to reregister for continued shipment, sale and use products formerly approved by them and the likelihood that such registration contravenes at least the spirit, and in some cases possibly the letter, of a Federal cancellation order.

Action:

In order to clarify existing ambiguities concerning the legal status of these non-Federally registered products with respect to Federal jurisdiction over their production, shipment, sale, and use, and to insure even-handed enforcement of the Aldrin and Dieldrin cancellation and suspension orders, the Agency will formally implement Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136 et seq.) by notice in the Federal Register. This notice will contain an exemption,

pursuant to the provisions of Sections 6(a)(1) and 15(b)(2) of the Act, allowing States to register for orderly disposition through shipment, sale and use in that State, existing stocks of products containing Aldrin and Dieldrin produced on or before the date of signature by the Administrator of the order implementing Section 3 of the Act as to these State-registered products. Effective the day following signature of the order implementing Section 3 of the Act, production of products containing Aldrin and Dieldrin must cease, and States must cease to register for shipment, sale and use any but existing stocks of such products.

Regional offices should arrange to advise appropriate authorities in States in that Region, in advance, of the planned activation of Section 3 and its attendant prohibitions, and should request State authorities to notify all State registrants and any other potentially affected parties of the activation of Section 3 and of the effective date of related prohibitions. States are to be asked to provide to the appropriate Regional Offices lists of State registrants or persons with registration applications pending for products containing Aldrin or Dieldrin. Information relating to location and relative amounts of these State-registered products also is to be sought.

The Agency's pesticides enforcement personnel will enlist State cooperation in continuing its on-going investigation of the formulation since December 7, 1972, of products containing Aldrin or Dieldrin for State registration. Should it be the case that Federal registrants of technical Aldrin or Dieldrin have not relabeled their products in conformance with the Administrator's Order of December 7, 1972, or that pesticide producers have formulated products containing Aldrin or Dieldrin in contravention of labeling prohibitions against use in non-Federally registered products, such violations will be prosecuted in accordance with the appropriate provisions of the Act.

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

JAN 14 1975

To: [Enforcement Division Directors]

From: A. E. Conroy II, Director
Pesticides Enforcement Division

Subject: Non-Federally Registered Products Containing Aldrin or Dieldrin

Background:

In his memorandum of December 10, 1974, Point #4, the Director advised that production of non-Federally registered products containing Aldrin and Dieldrin contravened the December 7, 1972 Order of the Administrator (37 F.R. 26463, 26465). The intent of that order was to restrict use of technical Aldrin and Dieldrin to use in EPA-registered products only. The Director's memorandum continued that production of non-Federally registered products containing Aldrin and Dieldrin could subject such products to stop sale and their producers to liability under Sections 12(a)(2)(G) and (K) of the Act.

Subsequent to the Director's memorandum, it has come to the Agency's attention that numerous products containing Aldrin and Dieldrin may have been produced since December 7, 1972 and registered by States under circumstances not strictly contravening the December, 1972 Order. Details concerning this production and questions relating to the scope of Federal jurisdiction over such production under the December, 1972 Order are elaborated in the attached memorandum and strategy paper, which were sent to all Regional Administrators on January 10, 1975.

Action:

For purposes of Federal enforcement activity, the following developments are important:

1) The Agency has determined to implement Section 3 of the Act with respect to products containing Aldrin and Dieldrin intended for intrastate shipment. States will be permitted to register and allow shipment, sale and use in that State of stocks of products containing Aldrin or Dieldrin in existence on the date of the signature by the Administrator of the order activating Section 3. After that date, all production of products containing Aldrin or Dieldrin must cease,

and States must cease to permit registration or to allow shipment, sale or use of any but existing stocks. Violations of the Act will be subject to prosecution 60 days after Federal Register publication of the Administrator's order. (This of course will not apply to those products registered Federally and by States for uses which have not been suspended: 1) subsurface ground insertion for termite control; 2) dipping of non-food roots and tops; 3) moth-proofing in a closed system.)

2) It is the obligation of each Region to notify, in advance, appropriate State authorities of this development and its attendant prohibitions and to enlist their aid in notifying registrants and other affected persons in their State. Attached is a sample letter which States may wish to employ as a guide in the notification process.

3) Immediately upon signature, of the Section 3 order, Headquarters staff will notify Regional officials who should contact the State authorities directly.

4) Cooperation and aid of State authorities is to be enlisted in obtaining for Federal use:

   - lists of State registrants or persons with applications pending for Aldrin-Dieldrin product registration;

   - information on location and relative amounts of such products within the State;

   - assistance of State enforcement authority to achieve compliance with the production, registration, and shipment, sale and use cut-off.

5) EPA regional personnel are to continue their investigations of production since December 7, 1972 of products containing Aldrin and Dieldrin for State registration. Should it be determined that Federal registrants of technical Aldrin or Dieldrin have not relabeled their products in conformance with the Administrator's Order of December 7, 1972, or that pesticide producers have formulated products containing Aldrin or Dieldrin in contravention of labeling prohibitions against use in non-Federally registered products, such violations are to be prosecuted in accordance with the appropriate provisions of the Act.

Should you have questions or encounter difficulty with regard to any of these matters, please notify the appropriate Regional Coordinator.

Attachments:

Attachment I

Aldrin - Dieldrin Strategy

1. R.C.'s phone Region in advance of order - inform of strategy
2. R.C.'s send Director's enforcement package to Regions
3. Regions inform States of pending action and request names of State registrants
4. PED sends Administrator's order to Regions
5. HDQ sends Administrator's order to States
6. States or Regions notify State registrants of order (See Attachment II).
7. Regions follow-up at each State registrant.

Attachment II SAMPLE LETTER

State Registrant
(Address)

Gentlemen:

On (date), the Administrator of the United States Environmental Protection Agency issued an Order asserting Federal jurisdiction over all non-Federally registered Aldrin-Dieldrin products in intrastate commerce by invoking Section 3 of the Federal Insecticide Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136 et seq.). As a result of this Order, the shipment, sale, and use of non-Federally registered Aldrin-Dieldrin products, produced after the effective date of the Order will be prohibited. Accordingly, the State of (name) can register or continue registrations only of non-Federally registered Aldrin-Dieldrin products which were produced on or before the date of the Order. Such registrations are being permitted to allow the orderly disposition of non-Federally registered products through shipment, sale, and use in the registering State.

Any further questions regarding the Order should be directed to Mr. _____, EPA, Region_____, street_____, city, _____, State_____, telephone number_____.

Sincerely,

Attachment III

Types of Violations Involving Non-Federally Registered products containing Aldrin or Dieldrin

1. Failure of a Federal registrant to place a statement such as "For use only in formulating products bearing EPA-approved FIFRA registrations" on manufacturing use only labels.

   Violation: Misbranded, inadequate directions Section 12(a)(1)(E)
   Action: Civil/Criminal/Stop Sale

2. Use of a "manufacturing use only" product bearing a statement such as "For use only in formulating products bearing EPA-approved FIFRA registrations" on the label in a non-Federally registered Aldrin - Dieldrin product.

   Violation: Misuse Section 12(a)(2)(G)
   Action: Civil/Criminal/Stop Use

3. Sale of a non-Federally registered Aldrin - Dieldrin product produced after the effective date of the Order, but before violations are actionable (60 days after publication in the Federal Register).

   Action: Stop Sale

4. Sale of a non-Federally registered Aldrin-Dieldrin product produced after the effective date of the Administrator's Order (day after signature) and after the date violations become enforceable (60 days after publication in the Federal Register).

   Violation: Non registration Sec. 12(a)(1)(A)
   Action: Civil/Criminal/Stop Sale

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, DC 20460

JUN 6 1989

OFFICE OF
PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Compliance Strategy for the Cancellation of Non-wood Uses of the Inorganic Arsenicals

FROM: John J. Neylan III, Director
Policy and Grants Division
Office of Compliance Monitoring

TO: Addressees

Attached is the Compliance Strategy for the Cancellation of the Non-wood Uses of the Inorganic Arsenicals. On June 30, 1988, the Agency published "Inorganic Arsenicals; Intent to Cancel Registrations for Pesticide Products Registered for Non-Wood Preservative Use; Conclusion of Special Review" in the FEDERAL REGISTER (53 FR 24787). This notice, which is also attached, cancelled all minor uses of inorganic arsenicals with the exception of the insecticide use of arsenic trioxide in a solid formulation and packaged in a sealed metal container, and the solid formulation of arsenic trioxide for the control of moles, gophers and pocket gophers. Also attached is a summary of the action for your convenience.

The turf herbicidal use of the flowable formulation of calcium arsenate, the grapefruit growth regulator use of lead arsenate, the grape fungicidal use of sodium arsenite, and the desiccant uses of arsenic acid on cotton and okra grown for seed, i.e., the major uses, are still under special review awaiting food crop residue data from registrants as requested under FIFRA §3(c)(2)(B).

Compliance with the NOIC will be determined by inspection of registrants and producers of cancelled products to determine if production and sale for distribution within the U.S. has ceased and that distributors have been notified of the action as required by the Notice. Inspections of dealers and users will be conducted to ensure that cancelled products are no longer being sold or used. Tips and complaints are to be investigated as received.

The cancellation has been appealed and a list of those persons appealing the cancellation is attached. If you have any questions concerning this action please contact David Stangel of my staff at 382-3477.

Attachments

ADDRESSEES

Douglas D. Campt	(TS-766C)
Edwin F. Tinsworth	(TS-767C)
Anne Lindsay	(TS-767C)
Frederick F. Stiehl	(LE-134A)
Mark Greenwood	(LE-132A)
A. E. Conroy II	(EN-342)
Connie Musgrove	"
John J. Neylan III	"
David Dull	"
Mike Wood	"
Phyllis Flaherty	"
Jerry Stubbs	"
Maureen Lydon	"
Ken Kanagalingam	"
Bob Zisa	"
Sherry Sterling	"

Jake Mackenzie
Western Regional Compliance Director

	Louis F. Gitto, Director Air Management Division	Marvin Rosenstein, Chief Pesticides & Toxic Substances Br
	Barbara Metzger, Director Environmental Services Division	Ernest Regna, Chief Pesticides & Toxic Substances Br
III	Stephen R. Wassersug, Director Hazardous Waste Management Div	Larry Miller, Chief Toxic & Pesticides Branch
IV	Winston A. Smith, Director Air, Pest. & Toxics Mangt. Div	Richard DuBcse, Chief Pesticides & Toxic Substances Br
V	William H. Sanders III, Director Environmental Services Division	Phyllis Reed, Chief Pesticides & Toxic Substances Br
VI	William B. Hathaway, Director Air, Pesticides & Toxic Division	Robert Murphy, Chief Pesticides & Toxic Substances Br
VII	William A. Spratlin, Director Air and Toxics Division	Carl Walters, Acting Chief Pesticides & Toxic Substances Br
VIII	Irwin L. Dickstein, Director Air and Toxics Division	Alvin Yorke, Chief Toxic Substances Branch
IX	David P. Howekamp, Director Air Management Division	Davis Bernstein, Chief Pesticides & Toxics Branch
X	Gary O'Neal, Director Air and Toxics Division	Kenneth Feigner, Chief Pesticides & Toxic Substances Br

cc:	Michael Walker	(LE-134P)
	Jim Roeloffs	(TS-788)
	John Tice	(TS-769C)

COMPLIANCE STRATEGY FOR THE CANCELLATION OF NONWOOD USES OF THE INORGANIC ARSENICALS

OVERVIEW

On June 30, 1988, the Agency published "Inorganic Arsenicals; Intent to Cancel Registrations for Pesticide Products Registered for Non-Wood Preservative Use; Conclusion of Special Review" in the FEDERAL REGISTER (53 FR 24787), which cancelled all minor uses of inorganic arsenicals with the exception of the insecticide use of arsenic trioxide in a solid formulation and packaged in a sealed metal container, and the solid formulation of arsenic trioxide for the control of moles, gophers and pocket gophers.

The turf herbicidal use of the flowable formulation of calcium arsenate, the grapefruit growth regulator use of lead arsenate, the grape fungicidal use of sodium arsenite, and the desiccant uses of arsenic acid on cotton and okra grown for seed, i.e., the major uses, are still under special review awaiting food crop residue data from registrants requested under FIFRA §3(c)(2)(B). A reassessment of the carcinogenic potency of inorganic arsenic as it relates to dietary and dermal exposures will be conducted when this data is received.

REQUIREMENTS OF THE RULE

All minor uses of inorganic arsenicals with the exception of the insecticide use of arsenic trioxide in a solid formulation and packaged in a sealed metal container, and the solid formulation of arsenic trioxide for the control of moles, gophers and pocket gophers are cancelled effective August 8, 1988. Manufacturers of cancelled products are required to notify their distributors of the time limits on distribution and sale of cancelled products in the possession of the distributor by July 25, 1988, and to keep records of the date of contact with the distributor.

Regulated Industry

All registrants, producers, distributors, and users of the minor use products of inorganic arsenicals with the exception of arsenic trioxide products registered as an insecticide for use in a solid formulation and packaged in a sealed metal container or as a solid formulation for the control of moles gophers and pocket gophers. This action affects 45 registrants producing 60 products.

Existing Stocks

As of August 8, 1988, no existing stock of any cancelled product may be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having so received) delivered or offered to deliver, or used. This includes products voluntarily cancelled which would otherwise still be allowed to be sold under the terms of the voluntary cancellation. Persons holding existing stocks of cancelled products must dispose of them in accordance with the applicable requirements of the Resource Conservation and Recovery Act (RCRA). Noncompliance with the cancellation order is a violation of FIFRA §§12(a)(1)(A) and 12(a)(2)(K).

COMPLIANCE MONITORING

Compliance with the NOIC will be determined by inspection of registrants and producers of cancelled products to determine if production and sale for distribution within the U.S. has ceased and that distributors have been notified of the action as required by the Notice. These inspections are to be carried out within 6 months of receipt of this compliance strategy. During routine inspections of dealers and users, inspectors should ensure that cancelled products are no longer being sold or used. Tips and complaints are to be investigated as received.

Neutral Administrative Inspection Scheme

Since the issuance of the Cancellation Order is an administrative action which cancels all minor non-wood preservative uses of the inorganic arsenicals with the exception of the two previously mentioned uses of arsenic trioxide, inspections for violations of this cancellation order will take place within the existing compliance monitoring framework.

ALLOCATION OF RESPONSIBILITIES

Office of Pesticide Programs

Will develop and provide OCM with a list of products affected by this Notice and their registration status.

Office of Compliance Monitoring

Will develop and transmit the Compliance Monitoring Strategy to the Regions.

Will transmit the list of those products which have been cancelled to the Regions.

Will transmit the list of registrants and producing establishments of inorganic arsenicals to the Regions.

Regions

Will provide copies of the Compliance Monitoring Strategy to the States.

Will distribute a list of products, registrants and producing establishments affected by this Notice to the States.

Will conduct inspections in States without Cooperative Enforcement Agreements as part of their routine inspectional schedule.

Will take enforcement actions as appropriate.

States

Will conduct inspections of registrants within 6 months of receipt of the compliance strategy.

Will conduct inspections of dealers as part of their routine inspectional schedule.

Will take enforcement actions as appropriate.

Will report to the Regions on actions taken under this Notice.

INORGANIC ARSENICALS NON-WOOD PRESERVATIVE USES NOTICE OF INTENT TO CANCEL

All non-wood preservative uses of inorganic arsenical pesticide products are cancelled effective August 8, 1988, with the exception of the following uses.

The following registrations will be retained without change:

1. Arsenic trioxide insecticide use (solid formulation manufactured in a sealed metal container only) for:

   Domestic outdoor - domestic dwellings
   Domestic indoor - domestic dwellings

2. Arsenic trioxide mole, gopher, and pocket gopher killer use (solid formulation only) for:

   Domestic outdoor - domestic dwellings
   Terrestrial non-food crops - golf courses, ornamental plants and lawns, non-crop areas

Registrations not considered in this action:

1. Lead arsenate plant growth regulator use on grapefruit.

2. Sodium arsenite fungicide use on grapes.

3. The desiccant uses of arsenic acid on okra (grown for seed) and cotton.

4. The flowable formulation of calcium arsenate for use on turf.

Decisions on these uses are deferred pending the Agency's Risk Assessment Council's reassessment of the carcinogenic potency of inorganic arsenic for dermal exposure and the receipt of dietary exposure data the Agency has requested.

Effective Dates

As of August 8, 1988, no existing stock of any cancelled product may be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having so received) delivered or offered to deliver, or used. This includes products voluntarily cancelled which would otherwise still be allowed to be sold under the terms of the voluntary cancellation.

Registrants were required to notify their distributors of cancelled inorganic arsenical products by July 25, 1988, to inform them of the time limitations on distribution and sale of existing stocks in the hands of the distributor.

PARTIES REQUESTING A HEARING

Jones Products Company
Box 204
Middleton, WI 53562

Jones Ant Killer EPA Reg. No. 29-4

Senoret Chemical Company
566 Leffingwell Ave.
Kirkwood, MO 63122

Terro Ant Killer EPA Reg. No. 149-2

General Pest Service Co.
1819 Goldfield Street #B
North Las Vegas, NV 89030

Ant Jex Redwood Ant Stakes EPA Reg. No. 3324-3

Protexall Products, Inc.
1109-11 Hwy 427 N.
Longwood, FL 32750

Protexall "Ant-Kil" EPA Reg. No. 4972-8

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

JUL 6 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTA

MEMORANDUM

SUBJECT: Compliance Strategy for the Conditional Registration and Cancellation of Certain Bromoxynil Products

FROM: John J. Neylan III, Director
Policy and Grants Division
Office of Compliance Monitoring

TO: Addressees

On May 5, 1989 the Agency approved an Agreement with Rhone-Poulenc to conditionally amend the registrations of three bromoxynil pesticide products (buctril, bronate, and buctril + atrazine), pursuant to FIFRA section 3(c)(7)(A).

On June 5, 1989 the Director of the Office of Pesticide Programs, Office of Pesticides and Toxic Substances, signed a FEDERAL REGISTER Notice entitled: "Order Cancelling Registrations For Pesticide Products Containing Bromoxynil Butyrate." The registrant requested voluntarily cancellation of bromoxynil butyrate products and proposed to conduct a recall of the cancelled products down to the user level.

Attached are the Final Compliance Monitoring Strategy, a summary of the Strategy, a copy of the Agreement between the registrant and EPA, and the Cancellation Order. Please transmit a copy of the Strategy and other attachments to the States. Please note that because of the nature of this action, this Compliance Strategy is immediately effective. If you have any questions or comments regarding the Strategy, contact Steve Howie (E-mail EPA 7201, FTS 475-7786) of my staff.

Thank you for your cooperation.

Attachments

ADDRESSEES

Douglas D. Campt	(H7501C)
Edwin F. Tinsworth	(H7505C)
Anne Lindsay	(H7505C)
Frederick F. Stiehl	(LE-134A)
Mark Greenwood	(LE-132A)
A. E. Conroy II	(EN-342)
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IX	David P. Howekamp, Director Air Management Division	Davis Bernstein, Chief Pesticides & Toxics Branch
X	Gary O'Neal, Director Air and Toxics Division	Kenneth Feigner, Chief Pesticides & Toxic Substances Br

cc:	Michael Walker	(LE-134P)
	Jim Roeloffs	(TS-788)
	John Tice	(TS-769C)
	Al Heier	(A-107)

BROMOXYNIL CONDITIONAL REGISTRATION AND VOLUNTARY CANCELLATION

COMPLIANCE MONITORING STRATEGY SUMMARY SHEET

1. Conditional Registration of products containing Buctril, Bronate, and Buctril + Atrazine.

TARGET DATE FOR INSPECTION	CONDITIONS OF REGISTRATION TO BE MONITORED BY INSPECTION	LEV
by 8/7/89	Restickering of products released for shipment after 5/5/89; Stickers sent to dealers for relabeling by 5/15/89.	Regist Produce
by 9/6/89*	Restickering of dealer stocks carried out by 5/25/89; Point-of-purchase communication carried out by registrant per schedule in conditions of registration.	Distrib
by 9/6/89*	Used only by certified applicators according to conditions of registration.	User
between 10/1/89 and 11/1/89	Revised Labelling on all products by 10/1/89; all bulk containers have correct transfer mechanism by 10/1/89.	Registr Produce
between 10/1/89 and Spring, 1990 growing season	Compliance with EPA-approved user training plan. Plan must be implemented prior to 1990 Spring growing season.	Registra User Interfac

2. Voluntary Cancellation of Bromoxynil Butyrate Products**

TARGET DATE FOR INSPECTION	ACTIVITY TO BE MONITORED BY INSPECTION, PER TARGET DATE	LEVEL
by 8/7/89	No shipments intended for sale/use after 6/12/89	Registra Producer
by 9/6/89*	No sale after 6/12/89	Distribut
by 9/6/89*	No use after 6/12/89	User

* As part of routine inspections.

** Includes the following products: Dragonmate, ME 4 Brominal, Torch Twin Pak, 3+3 Brominal, Bromoxynil Butyrate Technical, Certrol, and Buctril 4 EC.

COMPLIANCE STRATEGY FOR THE CONDITIONAL REGISTRATION AND CANCELLATION OF CERTAIN BROMOXYNIL PRODUCTS

OVERVIEW

Bromoxynil is a selective, postemergence herbicide used to control broadleaf weeds primarily in field corn, wheat, garlic, barley, oats, rye, sorghum, onions and flax. Most use occurs between February and June on small grains and corn.

On May 5, 1989 the Agency approved an Agreement with Rhone-Poulenc to conditionally amend the registrations of three bromoxynil pesticide products (buctril, bronate, and buctril + atrazine), pursuant to FIFRA section 3(c)(7)(A).

On June 5, 1989 the Director of the Office of Pesticide Programs, Office of Pesticides and Toxic Substances, signed a FEDERAL REGISTER Notice entitled: "Order Cancelling Registrations For Pesticide Products Containing Bromoxynil Butyrate." The registrant requested voluntarily cancellation of bromoxynil butyrate products and proposed to conduct a recall of the cancelled products down to the user level.

REGULATED COMMUNITY

Rhone-Poulenc, the only registrant, producers, distributors, and users of bromoxynil are affected by the Agreement and the Cancellation Order, although responsibility for meeting the terms of the conditional registration Agreement is on the registrant. At the time of the Agreement and Cancellation Order there were 8 registrations and 6 producer establishments. A list of these can be found in the Appendix.

REQUIREMENTS OF CONDITIONAL REGISTRATION

Under FIFRA Section 3(c)(7)(A), EPA has imposed certain conditions for the continued registration of three bromoxynil octanoate products (buctril, bronate, and buctril + atrazine). These conditions include adding warning statements to the product labels stating that exposure during pregnancy causes birth defects in laboratory animals, restricting its use to certified applicators, and requiring additional protective clothing for mixers, loaders and applicators.

The registrant is also required to conduct an extensive notification and educational program for bromoxynil users to inform them of the potential birth defect risks for mixing, loading and applying bromoxynil as well as the importance of following the new risk reduction measures.

The registrant is also required to provide extensive data within specified time frames and interim reports to enable

the Agency to better estimate the magnitude of risk to exposed workers.

Stocks of Products With Amended Stickering/Labeling

By May 6, 1989 the registrant was required to halt shipment of all bromoxynil products until approved amended stickers are affixed to each container within the company's possession.

By May 15, 1989, the registrant was required to provide each distributor holding inventory of bromoxynil products sufficient stickers for such inventory.

By May 25, 1989 the registrant was required to provide each reseller and retailer holding inventory of bromoxynil products sufficient stickers for such inventory.

The registrant was also required to provide each distributor, reseller, and retailer with instructions concerning the manner in which the sticker must be affixed to each container, and to implement the attached labeling communication plan by the dates described therein.

The registrant is also required to assume responsibility for insuring that each distributor, reseller or retailer attaches the sticker to each container which is sold or distributed by the distributor, reseller or retailer after the date the stickers are received.

After October 1, 1989, revised labeling, which deletes all claims, references, and use directions pertaining to the previously permissible uses for turf and non-crop areas, and which includes all new label provisions as required by the agreement, must be attached to the containers of all bromoxynil products released for shipment by the registrant.

Additional Requirements

By October 1, 1989, the registrant must develop and submit to EPA a proposed program to provide additional training to users of bromoxynil products prior to the 1990 spring use season and will implement the program once it has been approved by EPA.

By October 1, 1989, the registrant is also required to establish a program to provide assistance to users who do not own a mechanical transfer system which terminates in a drop-free hard coupling and who wish to obtain such a system or to modify their present system.

After October 1, 1989, the registrant is required to insure that all bulk containers released for shipment include a mechanical transfer mechanism which terminates in a drip-free hard coupling which may be used only with a spray or mix tank which has been fitted with a compatible coupling.

By January 1, 1990, the registrant is required to have investigated and reported to EPA, the feasibility of packaging bromoxynil products in containers which are smaller than 30 gallons and which include a hard coupling designed for use with a specific closed mixing and loading system.

By specified dates, the registrant is required to develop and submit rabbit dermal teratology, male reproduction effects and worker exposure studies to EPA. The agreement requires the registrant to submit one-line status reports on each required study on at least a quarterly basis to EPA.

CONDITIONS OF CANCELLATION

All pesticide products containing bromoxynil butyrate were automatically canceled, effective the day following publication of the Cancellation Order in the Federal Register.

Recall

In their request for voluntarily cancellation, the Company stated that it would institute a plan to recover remaining stocks of these products from distributors, dealers, and users.

Existing Stocks

Sale, distribution and use of existing stocks of bromoxynil butyrate product now in the possession of distributors, retailers and end-users is not permitted after the date of publication of the Cancellation Order in the Federal Register. The registrant also indicated that they will accept for disposal any stocks of bromoxynil butyrate products turned in by distributors, dealers and end-users. Persons holding existing stocks of cancelled bromoxynil butyrate products must dispose of them in accordance with the applicable requirements of the Resource Conservation and Recovery Act (RCRA). Noncompliance with the cancellation order or its terms is a violation of FIFRA sections 12(a)(1)(A) and/or 12(a)(2)(K).

COMPLIANCE MONITORING

Regional/State Activities

Inspections will be conducted by the States and EPA (in non-grant states) to monitor compliance with the Conditional Registration Agreement and the Cancellation Order. This will be accomplished through registrant; producer establishment, and marketplace inspections. Enforcement actions regarding the Cancellation Order will be taken, as appropriate, by the States and Regions, with reports of such actions and/or potential violations made to EPA headquarters. States and Regions will also report to EPA headquarters all violations or potential

and Regions, with reports of such actions and/or potential violations made to EPA headquarters. States and Regions will also report to EPA headquarters all violations or potential violations of the conditions of registration of bromoxynil octanoate products.

Registrant/Producer Level

Within 30 days of the date of this strategy, the Regions/States will schedule and conduct inspections of Rhone-Poulenc's producer establishments to obtain assurance that the company has complied with the requirements of the May 5, 1989 Agreement by not having released products for shipment without the amended stickers, and the June 5, 1989 Cancellation Order to determine if production and sale for distribution of cancelled bromoxynil products within the U.S. has ceased. Information obtained during inspections of registrants records regarding disposition of stocks of conditionally registered and cancelled products should be forwarded to other Regions for their use in scheduling inspections.

After October 1, 1989 inspections at producer establishments will assure that all products released for shipment by the registrant have the required revised labelling, and that all bulk containers released for shipment include the required mechanical transfer mechanism with a drip-free hard coupling.

After October 1, 1989, and before the Spring 1990 planting season, inspections will be conducted to determine registrant compliance with the EPA-approved plan for user training and assistance. This plan will be sent to the States and Regions following its approval. The inspections will be appropriately directed at the registrant-user interface and may, for example, include monitoring or inspection of training sessions/materials by Regions or States.

Within 60 days of the date of this strategy, the Regions/States will follow-up and track the recall of the cancelled bromoxynil butyrate products, that the registrant is undertaking, following the outlines in section 14 of the Pesticides Inspection Manual.

Distributor/Reseller/Retail Level

Within 60 days of the date of this strategy, the Regions/States will inspect, during routine scheduled inspections, distributors, resellers, and retailers to assure that the registrant has adhered to the time frames and requirements listed above under "Requirements of Conditional Registration," and the June 5, 1989 Cancellation Order to determine if sale and distribution of cancelled bromoxynil butyrate products within the U.S. has ceased.

User Level

Within 60 days of the date of this strategy, inspectors will assure, during routine scheduled inspections, that non-cancelled bromoxynil products are being used only by certified applicators and in accordance with the use directions and protective clothing requirements on the amended sticker/label, and that cancelled bromoxynil butyrate products are not being used.

ALLOCATION OF RESPONSIBILITIES

Office of Pesticide Programs

Will develop and provide OCM with a list of all products affected by the Conditional Registration Agreement and the Cancellation Order.

Office of Compliance Monitoring

Will develop and transmit the Compliance Monitoring Strategy to the Regions.

Will receive quarterly reports from Regions for one year following the date of this Strategy.

Will transmit to the Regions a list of those affected products and a list of producing establishments.

Will transmit to OPP any information regarding violation of the conditions of registration.

Regions

Will provide copies of the Compliance Monitoring Strategy to States.

Will report quarterly to the Director of the Compliance Division, OCM detailing State inspection activities per their quarterly reports, for one year following the date of this Strategy.

Will distribute a list of products and producing establishments to the States.

Will conduct inspections in States without Cooperative Enforcement Agreements as specified in this Strategy.

Will take enforcement action as appropriate.

noncompliance with the requirements of the Agreement, including information on tips and complaints received.

Will report to the Director of the Compliance Division, OCM regarding violations of the conditions of registrations immediately upon receiving such information.

States

Will conduct inspections as specified in this Strategy.

Will make quarterly reports to the Regions detailing the number and dates of inspections related to this Strategy, for one year after the date of this Strategy.

Will take enforcement action as appropriate provided they have the authority.

Will report to the Regions on potential violations of the bromoxynil conditional registration agreement, including whether training and assistance activities are conducted, and enforcement actions for violations of the Cancellation Order. Reports will be submitted within two weeks of knowledge of violation or enforcement action.

Will investigate tips and complaints as received. If States receive information which indicates possible noncompliance with the Agreement, they should investigate to ensure compliance.

APPENDIX

BROMOXYNIL REGISTRANT, PRODUCTS, AND PRODUCING ESTABLISHMENTS (1985-87)

Rhone-Poulenc AG Company
P.O. Box 12014 2 T.W. Alexander Drive
Research Triangle Park, NC 27709

Product Name	EPA Reg. No.	Estab. No.	Estab. Address
Buctril*	264-437	264-OR-001	Rhone-Poulenc AG Company 6200 NW St. Helens Rd. Portland, OR 97210
Broot 15GX (Bronate)*	264-438	264-OR-001	"
" " "	"	264-IA-001	Rhone-Poulenc AG Co 2100 S 21st St. Clinton, IA 52732
Buctril + Atrazine*	264-477	No USA Production Records for 1985-88	
ME 4 Brominal (Buctril ME 4)** (Also produced as 3+3 Brominal and Torch Twin Pack)	264-340	264-MO-001	Rhone-Poulenc PO Box 367 317 West Florence Rd St. Joseph, MO 64502
"	"	264-NC-001	Rhone-Poulenc AG Company T.W. Alexander Dr Research Triangle Pk, NC 27709
"	"	55259-IL-001	Bradford Ag Service Inc. 401 Phoenix Ave Bradford, IL 61421
"	"	2393-IL-003	Hopkins Agri. Chemical Co. 303 SW Arch St. Atlanta, IL 61723
Buctril 4 EC**	264-474	No USA Production Records for 1985-88	
Certrol**	264-421	264-MO-001	Rhone-Poulenc AG Company PO Box 367 317 West Florence Road St. Joseph, MO 64502
"	"	2393-IL-003	Hopkins Agricultural Chemical Co 303 SW Arch St. Atlanta, IL 61723

Dragonmate Broadleaf Herbicide**	264-339	264-MO-001	Rhone-Poulenc PO Box 367 317 West Florence Rd St. Joseph, MO 64502

* Conditionally registered products.

** Registrant has requested voluntary cancellation of these registered products and they are cancelled by the cancellation order published in the FEDERAL REGISTER (54 FR 24948).

Name of applicant	Location	Project description	Reviewing agency	Final action	Date of final action
Long Island Lighting Co. [1]	West Babylon, NY	Construction of a 220 MW gas turbine generation facility.	NYSDEC	PSD permit approval.	7/18/88
Nassau District Energy Corp.	Uniondale, NY	Contruction of a 57 MW cogeneration facility	NYSDEC	do	10/07/88
Kamine Carthage Cogeneration Co., Inc.	Carthage, NY	Construction of a 50 MW gas turbine/steam generator.	NYSDEC	do	10/19/88
Morrill Press Co	Fulton, NY	Construction of an 11 station rotogravure press and modification of an 8 station rotogravure press.	NYSDEC	do	12/05/88
Kamine South Glens Falls Cogeneration Co., Inc.	South Glens Falls, NY.	Construction of a 50 NW gas turbine/steam generator.	NYSDEC	do	12/05/88
Indeck-Yerkes Energy Services, Inc.	Tonawanda, NY	Construction of a 53 MW gas turbine/steam generator.	NYSDEC	do	1/09/89
Boise Cascade Corp	Beaver Falls, NY	Replacement of an existing oil-fired boiler with a new oil-fired boiler.	NYSDEC	PSD non-applicability determination.	1/11/89
Hoffmann La Roche Inc	Belvidere, NJ	Revision of the nitrogen oxide emission limit previously permitted for a 23.3 MW cogeneration system.	EPA region II	PSD permit revision	1/17/89
Hercules Inc	Parlin, NJ	Revision of the particulate matter emission limit previously permitted for three coal-fired boilers.	EPA region II	do	1/17/89
Long Island Lighting Co	Shoreham, NY	Construction of a 220 MW gas turbine generation facility.	NYSDEC	PSD permit approval.	1/23/89
Life Savers, Inc	Las Piedras, PR	Construction of a new steam boiler and a new generator and conversion of an existing generator and boiler to standby operation.	EPA region II	PSD non-applicability determination.	3/01/89
Abbott Laboratories	Barceloneta, PR	Revision of the PM emission limit previously permitted for a 20.2 MW cogeneration facility.	EPA region II	PSD permit revision	3/06/89
Megan-Racine Associates, Inc.	Carlton, NY	Construction of a 49 MW gas turbine/steam generator.	NYSDEC	PSD permit approval.	3/06/89
United Development Group-Niagara, Inc.	Niagara Falls, NY	Construction of a coal fired cogeneration system	NYSDEC	do	3/10/89
Town of North Hempstead Solid Waste Management Authority.	Port Washington, NY.	Construction of a 990 tons per day municipal waste resources recovery facility.	NYSDEC	PSD applicability determination.	3/15/89
L&J Energy Systems, Inc	Lowville, NY	Construction of a 49 MW gas turbine/steam generator.	NYSDEC	PSD permit approval.	3/20/89
Pennsauken Solid Waste Management Authority [2].	Pennsauken, NJ	Construction of two 250 tons per day municipal solid waste incinerators.	NJDEP	do	4/20/89

[1] On May 18, 1988, the Long Island Lighting Company (LILCO) was issued a PSD permit by the New York State Department of Environmental Conservation for a 220 Megawatt (MW) gas turbine cogeneration facility for its West Babylon plant. The permit was not considered effective and therefore was not included in EPA Region II's November 25, 1988 FEDERAL REGISTER notice on final PSD actions because adverse comments were received during the public comment period. However, all issues were resolved during an "issues conference" held by NYSDEC. Furthermore, the comments did not result in any change in the May 18, 1988 permit. Therefore LILCO's PSD permit for the West Babylon plant is considered effective as of July 18, 1988.

[2] The Pennsauken Solid Waste Management Authority (PSWMA) was issued a PSD permit on February 10, 1989 by the New Jersey Department of environmental Protection. This permit would have become effective on March 13, 1989 if no petition for administrative review was filed with the EPA Administrator in Washington, DC. However, a petition for review was filed by the Township of Cinnaminson, the Borough of Palmyra, and the Borough of Riverton on March 7, 1989. On April 20, 1989, the EPA Administrator decided, after careful review of the appeal, not to grant further review of the petition. Therefore, the PSWMS PSD permit is effective as of April 20, 1989.

This notice lists only the sources that have received final PSD determinations. Anyone who wishes to review these determinations and related materials should contact the following offices:

EPA Actions

United States Environmental Protection Agency, Region II Office, Permits Administration Branch—Room 505, 26 Federal Plaza, New York, New York 10278.

NYSDEC Actions

New York State Department of Environmental Conservation, Division of Air Resources, Source Review and Regional Support Section, 50 Wolf Road, Albany, New York 12233-0001.

NJDEP Actions

New Jersey Department of Environmental Protection, Division of Environmental Quality, Bureau of Engineering & Technology, 401 East State Street, Trenton, New Jersey 08625.

Available pursuant to the Consolidated Permit Regulations (40 CFR Part 124), judicial review of these determinations under section 307(b)(1) of the Clean Air Act (the Act) may be sought only by the filing of a petition for review in the United States Court of Appeals for the appropriate circuit within 60 days from the date on which these determinations are published in the **Federal Register**. Under section 307(b)(2) of the Act, these determinations shall not be subject to later judicial review in civil or criminal proceedings for enforcement.

Dated: June 1, 1989.

William J. Muszynski,

Acting Regional Administrator.

[FR Doc. 89-13849 Filed 6-9-89; 8:45 am]

BILLING CODE 6560-50-M

[OPP-66138; FRL-3600-4]

Order Canceling Registration for Pesticide Products Containing Bromoxynil Butyrate

AGENCY: Environmental Protection Agency (EPA).

ACTION: Cancellation notice and order.

SUMMARY: This notice announces EPA's decision to cancel all registrations issued under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for pesticide products containing the butyric acid ester of bromoxynil (3,5-dibromo-4-hydroxybenzonitrile). The registrant Rhone-Poulenc AG Company has requested voluntary cancellation of these products. Because of the developmental risks associated with exposure to these products, EPA will not permit and the cancellation order will explicitly prohibit the sale, distribution, and use of existing stocks of affected products.

DATE: The cancellation order incorporated in this notice will become effective June 13, 1989.

FOR FURTHER INFORMATION CONTACT:

Jude Andreasen, Special Review/ Reregistration Division (H7508C), Office of Pesticide Programs, Environmental Protection Agency, 401 M Street SW., Washington, DC 20460

Office location and telephone number: Rm. 1006F, CM #2, 1921 Jefferson Davis Highway, Arlington, VA, (703) 557-1170.

SUPPLEMENTARY INFORMATION:

I. Request for Voluntary Cancellation

On May 1, 1989, as a result of discussion between EPA and Rhone-Poulenc AG Company concerning measures to minimize potential risk of developmental toxicity associated with exposure to bromoxynil, Rhone-Poulenc requested voluntary cancellation of its registered pesticide products containing bromoxynil butyrate (the butyric acid ester of 3,5-dibromo-4-hydroxybenzonitrile). Rhone-Poulenc stated in its request that it would institute a plan to recover remaining stocks of these products from distributors, dealers, and users. Under this plan, Rhone-Poulenc will replace these products with an equal quantity of a corresponding product containing bromoxynil octanoate, and will pay shipping and handling costs. Distributors and dealers holding stocks of affected products should contact Rhone-Poulenc customer service. Users holding stocks of affected products should return them to the dealer.

Rhone-Poulenc had previously requested voluntary cancellation of a number of registered bromoxynil products, including some but not all of its products containing bromoxynil butyrate, on October 27, 1988. EPA canceled certain bromoxynil products pursuant to this request, but was unwilling to accept the remaining requests for voluntary cancellation because those requests were made contingent on the Agency's permission to sell and use existing stocks of affected products. Given the unresolved concerns regarding the developmental toxicity of bromoxynil, EPA considered it inappropriate to issue an existing stocks order for such products.

II. Existing Stocks

In its May 1, 1989 letter, Rhone-Poulenc did not request that EPA permit the sale, distribution, or use of existing stocks of canceled products containing bromoxynil butyrate. EPA has determined that continued use of products containing bromoxynil butyrate would present an unacceptable risk of developmental toxicity in persons handling such products. Accordingly, EPA will not permit the continued sale, distribution, or use of any canceled product containing bromoxynil butyrate. EPA encourages all persons holding stocks of canceled products containing bromoxynil butyrate to participate in the recovery program established by Rhone-Poulenc.

III. Cancellation Order

Effective June 13, 1989, the registrations for all pesticide products containing the butyric acid ester of bromoxynil (3,5-dibromo-4-hydroxybenzonitrile) are canceled pursuant to section 6(f)(1) of FIFRA, 7 U.S.C. 136d(f)(1). Effective June 13, 1989, it shall be unlawful under FIFRA section 12(a)(1)(A) and/or FIFRA section 12(a)(2)(K), 7 U.S.C. 136j(a)(1)(A), 136j(a)(2)(K), for any person to distribute or sell, or to use for any pesticidal purpose, any of the following canceled products containing the butyric acid ester of bromoxynil:

EPA registration No.	Previous registration No.	Product
264-339		Dragonmate.
264-340		ME 4 Brominal.
264-340		Torch Twin Pak.
264-340		3+3 Brominal
264-394		Bromoynil Butyrate Technical
264.421		Centrol
264.474	359-716	Buctril 4 EC.

This Order does not prohibit any shipments of canceled products containing the butyric acid ester of bromoxynil which are associated with the program to recover stocks of such products established by Rhone-Poulenc AG Company, or which are otherwise necessary to facilitate proper storage or disposal of such products.

Dated: June 5, 1989.

Douglas D. Campt,

Director, Office of Pesticide Programs.

[FR Doc. 89-13648 Filed 6-9-89; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL MARITIME COMMISSION

Agreement(s) Filed

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, DC Office of the Federal Maritime Commission, 1100 L Street, NW., Room 10325. Interested p may submit comments on each agreement to the Secretary, Fed Maritime Commission, Washing 20573, within 10 days after the d the Federal Register in which th appears. The requirements for comments are found in § 5 46 of the Code of Federal R Interested persons should consu section before communicating w Commission regarding a pendin agreement.

Agreement No.: 202-010676-0

Title: South Europe-U.S.A. Fre Conference ("Conference").

Parties:

Achille Lauro
Compania Trasatlantica Espan S.A.
Costa Container Line (a Divisio Contship Containerlines Limi
d'Amico Societa di Navigazione S.p.A.
Evergreen Marine Corporation (Taiwan) Ltd.
Farrell Lines, Inc.
"Italia" di Navigazione S.p.A.
Jogolinija
Jugooceanija
Lykes Lines (Lykes Bros. Steams Co., Ltd.)
A.P. Moller-Maersk Line
Nedlloyd Lines (Nedlloyd Lijnen
Sea-Land Service, Inc.
P & O Containers (TFL) Ltd.
Zim Israel Navigation Company.

Synopsis: The proposed modifica would permit any member to disassociate itself from any Confer action on a rate or service item tha would result in a reduction in the o cost per cargo unit to the shipper by giving written notice to the other members prior to the time the rate c service item has been filed with the FMC and become effective.

Agreement No.: 217-010738-003.

Title: Barber Blue Sea/Open Bulk Carriers Chartering Agreement.

Parties:

Wilhelmsen Lines A/S
Open Bulk Carriers Limited

Synopsis: The proposed modificat would authorize the parties to discu and agree upon rates, charges and o competitive matters regarding intermodal movements. It would also permit the parties to agree upon saili schedules, service frequency, and po to be served by each party. It would further make other non-substantive administrative changes.

Agreement No.: 232-011184-002.

Title: Evergreen Marine Corporati (Taiwan) Ltd. Italia di Navigazione S

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

MAY - 5 1989

OFFICE OF
PESTICIDES AND TOXIC SUBST.

Mr. Nick Somma
Rhone-Poulenc Ag. Company
P.O. Box 12014
2 T.W. Alexander Drive
Research Triangle Park, NC 27709

Dear Mr. Somma:

Subject: Application for Conditional Amendment - Revised Labeling/Restricted Use Classification/Data Requirements/Additional Conditions.
Buctril Herbicide
EPA Registration No. 264-437
Bronate Herbicide
EPA Registration No. 264-438
Buctril + Atrazine Herbicide
EPA Registration No. 264-477
Your Submission Dated May 1, 1989

Your application dated May 1, 1989 to conditionally amend the subject pesticide registrations to incorporate revised labeling, a new classification for restricted use, additional claims, and specific conditions for continued registration is granted, effective immediately. Continued registration of these pesticides will be contingent on satisfaction of each of the conditions set forth in the approved amendment. Please submit for each of the subject registrations five (5) copies of the final printed stickers incorporating this amendment. A stamped copy of the approved text for these stickers is enclosed for your records.

Sincerely yours,

Frank Sanders for

Robert J. Taylor
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (H7505C)

DATE: MAY 1, 1992 TIME: 11:00 AM TOTAL NO. OF PAGES (INCLUDING COVER PAGE) 35

TO: EDWIN TINSWORTH LOCATION: EPA - ARLINGTON

FAX NO: 703-557-3106 SENDER: NICK SOMMA

PLEASE ADVISE BY FACSIMILE OR PHONE IF MESSAGE IS NOT LEGIBLE OR ALL PAGES ARE NOT RECEIVED.

FACSIMILE NO. IS: 919-549-9639

DIRECT LINE TO TELECOMMUNICATIONS OPERATOR IS: 919-549-2495

MESSAGE

TO: Edwin Tinsworth
EPA

Attached is the Application for Amended Registration of bromoxynil products. It should contain all the revisions discussed. A copy is also being sent overnight mail. If there are any questions, please let me know.

Sincerely,

Nick Somma

'513A

RHÔNE-POULENC

RHÔNE-POULENC AG COMPANY

May 1, 1989

Robert Taylor
Environmental Protection Agency
Office of Pesticide Programs
Crystal Mall, Building 2
Arlington, Virginia 22202

Dear Mr. Taylor:

SUBJECT: Buctril (264-437), Bronate (264-438)
Buctril + Atrazine (264-477)

Rhône-Poulenc Ag Company hereby applies to conditionally amend pursuant to FIFRA §3 (c) (7) (a) the pesticide product referenced above to incorporate the revised labeling, new classification for restricted use, additional claims, and specific conditions for continued registration set forth below. Rhône Poulenc hereby claims in connection with this application for amended registration that it will conform to the following conditions as part of its distribution and sale of these products.

The text for stickers which incorporates new language adding a classification for restricted use, a new label warning concerning developmental toxicity, and specific use directions requiring additional protective clothing and equipment and new use practices is appended to this Application as Attachment A. Rhone Poulenc agrees as a condition of registration that it will attach the stickers appended to this Application as Attachment A to all containers of these products that are released for shipment by Rhone-Poulenc after the date of approval of this amendment by EPA. Rhône Poulenc further agrees as a condition of registration that it will

PO BOX 12014 2 TW ALEXANDER DRIVE
RESEARCH TRIANGLE PARK, NC 27709
(919) 549 2000
INTERNATIONAL TELEX NUMBER 4990378 ANSWERBACK APC RTP
INTERNATIONAL DISTRIBUTION SERVICES TELEX NUMBER 4990377-ANSWERBACK APC IDS

CONDITIONAL REGISTRATION

I. Revised Labeling
- A. What
  - 1. Classification
  - 2. Warning Label
  - 3. New use pracices
- B. How
  - 1. Stickers
    - a. All stocks leaving RP after 5/5/89
    - b. All stocks leaving distributors after 5/15/89
      - (1) instructions
      - (2) enough for all inventory by 5/25/89
  - 2. New permanent labels
    - a. Plan by 5/22/89
    - b. On products by 10/1/89
    - c. states:
      - (1) deletes claims for turf and non-crop uses
      - (2) all restickering provisions
      - (3) equipment needs

II. User Training
- A. Training of users
  - 1. prior to 1990 spring use
  - 2. pending EPA approval
- B. Hard-coupling transfer systems
  - 1. program to assist users not owning such system
  - 2. plan by 10/1/89

III. Repackaging
- A. Hard-coupling for all bulk (>30 gal) by 10/1/89
- B. Feasibility study for small containers by 1/1/90

IV. Safety assessment data
- A. Rabbit dermal Tox--5/1/90
- B. Male repro--6/1/90
- C. Worker exposure--12/31/90

provide to each distributor holding inventory of these products quantities of these stickers sufficient for such inventory within ten days after the date of approval of this amendment by EPA, and that Rhône Poulenc will assume responsibility for insuring that each distributor attaches the sticker to each container of these products which are sold or distributed by the distributor after the date the stickers are received. Rhône Poulenc further agrees as a condition of registration that it will provide to each reseller and retailer holding inventory of these products quantities of this sticker sufficient for such inventory within twenty days after the date of approval of this amendment by EPA, and that Rhône Poulenc will assume responsibility for insuring that each such reseller or retailer attaches the sticker to each container which is sold or distributed by the reseller or retailer after the date the stickers are received. Rhône Poulenc further agrees as a condition of registration that it will provide to each distributor, reseller, and retailer along with such stickers the information package and the instructions concerning the manner in which the sticker must be affixed to each container of these products which are appended to this application as Attachment B. Rhône Poulenc further agrees as a condition of registration that it will implement the communication plan appended to this application as Attachment C in the manner and by the dates described therein.

Rhone-Poulenc further agrees as a condition of registration that it will submit by May 22, 1989 a complete copy of revised labeling for subject products which (1) deletes all claims, references, and use directions pertaining to the previously permissible uses for turf and n0n-crop areas, (2) includes all the new label provisions included in the sticker which is appended to this application as Attachment A, and (3) incorporates the additional revised labeling concerning the equipment which must be used for mixing and loading as set forth in Attachment D. Rhone-Poulenc agrees as a condition of registration that, after review and approval by EPA of the complete revised labeling to be submitted by May 22, 1989, such revised labeling will be attached to each container of these products which are released for shipment by Rhone-Poulenc after October 1, 1989.

Rhône Poulenc further agrees as a condition of registration that it will develop and submit to EPA by October 1, 1989 a proposed

PO BOX 12014, 2 TW Alexander Drive
RESEARCH TRIANGLE PARK, NC 27709
(919) 549-2000
INTERNATIONAL TELEX NUMBER 4990378 ANSWERBACK RPC RTP
INTERNATIONAL DISTRIBUTION SERVICES TELEX NUMBER 4999077 ANSWERBACK RPC IDS

program to provide additional training to users of bromoxynil products prior to the 1990 spring use season, and will upon approval by EPA implement such a training program. Rhone-Poulenc further agrees as a condition of registration that it will by October 1, 1989 establish a program to provide assistance to users who do not own a mechanical transfer system which terminates in a drip-free hard coupling (the type required for 30 gallon drums in the labeling which must appear on containers after October 1, 1989) and who wish either to obtain such a system or to modify their present system. Rhone-Poulenc further agrees as a condition of registration that it will thoroughly investigate the feasibility of packaging these products in containers which are smaller than 30 gallons and which include a hard coupling designed for use with a specific closed mixing and loading system, and will provide to EPA a detailed report of its findings and conclusions no later than January 1, 1990. For products sold in bulk containers: Rhone-Poulenc hereby applies to amend its registration for these products to provide, and agrees as a condition of registration, that all bulk containers of these products which are released for shipment by Rhone-Poulenc after October 1, 1989 will include a mechanical transfer mechanism which terminates in a drip-free hard coupling which may be used only with a spray or mix tank which has been fitted with a compatible coupling.

For each of the specific data requirements described below, Rhône Poulenc agrees as a condition of registration that it will develop and submit the specified data according to the specified schedule. Rhône Poulenc agrees that failure to submit the required data, or to adhere to any element of the specified schedule for development and submission of the data, will constitute grounds for cancellation of this registration under FIFRA § 6(e), unless Rhône Poulenc demonstrates that it has undertaken in good faith and in a timely manner all steps necessary to develop and submit the data according to the specified schedule and that its failure to submit the data or to adhere to the schedule was due to factors that could not reasonably have been within its control.

Rabbit Dermal Teratology Study

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(919) 549-2000
INTERNATIONAL TELEX NUMBER 4999378 - ANSWERBACK RPC RTP
INTERNATIONAL DISTRIBUTION SERVICES TELEX NUMBER 4999377 - ANSWERBACK RPC IDS

RHÔNE-POULENC AG COMPANY

Pilot:

Submit Protocol--May 8, 1989
EPA Approval of Protocol by--May 23, 1989
Study Initiation--May 31, 1989
Study Completed--September 1, 1989
Final Report--October 16, 1989

Full:

Submit Protocol--June 1, 1989 (without dose selection)
EPA Approval of Protocol by--July 15, 1989
Discussion of Dose Selection--October 2, 1989
EPA Approval of Dose Selection by--October 23, 1989
Study Initiation--November 1, 1989
Study Completed--March 1, 1990
Final Report--May 1, 1990

Male Reproduction Effects Study

Pilot:

Submit Protocol--June 15, 1989
EPA Approval of Protocol by--July 3, 1989
Study Initiation--July 14, 1989
Study Completed--September 1, 1989
Final Report--October 2, 1989

Full:

Submit Protocol--July 3, 1989 (without dose selection)
EPA Approval of Protocol by--August 4, 1989
Discussion of Dose Selection--October 2, 1989
EPA Approval of Dose Selection--October 14, 1989
Study Initiation--November 1, 1989
In-Life Completed--February 1, 1990
Final report--June 1, 1990

Worker Exposure Study

Submit Protocol--June 15, 1989

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RESEARCH TRIANGLE PARK NC 27709
(919) 549 2000
INTERNATIONAL TELEX NUMBER 4990378 ANSWERBACK ARC RTP
INTERNATIONAL DISTRIBUTION SERVICES TELEX NUMBER 4990377--ANSWERBACK ARC IDS

(Protocol is to be based on scope of study as presented in Attachment E)
EPA Approval of Protocol--August 18, 1989
Draft Report (Non- QA'd)--November 15, 1990
Final Report--December 31, 1990

The schedules given above are based on Rhone-Poulenc's expectation that EPA will respond to the protocols and dose selection in a timely manner. If EPA does not provide a full response to a proposed protocol or proposed dose selection by the date specified for EPA approval, the agreed schedule may be adjusted to permit an equal delay in completion of subsequent steps. However, if EPA responds in a timely manner but is unable to approve a proposed protocol or proposed dose selection by the specified date due to substantive concerns regarding the content of the proposal, Rhone-Poulenc agrees that it will adhere to the established schedule unless EPA approves an extension.

Rhone-Poulenc will submit one-line status reports on each of the required studies on at least a quarterly basis. The proposed protocol for the Worker Exposure Study will also describe and require submission of appropriate interim reports. In addition to submission of these reports, Rhone-Poulenc will immediately notify EPA if any problems arise which might prevent the timely completion or submission of any of the required studies.

Rhône Poulenc acknowledges that this application for conditional amendment is based on the Agency's assessment of the data concerning the risks and benefits of bromoxynil use available to EPA as of the date of this application. Rhône Poulenc declares that it is Rhône Poulenc's present intention not to request additional amendments of this registration during the time required to develop and submit the data described above. Rhône Poulenc specifically agrees that EPA may deny without hearing any additional application to amend this registration which Rhône Poulenc may submit during the time required to develop and submit the data required above, if: (1) EPA determines that Rhone-Poulenc has not submitted substantial new evidence which materially changes the Agency's

PO BOX 12014 2 TW ALEXANDER DRIVE
RESEARCH TRIANGLE PARK NC 27709
(919) 549-2000
INTERNATIONAL TELEX NUMBER 4990378 ANSWERBACK APC RTP
INTERNATIONAL DISTRIBUTION SERVICES TELEX NUMBER 4990377 ANSWERBACK APC IDS

assessment of the risks and benefits of use of bromoxynil and which was not available to either EPA or Rhone-Poulenc at the time this application was submitted and (2) EPA provides a written explanation of the basis for its determination.

Sincerely,

Nick Somma
Registration Manager

COPY: Mr. Edwin Tinsworth

PO BOX 12014 2 TW ALEXANDER DRIVE
RESEARCH TRIANGLE PARK, NC 27709
(919) 549-2000
INTERNATIONAL TELEX NUMBER 4998378 ANSWERBACK RPC RTP
INTERNATIONAL DISTRIBUTION SERVICES TELEX NUMBER 4998377 ANSWERBACK RPC IDS

United States Environmental Protection Agency
Office of Pesticide Programs (TS 767)
Washington, DC 20460

EPA Application for Pesticide: ☐ Registration ☒ Amendment

OPP Identifier Number: 102852

Section I

1. Company/Product Number	2. Date	3. Product Manager	4. Proposed Classification
264-477	May 1, 1989	Robert Taylor	☐ General ☒ Restricted

5. Name and Address of Applicant (Include ZIP Code)

Rhone-Poulenc Ag Company
P. O. Box 12014, 2 T. W. Alexander Drive
Research Triangle Park, NC 27709

☐ Check if this is a new address

6. Product Name: Buctril + Atrazine Herbicide

Section II - Amendment Information

1. Subject
☐ Resubmission in response to Agency letter ☐ Final printed label in response to Agency letter ☒ Other (explain below)

Date of Letter: May 1, 1989

Label modification to include Restricted Use Classification and additional label restrictions.

Section III

1. Material This Product Will Be Packaged In

Child-Resistant Packaging	Unit Packaging	Water-Soluble Packaging	2. Type of Container
☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)
	If "Yes," Unit package wgt / No. per container	If "Yes," Package weight / No. per container	

3. Location of Net Contents Information: ☐ Label ☐ Container

4. Size(s) of Retail Container

5. Location of Label Directions
☐ On Label
☐ On material accompanying product

6. Manner in Which Label is Affixed To Product
☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other (Specify)

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted if necessary to process this application).

Name: Nick Somma

Title	Telephone No. (Include Area Code)	6. Date Application Received (Stamped)
Registration Manager	919-549-2372	

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	
Nick Somma	Registration Manager	
4. Typed Name: Nick Somma	5. Date Signed: May 1, 1989	

EPA Form 8570-1 (Rev. 4-88) Previous editions are obsolete.

RHONE-POULENC AG COMPANY

BROMOXYNIL SPECIAL LABELING COMMUNICATION PLAN 09:20:38A May 1, 1989

COMMUNICATION MEDIA	INFORMATION DISSEMINATED	TARGET AUDIENCE	ESTIMATED NO. INDIVIDUALS	DELIVERY TIME FRAME
FAX	RESTRICTIONS/ USE DIRECTIONS	DISTRIBUTORS/ RPAC SALES/FD	160 169	DAY 2
DIRECT MAIL	RESTRICTIONS/ USE DIRECTIONS | v	DISTRIBUTORS RESELLER/CUST APPLTR UNIVERSITY EXTENSION GROWERS (RESELLER MAIL)	50 6,000 4,000 5,000	DAY 5 | v WEEK 3
PERSONAL CONTACTS	RESTRICTIONS/ USE DIRECTIONS | v	UNIVERSITY EXTENSION - WEED SCIENTISTS RESELLERS CONSULTANTS/FARM MGRS	 100 3,000 100	WEEK 1 WEEK 1 - 1,500 WEEK 2 - 1,500 WEEK 2
STICKER PERSONAL DELIVERY	PACKAGE STICKERS	DISTRIBUTORS RESELLERS	160 2,000	WEEK 1-2 WEEK 2-3
DATA-LINE	RESTRICTIONS/ USE DIRECTIONS	GROWERS	35,000	WEEK 3
RADIO	RESTRICTIONS (SEE DEALER FOR FURTHER INFORMATION)	GROWERS	143,000	WEEK 3
POINT OF PURCHASE	RESTRICTIONS/ USE DIRECTIONS	GROWERS(VIA RESELLERS PLACE OF BUSINESS)	40,000	WEEK 2-3
TOTAL NUMBER CONTACTS:			238,739	

FILE: [illegible]

United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

EPA Application for Pesticide: [ ] Registration [X] Amendment

OPP Identifier Number: 10285

Section I

1. Company/Product Number	2. Date	3. Product Manager	4. Proposed Classification
264-438	May 1, 1989	Robert Taylor	[ ] General [X] Restricted

5. Name and Address of Applicant (Include ZIP Code)

Rhone-Poulenc Ag Company
P. O. Box 12014, 2 T. W. Alexander Drive
Research Triangle Park, NC 27709

[ ] Check if this is a new address

6. Product Name: Bronate Herbicide

Section II - Amendment Information

1. Subject

[ ] Resubmission in response to Agency letter [ ] Final printed label in response to Agency letter [X] Other (explain below)

Date of Letter: May 1, 1989

Label modification to include Restricted Use Classification and additional label restrictions.

Section III

1. Material This Product Will Be Packaged In

Child-Resistant Packaging	Unit Packaging	Water-Soluble Packaging	2. Type of Container
[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify)
	If "Yes," Unit package wgt / No. per container	If "Yes," Package weight / No. per container	

3. Location of Net Contents Information: [ ] Label [ ] Container

4. Size(s) of Retail Container

5. Location of Label Directions: [ ] On Label [ ] On material accompanying product

6. Manner in Which Label is Affixed To Product: [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other (Specify)

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)

Name: Nick Somma

Title	Telephone No. (Include Area Code)	6. Date Application Received (Stamped)
Registration Manager	919-549-2372	

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

7. Signature	8. Title	
Nick Somma	Registration Manager	
9. Typed Name: Nick Somma	10. Date Signed: May 1, 1989	

EPA Form 8570-1 (Rev. 4-88) Previous editions are obsolete

... before completing form   Form Approved OMB No 2070-00...

United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

EPA

Application for Pesticide: [ ] Registration [X] Amendment

OPP Identifier Number: 102850

Section I

1. Company/Product Number	2. Date	3. Product Manager	4. Proposed Classification
264-437	May 1, 1989	Robert Taylor	[ ] General [X] Restricted

5. Name and Address of Applicant (Include ZIP Code)

Rhone-Poulenc Ag Company
P. O. Box 12014, 2 T. W. Alexander Drive
Research Triangle Park, NC 27709

[ ] Check if this is a new address

6. Product Name: Buctril Herbicide

Section II - Amendment Information

1. Subject

[ ] Resubmission in response to Agency letter
[ ] Final printed label in response to Agency letter
[X] Other (explain below)

Date of Letter: May 1, 1989

Label modification to include Restricted Use Classification and additional label restrictions.

Section III

1. Material This Product Will Be Packaged In

Child-Resistant Packaging: [ ] Yes [ ] No

Unit Packaging: [ ] Yes [ ] No
If "Yes," Unit package wgt / No. per container

Water-Soluble Packaging: [ ] Yes [ ] No
If "Yes," Package weight / No. per container

2. Type of Container: [ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify)

3. Location of Net Contents Information: [ ] Label [ ] Container

4. Size(s) of Retail Container

5. Location of Label Directions: [ ] On Label [ ] On material accompanying product

6. Manner in Which Label is Affixed To Product: [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other (Specify)

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application).

Name: Nick Somma

Title: Registration Manager

Telephone No. (Include Area Code): 919-549-2372

6. Date Application Received (Stamped)

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature: [signature]

3. Title: Registration Manager

4. Typed Name: Nick Somma

5. Date Signed: May 1, 1989

EPA Form 8570-1 (Rev. 4-86) Previous editions are obsolete.

ATTACHMENT A

THIS PRODUCT IS NOT REGISTERED FOR USE ON TURF AND IN/ON/OR AREAS. APPLICATION TO TURF SITES IS PROHIBITED

RESTRICTED USE PESTICIDE

For retail sale to and use only by Certified Applicators or persons directly under their supervision and only for those uses covered by the Certified Applicator's certification. See precautionary statements for reasons this product is classified Restricted Use.

BUCTRIL® HERBICIDE

FOR THE CONTROL OF CERTAIN BROADLEAF WEEDS IN SMALL GRAINS, SEEDLING ALFALFA, CORN, SORGHUM, FLAX, GARLIC, ONION, ANNUAL CANARYGRASS AND MINT.

ACTIVE INGREDIENT:	
Octanoic acid ester of bromoxynil* (3,5-dibromo-4-hydroxybenzonitrile)	33.4%
INERT INGREDIENTS	66.6%

*Bromoxynil octanoate equivalent to 22.9% of bromoxynil or not less than 2.0 pounds of bromoxynil per gallon.

KEEP OUT OF REACH OF CHILDREN

AVISO WARNING

PRECAUTION AL USUARIO: Si usted no lee ingles, no use este producto hasta que le etiquete haya sido explicado ampliamente

E.P.A. Reg. No. 264-437

For PRODUCT USE Information Call 1-800-334-9745.

For EMERGENCY Information ONLY Call 24 Hours A Day 1-800-334-7577.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING - RESTRICTED USE

Use of this product may be hazardous to your health. Exposure to this product has been shown to cause birth defects in laboratory animals. Women of childbearing age should be particularly careful when handling this product to avoid ingestion and skin contact.

Harmful if swallowed or absorbed through skin or inhaled. Avoid contact with skin, eyes or clothing. Avoid breathing spray mist.

Users of this product are encouraged to participate in Rhone-Poulenc's educational program dealing with potential hazards and safer use of this product. Further information on this program can be obtained by contacting Rhone-Poulenc Ag Company at 1-800-334-9745.

ALL PERSONS HANDLING THE CONCENTRATE MUST OBSERVE THE FOLLOWING REQUIREMENTS.

Wear clean cotton (or cloth) coveralls that cover all parts of the body except the head, hands, and feet. The coveralls must be worn over a long sleeve shirt and long pants. Wear clean nitrile gloves, a chemical resistant apron, goggles or face shield, and chemical resistant shoes, shoe coverings, or boots. If you use a mechanical transfer system for all mixing and loading operations, use of a chemical resistant apron is optional.

If this product is packaged in a 30 gallon drum or if you handle a total of 30 gallons or more of this product per day, you must: use a mechanical transfer system for all mixing and loading operations. When using a mechanical transfer system, do not remove or disconnect the pump or probe from the container until the container has been emptied and rinsed. The pump or probe system must be used to rinse the empty container and to transfer the rinsate directly to the mixing or spray tank.

ALL PERSONS APPLYING THIS PRODUCT, OR REPAIRING OR CLEANING EQUIPMENT USED WITH THIS PRODUCT, MUST OBSERVE THE FOLLOWING REQUIREMENTS

When applying this product from a tractor (unless the tractor has a completely enclosed cab), or when repairing or cleaning equipment used with the product, you must: wear clean nitrile gloves and clean cotton (or cloth) coveralls that cover all parts of the body except the heads, hands, and feet. Coveralls must be worn over a long sleeve shirt and long pants.

All applicators (except for pilots) and all persons repairing or cleaning equipment used with this product must wear chemical resistant: shoes, shoe coverings, or boots.

Application from a tractor with a completely enclosed cab or aerial application is required whenever this product is applied to 100 or more acres in a day. To avoid contamination, coveralls and gloves worn when handling the concentrate must be removed prior to entering an enclosed cab or cockpit. When applying from a tractor with an enclosed cab, clean coveralls and clean nitrile gloves must be kept inside the cab, and must be worn when exiting the cab to perform in-field maintenance or repair.

To reduce exposure to residues, wash the spray rig, tractor, and all other equipment used to handle or apply this product with water daily or before using the equipment for any other purpose.

APPLICATION BY CHEMIGATION must be done by fixed pipe, overhead sprinkler systems or hand moved pipe. If hand moved pipe is used for chemigation, the pipe must not be handled in any way until 24 hours after chemigation has been completed and residues have been flushed from the system. When applying by chemigation, no person may enter the application site unless in an enclosed vehicle.

DURING AERIAL APPLICATION, human flaggers are prohibited unless in enclosed vehicles. Aerial application is prohibited within 300 feet of residential areas (e.g., homes, schools, hospitals, shopping areas, etc.).

GENERAL REQUIREMENTS FOR ALL USE

IMPORTANT! Before removing gloves or starting a new work operation, rinse the outside of the gloves thoroughly with water. Always remove gloves and wash your hands and face with soap and water before smoking, eating, drinking, or toileting.

AFTER WORK, Gloves must be discarded at the end of each day. Take off all clothes and shoes. Shower with soap and water. Do not wear or reuse contaminated clothing. Wash protective equipment with water after each use. Protective clothing worn during use must be laundered separately from other household articles.

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: Get medical attention. Do not induce vomiting, contains petroleum distillates. Do not give anything by mouth to an unconscious person.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF IN EYES: Flush with water for 15 minutes. Get medical attention.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to wildlife and fish. Use with care when applying to areas frequented by wildlife or adjacent to any body of water. Do not apply directly to water. Do not apply when weather conditions favor drift from target areas. Do not contaminate water by cleaning of equipment or disposal of wastes.

PHYSICAL AND CHEMICAL HAZARDS

Do not use or store near heat or open flame.

DIRECTIONS FOR USE -See attached booklet

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

STORAGE AND DISPOSAL

STORAGE

Do not contaminate water, food, or feed by storage or disposal.

Do not store near fertilizers or seeds. Store at temperatures above 3° F. If allowed to freeze, remix before using.

PESTICIDE DISPOSAL

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Refer to first number of lot number for packaging location:
1-EPA Est. No. 264-OR-1
2-EPA Est. No. 264-MO-1

Rhône-Poulenc Ag Company
P.O. Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, North Carolina 27709

Made in U.S.A.

ATTENTION: [illegible] THE USE DIRECTIONS AND [illegible] ON THIS STICKER [illegible] ANY INCONSISTENT LANGUAGE OR DIRECTIONS WHICH APPEAR ELSEWHERE ON THE LABEL [illegible] FOR THIS PRODUCT

RESTRICTED USE PESTICIDE

For retail sale to and use only by Certified Applicators or persons directly under their supervision and only for those uses covered by the Certified Applicator's certification. See precautionary statements for reasons this product is classified Restricted Use.

BUCTRIL® + Atrazine Herbicide

POSTEMERGENT HERBICIDE FOR CONTROL OF CERTAIN BROADLEAF WEEDS IN CORN AND SORGHUM.

ACTIVE INGREDIENT

Octanoic acid ester of bromoxynil* (3,5-dibromo-4-hydroxybenzonitrile)	15.74%
Atrazine** (2-chloro-4-ethylamino-6-isopropylamino-S-triazine)	21.62%
INERT INGREDIENTS	62.64%

*Product contains bromoxynil octanoate equivalent to 10.81% of bromoxynil or 1.0 pound of bromoxynil per gallon.

**Product contains 2.0 pounds of atrazine per gallon

KEEP OUT OF REACH OF CHILDREN

CAUTION

SHAKE WELL BEFORE USING

EPA Reg. No. 264-477 | EPA Est. No. 264-MO-02

For PRODUCT USE Information Call 1-800-334-9745

For EMERGENCY Information ONLY Call 24 Hours A Day 1-800-334-7577

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING - RESTRICTED USE

Use of this product may be hazardous to your health. Exposure to this product has been shown to cause birth defects in laboratory animals. Women of childbearing age should be particularly careful when handling this product to avoid ingestion and skin contact.

Harmful if swallowed or absorbed through skin or inhaled. Avoid contact with skin, eyes or clothing. Avoid breathing spray mist.

Users of this product are encouraged to participate in Rhone-Poulenc's educational program dealing with potential hazards and safer use of this product. Further information on this program can be obtained by contacting Rhone-Poulenc Ag Company at 1-800-334-9745.

ALL PERSONS HANDLING THE CONCENTRATE MUST OBSERVE THE FOLLOWING REQUIREMENTS

Wear clean cotton (or cloth) coveralls that cover all parts of the body except the head, hands, and feet. The coveralls must be worn over a long sleeve shirt and long pants. Wear clean nitrile gloves, a chemical resistant apron, goggles or face shield, and chemical resistant shoes, shoe coverings, or boots. If you use a mechanical transfer system for all mixing and loading operations, use of a chemical resistant apron is optional.

If this product is packaged in a 30 gallon drum or if you handle a total of 30 gallons or more of this product per day, you must use a mechanical transfer system for all mixing and loading operations. When using a mechanical transfer system, do not remove or disconnect the pump or probe from the container until the container has been emptied and rinsed. The pump or probe system must be used to rinse the empty container and to transfer the rinsate directly to the mixing or spray tank.

ALL PERSONS APPLYING THIS PRODUCT, OR REPAIRING OR CLEANING EQUIPMENT USED WITH THIS PRODUCT, MUST OBSERVE THE FOLLOWING REQUIREMENTS.

When applying this product from a tractor (unless the tractor has a completely enclosed cab), or when repairing or cleaning equipment used with the product, you must wear clean nitrile gloves and clean cotton (or cloth) coveralls that cover all parts of the body except the heads, hands, and feet. Coveralls must be worn over a long sleeve shirt and long pants.

All applicators (except for pilots) and all persons repairing or cleaning equipment used with this product must wear chemical resistant shoes, shoe coverings, or boots.

Application from a tractor with a completely enclosed cab or aerial application is required whenever this product is applied to 180 or more acres in a day. To avoid contamination, coveralls and gloves worn when handling the concentrate must be removed prior to entering an enclosed cab or cockpit. When applying from a tractor with an enclosed cab, clean coveralls and clean nitrile gloves must be kept inside the cab, and must be worn when exiting the cab to perform in-field maintenance or repair.

To reduce exposure to residues, wash the spray rig, tractor, and all other equipment used to handle or apply this product with water daily or before using the equipment for any other purpose.

APPLICATION BY CHEMIGATION must be done by fixed pipe, overhead sprinkler systems or hand moved pipe. If hand moved pipe is used for chemigation, the pipe must not be handled in any way until 24 hours after chemigation has been completed and residues have been flushed from the system. When applying by chemigation, no person may enter the application site unless in an enclosed vehicle.

Rhône-Poulenc Ag Company
P O Box 12014, 2 T W Alexander Drive
Research Triangle Park, North Carolina 27709

DURING AERIAL APPLICATION, human flaggers are prohibited unless in enclosed vehicles. Aerial application is prohibited within 200 feet of residential areas (e.g., homes, schools, hospitals, shopping areas, etc.)

GENERAL REQUIREMENTS FOR ALL USE

IMPORTANT! Before removing gloves or starting a new work operation, rinse the outside of the gloves thoroughly with water. Always remove gloves and wash your hands and face with soap and water before smoking, eating, drinking, or toileting.

AFTER WORK. Gloves must be discarded at the end of each day. Take off all clothes and shoes. Shower with soap and water. Do not wear or re-use contaminated clothing. Wash protective equipment with water after each use. Protective clothing worn during use must be laundered separately from other household articles.

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: Get medical attention. Do not induce vomiting, contains petroleum distillates. Do not give anything by mouth to an unconscious person.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF IN EYES: Flush with water for 15 minutes. Get medical attention.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to wildlife and fish. Use with care when applying to areas frequented by wildlife or adjacent to any body of water. Do not apply directly to water. Do not apply when weather conditions favor drift from target areas. Do not contaminate water by cleaning of equipment or disposal of wastes.

PHYSICAL AND CHEMICAL HAZARDS

Do not use or store near heat or open flame.

DIRECTIONS FOR USE - See attached booklet.

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

STORAGE AND DISPOSAL

STORAGE

Do not contaminate water, food or feed by storage or disposal.

Do not store near fertilizers or seeds. Store at temperatures above 32° F. If exposed to freezing temperatures, store at temperatures above 65° F for 24 hours or until completely thawed. Shake well before using.

PESTICIDE DISPOSAL

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL

Plastic

Triple rinse (or equivalent). Then puncture and dispose of in a sanitary landfill, or incineration, or if allowed by State and Local authorities, by burning. If burned, stay out of smoke.

Metal

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration or if allowed by State and Local authorities.

[illegible] STATEMENTS ON THE STICKER SUPERSEDE ANY INCONSISTENT LANGUAGE OR DIRECTIONS WHICH APPEAR ELSEWHERE ON THE LABEL [illegible] THE PRODUCT IS NO LONGER REGISTERED ON TURF AND NON-CROP AREAS. APPLICATION TO THESE SITES IS PROHIBITED.

RESTRICTED USE PESTICIDE

For retail sale to and use only by Certified Applicators or persons directly under their supervision and only for those uses covered by the C[illegible] Applicator's certification. See precautionary statements for reasons this product is classified Restricted Use.

BRONATE® Herbicide

FOR CONTROL OF CERTAIN BROADLEAF WEEDS IN WHEAT, BARLEY, OATS, AND RYE.

ACTIVE INGREDIENT	
Octanoic acid ester of bromoxynil* (3,5-dibromo-4-hydroxybenzonitrile)	31.7%
Isooctyl ester of 2-methyl-4-chlorophenoxyacetic acid**	34.0%
INERT INGREDIENTS:	34.3%

*Bromoxynil octanoate equivalent to 21.8% of bromoxynil or not less than 2.0 pounds of bromoxynil per gallon.

** Equivalent to 21.8% 2-methyl-4-chlorophenoxyacetic acid or not less than 2.0 pounds MCPA acid per gallon.

KEEP OUT OF REACH OF CHILDREN

WARNING

EPA Reg. No. 264-438 EPA Est. No.

For PRODUCT USE Information Call 1-800-334-9745.

For EMERGENCY Information ONLY Call 24 Hours A Day 1-800-334-7577

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING · RESTRICTED USE

Use of this product may be hazardous to your health. Exposure to this product has been shown to cause birth defects in laboratory animals. Women of childbearing age should be particularly careful when handling this product to avoid ingestion and skin contact.

Harmful if swallowed or absorbed through skin or inhaled. Avoid contact with skin, eyes or clothing. Avoid breathing spray mist.

Users of this product are encouraged to participate in Rhone-Poulenc's educational program dealing with potential hazards and safer use of this product. Further information on this program can be obtained by contacting Rhone-Poulenc Ag Company at 1-800-334-9745.

ALL PERSONS HANDLING THE CONCENTRATE MUST OBSERVE THE FOLLOWING REQUIREMENTS.

Wear clean cotton (or cloth) coveralls that cover all parts of the body except the head, hands, and feet. The coveralls must be worn over a long sleeve shirt and long pants. Wear clean nitrile gloves, a chemical resistant apron, goggles or face shield, and chemical resistant shoes, shoe coverings, or boots. If you use a mechanical transfer system for all mixing and loading operations, use of a chemical resistant apron is optional.

If this product is packaged in a 30 gallon drum or if you handle a total of 30 gallons or more of this product per day, you must use a mechanical transfer system for all mixing and loading operations. When using a mechanical transfer system, do not remove or disconnect the pump or probe from the container until the container has been emptied and rinsed. The pump or probe system must be used to rinse the empty container and to transfer the rinsate directly to the mixing or spray tank.

ALL PERSONS APPLYING THIS PRODUCT, OR REPAIRING OR CLEANING EQUIPMENT USED WITH THIS PRODUCT, MUST OBSERVE THE FOLLOWING REQUIREMENTS.

When applying this product from a tractor (unless the tractor has a completely enclosed cab), or when repairing or cleaning equipment used with the product, you must wear clean nitrile gloves and clean cotton (or cloth) coveralls that cover all parts of the body except the heads, hands, and feet. Coveralls must be worn over a long sleeve shirt and long pants.

All applicators (except for pilots) and all persons repairing or cleaning equipment used with this product must wear chemical resistant shoes, shoe coverings, or boots.

Application from a tractor with a completely enclosed cab or aerial application is required whenever this product is applied to 100 or more acres in a day. To avoid contamination, coveralls and gloves worn when handling the concentrate must be removed prior to entering an enclosed cab or cockpit. When applying from a tractor with an enclosed cab, clean coveralls and clean nitrile gloves must be kept inside the cab, and must be worn when exiting the cab to perform in-field maintenance or repair.

To reduce exposure to residues, wash the spray rig, tractor, and all other equipment used to handle or apply this product with water daily or before using the equipment for any other purpose.

APPLICATION BY CHEMIGATION must be done by fixed pipe, overhead sprinkler systems or hand moved pipe. If hand moved pipe is used for chemigation, the pipe must not be handled in any way until 24 hours after chemigation has been completed and residues have been flushed from the system. When applying by chemigation no person may enter the application area unless in an enclosed vehicle.

DURING AERIAL APPLICATION, human flaggers are prohibited unless in enclosed vehicles. Aerial application is prohibited within 300 feet of residential areas (e.g. [illegible] schools, hospitals, shopping areas, etc.)

GENERAL REQUIREMENTS FOR ALL USE

IMPORTANT! Before removing gloves or starting a new work operation, rinse the outside of the gloves thoroughly with water. Always remove gloves and wash your hands and face with soap and water before smoking, eating, drinking, or toileting.

AFTER WORK, Gloves must be discarded at the end of each day. Take off all clothes and shoes. Shower with soap and water. Do not wear or re-use contaminated clothing. Wash protective equipment with water after each use. Protective clothing worn during u[illegible] be laundered separately from other household articles.

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: Get medical attention. Do not induce vomiting; contains petroleum distillates. Do not give anything by mouth to an unconscious person.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF IN EYES: Flush with water for 15 minutes. Get medical attention.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to wildlife and fish. Use with care when applying to areas frequented by wildlife or adjacent to any body of water. Do not apply directly to water. Do not apply when weather conditions favor drift from target areas. Do not contaminate water by cleaning of equipment or disposal of wastes.

PHYSICAL AND CHEMICAL HAZARDS

Do not use or store near heat or open flame.

DIRECTIONS FOR USE - See attached booklet.

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

STORAGE AND DISPOSAL

STORAGE

Do not contaminate water, food or feed by storage or disposal. Store at temperatures above 3[illegible] F. If allowed to freeze, remix before using.

PESTICIDE DISPOSAL

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration or if allowed by state and local authorities by burning. If burned, stay out of smoke.

Rhône-Poulenc Ag Company
P.O. Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, North Carolina 27709

ATTACHMENT B

BROMOXYNIL CONTAINER RELABELING SCHEDULE

FOLLOWING IS A DETAILED PLAN DESIGNED TO APPROPRIATELY RELABEL ALL BROMOXYNIL PRODUCT CONTAINERS EXISTING WITHIN THE CHANNELS OF TRADE, INCLUDING RHONE-POULENC, DISTRIBUTOR AND DEALER INVENTORIES, IN A TIMEFRAME CONSISTENT WITH THE APPLICATION FOR AMENDED REGISTRATION. UPON FINAL EPA APPROVAL THESE STEPS WILL IMMEDIATELY BE IMPLEMENTED:

DAY 1 FOLLOWING EPA AMENDED REGISTRATION APPROVAL

RHONE-POULENC WILL INITIATE THE PRINTING OF APPROVED AMENDED LABELS FOR BUCTRIL®, BUCTRIL® + ATRAZINE AND BRONATE® HERBICIDES IN SUFFICIENT QUANTITIES TO RELABEL ALL EXISTING BROMOXYNIL CONTAINERS HELD BY RPAC, DISTRIBUTORS AND RETAILERS, AS WELL AS FUTURE PRODUCTION QUANTITIES SCHEDULED FOR THE REMAINDER OF 1989 USE SEASON.

RPAC WILL IMMEDIATELY HALT SHIPMENT OF ALL BROMOXYNIL PRODUCTS UNTIL APPROVED AMENDED LABELS CAN BE PRINTED AND AFFIXED TO EACH CONTAINER WITHIN RPAC POSSESSION, IN A MANNER CONSISTENT WITH THE "RELABELING PROCEDURES" OUTLINED IN ATTACHMENT A.

DAY 4-10 FOLLOWING EPA AMENDED REGISTRATION APPROVAL

REVISED LABELS WILL BE DELIVERED AND STICKERING OF RPAC INVENTORIES AT PLANTS AND WAREHOUSES WILL BEGIN. NEWLY L.E H [illegible] W LL BE RELEASED FOR SHIPMENT TO DISTRIBUTORS.

ADEQUATE QUANTITIES OF EACH APPROPRIATE LABEL, ACCOMPANIED WITH "RELABELING PROCEDURES", WILL BE SHIPPED TO RPAC FIELD SALES REPRESENTATIVES FOR IMMEDIATE DELIVERY TO DISTRIBUTOR WAREHOUSE LOCATIONS WHERE BROMOXYNIL INVENTORIES EXIST OR WILL BE DIRECTLY MAILED TO DISTRIBUTOR LOCATIONS. APPROPRIATE COMPENSATION FEES WILL BE PAID TO DISTRIBUTOR FOR RELABELING. AND VERIFICATION OF LABEL DELIVERY WILL BE MADE BY DISTRIBUTOR SIGNING THE "RP LABELING COMPENSATION" FORM. MONITORING BY RPAC FIELD REPS WILL BE PERFORMED TO INSURE COMPLIANCE. DISTRIBUTORS WILL BE INFORMED THAT NO BROMOXYNIL PRODUCTS MAY BE SHIPPED PRIOR TO RELABELLING ONCE LABELS ARE RECEIVED.

BRONATE®/BUCTRIL®/BUCTRIL® + ATRAZINE

RELABELING COMPENSATION PROGRAM

THIS PROGRAM IS DESIGNED TO COMPENSATE THE DISTRIBUTOR AND RESELLER FOR RELABELING HIS CURRENT INVENTORIES OF BRONATE®, BUCTRIL® AND/OR BUCTRIL® + ATRAZINE BROADLEAF HERBICIDES TO COMPLY WITH EPA REQUIREMENTS.

TO PERFORM THIS TASK IN ACCORDANCE WITH SPECIFIED RELABELING DIRECTIONS, DISTRIBUTOR/RESELLER WILL BE COMPENSATED AT A RATE OF $0.50 PER CARTON, 30-GALLON DRUM, OR 110-GALLON MINI-BULK CONTAINER.

CURRENT PHYSICAL INVENTORY AS OF _____ (DATE)

	BRONATE®	BUCTRIL®	BUCTRIL® + ATRAZINE
CASES	_____	_____	_____
DRUMS	_____	_____	_____
MINI's	_____	_____	_____

I HEREIN CERTIFY THAT AS OF DATE SPECIFIED ABOVE, WE HAD IN OUR INVENTORY THE QUANTITIES OF RHONE-POULENC BROMOXYNIL PRODUCTS AS LISTED ABOVE, AND HAVE RECEIVED ADEQUATE QUANTITIES OF REVISED LABELS FOR RELABELING ABOVE INVENTORIES.

BUSINESS NAME: _____

STREET ADDRESS: _____

CITY: _____ COUNTY: _____ STATE: _____ ZIP: _____

OWNER/MANAGER: _____ (SIGNATURE) PHONE: _____

RHONE-POULENC REPRESENTATIVE: _____ (SIGNATURE) _____ TERR. #

DAY 11-20 FOLLOWING EPA AMENDED REGISTRATION APPROVAL

FIELD REPRESENTATIVES WILL INITIATE DELIVERY OF APPROPRIATE LABELS TO EACH ACTIVELY SELLING BROMOXYNIL RESELLER, BEGINNING FIRST WITH PRIORITY ACCOUNTS WHERE LARGE INVENTORIES ARE KNOWN TO EXIST. INSTRUCTIONS FOR PROPER RELABELING WILL BE PROVIDED AND COMPENSATION MADE TO INSURE COMPLIANCE. RESELLERS WILL BE INFORMED THAT NO BROMOXYNIL MAYBE SOLD PRIOR TO RELABELLING ONCE LABELS ARE RECEIVED. RETAILERS WILL BE SUPPLIED WITH ADEQUATE NUMBER OF LABELS TO PROVIDE TO GROWERS. VERIFICATION OF LABEL DELIVERY WILL BE MADE BY RESELLER SIGNING THE "RELABELING COMPENSATION" FORM.

EFFORTS TO HAND DELIVER NEW LABELS TO ALL RETAILERS WITH BROMOXYNIL INVENTORIES WILL BE MADE, HOWEVER, MAILINGS TO MINOR BUSINESSES MAY OCCUR TO INSURE DELIVERY IN TIMELY MANNER. THESE MAILINGS WILL BE DONE USING REGISTERED MAIL TO VERIFY LABEL DELIVERY.

DAY 20 FOLLOWING EPA AMENDED REGISTRATION APPROVAL

LABEL DELIVERY FOR BROMOXYNIL FIELD INVENTORIES WILL BE COMPLETE AND MONITORING BY RPAC FIELD REPRESENTATIVES WILL CONTINUE, TO INSURE ALL CONTAINERS PROPERLY LABELED FOR SALE.

ATTACHMENT A

BUCTRIL®, BUCTRIL® + ATRAZINE, BRONATE®
RELABELING PROCEDURE

2½-GALLON JUG

1. DEPALLETIZE CARTONS (36 PER PALLET).

2. USING THIN, FLAT METAL BAR, OPEN THE CARTON BY SLIDING BAR UNDER TOP FLAPS FROM MIDDLE OF CARTON TOWARDS END OF CARTON. USE BAR TO BREAK GLUE SEALANT ON BOTH FLAPS BEING CARFUL NOT TO DAMAGE FLAPS.

3. REMOVE NITRILE GLOVES AND SET ASIDE.

4. REMOVE BOTH JUGS FROM CARTON.

5. REMOVE THE PRODUCT BOOKLET FROM THE LABEL ON SIDE OF JUG, ROLL BOOKLET AND PLACE INTO HANDLE HOLE OF JUG.

6. PEEL BACKING FROM NEW PRODUCT LABEL AND PLACE NEW LABEL COMPLETELY OVER EXISTING LABEL ON THE JUG.

7. RETURN JUGS TO CARTON AND REPLACE GLOVES ON TOP OF JUGS.

8. FOLD DOWN THE TWO SMALL FLAPS OF CARTON AND FOLLOW WITH TWO LARGE FLAPS.

9. TAPE CARTON CLOSED WITH COLORED PACKING TAPE CENTERING ALONG THE CARTON OPENING AND EXTENDED DOWN BOTH SIDES 2-3 INCHES.

10. REPALLETIZE CARTONS IF NECESSARY INCLUDING RESTRETCH WRAPPING IF AVAILABLE.

30-GALLON DRUM AND 110-GALLON MINI-BULK

PEEL BACKING FROM NEW PRODUCT LABEL AND POSITION NEW LABEL OVER THE EXISTING LABEL ON EITHER THE 30-GALLON DRUM OR 110 MINI-BULK CONTAINER.

ATTACHMENT C

RHÔNE-POULENC

RHÔNE-POULENC AG COMPANY

OFFICE MEMORANDUM

TO: Nick Somma DATE: May 1, 1989

FROM: Dave Downing

Please find attached the Bromoxynil Label Amendment Communication Plan. Our goal is to reach all persons who sell, apply or recommend bromoxynil products within the agricultural community in an orderly, logical and timely manner. With this in mind, we plan to first communicate new restrictions the day following EPA approval to all RPAC Field and Office Personnel involved with the sale, promotion, development, field testing and distribution of bromoxynil products. By the second day all bromoxynil product distributors will be contacted with this information via overnight mail. All resellers, university extension personnel and weed scientists will have bromoxynil label restrictions direct mailed to them within the first week following EPA approval of copy.

In addition to written communication, distributors, resellers, university extension personnel and weed scientists will be personally contacted by our field representatives within 2 weeks of EPA approval. Resellers will be contacted on a priority basis according to their past sales volumes as recorded by Rhône-Poulenc.

Following these written and personal contacts, with those who will be called upon to provide information, mass communication to growers, crop consultants and farm managers will begin via radio spots, data-line information system, and point of purchase posters, informing them of the new "Restricted Use" classification for bromoxynil products and to contact their local reseller for detailed information.

Rhône-Poulenc feels that this communication plan will serve the intended need to alert the agricultural industry of the proper manner to handle and apply bromoxynil products with minimal risk during the 1989 use season.

D.P. Downing

DPD:vwg
Attachment
cc: J.N. Harton
S.A. Schmotzer

BROMOXYNIL LABEL AMENDMENT COMMUNICATION PLAN

UPON RECEIVING FINAL APPROVAL FROM THE EPA OF 1989 LABEL AMENDMENTS FOR COMMERCIAL BROMOXYNIL OCTANOATE FORMULATIONS, AND APPROVED COPY OF INTENDED INDUSTRY COMMUNICATIONS, RPAC WILL IMMEDIATELY INITIATE A COMPREHENSIVE PLAN TO DISSEMINATE NEW PRODUCT PRECAUTIONS AND RESTRICTIONS TO APPROPRIATE AUDIENCES WITHIN THE PESTICIDE CUSTOMER/USER NETWORK. FOLLOWING IS A DETAILED DESCRIPTION AND TIMETABLE OF HOW THAT PLAN WILL UNFOLD:

DAY 1 FOLLOWING EPA APPROVAL OF COPY

COMPLETE LABEL AMENDMENTS, WITH A COVER LETTER HIGHLIGHTING EACH PRECAUTION AND RESTRICTION OF THE BROMOXYNIL LABEL, AS WELL AS A DESCRIPTION OF THE PRODUCT RELABELING PLAN, WILL BE TELEFAXED TO EACH DISTRICT AND REGIONAL OFFICE WITHIN RHONE-POULENC AG COMPANY.

OVERNIGHT MAIL, INCLUSIVE OF IDENTICAL INFORMATION, WILL BE SENT TO EACH FIELD REPRESENTATIVE WITHIN THE COMPANY, AS WELL AS APPROPRIATE RPAC ADMINISTRATIVE AND PLANT PERSONNEL.

DAY 2 FOLLOWING EPA APPROVAL OF COPY

ANNOUNCEMENT OF THE BROMOXYNIL LABEL CHANGES AND THE PRODUCT RELABELING PLAN WILL BE SENT, VIA OVERNIGHT MAIL TO ALL BROMOXYNIL DISTRIBUTORS.

RPAC FIELD SALES PERSONNEL WILL BEGIN MAKING PERSONAL CONTACT CALLS ON BROMOXYNIL DISTRIBUTORS AND RESELLERS GIVING CONTACT PRIORITY TO THOSE RETAILERS REPRESENTING THE MAJORITY OF BROMOXYNIL SALES TO GROWERS. IN ADDITION RPAC FIELD DEVELOPMENT REPRESENTATIVES WILL BEGIN CONTACTING UNIVERSITY EXTENSION PERSONNEL AND WEED SCIENTISTS. AN ESTIMATED 3,000 TOTAL CONTACTS CAN BE MADE WITHIN TWO WEEKS.

DAY 5 FOLLOWING EPA APPROVAL OF COPY

DIRECT MAIL LETTERS OUTLINING THE LABEL AMENDMENTS AND NEW RESTRICTIONS WILL BE SENT TO DISTRIBUTORS, DEALERS, CUSTOM APPLICATORS AND UNIVERSITY EXTENSION PERSONNEL - AN ESTIMATED 12,000 INDIVIDUALS. THIS WILL REINFORCE PERSONAL CONTACTS BY RPAC FIELD PERSONNEL.

DAY 14 FOLLOWING EPA APPROVAL OF COPY

"RESTRICTED USE" CLASSIFICATION OF BROMOXYNIL HERBICIDES WILL BE COMMUNICATED TO SOME 35,000 GROWERS THROUGHOUT HIGH INTENSITY USE-AREAS, VIA DATA-LINE, A COMPUTERIZED INFORMATIONAL SYSTEM, WITH COPY THAT INSTRUCTS GROWER TO SEEK DETAILED LABEL USE AND HANDLING PRECAUTIONARY INFORMATION THROUGH THEIR AG CHEMICAL SUPPLIER.

DIRECT MAIL LETTERS OUTLINING THE LABEL AMENDMENTS AND NEW RESTRICTIONS WILL BE SENT TO FARM MANAGERS AND CROP CONSULTANTS.

PRINTING OF POINT-OF-PURCHASE POSTERS WILL BE COMPLETED AND SENT TO RESELLERS, TO BE DISPLAYED AT THE RETAILER LOCATION TO ALERT GROWERS WHO PURCHASE BUCTRIL®, BUCTRIL® + ATRAZINE OR BRONATE® HERBICIDES OF THEIR "RESTRICTED USE" CLASSIFICATION.

A RADIO CAMPAIGN, TARGETED AT GROWERS WITHIN BROMOXYNIL USE-AREAS WILL KICK-OFF ON DAY 14 TO COMMUNICATE THE "RESTRICTED-USE" CLASSIFICATION OF BUCTRIL®, BUCTRIL® + ATRAZINE AND BRONATE® AND TO INSTRUCT GROWERS TO SEEK DETAILED LABEL AND PRECAUTIONARY INFORMATION THROUGH THEIR AG CHEMICAL SUPPLIER. APPROXIMATELY 143,000 GROWERS ARE EXPECTED TO BE REACHED OVER A SEVEN DAY PERIOD WITH 30-SECOND RADIO SPOTS RUNNING TWICE A DAY.

DEALER/DISTRIBUTOR LETTER

ATTENTION - LABEL CHANGES FOR BRONATE®, BUCTRIL® AND BUCTRIL® + ATRAZINE

This is to inform you that BRONATE®, BUCTRIL® and BUCTRIL® + Atrazine broadleaf herbicides have recently been reclassified as "RESTRICTED USE PESTICIDES" and that the labels have been amended to include new precautionary statements, additional protective clothing requirements, and new handling and application restrictions.

These changes have been implemented because recent tests have shown that exposure to the active ingredient in these products has caused birth defects in laboratory animals. The new label amendments have been added to substantially reduce the exposure to these products when handling or applying.

Enclosed you will find copies of each new label for your review. Please take time to become familiar with this information in order that you are in full compliance with each important amendment. Significant additions include: 1) New warning statements; 2) Specific use directions requiring additional protective clothing and clean-up procedures; 3) The requirement of mechanical transfer systems when handling 30 gallons or more product in a single day; 4) Use of enclosed cabs when applying 180 or more acres in a single day; and 5) New chemigation and aerial application restrictions.

In an effort to assure that all inventories of BRONATE®, BUCTRIL® and BUCTRIL® + Atrazine are stickered with these changes, a relabelling program is being implemented by Rhône-Poulenc and within the next several days your RP Field Representative will be delivering adequate quantities of self-adhesive labels with instructions for relabelling your current inventories. To perform this task Rhône-Poulenc will compensate your efforts at a rate of $0.50/case, 30-gallon drum or 120-gallon mini-bulk unit, and will verify your participation with an enrollment form at time of label delivery. In addition, your RPAC Field Rep will provide Resellers with a point-of-purchase poster for hanging, and grower handouts, both alerting him to the label changes of which he must comply.

Once you have received revised labels, no product may be shipped or sold until stickered with the new label. If for any reason distributors don't receive labels within 7 days of receipt of this letter (14 days for Retailers), please call the toll free Rhône-Poulence Hot-Line at 1-800-334-9745, and labels will be immediately shipped to you.

Thank you for your continued support and help in communicating this information. Please contact your RPAC Field Representative if you have questions or specific issues relating to this matter that you would like to discuss.

Sincerely,

UNIVERSITY/CROP CONSULTANT LETTER

ATTENTION - LABEL CHANGES FOR BRONATE®, BUCTRIL® AND BUCTRIL® + ATRAZINE

This is to inform you that BRONATE®, BUCTRIL® and BUCTRIL® + Atrazine broadleaf herbicides have recently been reclassified as "RESTRICTED USE PESTICIDES" and that the labels have been amended to include new precautionary statements, additional protective clothing requirements, and new handling and application restrictions.

These changes have been implemented because recent tests have shown that exposure to the active ingredient in these products has caused birth defects in laboratory animals. The new label amendments have been added to substantially reduce the exposure to these products when handling or applying.

Enclosed you will find copies of each new label for your review. Please take time to become familiar with this information in order that you are in full compliance with each important amendment. Significant additions include: 1) New warning statements; 2) Specific use directions requiring additional protective clothing and clean-up procedures; 3) The requirement of mechanical transfer systems when handling 30 gallons or more product in a single day; 4) Use of enclosed cabs when applying 180 or more acres in a single day; and 5) New chemigation and aerial application restrictions.

Thank you for your continued support and help in communicating this information. Please contact your RPAC Field Representative if you have questions or specific issues relating to this matter that you would like to discuss.

Sincerely,

GROWER LETTER TO BE AVAILABLE AT RESELLER LOCATION

RHÔNE-POULENC

RHÔNE-POULENC AG COMPANY

TO: BUCTRIL®/BUCTRIL® + Atrazine/BRONATE® Users

BUCTRIL®, BUCTRIL® + Atrazine and BRONATE® herbicides have been reclassified "Restricted Use Pesticides", and additional label restrictions and precautions have been added to minimize user exposure.

Please note when review the revised product labels the following changes have been made:

* Warning Statement: This product has been shown to cause birth defects in laboratory animals. Women of childbearing age should be particularly careful when handling this product to avoid ingestion and skin contact.

* Protective clothing requirements such as nitrile gloves, cotton coveralls, chemical resistant shoes, and chemical resistant apron for mixer/loaders have been added. Please review the label for full details.

* Mechanical transfer systems are required to be used for loading of 30 or more gallons of product are used per day.

* Enclosed cabs are required for ground applications if 180 or more acres are treated per day.

* New chemigation and aerial application restrictions have been added. Please review the label for details.

Please thoroughly familiarize yourself with and strictly adhere to the label requirements because the safety of you, the user, is our foremost concern. Please contact your local chemical supplier if you have questions or require further information.

BUCTRIL and BRONATE are registered trademarks of Rhône-Poulenc Ag Company.

PO BOX 12014, 2 TW ALEXANDER DRIVE
RESEARCH TRIANGLE PARK NC 27709
(919) 549-2000
INTERNATIONAL TELEX NUMBER 4990378-ANSWERBACK APC RTP
INTERNATIONAL DISTRIBUTION SERVICES TELEX NUMBER 4999377-ANSWERBACK APC IDS

RADIO/DATA-LINE COPY

ATTENTION GROWERS!

BUCTRIL®, BUCTRIL® + ATRAZINE AND BRONATE® HERBICIDES, USED FOR POST-EMERGENCE BROADLEAF WEED CONTROL, HAVE BEEN RE-CLASSIFIED AS RESTRICTED USE PESTICIDES.

FOR COMPLETE DETAILS AND INFORMATION, CONTACT YOUR FARM CHEMICALS SUPPLIER. AND REMEMBER ... YOUR SAFETY IS OUR TOP PRIORITY. SO, AS WITH ANY CROP PROTECTION CHEMICALS, ALWAYS READ AND FOLLOW INSTRUCTIONS ON THE LABEL.

POSTER FOR RESELLER

BUCTRIL®
BRONATE®
BUCTRIL® + ATRAZINE

ARE NOW
RESTRICTED USE PESTICIDES

ASK HERE FOR COMPLETE
DETAILS AND INFORMATION.

RHONE-POULENC AG COMPANY

ATTACHMENT D

In lieu of the sentence which states, "If this product is packaged in a 30 gallon drum or you will handle a total of 30 gallons or more of this product per day, you must use a mechanical transfer system for all mixing and loading operations," the complete revised labeling will state, "If you will handle a total of 30 gallons or more of this product per day, you must use a mechanical transfer system for all mixing and loading operations. If this product is packaged in a 30 gallon drum, you must use a mechanical transfer system which terminates in a drip-free hard coupling which may be used only with a spray or mix tank which has been fitted with a compatible coupling. If you do not presently own or have access to a mechanical transfer system with this type of coupling, contact your dealer for information on how to obtain such a system or to modify your present system."

ATTACHMENT E

APR 25 198

DRAFT PROPOSED PROTOCOL: BROMOXYNIL EXPOSURE STUDY

1.0 INTRODUCTION

A passive dosimetry study shall be conducted to assess the dermal and inhalation exposure occurring during routine use of bromoxynil. The study shall be designed so that the Environmental Protection Agency may be able to: (1) quantify the exposure occurring during mixing/loading, application, and clean-up when bromoxynil is applied by ground boom to field crops employing rigs where boom lengths typically exceed 50'; (2) quantify the exposure occurring during mixing/loading, application, and clean-up when bromoxynil is applied by ground boom to crops where rigs of 20' to 40' predominate; (3) within each subgroup estimate the total potential dermal exposure and the actual deposition to the skin under the clothing worn by each study participant. As an additional objective, this study or a seperate study will quantify the potential dermal exposure and skin deposition occurring during oper pour mixing and loading with the new Rhone-Poulenc 2.5 gallon container and a conventional 2.5 gallon container.

2.0 MATERIALS AND METHODS

2.1 Site Selection

The study will address two main crop groupings. The first grouping shall be crops to which daily treatments of 150 acres or more are typical and boom sizes of 50' or greater are the norm. The usual application speed is expected to be approximately 0.5 acres/minute. The second grouping shall be crops to which daily treatment of 50 to 120 acres is standard and boom sizes average 20' to 40'. The usual application speed is expected to be approximately 0.25 to 0.35 acres/minute.

Within each grouping the sites shall be selected based on routine use of bromoxynil or other early post emergent herbicides in that area. A minimum of ten sites are to be used within each grouping.

2.2 Cooperator Selection

Cooperators used in the study are to be individuals intending to apply a post emergent herbicide independent of possible participation in the study. The candidates are to be selected in a manner identical to that employed in the May & Baker Canada/Rhone-Poulenc Study with the exception that a minimum number of participants with enclosed tractor cabs shall be required. The questionnaire used should be similar to that used in the Canadian study. Selected cooperators will receive

bromoxynil in a manner identical to a non-cooperator who would be obtaining bromoxynil for his/her use except that bromoxynil may be provided in a non-standard container as necessary to effectuate the study. Rhone-Poulenc may provide clean coveralls and nitrile gloves to study participants. The study participants will initially be instructed to follow label directions. Should the participant attempt to handle bromoxynil with less than the label required protective clothing, Rhone-Poulenc will record such deviation from the label directions and then require the participant to utilize all required clothing. The normal and typical work routines of the participants are not to be altered once the study participant has begun handling bromoxynil during the monitoring portion of the study.

2.3 Application Details

Information collected for each application of bromoxynil shall include target crop, data involving cultivar, growth stage, date of planting, and row spacing. Equipment information shall include sprayer model and make, tractor model and make, procedure and time required to mix and load the sprayer and the date and method of sprayer calibration. Alterations to the equipment such as shielding of booms and opening of windows in closed cab tractors will be recorded. Application rate and amount of active ingredient handled shall be recorded as will the actual time of application.

Field conditions including wind speed and direction, relative humidity, rainfall, temperature, and cloud cover shall be recorded at each monitoring site for the duration of each monitoring period. A description of each test site will be recorded.

2.4 Dermal Exposure

Dermal exposure to all body areas with the exception of the hands will be monitored in a manner that will permit the estimation of potential dermal exposure and dermal exposure to the skin. Potential dermal exposure will be monitored by the Durham-Wolfe patch method (Measurement of Exposure of Workers to Pesticides, Bull. Wld Hlth Org., 1962, 26:75-91). Patches shall be placed in a manner specified in Subdivision U of the Agency's Pesticide Assessment Guidelines on the outside of the cooperator's clothing. Dermal exposure to body areas covered by clothing shall be monitored using either whole body dosimeters composed of a long sleeve cotton T-shirt and long legged cotton underpants or by a fluorescent tracer technique. The whole body dosimeters, if selected, will be provided to each cooperator by Rhone-Poulenc at least one day prior to the study and shall be placed on each cooperator, by the cooperator, at the time that the cooperator gets dressed to perform the day's work routine. The whole body dosimeters are to be worn under all clothing

normally worn by the cooperators. Facial exposure may be monitored by the use of facial swabbing in lieu of dosimeters. Hand exposure will be monitored by use of hand rinses.

The monitoring period will consist of the handling of not less than 15 lbs active ingredient with the exception that external patches will be changed and hand rinses will be conducted at the end of each mix/load cycle and each application cycle.

2.5 Inhalation Exposure

Inhalation exposure will be monitored by use of personal air samplers. The air samplers will be turned off during each break in the work routine likely to exceed 30 minutes. The duration of the sampling period should be the entire day's work routine; however, caution must be taken to prevent breakthrough from saturation of the collection media. The duration of sampling and calibration of air flow will be conducted for each sample period.

2.6 REPLICATIONS

A replicate is defined as one monitoring period consisting of the handling of at least 15 lbs active ingredient. The residue levels of external patches for each body area and hand rinses will be combined in the calculation of total potential daily exposure for each job function and the combined mixing, loading, and application functions. For each crop grouping a minimum of ten sites are to be selected. For each crop grouping a minimum of 20 replicates shall be monitored. For each set of 20 replicates, a minimum of 7, but no more than 13 replicates, shall involve application from enclosed tractor cabs. A total of at least 40 mixer/loader/applicator replications will be conducted for the study. Monitoring of the exposure resulting from the use of the new 2.5 gallon container may be conducted either as an ancillary portion of the study or as a seperate study and must consist of a minimum of 15 replications of the new 2.5 gallon container and 15 replications involving a conventional 2.5 gallon container. Each set of 15 replications will involve a minimum of five individuals at three different sites. A replicate for this portion of the study is defined as one mix/load cycle in which a spray tank is filled to capacity.

2.7 QUALITY ASSURANCE

All quality assurance as defined in Subdivision U of the EPA's Pesticide Assessment Guidelines will be required.

3.0 DATA ANALYSIS

The purposes of this study are to quantify the exposure

received during the use of bromoxynil and the identification of regulatory options that may be required to reduce exposure.

The data will be presented as a mean exposure and a range. The standard deviation will also be determined. Non-parametric or other appropriate statistics may be employed to determine the statistical significance of different variables in determining exposure. Major emphasis will be placed on tractor type, boom size, and tank size. Post priori analyses may be conducted on other variables depending on observed patterns in the data. A priori statistical tests will be defined in the protocol by the Agency.
A priori statistical methods will test the following null hypotheses: 1) Exposure during mixing/loading with standard 2.5 gallon containers is the same as with the new 2.5 gallon containers; 2) Exposure during application involving small rigs is the same as those involving large rigs; and 3) Exposure during application from open tractors is the same as from enclosed tractor cabs. Any post priori statistical analysis will be determined upon receipt and assessment of the data. The Agency fully recognizes the fact that exposure data is inherently highly variable (C.V. > 100%) and that identification of variables having statistical significance at $p \leq 0.05$ may not occur without requiring an even greater number of replications. Such an undertaking would be prohibitive in cost. Trend analysis of the data may be conducted in the absence of statistical significance.

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

JUL 13 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCE

MEMORANDUM

SUBJECT: Compliance Strategy for the Cancellation of Carbon Tetrachloride

FROM: John J. Neylan III, Director
Policy and Grants Division
Office of Compliance Monitoring

TO: Addressees

Attached is the Compliance Strategy for the Cancellation of Carbon Tetrachloride. The attached strategy provides guidance for the enforcement of the November 12, 1986 order which cancelled all pesticide products containing carbon tetrachloride, except those registered for use on encased museum specimens.

This strategy is effective immediately and calls for compliance monitoring of the cancellation order through inspections of registrants, producers, dealers and users of cancelled products. Inspections will be conducted by States with Cooperative Enforcement Agreements, and EPA in States without Cooperative Enforcement Agreements, as part of their current routine inspections.

We appreciate the comments offered on the May 5, 1987 draft of this strategy. Most of the comments were editorial and have been incorporated into the final document. However, one commenter suggested that the strategy should also address the disposal of any carbon tetrachloride products. OCM does not believe that this issue should be addressed in the strategy. OCM recommends that the disposal of any remaining stocks of carbon tetrachloride should be in accordance with the label directions.

If you have any questions concerning the attached strategy, please contact Dan Helfgott of my staff at FTS 382-7825.

Attachments

ADDRESSEES

Douglas D. Campt	(TS-766C)
Frederick F. Stiehl	(LE-134A)
Stanley Abramson	(LE-132A)
Peg Anthony	(EN-342)
Ken Shiroishi	"
David Hannemann	"
John Martin	"
John J. Neylan III	"
Jerry Stubbs	"
Mike Wood	"
Dexter Goldman	"

Jake Mackenzie
Western Regional Compliance Director

A. Charles Lincoln
Eastern Regional Compliance Director

I	Louis F. Gitto, Director Air Management Division	Gerald M. Levy, Chief Office of Pesticides & Toxic Sub.
II	Barbara Metzger, Director Environmental Services Div.	Ernest Regna, Chief Pesticides & Toxics Sub. Branch
III	Stephen R. Wassersug, Director Hazardous Waste Management Div.	Larry Miller, Chief Toxic & Pesticides Branch
IV	Winston A. Smith, Director Air, Pest. & Toxic Mgmt Div.	H. Kirk Lucius, Chief Pesticides & Toxic Subs. Branch
V	William H. Sanders III, Director Environmental Services Div.	Phyllis Reed, Chief Pesticides & Toxic Subs. Branch
VI	William B. Hathaway, Director Air, Pesticides & Toxics Div.	Norman E. Dyer, Chief Pesticides & Toxics Subs. Branch
VII	William A. Spratlin, Director Air & Toxics Division	Leo Alderman, Chief Toxics & Pesticides Branch
VIII	Irwin L. Dickstein, Director Air & Toxic Subs. Division	Alvin Yorke, Chief Toxic Substances Branch
IX	Jeffrey Zelikson, Acting Director Toxics & Waste Management Div.	Richard Vaille, Chief Pesticides & Toxics Branch
X	Gary O'Neal, Director Air & Toxic Division	Anita Frankel, Chief Pesticides & Toxic Subs. Branch

cc: Jim Lamb (TS-788)

COMPLIANCE STRATEGY FOR THE CANCELLATION OF CARBON TETRACHLORIDE

OVERVIEW

In 1984, the Agency suspended all registrations of pesticide products containing carbon tetrachloride, except those products registered for use on encased museum specimens, after registrants failed to respond to a FIFRA §3(c)(2)(B) Data Call-In. On July 23, 1985, the Agency issued a Stop Sale, Use, or Removal Order (SSURO) to all registrants covered by the suspension order. This SSURO stated that registrants may not legally distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver pesticide products containing carbon tetrachloride after the date of receipt of the SSURO. Registrants who later agreed to voluntarily cancel their registrations, as well as all persons who sell or distribute pesticide products containing carbon tetrachloride, were allowed to distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver carbon tetrachloride until December 31, 1985. Stocks were allowed to be used until June 30, 1986.

On November 12, 1986 (51 FR 41004), the Agency issued a Notice of Intent to Cancel (NOIC) for all remaining suspended registrations of pesticide products containing carbon tetrachloride except those products registered for use on encased museum specimens.

Carbon tetrachloride was present as an active ingredient in pesticide products registered for use as fumigants on stored grain, in flour milling and grain processing plants, as well as on encased museum specimens in storage. All registrations for pesticide products containing carbon tetrachloride as an active ingredient, except for use on encased museum specimens, have now been cancelled.

Carbon tetrachloride poses significant toxicological risks, and may contribute to the breakdown of the atmosphere's ozone layer. The use on encased museum specimens will be allowed to continue because the current label instructions are sufficient to reduce applicator exposure so that the benefits outweigh the risks.

Compliance with the Cancellation Order will be determined through inspections of registrants, producers, dealers, and users of cancelled products. Inspections will be conducted by States with Cooperative Enforcement Agreements, and EPA in States without Cooperative Enforcement Agreements, as part of their current routine inspections.

REQUIREMENTS OF THE RULE

All pesticide products containing carbon tetrachloride, except for use on encased museum specimens, were cancelled thirty days after publication of the NOIC or the date of receipt of the Notice by the registrant, whichever date was later.

Regulated Industry

All registrants, producers, distributors, and users of carbon tetrachloride other than those with products registered for use on encased museum specimens. At the time of the original Data Call-In, there were 52 registrants and 114 registrations. Vulcan Formula 72 (EPA Registration Number 5382-2) is the only product registered for use on encased museum specimens.

Carbon tetrachloride is also known as perchloromethane and tetrachloromethane.

Existing Stocks

Previous regulatory action has already prohibited registrants and retailers from distributing, selling, offering for sale, holding for sale, shipping, delivering shipment, or receiving and (having so received) delivering or offering to deliver carbon tetrachloride after December 31, 1985. Additionally, all provisions for use, except use on encased museum specimens, have been prohibited since June 30, 1986. Therefore, the November 12, 1986 NOIC provides for no additional existing stocks or use provisions. Noncompliance with the carbon tetrachloride cancellation order is a violation of FIFRA §§12(a)(1)(A) and 12(a)(2)(K).

COMPLIANCE MONITORING

Compliance with the Cancellation Order will be determined by inspection of registrants and producers of cancelled products, inspections of dealers and users, and investigation of tips and complaints.

Neutral Administrative Inspection Scheme

Since the issuance of the Cancellation Order is an administrative action which cancels all carbon tetrachloride pesticide products suspended for noncompliance with the FIFRA §3(c)(2)(B) Data Call-In, inspections for violations of this cancellation order will take place within the existing compliance monitoring framework.

ALLOCATION OF RESPONSIBILITIES

Office of Pesticide Programs

° Will develop and provide OCM with a list of those products which have been cancelled.

Office of Compliance Monitoring

° Will develop and transmit the Compliance Monitoring Strategy to the Regions.

° Will transmit the list of those products which have been cancelled to the Regions.

° Will transmit the list of registrants and producing establishments of carbon tetrachloride.

Regions

° Will provide copies of the Compliance Monitoring Strategy to States.

° Will distribute a list of products, registrants and producing establishments to the States.

° Will conduct inspections in States without Cooperative Enforcement Agreements as part of their routine inspectional schedule.

° Will take enforcement action as appropriate.

States

° Will conduct inspections as part of their routine inspectional schedule.

° Will take enfocement action as appropriate provided they have the authority.

° Will report to the Regions on actions taken under the carbon tetrachloride cancellation.

ATTACHMENT

CARBON TETRACHLORIDE REGISTRANTS AND PRODUCTS

REGION I (1)

Uniroyal Chem. Co.
74 Amity Rd.
Bethany, CT 06525
EPA Reg. No. : 400-192,-193,-197,-200,-203,-268

REGION II (3)

Rochester Midland
Box 1515
Rochester, NY 14603
EPA Reg. No. : 527-11

Prentiss Drug & Chem. Co.
21 Vernon St. C.B. 2000
Floral Park, NY 11001
EPA Reg. No. : 655-624

Bernard Sirotta Co., Inc.
67 35th St.
Brooklyn, NY 11232
EPA Reg. No. : 2826-1

REGION III (0)

REGION IV (11)

Lester Labs
2370 Lawrence St.
Atlanta, GA 30344
EPA Reg. No. : 337-16

Hill Manufacturing, Inc.
1500 Jonesboro Rd., SE
Atlanta, GA 30315
EPA Reg No. : 402-54

Quinn Drug & Chem. Co.
Box 847
Greenwood, MS 38930
EPA Reg. No. : 416-48

Selig Chem. Industries, The
840 Selig Dr., SW
Atlanta, GA 30378
EPA Reg. No. : 491-2,-47,-82,-154,-190

Southland Pearson and Co.
Drexel Chem. Co.
Box 9306
Memphis, TN 38109
EPA Reg. No. : 728-19

Peach County Property Inc.
Sureco
E. Main St. Box 938
Fort Valley, GA 31030
EPA Reg. No. : 769-70

Oxford Chemicals
P. O. Box 80202
Atlanta, GA 30366
EPA Reg. No. : 3635-136

Stephenson Chem. Co. Inc.
Box 87188
College Park, GA 30337
EPA Reg. No. : 4887-57,-127

Vulcan Materials Co. Chem. Div.
P. O. Box 7689
Birmingham, AL 35253
EPA Reg. No. : 5382-1,-2,-4,-6,-7,-9,-11,-31,DC38000100

Big F Insecticides, Inc.
Box 3346
Jackson, TN 38303
EPA Reg. No. : 33161-2

Mid America Chem. Co.
P. O. Box 490
Montrose, AL 36559
EPA Reg. No. : 36480-47,-48,-49,-50,-51

REGION V (5)

Riverdale Chem. Co.
220 E. 17th St.
Chic. Heights, IL 60411
EPA Reg. No. : 228-8

Dow Chemical USA
P. O. Box 1706
Midland, MI 48640
EPA Reg. No. : 464-32,-34,-97,-171,-181,-188,-193,-216,-227

Walter Haertel Co.
8719 Lyndale Ave So.
Minneapolis, MN 55420
EPA Reg. No. : 821-2

E. H. Leitte Co.
Box 180
Lake Elmo, MN 55042
EPA Reg. No. : 939-25

Universal Cooperatives Inc
7801 Metro Parkway P. O. Box 460
Minneapolis, MN 55440
EPA Reg. No. : 1386-463

REGION VI (6)

Main Pro. Inc.
P. O. Box 153249
Irving, TX 75015
EPA Reg. No. : 1325-22,-51

Staffel
ESCO Distributor Inc.
301 1/2 Staples St.
Corpus Christi, TX 78411
EPA Reg. No. : 3286-8098

Voluntary Purchasing Group, Inc.
P. O. Box 460
Bonham, TX 75418
EPA Reg. No. : 7401-82

Grain Conditioners, Inc.
2622 Poydras St.
New Orleans, LA 70119
EPA Reg. No. : 10203-1

Soweco, Inc.
411 So. Parker St.
Amarillo, TX 79106
EPA Reg. No. : 21327-8145

J. Chem. a division of Fumigators Inc.
P. O. Box 5421
Houston, TX 77012
EPA Reg. No. : 36301-5

REGION VII (17)

Bartels and Shore Chem. Co.
1400-02 St. Louis Ave.
Kansas City, MO 63110
EPA Reg. No. : 413-51

Industrial Fumigant Co.
601 E. 159th St.
Olathe, KS 66061
EPA Reg. No. : 485-7,-9,-13,-15,-16,-17

MFA Oil CO.
Box 423
Shenandoah, IA 51601
EPA Reg. No. : 746-93

Douglas Chem. Co.
P. O. Box 297
Liberty, MO 64068
EPA Reg. No. : 1015-10,-20,-22,-27,-29,-33,-36,-53

Warren Dougas Chem Co., Inc.
3002 F St.
Omaha, NE 68107
EPA Reg. No. 1616-4

Weevil-Cide Co. a subs. of Research Products Co.
411 N. 7th St.- Box 1057
Salina, KS 67401
EPA Reg. No. : 1629-1

Knox Chem. Co.
7625 Page Blvd.
St. Louis, MO 63133
EPA Reg. No. : 1645-12

Farmland Industries Inc.
P. O. Box 7305
Kansas City, MO 64116
EPA Reg. No. : 1990-116,-184,-392,KS-83000400

Patterson Green-Up Co. Div of Curry Cartwright, Inc.
1400 Union Ave.
Kansas City, MO 64101
EPA Reg. No. : 2169-92

PBI/Gordon Corporation
1217 W. 12th St.- P. O. Box 4090
Kansas City, MO 64101
EPA Reg. No. : 2217-108

The Huge Company, Inc.
7625 Page Ave.
St. Louis, MO 63133
EPA Reg. No. : 2270-5

Research Products Co.
Box 1057
Salina, KS 67401
EPA Reg. No. : 2548-3,-13,-22,-30,-48

Chemi. Sol Chem. and Sales Co.
P. O. Box 1485
Hutchison, KS
EPA Reg. No. : 2618-2

Brayton Chem. Inc.
P. O. Box 437
West Burlington, IA 52655
EPA Reg. No. : 2993-7,-14,-23

Ferguson Fumigants, Inc.
93 Ford Lane
Hazlewood, MO 63042
EPA Reg. No. : 3886-13,-18,-136

Stewart Sanitary Supply Co., Ltd
P. O. Box 15061
St. Louis, MO 63110
EPA Reg. No. : 43954-6

Kaw Valley, Inc.
1801 S. 2nd St.
Leavenworth, KS 66048
EPA Reg. No. : 44215-58,-59,-60,-61,-62

REGION VIII (3)

Lystad Inc.
Box 1718
Grand Forks, ND 58201
EPA Reg. No. : 2881-21

Falls Chemicals Inc.
P. O. Box 2345
Great Falls, MT 59403
EPA Reg. No. : 40831-21

Morgro Chem. and Energy Corp.
145 W. Central Ave.- P. O. Box 151048
Salt Lake City, UT 84115
EPA Reg. No. : 42057-98

REGION IX (5)

Stauffer Chem. Co.
1200 S. 47th St.
Richmond, CA 94804
EPA Reg. No. : 476-537,-1112,-1113,-1543

Hockwald Chem., Div. of Oxford Chem.
275 Valley Dr.
Brisbane, CA 94005
EPA Reg. No. : 1111-132

Coyne Chem. Co.
999 Anderson Dr., Suite 140
San Rafael, CA 94901
EPA Reg. No. : 3050-23

Cardinal Chem. Co.
Green and Sansome Streets
San Francisco, CA 94111
EPA Reg. No. : 5440-6,-20,-22

Siskiyou County Dept. of Agriculture
525 S. Foothill Dr.
Yreka, CA 96097
EPA Reg. No. : CA79027400

REGION X (1)

Atomic Chem. Co.
Box 1111
Spokane, WA 91210
EPA Reg. No. : 6152-5,-6

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

JAN 15 1976

OFFICE OF ENFORCEMENT

SUBJECT: Enforcement of Administrator's Decision and Order Suspending Most Uses of Heptachlor and Chlordane

TO: Enforcement Division Directors
Pesticide Branch Chiefs

FROM: A. E. Conroy II, Director
Pesticides Enforcement Division (EN-342)

A E Conroy II

I. LEGAL DEVELOPMENTS

[redacted] istrator on the Suspension of Heptachlor-Chlordane (In re Velsicol Chemical Corporation, et al., FIFRA Docket No. 384) ordered the suspension of registrations of all pesticide products containing heptachlor or chlordane for use on corn, household, garden, lawn, and turf pests, use against ticks and chiggers, and use as a constituent in shelf paper. This Final Order reversed the December 12, 1975, "Recommended Decision" of Chief Administrative Law Judge Herbert L. Perlman dismissing the Administrator's July 29, 1975, "Notice of Intent to Suspend."*

On January 8, 1976, the Agency filed a "Suggestion for Clarifcation" (attached) requesting the Administrator to adopt the Agency's interpretation of the meaning and limitations of the Final Order. The Administrator has requested briefs on the issue of the appropriateness of a clarification.

Finally, appeals have been filed by the Environmental Defense Fund (in the Court of Appeals for the District of Columbia Circuit) and by Velsicol (in the Court of Appeals for the Sixth Circuit). The Velsicol appeal of the District Court's denial of its motion for preliminary injunction against the Administrator's issuance of the July

* Copies of the Administrator's "Conclusions" and the "Order" are attached.

29, 1975, "Notice of Intent to Suspend" remains in abeyance in the Sixth Circuit as well.

II. CURRENT AGENCY ACTIVITY

The office of the Hearing Clerk is preparing to serve by certified mail copies of the Final Order on all parties to the suspension proceeding. In addition, the Registration Division is preparing to notify all registrants by letter of their status under the Order and of what label amendments, if any, are necessary for them to continue the registration of their products in accordance with the Order.

III. ENFORCEMENT

The Pesticides Enforcement Division is preparing a general strategy to enforce the Administrator's Order. This strategy will provide status of registrants vis a vis the cancellation and suspension proceedings, lists of formulators and distributors of chlordane and heptachlor products, and status of product uses as clarified by any subsequent Orders.

Pending the completion of this strategy, regions should proceed with normal surveillance and inspection activities relating to chlordane and heptachlor products. Enforcement actions should await official notice of suspension to subject registrants.

Until that time you may find it helpful to deal with general inquiries as follows.

1) So far as PED is able to determine at this time, stocks of products intended for suspended uses which were formulated after July 29, 1975, are illegal for further shipment, sale or use.

2) Persons desiring to dispose of illegal stocks may arrange with involved regions to ship the products for assorted disposal, including for return to a supplier, for export, or in accordance with directions provided by the Office of Solid Waste Management. Disposal questions may be referred to Ray Kreuger in Washington at (202) 755-8050. Regional offices should cooperate in every way possible with responsible efforts to dispose of suspended chlordane/heptachlor stocks.

3) Questions relating to label status should be referred to Tim Gardner of the Registration Division, Washington, (202) 426-9425. As soon as firm policy exists as to this issue you will be informed of its substance.

Should you have questions concerning any facet of the chlordane/heptachlor suspension, please contact the appropriate regional coordinator.

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

JAN 22 1976

OFFICE OF ENFORCEMENT

SUBJECT: Clarification of Heptachlor/Chlordane Suspension Order

TO: Enforcement Division Directors
Pesticide Branch Chiefs

FROM: A. E. Conroy II, Director
Pesticides Enforcement Division (EN-342) A E Conroy II

Please find attached a copy of the Administrator's "Clarification of Order of December 24, 1975 (In re Velsicol Chemical Corporation et al., FIFRA Docket No. 384)," dated January 19, 1975. Although the Administrator did not adopt per se Respondent EPA's proposed order and table for clarification (see my January 15th memorandum and enclosures), this document makes patent that all registrations (Federal and State) of pesticide products containing heptachlor and chlordane for uses not specifically continued (as set forth in paragraph 4 of the Conclusion to the December 24th Decision) were suspended. For purposes of enforcement, "Attachment A" will be used as the list of uses not suspended.

Should questions arise concerning the Clarification, or any other matter relating to the heptachlor/chlordane proceedings, please contact the appropriate regional coordinator.

UNITED STATES OF AMERICA
ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

Velsicol Chemical Corporation et al., Registrants.	)	FIFRA Docket No. 384

CLARIFICATION OF
ORDER OF DECEMBER 24, 1975

On January 7, 1975, Respondent EPA filed a Suggestion for Clarification of the Order of December 24, 1975, in the above-captioned proceeding, seeking clarification of the uses of products containing heptachlor and chlordane for which registrations are not suspended by the December 24 Decision and Order. Respondent also submitted a Proposed Order, including an attachment setting forth a proposed list of uses not suspended, together with certain explanatory notes.

On January 13, 1976, I issued a notice of the filing of Respondent's Suggestion for Clarification and Proposed Order and requested written comments from the parties, thereby indicating my intention to consider the possible need for clarification of the December 24 Decision and Order.* On January 15, 1976, written comments were received from counsel for Velsicol Chemical Corporation; counsel for the Pineapple Growers Association of Hawaii and the Attorney General and Department of

* Written comments in response to Respondent's suggested clarification were submitted by counsel for Velsicol Chemical Corporation on January 12, 1976, but not sufficiently in advance of the preparation of the January 13 notice to be considered therein.

Agriculture of the State of Hawaii; counsel for some 300 registrants of various products containing heptachlor or chlordane; the Environmental Defense Fund; the U.S. Department of Agriculture; and Respondent EPA. All of the foregoing parties, except the Environmental Defense Fund, oppose Respondent's suggested clarification of the December 24 Order, both on grounds that the Administrator lacks jurisdiction or authority to clarify, modify, or alter the Order and that the Order is final and cannot now be changed in the manner proposed by Respondent.

Even though not expressly provided for in the Rules of Practice governing expedited hearings under the FIFRA, I have determined that authority does exist to clarify the December 24 Order and that some clarification is warranted, in view of the apparent possibility that its provisions may be unclear. In my view, the December 24 Decision and Order are clear and specific in their terms and should not require any further elaboration. Implicit in Respondent's suggested clarification, however, is the notion that proper administration of the Decision and Order by the Agency and explicit understanding thereof by all the parties require a clear statement of the uses of products containing heptachlor and chlordane for which registrations have not been suspended. In an abundance of caution and concern, therefore, I believe proper administration of the Decision and Order will be served and facilitated by the following clarification of the December 24 Order.

In reviewing the Decision and Order and the possible need for clarification, I have not considered any new evidence or argumentation. I have sought only to discern any possible source or sources of any lack of clarity in the expression of my intentions at the time I issued the Decision and Order. Comments received from the parties have been most helpful in determining whether or not my intentions were clearly expressed. The sole purpose of this clarification is to add clarity to the expression of my intentions at the time I issued the December 24 Decision and Order.

The December 24 Order, by its terms, provides that all pesticide products containing heptachlor or chlordane for use (1) on corn pests, (2) on household, garden, lawn, and turf pests (both by private homeowners and by pesticide control operators), (3) against ticks and chiggers, and (4) as a constituent in shelf paper, are suspended [the suspension of products for use on corn having a post-effective date of August 1, 1976]. The Order further provides that any stocks of technical grade heptachlor or chlordane formulated into products intended for such uses [after July 29, 1975] may not be placed in commerce, sold, or used for such purposes or any other purpose not specifically exempted [in the November 18, 1974, cancellation order] or specifically permitted in accordance with the Decision of the Administrator attached thereto.

The uses specifically permitted or continued by the Decision accompanying the December 24 Order include only those set forth in paragraph 4 of the Conclusions contained in the Decision* and, therefore, these uses (together with the exempted uses for subsurface ground injection for termite control and dipping of roots or tops of nonfood plants) are the only uses not suspended by the December 24 Decision and Order. All other registrations for uses of products containing heptachlor or chlordane are suspended. Because the words "intended for such uses" in line 12 of the Order might be interpreted as limiting the suspended uses to the four uses enumerated in the first sentence of the Order, the words "intended for such uses" are hereby deleted from the December 24 Order.

The reasons for the specific enumeration of four uses suspended in the first sentence of the Order, while suspending uses for "any other purpose" in blanket form in the second sentence, are twofold: (1) other than an occasional reference to certain fruits and vegetables and other miscellaneous crops, the record (including the Recommended Decision of the Administrative Law Judge) does not adequately address many other (presumably minor) uses of heptachlor and chlordane, as to which little or no benefits evidence was presented at the hearing, and, indeed, because the record was so inadequate in this regard, the Administrative Law Judge recommended that such other uses not be continued, and

* Decision of the Administrator, p. 76

(2) the four uses enumerated specifically in the December 24 Order are among the uses as to which sufficient benefits evidence was presented at the hearing to permit a risk-benefit assessment. Blanket suspension of uses as to which there was little or no evidence on benefits was necessary because the evidence on carcinogenicity risk was applicable to all uses. In view of the risk so established, and in the absence of sufficient benefits evidence as to uses for "any other purpose," it was of course necessary to suspend such other uses, even though (for the reasons indicated above) they could not be enumerated specifically in the Order.

As to the grouping of uses on "certain fruits and vegetables and other miscellaneous crops" [referred to in paragraph 5 of the Conclusions in the Decision], it was my intention that the provision in the Order applicable to uses for "any other purpose" apply as well to this grouping of uses. In stating that "the record in this proceeding is not sufficient to reach a conclusion" regarding this grouping of uses,* I stated only that the evidence on benefits was insufficient to permit the kind of discussion of the risk-benefit assessment which I had used for better documented uses. Therefore, with respect to this grouping of uses, I reached the same ultimate conclusion as discussed above concerning uses for

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* Decision of the Administrator, p. 76.

"any other purpose" generally, i.e. that, in view of the evidence on carcinogenicity risk, and in the absence of sufficient benefits evidence, these uses are suspended, even though they could not be enumerated specifically in the Order. Thus, there is no inconsistency between paragraph 5 of the Conclusions in the Decision and the provisions of the Order.

In view of the foregoing, I do not find it necessary to either adopt or reject the Proposed Order submitted by Respondent.

Russell E. Train

Dated: January 19, 1976

ATTACHMENT A

SPECIFIC USES[1] OF CHLORDANE & HEPTACHLOR NOT SUSPENDED BY ADMINISTRATOR'S ORDER OF 12/24/75

COMPOUND(s)	USE(s)	STATUS OF USE(s)
chlordane & heptachlor	Subsurface ground insertion for termite control[2,3]	continued
chlordane & heptachlor	Dipping of roots or tops of non food plants[2]	continued
chlordane & heptachlor[4]	Control of cutworms on corn (both pre and post emergence)	continued until 8/1/76 only
heptachlor[4]	Control of narcissus bulb fly	continued
heptachlor	Seed treatment	continued
heptachlor	Ant control to achieve pineapple mealy bug control in Hawaii[5]	continued
chlordane	In Federal/State quarantine programs for Japanese Beetle[6] and imported fire ant[5,6]	continued
chlordane	Control of black vine weevil on Japanese Yew in Michigan	continued
chlordane	Control of Texas harvester ant in Oklahoma	continued
chlordane	Control of imported fire ant by private individuals[5,7]	continued
chlordane	Control of white fringed beetle attacking food crops[8] in 8 S.E. States (AL, FL, GA, LA, MS, NC, SC, TN)	continued
chlordane	Control of soil insects[9] attacking Florida citrus	continued
chlordane	Control of strawberry root pests by pre-plant treatments	continued
chlordane	Control of white grubs in Michigan	continued

1. All registrations (Federal and State) of pesticide products containing heptachlor and chlordane for uses not specifically continued are suspended by the Administrator's Decision and Order on the Suspension of Heptachlor-Chlordane. The effect of the Order is to further prohibit the manufacture, formulation or reformulation of products containing Heptachlor or Chlordane for any purpose other than for those registered uses which have been exempted in the Order and for manufacturing uses as an interim step in the ultimate formulation for such registered uses. Sale and use of existing stocks of registered products which were formulated prior to July 30, 1975 are permitted for both continued and suspended uses.
2. PR Notice 74-11 (39 FR 41298) exempted this use from cancellation. Such use was similarly exempted from the Notice of Intention to Suspend, 40 FR 34456 (7/29/75).
3. Clarified at 40 FR 30522 (7/21/75) to apply to the use of emulsifiable or oil concentrate formulations for controlling subterranean termites on structural sites such as buildings, houses, barns, and sheds, using current control practices.
4. Velsicol has represented that it would voluntarily suspend domestic shipments of heptachlor for this use pending resolution of the cancellation proceedings.
5. On the assumption that Mirex is not available.
6. To include treatments required to certify to pest-free conditions as well as for use in suppression and control programs.
7. To include use on both public and private property by either owner, agent, employee, or contractor.
8. Not intended to preclude use on cotton. However, use on tobacco is suspended.
9. Restricted to citrus root weevils.

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

FEB 19 1976

OFFICE OF ENFORCEMENT

SUBJECT: Status Report on the Heptachlor/Chlordane Suspension

TO: Enforcement Division Directors
Pesticides Branch Chiefs

FROM: A. E. Conroy II, Director
Pesticides Enforcement Division

The purpose of this informational memorandum is to keep you abreast of Agency activity relating to the Administrator's suspension of most heptachlor/chlordane registrations.

The Office of the Hearing Clerk has completed an uncertified mail service of the final order and the clarification in the heptachlor/chlordane proceeding to the approximately 425 parties involved. The Agency has sent to the Federal Register the "Notice of Intent to Suspend," the "Initial Decision," the "Administrator's Decision and Order," and the "Clarification" for publication. An expedited publication is expected.

The Registration Division is currently in the process of serving by certified mail a notice of suspension to all affected registrants of heptachlor/chlordane products. Please find attached three form letters being used to notify registrants of their products' status under the December 24 Order. These letters will apprise the particular registrant that it's products registration (1) has been finally suspended, (2) was suspended, but by discontinuing the use of heptachlor and chlordane in the product's formulation, continued registration is permitted, or (3) was suspended, but may continue to be sold and distributed if the registration is provisionally amended.

You will be receiving shortly a region specific list of all suspended registrations on the basis of which you may begin surveillance and enforcement activities to ensure compliance with the Administrator's order.

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

CERTIFIED MAIL

Gentlemen:

Subject : Notice of Suspension for:

On December 24, 1975, the Administrator issued his Decision and Order on the suspension of Heptachlor and Chlordane. Most federal and state registrations of Heptachlor and Chlordane were suspended although certain uses were specifically exempted, (Refer to the enclosure). Any registration which included a suspended use was suspended effective December 24, 1975. This letter is to notify you that your above registration contained a use suspended by the Order and therefore has been suspended effective December 24, 1975.

If you wish to be permitted to continue your registration, you have two alternatives. First, you may simply discontinue the use of Chlordane or Heptachlor in the formulation of your product. If you select this approach you will not be required to submit a petition for an amendment if your product contains no other insecticides and all insecticide claims are eliminated. If other insecticides are contained you must apply for an amended label which in certain instances may require new efficacy data. If you wish to continue to formulate your product with either Heptachlor or Chlordane you may continue to do so only for uses not suspended and only after you have submitted a petition for a label amendment in which all references to suspended uses have been deleted.

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

CERTIFIED MAIL

Gentlemen:

Subject : Notice of Suspension for:

On December 24, 1975, the Administrator issued his Decision and Order on the suspension of Heptachlor and Chlordane. Most federal and state registrations of Heptachlor and Chlordane were suspended although certain uses were specifically exempted (Refer to the enclosure). Any registration which included a suspended use was suspended effective December 24, 1975. This letter is to notify you that your subject registration contained a use suspended by the Order and therefore has been suspended effective December 24, 1975.

If you wish to be permitted to continue to formulate and/or sell Heptachlor and/or Chlordane for uses not suspended, you will be required to petition for a provisional amendment of registration. Such petition should request the elimination from your labels of any reference to suspended uses. It is sufficient to send a cover letter with an amended label or label in which the suspended uses including any claims referring to these uses have been blocked out. The granting by the Agency of such a petition will permit you to continue formulation and/or sale of Heptachlor and/or Chlordane for exempted uses. Petitions for a provisional labeling amendment in accordance with the enclosure must be received within 30 days of receipt of this letter at the following address:

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

CERTIFIED MAIL

Gentlemen:

Subject : Notice of Suspension for:

This is to notify you that on December 24, 1975, the Administrator issued his Decision and Order on the suspension of Chlordane and Heptachlor.

This document provides that all uses of Chlordane and Heptachlor are suspended except those set forth on the enclosure. Your subject registration was suspended effective December 24, 1975.

As stipulated in the Administrator's Notice of Intent to Suspend, issued on July 29, 1975, the product under this registration may not be formulated, shipped, sold or used after July 29, 1975.

The Administrator's Decision and Order will be published in the Federal Register in the near future.

Sincerely yours,

John B. Ritch, Jr.
Director
Registration Division (WH-567)

Enclosure

It is sufficient to send a cover letter with an amended label or lab in which the suspended uses including any claims referring to these uses have been blocked out. The granting by the Agency of such a petition will permit you to continue formulation and/or sale of Heptachlor and/or Chlordane for exempted uses. Petitions for a provisional labeling amendment in accordance with the enclosure must be received within 30 days of receipt of this letter at the following address:

Mr. Timothy A. Gardner
Product Manager (15)
Registration Division (WH-567)
Environmental Protection Agency
Washington, D.C. 20460.

The amendment will not abrogate your right to defend both suspended or nonsuspended uses in the continuing cancellation proceeding.

Existing stocks of EPA registered pesticides containing Heptachlor or Chlordane may be distributed and sold for suspended uses only if the stocks were formulated prior to July 30, 1975. This date was stipulated in the Administrator's Notice of Intent to Suspend, issued on July 29, 1975. Stocks of Heptachlor or Chlordane formulated after July 29, 1975, may only be distributed and sold for those exempted uses included in the enclosure and under labels containing no suspended uses. Stocks which you may presently have on hand, if manufactured or formulated after July 29, 1975, may not be shipped or sold until you receive EPA appr[illegible] of your amended label.

The Administrator's Decision and Order will be published in the Federal Register in the near future.

Sincerely yours,

John B. Ritch, Jr.
Director
Registration Division (WH-567)

Enclosure

SPECIFIC USES OF CHLORDANE & HEPTACHLOR
NOT SUSPENDED BY ADMINISTRATOR'S ORDER OF 12/24/75

COMPOUND(s)	USE(s)	STATUS OF USE(s)
chlordane & heptachlor	Subsurface ground insertion for termite control [2,3]	continued
chlordane & heptachlor	Dipping of roots or tops of non food plants [2]	continued
chlordane & heptachlor [4]	Control of cutworms on corn (both pre and post emergence)	continued until 8/1/76 only
heptachlor [4]	Control of narcissus bulb fly	continued
heptachlor	Seed treatment	continued
heptachlor	Ant control to achieve pineapple mealy bug control in Hawaii [5]	continued
chlordane	In Federal/State quarantine programs for Japanese Beetle [6] and imported fire ant [5,6]	continued
chlordane	Control of black vine weevil on Japanese Yew in Michigan	continued
chlordane	Control of Texas harvester ant in Oklahoma	continued
chlordane	Control of imported fire ant by private individuals [5,7]	continued
chlordane	Control of white fringed beetle attacking food crops [8] in 8 S.E. States (AL, FL, GA, LA, MS, NC, SC, TN)	continued
chlordane	Control of soil insects [9] attacking Florida citrus	continued
chlordane	Control of strawberry root pests by pre-plant treatments	continued
chlordane	Control of white grubs in Michigan	continued

1. All registrations (Federal and State) of pesticide products containing heptachlor and chlordane for uses not specifically continued are suspended by the Administrator's Decision and Order on the Suspension of Heptachlor-Chlordane. The effect of the Order is to further prohibit the manufacture, formulation or reformulation of products containing Heptachlor or Chlordane for any purpose other than for those registered uses which have been exempted in the Order and for manufacturing uses as an interim step in the ultimate formulation for such registered uses. Sale and use of existing stocks of registered products which were formulated prior to July 30, 1975 are permitted for both continued and suspended uses.
2. PR Notice 74-11 (39 FR 41273) exempted this use from cancellation. Such use was similarly exempted from the Notice of Intention to Suspend, 40 FR 34456 (7/29/75).
3. Clarified at 40 FR 30522 (7/21/75) to apply to the use of emulsifiable or oil concentrate formulations for controlling subterranean termites on structural sites such as buildings, houses, barns, and sheds, using current control practices.
4. Velsicol has represented that it would voluntarily suspend domestic shipments of heptachlor for this use pending resolution of the cancellation proceedings.
5. On the assumption that Mirex is not available.
6. To include treatments required to certify to pest free conditions as well as for use in suppression and control programs.
7. To include use on both public and private property by either owner, agent, employee, or contractor.
8. Not intended to preclude use on cotton. However, use on tobacco is suspended.
9. Restricted to citrus root weevils.

Mr. Timothy A. Gardner
Product Manager (15)
Registration Division (WH-567)
Environmental Protection Agency
Washington, D.C. 20460.

The amendment will not abrogate your right to defend both suspended or nonsuspended uses in the continuing cancellation proceeding.

Existing stocks of EPA registered pesticides containing Heptachlor or Chlordane may be distributed and sold for suspended uses only if the stocks were formulated prior to July 30, 1975. This date was stipulated in the Administrator's Notice of Intent to Suspend, issued on July 29, 1975. Stocks of Heptachlor or Chlordane formulated after July 29, 1975, may only be distributed and sold for those exempted uses included in the enclosure and under labels containing no suspended uses. Stocks which you may presently have on hand, if manufactured or formulated after July 29, 1975, may not be shipped or sold until you receive EPA approval of your amended label.

The Administrator's Decision and Order will be published in the Federal Register in the near future.

Sincerely yours,

John B. Ritch, Jr.
Director
Registration Division (WH-567)

Enclosure

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

23 MAR 1976

OFFICE OF ENFORCEMENT

SUBJECT: Heptachlor/Chlordane Suspension Order Enforcement Strategy

TO: Enforcement Division Directors
Pesticide Branch Chiefs

FROM: A. E. Conroy II, Director
Pesticides Enforcement Division

In my memorandum of February 19, 1976 regarding the status of Agency activity on the Administrator's December 24th Order suspending most heptachlor and chlordane product registrations, I alerted the appropriate Regional personnel that a more specific strategy for ensuring compliance would be forthcoming. This memorandum presents EPA's enforcement strategy concerning the three categories of these products: (A) Federally registered products, all uses of which have been suspended; (B) Federally registered products, some uses of which were suspended, but which may continue to be sold and distributed for continued uses upon amendment of the product's registration and labeling to delete any suspended uses; and (C) intrastate products afforded the opportunity to continue in intrastate commerce until the completion of the cancellation proceedings.

I. SUSPENSION ORDER PROVISIONS

In previous memoranda, the terms of the Administrator's Suspension Order have been discussed. To recap, the December 24th Order and January 19th Clarification provide the following:

(1) All registrations of pesticide products containing heptachlor and chlordane for uses not specifically continued [see "Attachment A - - Specific Uses of Chlordane and Heptachlor Not Suspended by Administrator's Order of 12/24/75" for the list of uses exempted] were suspended as of December 24, 1975.

(2) By invoking the "Special Rule" provision of section 15(b)(2), the Administrator has provided that stocks of EPA registered pesticides containing heptachlor or chlordane formulated prior to July 30, 1975, may be sold, distributed, or used for suspended uses.

(3) Stocks of heptachlor or chlordane products formulated after July 29, 1975 may be sold, distributed, or used only for exempted uses, as per "Attachment A".

II. CATEGORIES OF HEPTACHLOR/CHLORDANE PRODUCTS

As stated above, there are three categories of heptachlor/chlordane products:

(A) Federally registered products, all uses of which have been suspended. The Registration Division/Office of Pesticide Programs has notified, by certified mail, all affected registrants that their products have been finally suspended by the December 24th Order. 1/ An example of a product in this category would be a product registered for use only on ticks and chiggers. There are approximately 644 products registered by over 300 registrants which have been so suspended. You will find attached to this memorandum a list of suspended product registration numbers, product names, registrant names, and the names and addresses where such heptachlor/chlordane products have been produced.

(B) Federally registered products, some uses of which have been suspended. As noted in the introduction and in previous memoranda, there is a large category of registered products whose uses were suspended in part by the December 24th Order, but whose sale and distribution may continue upon ["provisional"] amendment of the product's registration and labeling to delete all suspended uses. A typical product in this category would be one registered and labeled for indoor roach control and for subterranean termite uses (the former being a suspended use, while the latter is a permitted use). Pending the decisions by the registrants to amend or not [such decision must be made within 30 days of receipt of the notice of suspension], it is not possible to determine the registration status of products in this category. Upon RD's completion of the necessary registration review, a region specific list will be forwarded to you noting the status of individual products in this category.

(C) Intrastate products. Although this third category is comprised of products similarly situated to those in above categories (A) and (B), for purposes of this enforcement strategy, "intrastate products" are being treated separately. The Registration Division has notified the

1/ See my February 19, 1976 memorandum entitled "Status Report on the Heptachlor/Chlordane Suspension," and its attachments.

registrants of 140 "intrastate" products as to the impact of the December 24th Order on their heptachlor/chlordane products. These products were being sold only in intrastate commerce when they became subject to the FEPCA registration requirements by the accelerated activation of section 3 in November 1974. Subsequently, all applications for Federal registration were denied and the applicants who timely requested a hearing were made parties to the cancellation proceeding and the subsequent suspension hearings. Accordingly, these products were equally affected by the December 24th Order in that to continue marketing them, registrants must delete suspended uses from their labeling. Please note the attached three Registration Division form letters used to apprise this category of registrants as to their products' status. You will find an attached list of forty-eight products in this category whose sale, distribution, and use was prohibited as of December 24, 1975, for formulations made after July 29, 1975. As soon as the suspension status of the remaining products in this category is available, you will be advised.

III. ENFORCEMENT POLICY

The Agency intends to ensure that the Administrator's Order of December 24th is strictly complied with by all affected persons, including manufacturers, formulators, registrants, wholesalers, retailers, and users. The Administrator, in his December 24th Order, provided that products formulated prior to July 29, 1975, should be permitted distribution and use through normal channels of trade until the stocks are exhausted. Affected persons were informed of the consequences of formulating after July 29th--those that chose to continue formulation despite the Notice of Intent to Suspend did so at their own risk. The Agency wants to ensure that the pesticide producing industry does not interpret a Notice of Intent to Suspend as a signal to increase production of the subject product during the pendency of the suspension proceeding.

It has been the general policy of the Agency to request national recall where product registrations have been suspended in order to prevent an imminent hazard to man or his environment. That policy will be applied in the instant case. As the initial step in implementing this policy, EPA has requested the recall, down to and including the retail level, of all heptachlor/chlordane products for which all uses were suspended and which were formulated after July 29, 1975 [category A products]. In addition, the Agency intends to request the recall--in some instances for relabeling--of all heptachlor/chlordane products formulated after July 29, 1975

whose labels contain both suspended and non-suspended uses [category B products]. "Intrastate" products [category C products] will be treated in a manner consistent with similarily situated Federally registered products.

IV. ENFORCEMENT ACTIONS.

As has been the established policy in such matters, enforcement actions will be taken, in accordance with normal procedures and at levels consistent with those provided for in the Pesticides Enforcement Division Case Proceedings Manual, against all persons found in violation of the heptachlor/chlordane suspension order.

There exist a number of enforcement action options available to ensure compliance with the Administrator's Suspension Order. As previously stated, the Agency has determined that a national recall of violative products would be the most effective and efficient means of ensuring compliance with the suspension order. Because of the extra-ordinary number of products and firms which are affected by the December 24th Order and the commensurate amount of Agency resources which would be involved in conducting a formal recall, the Agency feels that the procedures outlined in the Case Proceedings Manual, Chapter 12, for informal recalls would be more appropriate in this matter. Information and guidance with respect to specific enforcement related actions which may be directed toward each of the aforementioned categories of heptachlor/chlordane products follows:

(A) Federally registered products, all uses of which were suspended and which were formulated after July 29, 1975. As per recall initiation procedures, the Pesticide Enforcement Division has notified by certified mail those registrants who had all uses of their heptachlor/chlordane product(s) suspended by the December 24th Order, that EPA is requesting that all subject products formulated after July 29, 1975, be recalled immediately. This letter, a copy of which is attached to this memorandum, refers the addressee to the Registration Division suspension letter informing the registrant of the registration status of his product(s), and continues by specifically requesting that (a) the company initiate procedures to determine the locations of all quantities of their finally suspended product and the amount of such product at each such product location, (b) that the product be returned to the registrant from all locations, and (c) that the named regional contact person be informed of all actions taken in connection with the recall.

In your follow-up to determine compliance with the recall request, you should:

(1) be assured that the registrant has recalled the product from the retail level, and either

(i) disposed of the product,

(ii) exported product in accordance with section 17, or 2/

(iii) sought new registration for continued uses;

(3) stop sale any such product found in consumer channels under section 13; and

(4) where appropriate, initiate enforcement action under section 14. 3/

(B) Federally registered products with both suspended and continued uses and which were formulated after July 29, 1975. As soon as these products can be identified as to their registration status, PED will request each registrant to contact all known distributors, wholesalers, and retailers that the subject product should not be sold or otherwise distributed. Registrants will be instructed that they should recall from retail level as set forth above for category A products.

When following-up to determine compliance with the recall of these products, you should:

(1) be assured that the registrant has recalled the product from the retail level, and either

(i) disposed of product if amendment to labeling is not made,

(ii) exported product in accordance with section 17,

(iii) relabeled product with amended label deleting suspended uses, or

(iv) in accordance with EPA approved instructions, overlaid product with approved sticker labels, masked out suspended uses, or used other means to delete suspended uses from the labels;

2/ Registrants should be informed that the Agency would interpose no objection to the export of products affected by the suspension order, but wishes to caution registrants concerning the recent stipulation signed by the Department of State concerning the utilization of US funds for USAID procurements of such products. See USAID regulation entitled "Pest Management Program, Interim Pesticide Procedures," published in the Federal Register on January 7, 1976.

3/ Those persons who distribute or sell a suspended heptachlor/chlordane product in violation of the terms of the December 24th Suspension Order will be in violation of section 12(a)(1)(A) for non-registration, as well as section 12(a)(2)(J) for violation of a section 6 suspension order.

(2) stop sale any such product found in consumer channels under section 13; and

(3) where appropriate, will initiate enforcement action under section 14. 3/

(C) Intrastate products. The policies outlined above will also apply, as appropriate, to intrastate products as they become identified. At present, the 48 products thus far identified will be treated the same as Federally registered products, all uses of which have been suspended [category A products].

Now that all parties affected by the Administrator's Decision and Order in the heptachlor/chlordane suspension proceedings have been duly notified of this action and of their obligations attendant thereto, the Agency places the highest priority on assuring full and immediate compliance. The initiation and follow-up of the heptachlor/chlordane recall herein authorized will represent a significant addition to existing regional enforcement burdens. It is anticipated that regions will exercise initiative and energy in performing, in addition to programmed outputs, the surveillance, inspections, enforcement actions, and routine follow-up necessary to implement this recall.

The region should report the following information to the appropriate regional coordinator as soon as available:

(1) the number of firms subject to recall;

(2) the amount of each product recalled; and

(3) the methods of actual or planned disposal of recalled material.

V. DISPOSAL OF HEPTACHLOR/CHLORDANE PRODUCTS

Persons desiring to dispose of stocks of heptachlor/chlordane should be apprised that they may arrange with the appropriate regions to ship the product for disposal, including return to a supplier, for export, or in accordance with directions provided by the Office of Solid Waste Management. Disposal questions may be referred to Mr. Ray Kreuger, Operations Divison, Office of Pesticide Programs [(202) 755-8050]. Regional offices are encouraged to cooperate in every way possible with responsible efforts to dispose of suspended heptachlor/chlordane stocks.

VI. INDEMNITIES

The Office of Enforcement has been advised by the Office of General Counsel that the registrants of heptachlor/chlordane products suspended by the December 24th Order are not eligible for indemnification under section 15 of the amended FIFRA.

VII. INQUIRES

Should you have any questions concerning any facet of this memorandum and the heptachlor/chlordane suspension order, please contact the appropriate regional coordinator. Questions relating to registration and label status should be referred to Mr. Tim Gardner, Registration Division, Office of Pesticide Programs [(202) 426-9425].

VIII. ATTACHMENTS

Please find attached the following:

(1) "Attachment A -- Specific Uses of Chlordane and Heptachlor Not Suspended by Administrator's Order of 12/24/75."

(2) Copies of recall request letters sent to registrants by PED.

(3) Three form letters sent by RD/OPP to "intrastate" heptachlor/chlordane registrants.

(4) 41 FR 7552 (February 19, 1976) -- "Velsicol Chemical Co. et al., Consolidated Heptachlor/Chlordane Hearing."

(5) List of Federally registered heptachlor/chlordane products, all uses of which have been suspended [category A products] was mailed by PED to the regional pesticide branch chiefs under separate cover March 17, 1976.

(6) List of the 48 "intrastate" heptachlor/chlordane products, all use of which were suspended [category C products].

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

27 AUG 1976

OFFICE OF ENFORCEMENT

TO: Enforcement Division Directors
Pesticides Branch Chiefs

FROM: A. E. Conroy II, Director
Pesticides and Toxic Substances
Enforcement Division (EN-342)

RE: Heptachlor/Chlordane Suspension Order
Enforcement Strategy -- CORN USE

Some confusion has arisen concerning the enforcement response to certain heptachlor/chlordane products now on the market which are labeled for use on corn pests. The Administrator concluded in In re Velsicol Chemical Corporation, et al. (Expedited Hearing On Heptachlor-Chlordane), 41 Fed. Reg. 7552 (February 19, 1976) that

> the benefits of continued use of heptachlor and chlordane to control cutworms on corn crops during the time which may be required to reach a final decision in the cancellation proceeding are not sufficient to outweigh the human health risks identified; provided, however that particularly in view of the difficult transition required to implement alternative cutworm control methods, the use of heptachlor and chlordane to control cutworm on corn crops should be permitted during the 1976 corn growing season. Accordingly, I have concluded that the registration for use of heptachlor and chlordane to control cutworms on corn crops should be suspended effective August 1, 1976. */

As you are aware, the Administrator's heptachlor/chlordane orders provide the following concerning the legal status of the various products:

*/ See also, "Clarification of Order of December 24, 1975," 41 Fed. Reg. 7552 (February 19, 1976).

1. With the exception of the corn use, all registrations of pesticide products containing heptachlor and chlordane for uses not specifically continued (e.g., chlordane to control black vine weevil on Japanese yew in Michigan), were suspended as of December 24, 1975. **/

2. By invoking the "Special Rule" provision of FIFRA section 15(b)(2), the Administrator has provided that stocks of EPA registered pesticides containing heptachlor/chlordane formulated prior to July 30, 1975, may be sold, distributed, or used for suspended uses, including use on corn.

3. Stocks of heptachlor or chlordane products formulated after July 29, 1975, may be sold, distributed, or used only for exempted uses [see "Attachment A," enclosed]. Thus, for example, a chlordane product whose sole registered use was for cutworm control on corn could legally be produced, distributed, sold, and used without violating the December 24 suspension order until this product became finally suspended on August 1, 1976.

You will remember that prior to our request for the recall of violative heptachlor/chlordane products, Registration Division, Office of Pesticide Programs advised affected registrants that if amended labeling which deleted all reference to suspended uses was submitted and approved by EPA, the relabeled product could continue in commerce. To accomodate those producers of agricultural products listing corn uses, a decision was made to allow the registrant to continue to display the directions for use on corn, provided the following disclaimer was inserted immediately after the crop designation: "USE SUSPENDED EFFECTIVE AUGUST 1, 1976." Ten companies exercised their option to relabel accordingly; the 19 products are as follows:

279-2656	NIAGARA CHLORDANE 5 COATED GRANULES
279-2904	CHLOR KIL 10 DUST INSECTICIDE
449-123	SURE DEATH BRAND HEPTACHLOR 3E
449-74	SURE DEATH BRAND HEPTACHLOR 2E
876-55	VELSICOL CHLORDANE 72EC SOIL INSECTICIDE
876-89	VELSICOL BELT 72 ECF
876-99	VELSICOL BELT 33.3 G AGRICULTURAL INSECTICIDE GRANULARS FOR SOIL INSECT CONTROL
876-102	VELSICOL BELT 72 EC AGRICULTURAL INSECTICIDE
876-172	BELT 40% WP AGRICULTURAL INSECTICIDE
148-139	CHLORDANE E-8
226-178	TASCO BRAND CHLORDANE 20 GRANULAR
226-219	TOBACCO STATES 50% CHLORDANE WETTABLE POWDER
228-92	RIVERDALE 25% CHLORDANE GRANULES

**/ To arrive at a result consistent with the Administrator's intent to suspend all use of chlordane/heptachlor on corn, regardless of target pest, the use of these pesticides to control the white fringed beetle attacking corn crops in eight southeastern states (AL, FL, GA, LA, MS, NC, SC, and TN) and to control white grubs on corn in Michigan is also precluded.

1029-77	AIDEX CHLORDANE 8E
2935-151	RED TOP CHLORDANE 8 SPRAY
9859-51	CHLORDANE 10 GRANULAR
9859-53	CHLORDANE 5 GRANULAR
9859-55	CHLORDANE 25 GRANULAR
14775	CHLORDANE-TOXAPHENE BAIT NO. 11 (Florida "intrastate" --Asgrow Florida Company, P.O. Drawer D, Plant City, FL)

Therefore, after December 24, 1975, no product produced after July 29, 1975 for corn use could be legally distributed or sold without the above mentioned disclaimer. The detection of such violative product will continue to receive Agency response in the form of a FIFRA section 13(a) Stop Sale, Use or Removal Order and section 14 action, as appropriate. It is the Office of Enforcement view that enforcement action, including SSURO's, should not be taken against the sale and distribution after August 1, 1976 of products bearing the disclaimer. The use of such product on corn after August 1, 1976 is in violation of the suspension order [§12(a)(2)(J)], as well as a misuse [§12(a)(2)(G)].

To summarize: (1) products formulated prior to July 30, 1975, including those with directions for use on corn, may continue to be sold, distributed, and used; (2) products formulated after July 29, 1975, may be sold, distributed, and used only with labeling amended to include only continued uses; and (3) products formulated after July 29, 1975, with directions for use on corn, must bear the following disclaimer immediately after the corn use directions: "USE SUSPENDED EFFECTIVE AUGUST 1, 1976."

The Agency is not contemplating at this time the recall of the above products for relabeling to delete reference to corn uses. At the conclusion of the cancellation proceeding, heptachlor/chlordane labels will be revised to conform with the Administrator's final order.

All inquiries in this matter should be referred to the appropriate regional coordinator.

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

23 NOV 1976

OFFICE OF ENFORCEMENT

To: Enforcement Division Directors
and Pesticide Branch Chiefs

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

Re: Continued Enforcement of the Suspension of Registration for Certain Products Containing Chlordane and Heptachlor

On August 1, 1976, the suspension of existing registrations of heptachlor/chlordane products for use on corn was effective as to all products formulated after July 29, 1975. Thus, the Administrator's suspension order of December 24, 1975 became completely effective as to all subject products formulated after August 29, 1975 and not already cancelled. The recall of subject products initiated in March 1976 is now essentially complete and a final report should be submitted to PTSED for inclusion in the heptachlor/chlordane file. Therefore, each region should prepare a Recall Final Report (Exhibit 14-E, Pesticides Inspection Manual) for each product subject to our recall request which was produced after July 29, 1975. This report should be submitted to the appropriate Regional Coordinator no later than December 31, 1976.

Recently the Court of Appeals for the D.C. Circuit sustained the Administrator's decision to suspend certain uses of chlordane and heptachlor in all but one important respect. (Environmental Defense Fund v. EPA, No. 76-1247 (D.C. Cir., decided Nov. 10, 1976)). With respect to the Administrator's decision to allow use of existing stocks, the court remanded for reconsideration of such issues as amounts of existing stocks and the problems involved in their return or disposal. How the Agency will proceed in meeting the requirements of the remand has not been determined.

Future surveillance for compliance with the Administrator's order should be routine except in the case of firms refusing to recall. Additional visits to producers and/or distributors may be necessary to assure compliance in these situations. Regarding enforcement actions, pending a final outcome on the issue of the remand, the following should be pursued. Any suspended heptachlor/chlordane product produced after July 29, 1975, and remaining in commerce should be stop saled. Additionally, since all but retail distributors should have been notified to return the violative products, any suspended products found in channels of trade above the retail level should be sampled and civil penalty actions issued to the distributor and/or the producer, as appropriate. Civil penalty actions should also be issued for any violative samples previously collected above the retail level. Beyond stop sale, decisions on the level of action to be applied at the retail level are left to regional discretion, though any repetition of violation or evidence of bad faith should warrant civil penalty action. This policy is reiterated now because a period of grace was previously allowed for return or disposal of violative stocks. Now that the recall is complete and the suspension order close to a year old, such leniency is no longer appropriate.

Finally, in several instances recently, questions have arisen concerning indemnities. The Agency's position has been that such requests pursuant to section 15 of the Act are inappropriate in the absence of a final order of cancellation. (See letter attached).

Enclosures:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

12 OCT 1976

Mr. Ralph Engel
Executive Director
Chemical Specialties Manufacturers
Association, Incorporated
1001 Connecticut Avenue, N.W.
Suite 1120
Washington, D. C. 20036

Dear Mr. Engel:

Your letter of August 30, 1976, has been referred to this office for reply. Because of the Administrator's ongoing role in the chlordane/heptachlor proceedings, it would be improper under the Agency's rules of practice for him to respond to your inquiry.

Your letter asks that the Administrator invoke the "special rule" under §15(b)(2), in order to allow inventories of chlordane products formulated between July 29, 1975, and December 24, 1975, and currently on dealer shelves, to be sold until such stocks are exhausted.

Your request would necessitate modification of the order issued by the Administrator on December 24, 1975. Requests for such modifications must be made in conformance with the rules of practice set forth in 40 CFR Part 164. See especially 40 CFR 164.6(b), concerning enlargement of filing periods; 40 CFR 164.31, concerning intervention; and 40 CFR 164.110, concerning motions for reconsideration of orders.

CONCURRENCES								
SOL ▷	A-132	A-132						
SURNAME ▷								
DATE ▷	9/29/76	10/5	10/8					

OFFICIAL FILE COPY

Finally, candor requires that I inform you that the Agency staff would oppose any such motion to modify the suspension order, should one in fact be filed. Essentially, this is because the suspension order is a temporary order, which ultimately will be superceded by an order at the termination of the cancellation proceeding. The question of the extent to which distribution of existing stocks of chloroxane products should be allowed can and should be addressed in the cancellation proceeding, and resolved in the order at the conclusion of that proceeding. Sound considerations of procedural management militate against interruption of the cancellation proceeding to consider this question at this time.

Sincerely,

G. William Frick

G. William Frick
General Counsel (A-130)

CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION, INCORPORATED
EXECUTIVE OFFICES • SUITE 1120 • 1001 CONNECTICUT AVE., N.W., WASHINGTON, D.C. 20036 • (202) 872-8110

August 30, 1976

Mr. Russell E. Train
Administrator, EPA
401 M Street, S.W., Room W1200
Washington, D.C. 20460

Dear Mr. Train:

On August 16, CSMA counsel Robert Ackerly and Roger Copland of my staff met with several Agency officials, including those from the Enforcement Division and the Office of General Counsel, to discuss the situation pertaining to products containing chlordane.

Pursuant to that meeting, I hereby request that you invoke the Special Rule of §15(b)(2) and allow inventories of chlordane products formulated between July 29, 1975 and December 24, 1975 and currently on dealer shelves to be sold until such stocks are exhausted.

There are several reasons for this request:

1) Recall is in most cases a practical impossibility and constitutes an economic hardship, particularly to smaller formulators. There are literally thousands of small retailers who may have a few units of chlordane products in stock. It is not always possible for the formulator to ascertain where such products are being sold. If stocks are discovered, compliance with Department of Transportation regulations governing the shipment of hazardous materials becomes a major problem, especially in view of the fact that substantial numbers of retailers will have only a few units of various brands.

2) Invocation of the Special Rule will not create a health hazard. Use of the products as directed may be the safest way of disposing of remaining stocks. The remaining supply of chlordane products does not, in relative terms, constitute a large amount. We estimate that between 1,800,000

to 3,600,000 units remain on the shelves of some 75,000 retail dealers. While the recall or stop-sale of these units would have an adverse economic impact on many formulators, their normal, generally outdoor use would not significantly exacerbate a situation that has been ongoing for some 26 years. Furthermore, we have heard that some dealers are simply flushing unmarketable units away, thereby possibly creating a potential hazard more pronounced than that created by accepted uses before suspension. Indeed, safe disposal remains a problem for the formulator.

3) There has been some ambiguity concerning the sale of chlordane that has left a number of formulators confused and uncertain. On July 29, 1975 you, in your Notice of Intent to Suspend, announced that you were invoking the Special Rule for those products formulated as of the date of the notice. We believe that this action should have been taken when the registrations of chlordane for most uses was suspended on December 24, 1975. Had you issued an emergency suspension order on July 29th, the Special Rule could have been invoked. By letter dated September 23, 1975, the Office of General Counsel indicated that the sale of products formulated <u>after</u> July 29th was legal until final suspension decision was made. On December 24, you suspended most registrations and stated that products formulated after July 29th could not be sold. On March 23, 1976 the Enforcement Division requested formulators to undertake a <u>voluntary</u> recall of products formulated after July 29th. The net effect of these actions has been to engender confusion in many people over the mandatory nature of a ban on sales. While perhaps not decisive, we believe this factor should in good faith be considered.

4) Harassment of dealers by some Enforcement officials, especially in the Northeast, has fostered resentment of the Agency as a whole and, in some cases, strained relations along the distribution chain. The orderly sale of remaining inventories would reverse these counterproductive tensions.

Of course, should you invoke the Special Rule, it would alleviate indemnification problems that will arise with respect to products formulated prior to the Suspension Order.

I look forward to hearing from you concerning this important matter.

Sincerely,

Ralph Engel

Ralph Engel
Executive Director

RE:kas
cc: A.E. Conroy

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

APR 13 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Revised Compliance Strategy for the Cancellation and Suspension of Chlordane and Heptachlor Termiticides

FROM: John J. Neylan III, Director
Policy and Grants Division
Office of Compliance Monitoring

TO: Addressees

On February 23, 1987, in the case of the National Coalition Against the Misuse of Pesticides vs. EPA, the U.S. District Court ruled that the Agency's allowance of the continued sale and use of all cancelled chlordane and heptachlor products was void, and ordered EPA to take "whatever action is necessary ... so that on and after April 15, 1988, sales, commercial use, and commercial application of existing stocks of chlordane and heptachlor which have been the subject of voluntary cancellation shall cease..." Since sale, distribution, and use of Velsicol's chlordane and heptachlor products are already prohibited after April 15, 1988, the District Court Decision effectively only applies to the non-Velsicol chlordane and heptachlor products which have been voluntarily cancelled.

In order to implement that Court Decision, on April 5, 1988, EPA issued a "Chlordane/Heptachlor Termiticides; Notification of Cancellation and Amendment of Existing Stocks Determination." That Notice informed the public that the registrations of the products listed in that Notice are cancelled (see Appendix C for this list), and that it is a violation of the cancellation order for any person to distribute, sell, offer for sale, hold for sale, deliver for shipment, receive (and having so received) deliver or offer to deliver to any person, or to make commercial use or commercial application of those products after April 14, 1988.

In the spirit of the February 23, 1988 U.S. District Court Order, on April 5, 1988, EPA also issued a "Chlordane/ Heptachlor Termiticides; Notice of Intent to Suspend Registrations and to Place Limitations on Sale and Use of Existing Stocks". All of the chlordane/heptachlor termiticides affected by this April 5, 1988 Suspension Notice were previously suspended and issued Stop Sale, Use, or Removal Orders (SSUROs) for failure to respond to the FIFRA §3(c)(2)(B) Data Call-In. However, the limitations on sale and distribution of the previous suspension and SSUROs only affected the registrants. The recent April 5, 1988 Suspension Notice includes prohibitions on the sale, distribution, and use of existing stocks of the suspended products which are similar to those imposed by the U.S. District Court Order and the resulting Notification of Cancellation described above. That is, after the April 5, 1988 Notice of Intent to Suspend becomes final and effective, no person may distribute, sell, offer for sale, hold for sale, deliver for shipment, receive (and having so received) deliver or offer to deliver to any person, or to make commercial use or commercial application of suspended chlordane or heptachlor products (see Appendix D).

Please note that all persons adversely affected by the April 5, 1988 Suspension Notice may request a hearing within 30 days of publication of the notice. The existing stocks provisions of this suspension notice which affect persons other than registrants will only take effect 30 days after the date of publication in the Federal Register, or after completion of the suspension hearings, whichever is later. OCM will inform the Regions when the April 5, 1988 chlordane/heptachlor suspension notice becomes effective.

As stated in the April 5, 1988 Cancellation and Suspension Notices, the prohibition on sale, commercial use and commercial application applies to sales of chlordane and heptachlor termiticides in any situation, and to all use and application of such products in any situation, and to all use and applications of such products with the exception of use and application in accordance with label directions by individuals (as opposed to organizations, government agencies, corporations, etc.) on property owned by those individuals. However, this exception for individuals shall not apply to use or application by individuals on property which is owned by them but which is rented or leased to others and is occupied or intended to be occupied by human beings, nor will it apply to new structures under construction for sale or lease. Effectively, this means that the only non-Velsicol chlordane and heptachlor termiticides that may be used after April 14, 1988 are homeowner products used on property owned and occupied by the individual user.

The attached Revised Compliance Monitoring Strategy for the Cancellation and Suspension of Chlordane/Heptachlor Termiticides is identical to the January 29, 1988 strategy in regard to the Velsicol products. However, this revised strategy calls for inspections of producing establishments, distributors/dealers/retailers, and commercial users to assure that non-Velsicol chlordane and heptachlor termiticides (i.e., both suspended and cancelled) are not sold, distributed, or used in violation of the April 5, 1988 Cancellation Notice and Suspension Order. Inspections of distributors, dealers, retailers, and commercial users to assure compliance with the chlordane/heptachlor suspension and cancellation will be conducted by States with Cooperative Enforcement Agreements, and by EPA in States without Cooperative Enforcement Agreements, as part of their routine inspections.

The attached revised strategy also calls for a books and records inspection of registrants of the suspended chlordane and heptachlor termiticides to determine the first-line distributors of those products. The books and records inspection are to be conducted by States, or Regions in States without Cooperative Enforcement Agreements, within 60 days of the date of this strategy. States conducting the books and records inspections are to transmit information on the first-line distributors to the Regions where Stop Sale, Use, or Removal Orders (SSUROs) are to be issued to those persons. Regions are to transmit information on first-line distributors located in other Regions to those Regions. Additionally, States and Regions are to issue SSUROs to distributors, dealers, retailers, and users of suspended chlordane/heptachlor products as it is found during the course of routine inspections. Please note, registrants of the suspended products have already received SSUROs in response to the previous FIFRA §3(c)(2)(B) suspension action. Therefore, sale and distribution of these products by the registrant would be a violation of FIFRA §12(a)(2)(I). Sale, distribution, commercial use and commercial application of cancelled chlordane and heptachlor termiticides is a violation of FIFRA §12(a)(2)(K).

The attached revised strategy is effective immediately and replaces the January 29, 1988 strategy. Please transmit a copy of this strategy to the States within your Region immediately. If you have any questions regarding the revised strategy, please contact Dan Helfgott of my staff at FTS 382-7825.

Attachments

ADDRESSEES

Douglas D. Campt	(TS-766C)
Edwin F. Tinsworth	(TS-767C)
Frederick F. Stiehl	(LE-134A)
Mark Greenwood	(LE-132A)
A.E. Conroy II	(EN-342)
Connie Musgrove	"
Ken Shiroishi	"
Phyllis Flaherty	"
John J. Neylan III	"
Mike Wood	"
Jerry Stubbs	"
Dexter Goldman	"

Jake Mackenzie
Western Regional Compliance Director

I	Louis F. Gitto, Director Air Management Division	Marvin Rosenstein, Chief Pesticides & Toxic Substances Br
II	Barbara Metzger, Director Environmental Services Div	Ernest Regna, Chief Pesticides & Toxic Substances Br
III	Stephen R. Wassersug, Director Hazardous Waste Management Div	Larry Miller, Chief Toxic & Pesticides Branch
IV	Winston A. Smith, Director Air, Pest. & Toxics Mangt. Div	Richard DuBose, Chief Pesticides & Toxic Substances Br
V	William H. Sanders III, Dir Environmental Services Div	Phyllis Reed, Chief Pesticides & Toxic Substances Br
VI	William B. Hathaway, Dir Air, Pesticides & toxic Div	Robert Murphy, Acting Chief Pesticides & Toxic Substances Br
VII	William A. Spratlin, Director Air and Toxics Division	Leo Alderman, Chief Pesticides & Toxic Substances Br
VIII	Irwin L. Dickstein, Director Air and Toxics Division	Alvin Yorke, Chief Toxic Substances Branch
IX	Jeffrey Zelickson, Director Toxics and Waste Management Div	Davis Bernstein, Chief Pesticides & Toxics Branch
X	Gary O'Neal, Director Air and Toxics Division	Anita Frankel, Chief Pesticides & Toxic Substances Br

cc:	Michael Walker	(LE-134P)
	Jane Hopkins	(TS-788)
	Margaret Rostker	(TS-788)
	Phil Gray	(TS-766C)

REVISED
COMPLIANCE STRATEGY FOR THE CANCELLATION AND SUSPENSION OF CHLORDANE/HEPTACHLOR TERMITICIDES

OVERVIEW

This Strategy calls for monitoring compliance with the August 11, 1987 Memorandum of Understanding (MOU) between the Agency and Velsicol Chemical Corporation, the October 1, 1987 cancellation of Velsicol's chlordane and heptachlor termiticides, the April 5, 1988 "Chlordane/Heptachlor Termiticides; Notification of Cancellation and Amendment of Existing Stocks Determination", and the April 5, 1988 "Chlordane/Heptachlor Termiticides; Notice of Intent to Suspend Registrations and to Place Limitations on the Sale and Use of Existing Stocks."

Inspections will be conducted by States with Cooperative Enforcement Agreements, and by EPA Regions in States without these agreements, at the registrant, distributor/dealer/retailer, and user level in accordance with the neutral administrative inspection scheme outlined in this Strategy. Stop Sale, Use, or Removal Orders (SSUROs) are to be issued to any person who sells, distributes, or makes commercial use or commercial application of suspended chlordane or heptachlor products after the effective date of the April 5, 1988 suspension notice (see Appendix D for the list of these products). Civil penalties are to be assessed against registrants, who have already received a SSURO, and who sell or distribute suspended chlordane/heptachlor products (see Appendix E for the list of registrants who have received SSUROs). Finally, SSUROs will be issued, and civil penalties will be assessed to any person who sells, distributes, or makes commercial use or commercial application of any chlordane/heptachlor termiticide in violation of the October 1, 1987 or April 5, 1988 cancellation orders (see Appendix C for list of cancelled products).

BACKGROUND

On August 11, 1987, the EPA and Velsicol Chemical Corporation entered into a Memorandum of Understanding (MOU) in which Velsicol agreed to immediately discontinue the sale and distribution of all of its termiticide products containing chlordane or heptachlor. Persons other than Velsicol were not affected by this agreement, and were therefore not prohibited from sale, distribution, or use of existing stocks of Velsicol's termiticides under existing labeling.

Under the terms of the MOU, EPA also granted Velsicol a conditional registration for certain uses of some of Velsicol's chlordane and heptachlor products. Velsicol may only distribute these conditionally registered chlordane/heptachlor pesticide products as Restricted Use Pesticides if air monitoring tests reveal zero exposure from each use, and provided certain uses, such as use inside the home and high pressure injection, remain deleted from the label ("deleted uses", see Appendix A for deleted and retained uses). Regions and States will be notified if and when Velsicol has met the terms of the conditional registration, and therefore, when Velsicol may resume its sale of chlordane and heptachlor products.

On October 1, 1987, Velsicol agreed to voluntarily cancel its chlordane/heptachlor termiticide products which were not conditionally registered pursuant to the MOU. The October 1, 198 Cancellation Order was published in the Federal Register on November 3, 1987 (52 FR 42145). Under the Cancellation Order, Velsicol was still prohibited from the sale and distribution of its chlordane/heptachlor termiticides; however, existing stocks provisions were established which phased out sale, distribution, and use of Velsicol's chlordane/heptachlor termiticides by persons other than Velsicol. Between December 1, 1987 and April 15, 1988, stocks of Velsicol's chlordane/heptachlor termiticides may be sold, distributed, and used by persons other than Velsicol as a Restricted Use Pesticide (RUP), and only in accordance with the use directions found in the Cancellation Order. No sale, distribution, or use is to be permitted after April 15, 1988.

On April 5, 1988, EPA issued a "Chlordane/Heptachlor Termiticides; Notification of Cancellation and Amendment of Existing Stocks Determination". That notice informed the public that, after April 14, 1988, no person may distribute, sell, offer for sale, hold for sale, deliver for shipment, receive (and having so received) deliver or offer to deliver to any person, or to make commercial use or commercial application any non-Velsicol chlordane or heptachlor product which has been cancelled (see Appendix C for a list of these products).

Also on April 5, 1988, EPA issued a "Chlordane/Heptachlor Termiticides; Notice of Intent to Suspend Registrations and to Place Limitations on Sale and Use of Existing Stocks". All of the chlordane/heptachlor termiticides affected by that Notice were previously suspended and issued Stop Sale, Use, or Removal Orders (SSUROs) for failure to respond to the FIFRA section 3(c)(2)(B) Data Call-In. However, the limitations on sale and distribution of the previous suspension and SSUROs only affected the registrants. The April 5, 1988 Suspension Notice includes prohibitions on the sale, distribution, and use of existing stocks of the suspended products which are similar to those imposed by the U.S. District Court Order and resulting Notification of Cancellation described above. That is, after the April 5, 1988 Suspension Notice becomes final and effective, no person may distribute, sell, offer for sale, hold for sale, deliver for shipment, receive (and having so received) deliver or offer to deliver to any person, or to make commercial use or commercial application of suspended chlordane or heptachlor products (see Appendix D).

Please note that while the original Suspension Orders which affected only registrants remains in effect, all persons adversely affected by the April 5, 1988 suspension notice may request a hearing within 30 days of publication of that notice. The existing stocks provisions of the April 5, 1988 Suspension Notice which affect persons other than registrants will only take affect 30 days after the date of publication in the Federal Register, or after completion of the suspension hearings, whichever is later. OCM will inform the Regions when the April 5, 1988 chlordane/ heptachlor Suspension Notice becomes effective.

REGULATED INDUSTRY

The sole producer of technical chlordane and heptachlor in the United States is Velsicol Chemical Corporation. The October 1, 1987 cancellation order affects registrants [i.e., Velsicol and its supplemental registrants (see FIFRA Compliance Program Policy No. 3.9)], distributors/dealers/retailers, and users of Velsicol's chlordane/heptachlor. The October 1, 1987 cancellation order does not affect non-Velsicol chlordane and heptachlor termiticides.

The April 5, 1988 chlordane/heptachlor cancellation notice affects registrants (effectively, only the non-Velsicol registrants of chlordane and heptachlor termiticides), distributors/dealers/retailers, and commercial users and commercial applicators of cancelled chlordane and heptachlor products (see Appendix C). The April 5, 1988 chlordane/heptachlor suspension notice affects all registrants (again, the non-Velsicol registrants), distributors/dealers/retailers, commercial users and commercial applicators of chlordane and heptachlor products which have already been previously suspended because the registrant failed to submit data to the Agency pursuant to the FIFRA section 3(c)(2)(B) Data Call-In (see Appendix D).

Please note that for purposes of the April 5, 1988 chlordane and heptachlor suspension and cancellation notices, the prohibition on sale, commercial use and commercial application applies to sales of chlordane and heptachlor termiticides in any situation, and to all use and application of such products with the exception of use and application in accordance with label directions by individuals (as opposed to organizations, government agencies, corporations, etc.) on property owned by those individuals. However, this exception for individuals shall not apply to use or application by individuals on property which is owned by them but which is rented or leased to others and is occupied or intended to be occupied by human beings, nor will it apply to new structures under construction for sale or lease. In short, this means that the only non-Velsicol chlordane and heptachlor termiticides that may be used after April 14, 1988, are homeowner products used on property owned and occupied by the individual user.

REQUIREMENTS OF THE AUGUST 11, 1987 MEMORANDUM OF UNDERSTANDING

As per the August 11, 1987 MOU, Velsicol may not sell or distribute any of its chlordane/heptachlor termiticides after August 11, 1987. Products that remain conditionally registered may only be sold and distributed by Velsicol when the terms of the conditional registration are met (OCM will inform the Regions when this occurs). Other persons (i.e., distributors/dealers/retailers, users, and non-Velsicol registrants) were not affected by this agreement.

—[illegible] that the emulsion [illegible] the soil.
—[illegible] shall be made with pressures less than 50 p.s.i. at the nozzle using a course spray nozzle when establishing horizontal barriers.
—If concrete slabs cannot be poured over soil the same day it has been treated, a water-proof cover, such as polyethylene sheeting, should be placed over the soil to prevent erosion. This is not necessary if foundation walls have been installed around the treated soil.

Vertical Barriers

After the foundation walls have been poured or built but before slabs are poured, vertical barriers may be established in soil which will be under the perimeters of floating or supported slabs, around utilities which will penetrate the slab and in other critical areas which will be covered by concrete. After the final exterior grading is completed, vertical barriers may be created in back-filled soil against foundation walls or against the outside of monolithic slab. To produce a vertical barrier, apply the emulsion at the rate of 4 gallons per linear feet per foot of depth from grade to the top of the footing. For monolithic slabs apply to the bottom of the concrete.

—Low pressure rodding and/or trenching applications should not be made below the top of the footing except when the footing is exposed at or above grade. Special care should be taken to avoid soil washout around the footing.
—When rodding, use only low pressure (less than 25 p.s.i. at the nozzle). It is important that emulsion reaches the footing. Rod holes should be spaced to provide a continuous barrier.
—Trenches need not be wider than 6 inches.
—Emulsion should be mixed with the soil as it is being replaced in the trench. Cover treated soil with approximately 2 inches of untreated soil.

Crawl Space Foundations

For crawl space foundations, vertical barriers may be established in the soil on the outside perimeter of the foundation using a rate of 4 gallons of emulsion per 10 linear feet per foot of depth from grade to the top of the footing. Application may be made by low pressure rodding and/or trenching to the footing. If the footing is exposed at or above grade, application should be made with special care to avoid washout around the footing.

—Do not treat the footing through hollow masonry voids.
—Rod holes should be spaced to provide a continuous chemical barrier.
—When rodding the outside perimeter, use low pressure (less than 25 p.s.i. at the nozzle).
—Trenches need not be wider than 6 inches nor below the footing. The emulsion should be mixed with the soil as it is being replaced in the trench. Cover the treated soil with approximately 2 inches of untreated soil.
—A complete termite barrier may require treatment with another EPA-registered product to the inside perimeter of the foundations and to other interior critical areas.

Basement Foundations

Horizontal Barriers

After exterior grading is completed and prior to the pouring of concrete slabs, horizontal barriers may be established on soil which will be covered by concrete entrance platforms, and in other exterior critical areas which will be covered by concrete slabs. To produce a horizontal barrier, apply the emulsion at the rate of 1 gallon per 10 square feet to fill dirt. If fill is washed gravel or other coarse material, apply at 1½ gallons per 10 square feet.

—It is important that the emulsion reaches the soil.
—Applications shall be made (with pressures less than 50 p.s.i. at the nozzle) using a course spray nozzle when establishing horizontal barriers.
—If concrete slabs cannot be poured over soil the same day it has been treated, a water-proof cover, such as polyethylene sheeting, should be placed over the soil to prevent erosion.
—Do not apply to any area inside the foundation wall.

Vertical Barriers

After the final exterior grading is completed, vertical barriers may be created in back-filled soil against foundation walls. To produce a vertical barrier, apply the emulsion by low pressure rodding or trenching at the rate of 4 gallons per linear feet per foot of depth from grade to the top of the footing.

—Low pressure rodding and/or trenching applications should not be made below the top of the footing except when the footing is exposed at or above grade. Special care should be taken to avoid soil washout around the footing.
—When rodding, use low pressure (less than 25 p.s.i. at the nozzle). It is important that emulsion reaches the footing. Rod holes should be spaced to provide a continuous barrier.
—Trenches need not be wider than 6 inches.
—Emulsion should be mixed with the soil as it is being replaced in the trench. Cover treated soil with approximately 2 inches of untreated soil.

Postconstruction Treatments

Dilution Instruction for Gold Crest Termide

Use a .75% water emulsion for subterranean termites other than *Coptotermes* spp. Mix 1 gallon of Gold Crest Termide in 99 gallons of water to produce at 0.75% water emulsion. Use a 0.75–1.5% water emulsion for *Coptotermes* spp. where necessary. Mix 1–2 gallons of Gold Crest Termide in 99 gallons of water to produce a 0.75–1.5% water emulsion.

Dilution Instructions for Gold Crest C100 and Chlordane 8EC/Termite

Use a 1% water emulsion for subterranean termites other than *Coptotermes* spp. Mix 1 gallon of product in 95 gallons of water to produce a 1% water emulsion. Use a 1–2% water emulsion for *Coptotermes* spp. where necessary. Mix 1–2 gallons of product in 95 gallons to produce a 1–2% emulsion.

Dilution Instruction for Gold Crest H–60

Use a .5% water emulsion for subterranean termites other than *Coptotermes* spp. Mix 1 gallon of product in 59 gallons of water to prodcue a .5% water emulsion. Use a 1% water emulsion for *Coptotermes* spp. where necessary. Mix 2 gallons of product in 59 gallons of water to produce a 1% water emulsion.

Dilution Instruction for Gold Crest C–50

Use a 1% water emulsion for subterranean termites other than *Coptotermes* spp. Mix 1 gallon of product in 47 gallons of water to produce a 1% water emulsion. Use a 2% water emulsion for *Coptotermes* spp. where necessary. Mix 2 gallons of product in 47 gallons of water to produce a 2% water emulsion.

Do not apply this produce into hollow masonry voids.

Do not apply this product to soil beneath the interior of the structure. Do not apply to the soil beneath a plenum air space.

Do not apply emulsion until location of pipes, water and sewer lines and electrical conduits are known and identified.

Soil Construction

Vertical barriers may be established along the outside of the foundation by low pressure rodding and/or trenching at the rate of 4 gallons of emulsion per 10 linear feet. Low pressure rodding should not extend beyond the tops of the footings.

—When rodding, use only low pressure (less than 25 p.s.i. at the nozzle).

—Drill holes in outside slabs (patios, sidewalks, etc.) about 12 to 36 inches apart to provide a continuous chemical barrier.

—For shallow foundations, 1 foot or less, dig a narrow trench approximately six inches wide along the outside of the foundation walls. Do not trench below the bottom of the foundation. The emulsion should be applied to the trench and the soil at 4 gallons per 10 linear feet as the soil is replaced in the trench. Cover the treated soil with approximately 2 inches of untreated soil.

—For foundations deeper than 1 foot apply 4 gallons per 10 linear feet per foot of depth.

Basement and Crawl Space Foundations

For basement foundations, outside perimeter barriers may be applied only by trenching or the excavation technique below at a rate of 4 gallons of emulsion per 10 linear feet per foot of depth to be treated. Where exterior slabs are adjacent to the foundation wall, drill through the slab along the outside of the wall at a spacing that provides application of a continuous barrier and apply the emulsion just under the slab. After drilling, emulsion may be applied. Apply only at the lowest pressure that will start the flow of emulsion from an unobstructed rod. Apply up to 4 gallons of emulsion per 10 linear feet.

A complete termite barrier may require application of another EPA-registered product under interior slabs, through hollow masonry voids to the footing, and to other interior critical areas.

Excavation Technique

If treatment is to be made in difficult situations such as near wells or cisterns, along faulty foundation walls, and around pipes and utility lines which lead downward from the structure, application must be made in the following manner to avoid intrusion of termiticide into water supplies or the interior of the structure.

—Trench and remove the soil to be treated only heavy plastic sheeting or similar liner.

—Treat the soil at the rate of 4 gallons of emulsion per 10 linear feet per foot of depth of the trench. Mix the emulsion thoroughly into the soil taking care to prevent liquid from running off the liner.

—After the treated soil has dried adequately, replace the soil in the trench and cover with approximately 2 inches of untreated soil.

Retreatment Restrictions

Retreatment for subterranean termites should only be made when there is evidence of reinfestation subsequent to the initial treatment, or there has been disruption of the chemical barrier in the soil due to construction, excavation, landscaping, etc. Retreatment should be made as a spot application to these areas.

Retreatments may be made to critical areas in accordance with the application techniques described above. This application should be made as a spot treatment to these areas. Do not annually retreat entire premises.

Copies of the August 11, 1987, agreement and the October 1, 1987, supplementary agreement between EPA and Velsicol, can be obtained from the person listed under **FOR MORE INFORMATION CONTACT:**

Dated: October 23, 1987.

Douglas D. Campt,

Director, Office of Pesticide Programs.

[FR Doc. 87-25383 Filed 11-2-87, 8:45 am]

BILLING CODE 6560-50-M

[OPP-180747; FRL-3286-5]

California Department of Food and Agriculture; Receipt of Application for Emergency Exemption To Use Hydrogen Cyanamide; Solicitation of Public Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received a request for an emergency exemption from the California Department of Food and Agriculture (hereafter referred to as the "Applicant") to use the active ingredient hydrogen cyanamide ("Dormex") to promote uniform bud break in 18,800 acres of table grapes grown in the Coachella Valley in Riverside County, California. Dormex contains an unregistered active ingredient and, therefore, in acordance with 40 CFR 166.24, EPA is soliciting comment before making the decision whether or not to grant the exemption.

DATE: Comments must be received on or before November 18, 1987.

ADDRESSES: Three copies of written comments, bearing the identification notation "OPP-180747," should be submitted by mail to: Information Services Section, Program Management and Support Division (TS-757C), Office of Pesticide Programs, Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460.

In person, bring comments to: Rm. 236, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Information submitted in any comment concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information (CBI)." Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2. A copy of the comment that does contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice to the submitter. All written comments will be available for inspection in Rm. 236 at the address given above from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Libby Pemberton, Registration Division (TS-767C), Office of Pesticide Programs, Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

Office location and telephone number: Rm. 716, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. (703-557-1806).

SUPPLEMENTARY INFORMATION: Pursuant to section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136p), the Administrator may, at his discretion, exempt a State agency from any provisions of FIFRA if he determines that emergency conditions exist which require such exemption.

The Applicant has requested the Administrator to issue a specific exemption to permit the use of an unregistered plant regulator, hydrogen cyanamide (CAS 420-04-2), manufactured as Dormex, by SKW Trostberg Aktiengesellschaft, to promote uniform bud-break in table grapes grown in the Coachella Valley in Riverside County, California. Information in accordance with 40 CFR Part 166 was submitted as part of this request.

Approximately 18,800 acres of table grapes, *Vitis* spp., are grown in the Coachella Valley. The Applicant indicates that California growers of early market table grapes are facing economic losses due to increasing competition from foreign imports, particularly from Mexico. The Applicant

REQUIREMENTS OF THE OCTOBER 1, 1987 CANCELLATION ORDER

The registrations of Gold Crest Termide, Gold Crest C100, and Chlordane 8EC Termite were amended by splitting each registration into two separate registrations. A new EPA registration number was assigned for each of the above End Use products for the uses described in Appendix A as "retained uses". The remaining uses for each of the above products maintained their current EPA registration numbers of 876-233, 876-63, and 876-104 respectively.

The registrations of Gold Crest Termide, Gold Crest C100, and Chlordane 8EC Termite, which have maintained their current EPA registration numbers of 876-233, 876-63, and 876-104 have been voluntarily cancelled effective September 30, 1987 along with the following Velsicol products: Gold Crest C-50 (876-86), Gold Crest H-60 (876-85), California SLN for crawlspace perimeter spray (Termide) (CA-810012), California SLN for crawlspace perimeter spray (C-100) (CA-810012), and Hawaii SLN for crawlspace perimeter spray (C-100) (HI-850003). The cancellation order also affects Velsicol's supplementally distributed products (the list of supplemental registrations are in Appendix B).

The Gold Crest Termide, Gold Crest C100, and Chlordane 8EC Termite products which bear the "retained uses" and have been assigned new EPA registration numbers are not cancelled. These products continue to be conditionally registered with EPA but may not be sold and distributed by Velsicol until the terms of the conditional registration, as outlined in the August 11, 1987 MOU, are met. Additionally, the cancellation does not affect the following Velsicol chlordane and heptachlor products: Technical Chlordane/ Export (876-280); Technical Heptachlor/Export (876-288); and Technical Heptachlor/Formulation of Fire Ant Granular for Cable Closure Only (876-330). Please note, as per the MOU, except for the Technical Heptachlor/Formulation of Fire Ant Granular for Cable Closure, none of the above products may be sold or distributed by Velsicol in the United States even though they have not been cancelled.

Existing Stocks for Velsicol's Chlordane/Heptachlor Termiticides

As per the October 1, 1987 cancellation order, persons other than Velsicol [and its supplemental registrants(see 40 CFR 162.6(b)(4)(iii)] may sell, distribute, and use existing stocks of Velsicol's chlordane and heptachlor products in any manner consistent with the existing labeling until November 30, 1987. From December 1, 1987 until April 15, 1988, Velsicol's chlordane and heptachlor termiticide products will be restricted use pesticides for retail sale to and use only by certified applicators or persons under their direct supervision. Between December 1, 1987 and April 15, 1988, certified applicators, or persons under their direct supervision, are required to use Velsicol's chlordane and heptachlor products in accordance with the use directions found in the cancellation order (52 FR 42145; November 3, 1987). Sale, distribution, and use of such chlordane and heptachlor products will not be permitted after April 15, 1988.

Please note, the directions for use found in the cancellation order cannot be considered "labeling" unless they accompany the product. There is no requirement in the cancellation order that these directions for use accompany the product. Therefore, between December 1, 1987 and April 15, 1988, unless the directions for use found in the cancellation order accompanied the product at the time of sale, use of Velsicol's chlordane and heptachlor products not in accordance with the revised use directions must be considered a violation of the cancellation order and not "misuse." Additionally, unless Velsicol's chlordane and heptachlor products have been sold with the revised use directions, sale to or use by uncertified persons will be a violation of the cancellation order and not a violation of FIFRA §12(a)(2)(F).

REQUIREMENTS OF THE APRIL 5, 1988 NOTIFICATION OF CANCELLATION

The April 5, 1988 Notice of Cancellation announces the cancellation of the chlordane and heptachlor products listed in Appendix C, and establishes limitations on the sale and use of existing stocks of these products. Please note, the products affected by this notice were previously voluntarily cancelled at the request of the registrant.

Existing Stocks

It is unlawful for any person to distribute, sell, offer for sale, hold for sale, deliver for shipment, or receive (and having so received) deliver or offer to deliver to any person, or to make commercial use or commercial application, cancelled chlordane and heptachlor termiticides after April 14, 1988.

REQUIREMENTS OF THE APRIL 5, 1988 NOTICE OF INTENT TO SUSPEND

The April 5, 1988 Notice of Intent to Suspend will suspend the products listed in Appendix D of this strategy for continued failure to submit data within the time periods required by the chlordane and heptachlor Data Call-In, as contained in the December 31, 1986 Chlordane and Heptachlor Registration Standards. All products affected by this Notice have previously been suspended for failure to commit to comply with the terms of that Data Call-In. However, the previous chlordane/heptachlor suspensions did not place prohibitions of the sale or use of existing stocks of suspended products by persons other than the registrant. Any suspensions resulting from the April 5, 1988 Notice of Intent to Suspend will include prohibitions on the sale and use of existing stocks of suspended chlordane and heptachlor termiticides.

Existing Stocks

When the April 5, 1988 Notice of Intent to Suspend becomes final and effective for a particular product listed in Appendix D (either 30 days after publication in the Federal Register or upon completion of a suspension hearing) no person may distribute, sell, offer for sale, hold for sale, deliver for shipment, or receive (and having so received) deliver or offer to deliver to any person, or to make commercial use or commercial application, suspended chlordane and heptachlor termiticides.

COMPLIANCE MONITORING

Conformance with the August 11, 1987 MOU will be determined through inspections of Velsicol's establishments to determine whether any stocks of chlordane or heptachlor were sold or distributed after August 11, 1987. Please note, there is no violation under FIFRA for not conforming with the terms of an MOU, however, the Agency would like assurance that the terms of the MOU have been met.

Compliance with the October 1, 1987 Cancellation Order and the April 5, 1988 Notice of Cancellation and Notice of Intent to Suspend will be determined through inspections of producing establishments, distributors/dealers/retailers, and users of chlordane and heptachlor termiticides. Noncompliance with the October 1, 1987 Cancellation Order or the April 5, 1988 Notice of Cancellation is a violation of FIFRA sections 12(a)(1)(A) and 12(a)(2)(K).

The Agency, and States with authority, are to issue Stop Sale, Use, or Removal Orders (SSURO) to any person who distributes, sells, offers for sale, holds for sale, ships, delivers for shipment, or receives and (having so received) delivers or offers to deliver chlordane and heptachlor termiticides other than in accordance with the October 1, 1987 Cancellation Order and the April 5, 1988 Notice of Cancellation and Notice of Intent to Suspend.

Neutral Administrative Inspection Scheme (NAIS)

Except for the initial inspections of Velsicol's establishments, all inspections for violations of the October 1, 1987 Cancellation Order will take place as part of the Regions' and States' routine inspections. Inspections of Velsicol's producing establisments to assure conformance with the MOU and compliance with the October 1, 1988 Cancellation Order are to take place by April 29, 1988.

Inspections of distributors/dealers/retailers, and commercial users to assure compliance with the April 5, 1988 Notice of Intent to Suspend will also take place as part of the Regions and States routine inspections. However, within 60 days of the date of this strategy, States, or Regions in States without Cooperative Enforcement Agreements, are to also conduct a books and records inspection of registrants of the suspended chlordane and heptachlor termiticides to determine the first-line distributors of those products. States conducting the books and records inspections are to transmit information regarding the first-line distributors to the Regions. Upon receipt of this information, Regions are to issue SSUROs to those persons identified as first-line distributors in their Region. Regions are to transmit information on first-line distributors located in other Regions to those Regions, where the SSUROs are to be issued. Additionally, States and Regions are to issue SSUROs to distributors, dealers, retailers, and commercial users of suspended chlordane/heptachlor products as they are found during the course of routine inspections. Compliance with the SSUROs will be monitored in accordance with the Pesticides Inspector's Manual.

Regions/States will also investigate all tips and complaints, as appropriate.

Please note, registrants of the suspended products have already received SSURO's in response to the previous FIFRA §3(c)(2)(B) suspension action. Therefore, sale and distribution of these products by the registrant would be a violation of FIFRA §12(a)(2)(I). Sale, distribution, commercial use and commercial application of cancelled chlordane and heptachlor termiticides is a violation of FIFRA §12(a)(2)(K).

Registrant/Producer Level

By April 29, 1988, the Agency/States will schedule and conduct inspections of Velsicol's establishments to obtain assurance that Velsicol has complied with the October 1, 1987 Cancellation Order by not having released products for shipment after October 1, 1987. At this inspection the Agency/States will also obtain assurance that Velsicol has abided by the terms of the August 11, 1987 MOU by not having released the affected products for shipment after August 11, 1987.

Within 60 days of the date of this strategy, the Agency/States will conduct a books and records inspection of the non-Velsicol chlordane/heptachlor registrants to determine the first-line distributors of those products.

During the course of routine inspections, the Agency/States will obtain assurance that non-Velsicol registrants/producers have not sold or distributed their chlordane/heptachlor products in violation of the cancellation orders, suspension orders, or SSUROs.

Distributor/Dealer/Retail Level

After November 30, 1987, when conducting routine inspections at the distributor/dealer/retail level, inspectors will check to determine whether Velsicol's chlordane and heptachlor termiticide products are being sold and distributed in accordance with the October 1, 1987 Cancellation Order.

After April 15, 1988, when Agency/States conduct routine inspections at the distributor/dealer/retail level, they will assure that remaining stocks of cancelled chlordane and heptachlor termiticides are not being sold.

After the effective date of the suspension order, the Agency/States will conduct routine inspections at the distributor/dealer/retailer level to assure that remaining stocks of suspended chlordane and heptachlor termiticides have not been moved and are not being sold.

User Level

During routine use inspections prior to April 15, 1988, inspectors will assure that Velsicol's chlordane and heptachlor is being used only by certified applicators and in accordance with the use directions found in the Cancellation Order.

After April 15, 1988, during routine inspections at the user level, Agency/States will assure that any remaining stocks of Velsicol chlordane and heptachlor are not being used, and remaining stocks of non-Velsicol cancelled chlordane and heptachlor products are not being used for purposes of commercial use or commercial application.

After the effective date of the suspension order, and during routine inspections at the user level, the Agency/States will assure that remaining stocks of suspended chlordane and heptachlor are not being used for commercial use or commercial application.

ALLOCATION OF RESPONSIBILITIES

Office of Pesticide Programs

° Will develop and provide OCM with a list of those products which have been cancelled/suspended.

° Will notify OCM when registrants of suspended chlordane and heptachlor products agree to voluntarily cancel their products.

° Will notify OCM if and when Velsicol has met the terms of the conditional registrations of Gold Crest Termite, Gold Crest C100, and Chlordane *EC Termite, and therefore when these products may be sold and distributed.

Office of Compliance Monitoring

° Will develop and transmit the Compliance Monitoring Strategy to the Regions.

° Will issue SSUROs for non-Velsicol chlordane/heptachlor termiticides suspended under FIFRA §3(c)(2)(B).

° Will transmit to the Regions the list of those products which have been cancelled pursuant to the October 1, 1987 Cancellation Order, cancelled as specified in the April 5, 1988 notification, or suspended pursuant to the April 5, 1988 Notice of Intent to Suspend.

° Will transmit a list of establishments producing Velsicol's chlordane and heptachlor termiticides to the Regions.

° Will notify the Regions if and when Velsicol has met the terms of the conditional registrations of Gold Crest Termite, Gold Crest C100, and Chlordane 8EC Termite, and therefore when these products may be sold and distributed.

° Will notify Regions of the effective date of the April 5, 1988 Notice of Intent to Suspend Chlordane and Heptachlor Termiticides.

Regions

° Will provide copies of the Compliance Monitoring Strategy to States.

° Will distribute lists of products to the States.

° Will conduct distributor/dealer/retailer and user inspections in States without Cooperative Enforcement Agreements as part of their routine inspectional program.

° Will conduct a books and records inspection, in States without Cooperative Enforcement Agreements, of non-Velsicol chlordane/heptachlor registrants to determine the first-line distributors of those products.

° Will issue SSUROs to first-line distributors, of non-Velsicol chlordane and heptachlor products, located in their Region.

° Will transmit information on first-line distributors located in other Regions to those Regions.

° Will monitor SSUROs as per the Pesticides Inspectors' Manual.

° Will take enforcement action, including issuing SSUROs, as appropriate.

° Will report to OCM quarterly for one year on any enforcement actions taken within their Region, including State actions, under the cancellation and suspension actions. This report should include any occurrence of non-conformance with the terms of the MOU by Velsicol. As stipulated in the January 29, 1988 Chlordane/Heptachlor Compliance Monitoring Strategy, the first report is due April 15, 1988.

° Will notify the States when Velsicol has met the terms of the conditional registration, and therefore when Velsicol may sell the conditionally registered products.

° Will notify the States of the effective date of the chlordane/heptachlor suspension.

States

° Will conduct inspections by April 29, 1988, of Velsicol's establishments that produced chlordane and heptachlor within the past 2 years.

° Will inspect for compliance during routine distributor/dealer/retailer and user inspections.

° Will conduct a books and records inspection of non-Velsicol chlordane/heptachlor registrants to determine the first-line distributors of those products.

° Upon identification from the books and records inspections, States will transmit information on the identity of first-line distributors to the Regions.

° Will take enforcement action, including issuing SSUROs, as appropriate, provided they have the authority.

° Will report to the Regions quarterly for one year on enforcement actions taken for violations of the cancellation order. This report should include any occurrence of nonconformance with the terms of the MOU by Velsicol. As stipultaed in the January 29, 1988 Chlordane/Heptachlor Compliance Monitoring Strategy, the first report is due April 7, 1988.

Establishments Producing Velsicol's Chlordane and Heptachlor Termiticides

00876-IL-001
Velsicol Chemical Corporation
Box 39A Illinois HWY 1
Marshall, IL 62441

00876-TN-001
Velsicol Chemical Corporation
1199 Warford Street
Memphis, TN 38108

APPENDIX A

Retained and Deleted Uses of
Velsicol's Chlordane/Heptachlor Products

Velsicol classified the following uses of its end-use termiticide products as "deleted uses":

a. post-construction application of material from within a structure frequented by humans ("structure");

b. post-construction application of material from outside a structure to inside or underneath a structure;

c. the use of pressure rodding for post-construction application of material to a basement-type or crawl-space type structure;

d. pre- or post-construction treatment of the area underneath crawl-space and post and pier type structures;

e. treatment of voids and spaces in masonry or block walls or areas behind veneers;

f. applications by non-certified applicators;

g. soil-injection pressure rodding at pressures greater than 25 psi.

The agreement further classified the following uses of end-use termiticide products as "retained uses":

a. application to the outside perimeter of any structure by trenching, or drilling through sidewalks, patios, or other unenclosed slabs, and applying material to the soil without pressure (e.g., flow or gravity feed);

APPENDIX A

b. applications by the excavation technique to the exterior of any structure (i.e., by removing soil next to the foundation, placing on a tarp, treating with termiticide, and placing back in trench after soil dries);

c. pre-construction low-pressure (maximum 25 psi) vertical rodding (with the application rod equipped with a pressure control device to prevent higher pressures) of the perimeter outside any structure;

d. post-construction low-pressure (maximum 25 psi) vertical rodding (with the application rod equipped with a pressure control device to prevent higher pressures) outside slab and post and pier type structures;

e. pre-construction coarse spray surface treatment (maximum 50 psi) and low-pressure (maximum 25 psi) vertical rodding (with the application rod equipped with a pressure control device to prevent higher pressures) under the slab of slab type structures.

The agreement classified one use, the protection of underground cables, as an "unaffected use".

In addition to this classification of the uses of Velsicol's termiticide products, the agreement included, inter alia, the following provisions:

- The retained uses were converted to restricted uses as provided for in Sections 3(d) and 4 of FIFRA;

APPENDIX A

- The registrations of the retained uses were amended to conditional registrations, with no sale or distribution by Velsicol allowed until certain conditions set forth in the Conditions of Registration are met.

- No further sale or distribution by Velsicol of end-use products labeled for deleted uses was allowed.

- Velsicol amended the label of its manufacturing-use products to provide that such products could not be used to manufacture any end-use product (other than Velsicol products) for sale and distribution in the United States that is labeled for use as a subterranean termiticide.

APPENDIX B

Supplemental Registrants of Velsicol's
Chlordane/Heptachlor Termiticides

(876-00053-000192)	Drexol Chlordane 72% Termite Spray for Professional Termite Use
(876-00063-000430)	Durham's Chlordane Emulsifiable Consentrate Insecticide for Use Only By Professionals
(876-00063-002935)	Red-Top Chlordane 8 Spray
(876-00063-005887)	Black Leaf 72% Chlordane Emulsifiable Concentrate
(876-00063-010370)	Ford's Chlordane 8EC
(876-00063-025030)	Red Panther Chlordane 8EC
(876-00063-034704)	Pro-Chlordane 8-E
(876-00063-043227)	Chloro-800 Emulsifiable Consentrate Insecticide
(876-00085-035034)	Diversey 2.5 H
(876-00086-000016)	Dragon 45% Chlordane Spray
(876-00086-000192)	Dexol Chlordane 45% Termite Spray (Prof./Termite Use
(876-00086-004876)	AG Chlordane 4-EC Termite Control
(876-00086-005887)	Black Leaf 45% Chlordane Termite Killer
(876-00086-005887)	Black Leaf 45% Chlordane Termite Killer For Use Around Buildings
(876-00086-005887)	Black Leaf 45% Chlordane Emulsifiable Consentrate Insecticide
(876-00086-006723)	Red Wing Chlordane 4 EC
(876-00086-010370)	Ford's Chlordane 4 EC
(876-00086-012000)	K Mart 45% Chlordane Termite Killer
(876-00086-012000)	K Mart 45% Chlordane Termite Killer for Use Around Buildings
(876-00086-034704)	Pro-Chlordane 4-E
(876-00100-000192)	Dexol Chlordane Termite Spray
(876-00104-000430)	Durham's Chlordane 8EC Emulsifiable Concentrate
(876-00104-001812)	Pee Gee 8 lbs. per gallon Chlordane Emulsifiable Concentrate
(876-00104-004876)	Chlordane-8 Termite Control
(876-00104-006723)	Red Wing Chlordane 8EC
(876-00104-025030)	Red Panther Chlordane
(876-00104-042761)	Red Panther Chlordane 8EC
(876-00233-001927)	Terminix C-H
(876-00233-006754)	Orkil 2X

# of Products Containing
rdane and Heptachlor

STOP SALES ISSUED AS [illegible] OF SECTION 3(c)(2)(B)
SUSPENSIONS ISS[illegible] UNDER FIFRA

COMPANY	EPA REG.#	PROD	PRODUCT & CHEMICAL	SS ISSUED	EFFDATE	REGION	STATE
AMVAC CHEMICAL CORP. 4100 EAST WASHINGTON BLVD LOS ANGELES CA 90023	5481	223	CHLORDANE	01/06/88	/ /	09	CA
AMVAC CHEMICAL CORP. 4100 EAST WASHINGTON BLVD LOS ANGELES CA 90023	5481	226	CHLORDANE	01/06/88	/ /	09	CA
AMVAC CHEMICAL CORP. 4100 EAST WASHINGTON BLVD LOS ANGELES CA 90023	5481	315	CHLORDANE	01/06/88	/ /	09	CA
AMVAC CHEMICAL CORP. 4100 EAST WASHINGTON BLVD LOS ANGELES CA 90023	5481	50	CHLORDANE	01/06/88	/ /	09	CA
AR CHEMICAL CORP. 1514 ELEVENTH ST PORTSMOUTH OH 45662	7122	121	CHLORDANE	01/06/88	/ /	05	OH
AR CHEMICAL CORP. 1514 ELEVENTH ST PORTSMOUTH OH 45662	7122	3	CHLORDANE	01/06/88	/ /	05	OH
AR CHEMICAL CORP. 1514 ELEVENTH ST PORTSMOUTH OH 45662	7122	34	CHLORDANE	01/06/88	/ /	05	OH
B & G COMPANY 10539 MAYBANK DR BOX 20372 DALLAS TX 75220	8612	66	CHLORDANE	01/06/88	/ /	06	TX
BLACK LEAF PRODUCTS CO. 667 N STATE ST ELGIN IL 60120	5887	127	CHLORDANE	01/06/88	/ /	05	IL
BLACK LEAF PRODUCTS CO. 667 N STATE ST ELGIN IL 60120	5887	67	CHLORDANE	01/06/88	/ /	05	IL
BORDIE CHEMICAL CO., INC. 2 WURZ AVE. YORKVILLE NY 13495	4	274	CHLORDANE	01/06/88	/ /	02	NY
BORDIE CHEMICAL CO., INC. 2 WURZ AVE. YORKVILLE NY 13495	4	275	CHLORDANE	01/06/88	/ /	02	NY
BORDIE CHEMICAL CO., INC. 2 WURZ AVE. YORKVILLE NY 13495	4	286	CHLORDANE	01/06/88	/ /	02	NY

APPENDIX B

Supplemental Registrants of Velsicol's Chlordane/Heptachlor Termiticides

(876-00063-000192)	Drexol Chlordane 72% Termite Spray for Professional Termite Use
(876-00063-000430)	Durham's Chlordane Emulsifiable Consentrate Insecticide for Use Only By Professionals
(876-00063-002935)	Red-Top Chlordane 8 Spray
(876-00063-005887)	Black Leaf 72% Chlordane Emulsifiable Concentrate
(876-00063-010370)	Ford's Chlordane 8EC
(876-00063-025030)	Red Panther Chlordane 8EC
(876-00063-034704)	Pro-Chlordane 8-E
(876-00063-043227)	Chloro-800 Emulsifiable Consentrate Insecticide
(876-00085-035034)	Diversey 2.5 H
(876-00086-000016)	Dragon 45% Chlordane Spray
(876-00086-000192)	Dexol Chlordane 45% Termite Spray (Prof./Termite Use)
(876-00086-004876)	AG Chlordane 4-EC Termite Control
(876-00086-005887)	Black Leaf 45% Chlordane Termite Killer
(876-00086-005887)	Black Leaf 45% Chlordane Termite Killer For Use Around Buildings
(876-00086-005887)	Black Leaf 45% Chlordane Emulsifiable Consentrate Insecticide
(876-00086-006723)	Red Wing Chlordane 4 EC
(876-00086-010370)	Ford's Chlordane 4 EC
(876-00086-012000)	K Mart 45% Chlordane Termite Killer
(876-00086-012000)	K Mart 45% Chlordane Termite Killer for Use Around Buildings
(876-00086-034704)	Pro-Chlordane 4-E
(876-00100-000192)	Dexol Chlordane Termite Spray
(876-00104-000430)	Durham's Chlordane 8EC Emulsifiable Concentrate
(876-00104-001812)	Pee Gee 8 lbs. per gallon Chlordane Emulsifiable Concentrate
(876-00104-004876)	Chlordane-8 Termite Control
(876-00104-006723)	Red Wing Chlordane 8EC
(876-00104-025030)	Red Panther Chlordane
(876-00104-042761)	Red Panther Chlordane 8EC
(876-00233-001927)	Terminix C-H
(876-00233-006754)	Orkil 2X

APPENDIX C

CHLORDANE CANCELLATIONS

COMPANY	EPA REGISTRATION NO.	EFFECTIVE I
Bonide Chemical	4-96	3/17/88
	4-218	3/17/88
	4-274	3/17/88
	4-275	3/17/88
	4-287	3/17/88
Dragon Chemical Corporation	16-96	4/27/87
	16-116	4/27/87
	16-122	4/27/87
	16-124	4/27/87
Rigo Company Incorporated	70-119	4/27/87
Thompson-Hayward Chemical Company	148-27	6/01/87

	148-139	6/01/87
Dexol Industries	192-42	3/30/88
	192-43	3/30/88
	192-132	3/30/88
	192-133	3/30/88
Tobacco States Chemical Company	226-177	4/27/87
	226-184	4/27/87
Chevron Chemical Company	239-478	3/25/87
	239-1232	3/25/87
FMC Corporation	279-383	3/07/87
	279-538	11/01/86
C.J. Martin Company	299-171	3/25/87
Residex Corporation	373-26	3/25/87
Imperial Incorporated	407-269	3/25/87
	407-400	3/25/87
Boyle-Midway Inc.	475-192	3/25/87
Rockland Chemical Company Incorporated	572-65	3/25/87
Haviland Agricultural Chemical Company	595-129	3/25/87
	595-321	3/25/87
Federal Chemical Company Incorporated	654-12	6/01/87
	654-19	7/01/87
	654-67	7/01/87
	654-110	6/01/87
Prentiss Drug & Chemical Company	655-516	3/25/87
Perk Products & Chemical Company	690-53	7/01/87
Southland Pearson & Company	728-45	3/24/88
	728-47	3/24/88

MFA Oil Company	746-58	3/25/87
	746-76	3/25/87
	746-119	3/25/87
Security Lawn and Garden Products Co.	769-90	3/25/87
	769-511	3/25/87
Faesy & Besthoff Incorporated	779-82	6/02/87
Chas. H. Lilly Co.	802-71	9/11/87
Green Light Company	869-14	3/25/87
	869-188	3/25/87
Velsicol Chemical Co.	876-63	11/04/87
	876-86	3/25/87
	876-100	3/25/87
	876-104	11/04/87
	876-233	11/04/87
	876-281	9/28/87
	876-303	9/28/87
	876-304	9/28/87
	876-305	9/28/87
	876-306	9/28/87
	876-308	9/28/87
	876-309	4/28/87
	876-310	4/27/87
Miller Chemical & Fertilizer Corporation	904-135	3/25/87
	904-223	3/25/87
Cre-O-Tox Chemical Products Company	1066-26	7/01/87
	1066-28	7/01/87
	1066-29	3/19/88
Seacoast Labortories Incorporated	1159-102	7/01/87
	1159-178	7/01/87
Cotton States Chemical Company	1339-74	8/20/87
	1339-87	8/20/87
Land O'Lakes	1381-51	3/25/87
	1381-83	3/25/87
Universal Cooperatives Incorporated	1386-26	3/25/87

	1386-324	8/20/87
	1386-353	8/20/87
Dettlebach Chemical Corporation	1421-23	3/21/88
FCX, Incorporated	1598-145	4/27/87
	1598-244	4/27/87
Griffin Corporation	1812-242	7/01/87
	1812-243	7/01/87
Triangle Chemical Company	1842-41	5/14/87
	1842-42	5/14/87
Terminix Division of Cook Industries Incorporated	1927-5	2/19/87
	1927-20	2/19/87
	1927-21	2/19/87
	1927-49	2/19/87
ELCO Manufacturing Co.	1941-66	7/01/87
Farmland Industries Incorporated	1990-178	3/25/87
	1990-179	3/25/87
W.R. Grace & Company	2124-742	3/28/88
PBI-Gordon Corporation	2217-34	5/01/87
	2217-98	5/01/87
Hopkins Agricultural Chemical	2393-350	3/25/87
Colonial Products Incorporated	3314-73	7/01/87
	3314-74	7/01/87
LaRoche Industries	3442-747	3/25/87
	3442-816	3/25/87
	3442-846	3/25/87
	3442-847	3/25/87
Earl May Seed & Nursery L.P.	3772-8	3/25/87
Stephenson Chemical Company Incorporate	4887-19	3/22/88
	4887-48	3/22/88
	4887-183	3/22/88

Redwood Chemical, Incorporated	4981-5	6/29/87
	4981-6	6/29/87
Coastal Chemical Corporation	5549-41	3/17/88
Chacon Chemical Corporation	5719-24	7/01/87
GRO Chemical Company	5778-33	6/11/87
Helena Chemical Company	5905-97	3/25/87
	5905-102	3/25/87
Octagon Process Incorported	6830-15	7/01/87
ArChem Corporation	7122-3	3/17/88
	7122-34	3/17/88
	7122-121	3/17/88
Forshaw Chemical Company	7234-5	3/17/88
	7234-6	3/17/88
	7234-10	3/18/88
	7234-100	3/17/88
	7234-101	3/17/88
	7234-20	3/18/88
Voluntary Puchasing Group, Inc.	7401-78	6/18/87
	7401-348	6/18/87
B & G Company	8612-86	3/21/88
Sunniland Corporation	9404-6	3/23/88
Nationwide Chemical Products, Inc.	9591-6	10/01/87
	9591-7	10/01/87
Ross-Daniels, Inc.	9649-2	6/12/87
Cornbelt Chemical Company	10107-7	3/21/88
	10107-8	3/21/88

Ford's Chemical & Service Incorporated	10370-40	3/28/88
	10370-116	3/28/88
	10370-144	3/28/88
	10370-145	3/28/88
Hacienda Enterprises	11037-7	4/27/87
Puma Chemical Company	11611-4	7/17/87
Drexel Chemical Company	19713-214	3/24/88
	19713-215	3/24/88
Platte Chemical Company	34704-1	4/27/87
Falls Chemical Company	40831-5	3/24/88
	40831-24	3/24/88
Kaw Valley, Inc.	44215-7	9/08/87
	44215-20	12/12/87
Wilson Laboratories	50383-20	3/24/88
	50383-29	3/24/88
Cameron M. Baird	50415-27	7/01/87
Micro-Flo Company	51036-30	11/13/87
	51036-31	11/13/87
Garden Care by Farmingdale, Ltd.	53127-1	3/22/88
	53127-10	3/22/88

HEPTACHLOR CANCELLATIONS

COMPANY	EPA REGISTRATION NO.	EFFECTIVE DATE
Thompson-Hayward Chemical Co.	148-964	6/01/87
Velsicol Chemical Corporation	876-101	4/27/87
	876-85	9/28/87
	876-233	11/04/87
	876-308	9/28/87
	876-309	4/27/87
	876-310	4/27/87

Cre-O-Tox Chemical Products Company	1066-28	7/01/87
	1066-29	3/19/88
	1066-30	7/01/87
Griffin Corporation	1812-77	7/01/87
Triangle Chemical Co.	1842-183	5/14/87
Terminix Division of Cook Industries, Inc.	1927-50	4/21/87
Stephenson Chemical Company Incorporate	4887-59	3/22/88
	4887-85	3/22/88
Redwood Chemical, Inc.	4981-17	7/08/63
Red Wing Chemical Company	6723-8	6/07/84
ArChem Corporation	7132-6	3/17/88
Forshaw Chemical Company	7234-27	3/18/88
	7234-31	3/18/88
	7234-89	3/18/88
Chem-Nut, Inc.	37686-27	5/08/87
Farmco Industries Incorporated	46778-1	5/12/87
Micro-Flo Company	51036-50	4/27/87

APPENDIX D

CHLORDANE SUSPENSIONS

COMPANY	EPA REGISTRATION NO.	EFFECTIVE DATE
Van Waters & Rogers, Inc.	550-106	7/18/87
	550-107	7/18/87
Chapman Chemical Company	1022-502	7/15/87
Vaccinol Chemical Company Incorported	1353-4	7/15/87
AMVAC Chemical Corporation	5481-223	7/17/87
	5481-226	7/17/87
	5481-50	7/17/87
	5481-315	7/17/87
Carolina Chemical Corporation	5797-88	7/15/87
Black Leaf Products Company	5887-67	7/16/87
	5887-127	7/16/87
U.S. Marketing Distributors	6409-13	10/21/87
Southern Mill Creek Products Company	6720-2	7/15/87
	6720-71	7/15/87
	6720-138	7/15/87
	6720-176	7/15/87
	6720-280	7/15/87
	6720-361	7/15/87
	6720-363	7/15/87
Dettlebach Pesticide Corporation	6754-9	7/15/87
	6754-11	7/15/87
	6754-40	7/15/87
	6754-64	7/15/87
Mystic Chemical Products	36272-3	7/15/87

HEPTACHLOR SUSPENSIONS

COMPANY	EPA REGISTRATION NO.	EFFECTIVE DATE
Southern Mill Creek Products Company	6720-279	7/12/87
Dettlebach Pesticide Corporation	6754-5	7/15/87
	6754-40	7/15/87
	6754-54	7/15/87
	6754-64	7/15/87

Appendix C

of Products Containing
rdane and Heptachlor

STOP SALES ISSUED AS [illegible] ON SECTION 3(c)(2)(B)
SUSPENSIONS ISS[illegible] UNDER FIFRA

COMPANY	EPA REG.#	PRODUCT & CHEMICAL	SS ISSUED LIFTDATE	REGION	STAT
AMVAC CHEMICAL CORP. 4100 EAST WASHINGTON BLVD LOS ANGELES CA 90023	5481 223	CHLORDANE	01/06/88 / /	09	CA
AMVAC CHEMICAL CORP. 4100 EAST WASHINGTON BLVD LOS ANGELES CA 90023	5481 226	CHLORDANE	01/06/88 / /	09	CA
AMVAC CHEMICAL CORP. 4100 EAST WASHINGTON BLVD LOS ANGELES CA 90023	5481 315	CHLORDANE	01/06/88 / /	09	CA
AMVAC CHEMICAL CORP. 4100 EAST WASHINGTON BLVD LOS ANGELES CA 90023	5481 50	CHLORDANE	01/06/88 / /	09	CA
AR CHEMICAL CORP. 1514 ELEVENTH ST PORTSMOUTH OH 45662	7122 121	CHLORDANE	01/06/88 / /	05	OH
AR CHEMICAL CORP. 1514 ELEVENTH ST PORTSMOUTH OH 45662	7122 3	CHLORDANE	01/06/88 / /	05	OH
AR CHEMICAL CORP. 1514 ELEVENTH ST PORTSMOUTH OH 45662	7122 34	CHLORDANE	01/06/88 / /	05	OH
B & G COMPANY 10539 MAYBANK DR BOX 20372 DALLAS TX 75220	8612 86	CHLORDANE	01/06/88 / /	06	TX
BLACK LEAF PRODUCTS CO. 667 N STATE ST ELGIN IL 60120	5887 127	CHLORDANE	01/06/88 / /	05	IL
BLACK LEAF PRODUCTS CO. 667 N STATE ST ELGIN IL 60120	5887 67	CHLORDANE	01/06/88 / /	05	IL
BOUDIE CHEMICAL CO., INC. 2 MURI AVE. YORKVILLE NY 13495	4 276	CHLORDANE	01/06/88 / /	02	NY
BOUDIE CHEMICAL CO., INC. 2 MURI AVE. YORKVILLE NY 13495	4 275	CHLORDANE	01/06/88 / /	02	NY
BOUDIE CHEMICAL CO., INC. 2 MURI AVE. YORKVILLE NY 13495	4 286	CHLORDANE	01/06/88 / /	02	NY

Appendix E

STOP SALES ISSUED AS THE RESULT ON SECTION 3(c)(2)(B)
SUSPENSIONS ISSUED UNDER FIFRA

COMPANY	EPA REG.#	PRODUCT & CHEMICAL	SS ISSUED	LIFTDATE	REGION	STATE
BONDIE CHEMICAL CO., INC. 4 MERZ AVE. YORKVILLE NY 13495	4 287	CHLORDANE	01/06/88	/ /	02	NY
BONDIE CHEMICAL CO., INC. 4 MERZ AVE. YORKVILLE NY 13495	4 96	CHLORDANE	01/06/88	/ /	02	NY
BONDIE CHEMICAL CO., INC. 4 MERZ AVE. YORKVILLE NY 13495	4 228	CHLORDANE	01/06/88	/ /	02	NY
CAROLINA CHEMICAL CORP. P.O. BOX 70 WILSON NC 27893	5797 88	CHLORDANE	01/06/88	/ /	04	NC
TERMAN CHEMICAL CO. BOX 9158 MEMPHIS TN 38109	1022 502	CHLORDANE	01/06/88	/ /	04	TN
COASTAL CHEMICAL CORP. P.O. BOX 956 GREENVILLE NC 27834	5549 41	CHLORDANE	01/06/88	/ /	04	NC
CORN BELT CHEMICAL CO. P.O. BOX 410 MCCOOK NE 69001	10107 7	CHLORDANE	01/06/88	/ /	07	NE
CORN BELT CHEMICAL CO. P.O. BOX 410 MCCOOK NE 69001	10107 8	CHLORDANE	01/06/88	/ /	07	NE
CRE-O-TOX CHEMICAL PROD. CO. BOX 12598 MEMPHIS TN 38112	1066 29	CHLORDANE	01/06/88	/ /	04	TN
CRE-O-TOX CHEMICAL PROD. CO. BOX 12598 MEMPHIS TN 38112	1066 29	HEPTACHLOR	01/06/88	/ /	04	TN
DEITZ EACH PESTICIDE CORP. P.O. BOX 9986 ATLANTA GA 30319	6754 11	CHLORDANE	01/06/88	/ /	04	GA
DEITZ EACH PESTICIDE CORP. P.O. BOX 9986 ATLANTA GA 30319	6754 40	CHLORDANE	01/06/88	/ /	04	GA
DEITZ EACH PESTICIDE CORP. P.O. BOX 9986 ATLANTA GA 30319	6754 40	HEPTACHLOR	01/06/88	/ /	04	

STOP SALES ISSUED AS THE RESULT OF SECTION 3(c)(2)(B)
SUSPENSIONS ISSUED UNDER FIFRA

COMPANY	EPA REG.#	PRODUCT & CHEMICAL	SS ISSUED	LIFTDATE	REGION	STATE
DETTEL BACH PESTICIDE CORP. P.O. BOX 9986 ATLANTA GA 30319	6754 5	HEPTACHLOR	01/06/88	/ /	04	GA
DETTEL BACH PESTICIDE CORP. P.O. BOX 9986 ATLANTA GA 30319	6754 54	CHLORDANE	01/06/88	/ /	04	GA
DETTEL BACH PESTICIDE CORP. P.O. BOX 9986 ATLANTA GA 30319	6754 54	HEPTACHLOR	01/06/88	/ /	04	GA
DETTEL BACH PESTICIDE CORP. P.O. BOX 9986 ATLANTA GA 30319	6754 64	CHLORDANE	01/06/88	/ /	04	GA
DETTEL BACH PESTICIDE CORP. P.O. BOX 9986 ATLANTA GA 30319	6754 64	HEPTACHLOR	01/06/88	/ /	04	GA
DETTEL BACH PESTICIDE CORP. P.O. BOX 9986 ATLANTA GA 30319	6754 9	CHLORDANE	01/06/88	/ /	04	GA
DETTELBACH CHEMICALS CORP. 2676 APPLE VALLEY RD. ATLANTA GA 30319	1421 23	CHLORDANE	01/06/88	/ /	04	GA
DEXOL INDUSTRIES 1450 W. 228TH ST. TORRANCE CA 90501	192 132	CHLORDANE	01/06/88	/ /	09	CA
DEXOL INDUSTRIES 1450 W. 228TH ST. TORRANCE CA 90501	192 133	CHLORDANE	01/06/88	/ /	09	CA
DEXOL INDUSTRIES 1450 W. 228TH ST. TORRANCE CA 90501	192 42	CHLORDANE	01/06/88	/ /	09	CA
DEXOL INDUSTRIES 1450 W. 228TH ST. TORRANCE CA 90501	192 43	CHLORDANE	01/06/88	/ /	09	CA
DREXEL CHEMICAL COMPANY 2487 PENNSYLANIA ST. BOX 9306 MEMPHIS TN 38109	19713 214	CHLORDANE	01/06/88	/ /	04	TN
DREXEL CHEMICAL COMPANY 2487 PENNSYLANIA ST. BOX 9306 MEMPHIS TN 38109	19713 215	CHLORDANE	01/06/88	/ /	04	TN

STOP SALES ISSUED AS THE RESULT OF SECTION 3(C)(2)(B)
SUSPENSIONS ISSUED UNDER FIFRA

COMPANY	EPA REG.#	PRODUCT & CHEMICAL	SS ISSUED	DISTRATE	REGION	STATE
FALLS CHEMICALS, INC. P.O. BOX 2345 GREAT FALLS MT 59403	40481 24	CHLORDANE	01/06/88	/ /	01	MT
FALLS CHEMICALS, INC. P.O. BOX 2345 GREAT FALLS MT 59403	40811 5	CHLORDANE	01/06/88	/ /	01	MT
FORDS CHEMICAL & SERVICE INC. 2739 PASADENA BLVD. PASADENA TX 77502	10370 116	CHLORDANE	01/06/88	/ /	06	TX
FORDS CHEMICAL & SERVICE INC. 2739 PASADENA BLVD. PASADENA TX 77502	10370 144	CHLORDANE	01/06/88	/ /	06	TX
FORDS CHEMICAL & SERVICE INC. 2739 PASADENA BLVD. PASADENA TX 77502	10370 145	CHLORDANE	01/06/88	/ /	06	TX
FORDS CHEMICAL & SERVICE INC. 2739 PASADENA BLVD. PASADENA TX 77502	10370 40	CHLORDANE	01/06/88	/ /	06	TX
FORSEAW CHEMICAL CO. 650 STATE STREET CHARLOTTE NC 28208	7243 27	HEPTACHLOR	01/06/88	/ /	04	NC
FORSEAW CHEMICAL CO. 650 STATE STREET CHARLOTTE NC 28208	7243 31	HEPTACHLOR	01/06/88	/ /	04	NC
FORSEAW CHEMICAL CO. 650 STATE STREET CHARLOTTE NC 28208	7243 89	HEPTACHLOR	01/06/88	/ /	04	NC
FORSEAW CHEMICAL CO. 650 STATE STREET CHARLOTTE NC 28208	7234 100	CHLORDANE	01/06/88	/ /	04	NC
FORSEAW CHEMICAL CO. 650 STATE STREET CHARLOTTE NC 28208	7234 101	CHLORDANE	01/06/88	/ /	04	NC
FORSEAW CHEMICAL CO. 650 STATE STREET CHARLOTTE NC 28208	7234 5	CHLORDANE	01/06/88	/ /	04	NC
FORSEAW CHEMICAL CO. 650 STATE STREET CHARLOTTE NC 28208	7234 6	CHLORDANE	01/06/88	/ /	04	

STOP SALES ISSUED AS THE RESULT ON SECTION [illegible]
SUSPENSIONS ISSUED UNDER FIFRA

COMPANY	EPA REG.#	PRODUCT & CHEMICAL	SS ISSUED	LIFTDATE	REGION	STATE
GARDEN CARE BY FARMINGDALE 6[illegible] AUSTIN BLVD. COMMACK NY [illegible]	5[illegible]27 [illegible]	CHLORDANE	[illegible]	[illegible]	02	NY
GARDEN CARE BY FARMINGDALE 6[illegible] AUSTIN BLVD. COMMACK NY [illegible]	5[illegible]27 [illegible]	CHLORDANE	01/06/88	[illegible]	[illegible]	NY
MYSTIC CHEMICAL PRODUCTS [illegible] WEST 1[illegible]5TH ST. CLEVELAND OH 4[illegible]	16672 [illegible]	CHLORDANE	[illegible]/05/88	[illegible]	05	OH
PERK PRODUCTS & CHEM. CO. [illegible] LEWIS ST NASHVILLE TN 372[illegible]	69[illegible] 5[illegible]	CHLORDANE	01/06/88	[illegible]	04	TN
SOUTHERN MILL CREEK PROD. CO. P.O. BOX 1096 5514 N 56TH TAMPA FL 33601	6720 [illegible]3	CHLORDANE	[illegible]/06/88	[illegible]	04	FL
SOUTHERN MILL CREEK PROD. CO. P.O. BOX 1096 5514 N 56TH TAMPA FL 33601	6720 [illegible]	CHLORDANE	[illegible]	[illegible]	04	FL
SOUTHERN MILL CREEK PROD. CO. P.O. BOX 1096 5514 N 56TH TAMPA FL 33601	6720 2	CHLORDANE	[illegible]	[illegible]	04	FL
SOUTHERN MILL CREEK PROD. CO. P.O. BOX 1096-5514 N 56TH TAMPA FL 33601	6720 279	HEPTACHLOR	[illegible]	[illegible]	04	FL
SOUTHERN MILL CREEK PROD. CO. P.O. BOX 1096 5514 N 56TH TAMPA FL 33601	6720 280	CHLORDANE	[illegible]	[illegible]	04	FL
SOUTHERN MILL CREEK PROD. CO. P.O. BOX 1096 5514 N 56TH TAMPA FL 33601	6720 361	CHLORDANE	01/05/88	[illegible]	04	FL
SOUTHERN MILL CREEK PROD. CO. P.O. BOX 1096 5514 N 56TH TAMPA FL 33601	6720 363	CHLORDANE	01/06/88	[illegible]	04	FL
SOUTHERN MILL CREEK PROD. CO. P.O. BOX 1096 5514 N 56TH TAMPA FL 33601	6720 71	CHLORDANE	01/06/88	[illegible]	04	FL
SOUTHLAND PEARSON & CO. P.O. BOX 7344 MOBILE AL 36607	728 45	CHLORDANE	[illegible]	[illegible]	04	AL

[illegible]

STOP SALES ISSUED AS THE RESULT [illegible] SECTION [illegible]
SUSPENSIONS [illegible]

COMPANY	EPA REG.#	PRODUCT & CHEMICAL	[illegible] DATE	STATE
SOUTHLAND PEARSON & CO. P.O. BOX 7344 MOBILE AL 366[illegible]	7[illegible] 47	CHLORDANE	[illegible]	AL
STEPHENSON CHEM. CO., INC. BOX 871[illegible] COLLEGE PARK GA [illegible]	4687 [illegible]	CHLORDANE	[illegible]	GA
STEPHENSON CHEM. CO., INC. BOX 871[illegible] COLLEGE PARK GA [illegible]	4687 19	CHLORDANE	[illegible]	GA
STEPHENSON CHEM. CO., INC. BOX 871[illegible] COLLEGE PARK GA 30337	4687 49	CHLORDANE	[illegible]	GA
STEPHENSON CHEM. CO., INC. BOX 87188 COLLEGE PARK GA [illegible]337	4687 59	HEPTACHLOR	[illegible]	GA
STEPHENSON CHEM. CO., INC. BOX 87188 COLLEGE PARK GA [illegible]	4687 [illegible]	HEPTACHLOR	[illegible]	GA
SUNNILAND CORPORATION [illegible] DAY AVENUE P.O.BOX [illegible] SANFORD FL 32771	[illegible]	CHLORDANE	[illegible]	FL
VACCINOL CHEMICAL CO., INC. 1625 NORTH HIGHLAND MEMPHIS TN 38108	1353 4	CHLORDANE	[illegible]	TN
VAN WATERS & ROGERS 2256 JUNCTION AVENUE SAN JOSE CA 95131	550 [illegible]	CHLORDANE	[illegible]	CA
VAN WATERS & ROGERS 2256 JUNCTION AVENUE SAN JOSE CA 95131	550 [illegible]	CHLORDANE	[illegible]	CA
W R GRACE & COMPANY P.O.BOX 277 109 N MAIN ST. MEMPHIS TN 38103	2124 742	CHLORDANE	[illegible]	TN
WILSON LABS, INC. P.O. BOX 4557 SPRINGDALE CT 06907	50383 [illegible]	CHLORDANE	[illegible]	CT
WILSON LABS, INC. P.O. BOX 4557 SPRINGDALE CT 06907	50383 [illegible]	CHLORDANE	[illegible]	[illegible]

headquarters building at 401 M Street SW., Washington, DC.

The purpose of the meeting is to review the first draft of the Risk Reduction Group's strategy on environmental risk reduction.

The meeting is open to the public. Any member of the public wishing to attend, make brief oral comments, or submit written comments to the Group should notify Mrs. Kathleen Conway, Executive Secretary, or Mrs. Dorothy Clark, Staff Secretary, (A101-F) Science Advisory Board, by the close of business on Friday, November 20, 1987. The telephone number is (202) 382-2552

Terry F. Yosie,

Director, Science Advisory Board.

Date: October 29, 1987.

[FR Doc. 87-25389 Filed 11-2-87; 8:45 am]

BILLING CODE 6560-50-M

[FPL-3286-1]

Science Advisory Board Research Strategy Subcommittee Sources, Transport and Fate Group; Open Meeting

Under Pub. L. 92-463, notice is hereby given that the Sources, Transport and Fate Subgroup of the Science Advisory Board's Research Strategies Subcommittee will meet from 9:00 a.m. to 4:00 p.m. on December 8th at the Hyatt Regency Hotel, International Parkway (inside the Dallas Fort Worth Airport), in the Conference Room. The purpose of the Research Strategies Subcommittee is to advise the Administrator of the Environmental Protection Agency on the development of research strategies needed to enhance the Agency's ability to acquire scientific and technical information to support regulatory decision making, and to identify emerging environmental issues. The Sources, Transport and Fate Subgroup will evaluate environmental contaminants from both a media-specific and a multi-media basis.

The meeting is open to the public. Any member of the public wishing to attend or submit written comments should notify Dr. Terry F. Yosie, Director, Science Advisory Board, at 202-382-4126 or Joanna Foellmer by December 4, 1987.

Date: October 28, 1987.

Terry F. Yosie,

Director, Science Advisory Board.

[FR Doc. 87-25391 Filed 11-2-87; 8:45 am]

BILLING CODE 6560-50-M

[OPP-60011; FRL-3286-8]

Chlordane and Heptachlor Termiticides; Cancellation Order

AGENCY: Environmental Protection Agency (EPA).

ACTION: Order.

SUMMARY: On October 1, 1987, EPA issued an Order accepting the voluntary cancellation of certain chlordane and heptachlor termiticide registrations held by Velsicol Chemical Corporation, and limiting the use of existing stocks of Velsicol's chlordane and heptachlor termiticide products outside the company's control on August 11, 1987. Under the terms of the Order, such stocks may be sold, distributed or used according to their current labels until November 30, 1987. From December 1, 1987 until April 15, 1988, such stocks may only be sold, distributed or used in accordance with the Directions for Use accompanying the Order. No sale, distribution or use of such stocks will be permitted after April 15, 1988.

FOR FURTHER INFORMATION CONTACT:

By mail: George LaRocca, Registration Division (TS-767C), Office of Pesticide Programs, Environmental Protection Agency, 401 M Street SW., Washington, DC 20460.

Office location and telephone number: Rm. 204, Crystal Mall Building #2, 1921 Jefferson Davis Highway, Arlington, VA, (703) 557-2400.

SUPPLEMENTARY INFORMATION: On August 11, 1987, EPA and Velsicol Chemical Corporation (Velsicol) entered into an agreement affecting Velsicol's registrations of chlordane and heptachlor termiticide products (except for a registration involving underground cable treatments). Under the terms of the agreement, certain uses of Velsicol's termiticide products were deleted from the label and the remainder of the registrations were converted into conditional registrations. Under the terms of the conditional registrations, no further sale or distribution by Velsicol of its affected chlordane and heptachlor termiticide products was allowed unless and until Velsicol satisfied air monitoring requirements specified in the conditional registrations. The August 11th agreement did not affect existing stocks of Velsicol's termiticide products outside of Velsicol's control on or before that date (which EPA estimated at the time to be a volume equal to approximately 2 months average use, or about 110,000 gallons).

Portions of the August 11th agreement were challenged by a number of environmental groups in a federal court action.

The court in that action expressed concern that EPA might have underestimated the amount of existing stocks or that use of the existing stocks might continue indefinitely. While EPA continues to believe that its estimate was an accurate one, EPA and Velsicol agreed to supplement the August 11th agreement in order to alleviate the court's concerns.

Under the terms of the Supplement, ratified on October 1, 1987, Velsicol's chlordane and heptachlor termiticide registrations were split into product registrations containing the deleted uses and product registrations containing the retained uses. Those registrations containing the deleted uses were voluntarily canceled. EPA issued an Order on October 1, 1987, accepting the voluntary cancellation and placing a two-tiered cap on the use of existing stocks of Velsicol's chlordane and heptachlor termiticide products outside of Velsicol's control on August 11, 1987. These stocks may be sold, distributed and used in any manner consistent with their labeling until November 30, 1987. From December 1, 1987 until April 15, 1988, these stocks may be sold, distributed and used only in accordance with the specific directions for use attached to the October 1st Order. No use of existing stocks will be permitted after April 15, 1988.

The text of the October 1st Order and the attached Directions for Use are set forth below:

In the Matter of: The Voluntary Cancellation of Certain Pesticide Product Registrations Held by the Velsicol Chemical Corporation.

Order Accepting Voluntary Cancellation and Authorizing Use of Existing Stocks With Limitations

As explained more fully below, this order accepts the voluntary cancellation of the registrations of certain pesticide products registered by the Velsicol Chemical Corporation ("Velsicol") and imposes limitations on the continued sale, distribution, and use of existing stocks of such products. This Order is issued pursuant to the authority in section 6(a)(1) of the Federal Insecticide, Fungicide and Rodenticide Act.

On August 11, 1987, Velsicol and EPA entered into an agreement affecting Velsicol's registrations of chlordane and heptachlor products. The agreement is memorialized in a Memorandum of Understanding and accompanying Conditions of Registration and Monitoring Protocol. Under the terms of the August 11 agreement, Velsicol classified the following uses of its end-

use termiticide products as "deleted uses":

a. Post-construction application of material from within a structure to voids created by humans ("structure");

b. Post-construction application of material from outside a structure to inside or underneath a structure;

c. The use of pressure rodding for post-construction application of material to a basement-type or crawl-space type structure;

d. Pre- or post-construction treatment of the area underneath crawl-space and post and pier type structures;

e. Treatment of voids and spaces in masonry or block walls or areas behind veneers;

f. Applications by non-certified applicators;

g. Soil-injection pressure rodding at pressures greater than 25 psi.

The agreement further classified the following uses of end-use termiticide products as "retained uses":

a. Application to the outside perimeter of any structure by trenching, or drilling through sidewalks, patios, or other unenclosed slabs, and applying material to the soil without pressure (e.g., flow or gravity feed);

b. Applications by the excavation technique to the exterior of any structure (*i.e.*, by removing soil next to the foundation, placing on a tarp, treating with termiticide, and placing back in trench after soil dries);

c. Pre-construction low-pressure (maximum 25 psi) vertical rodding (with the application rod equipped with a pressure control device to prevent higher pressures) of the perimeter outside any structure;

d. Post-construction low-pressure (maximum 25 psi) vertical rodding (with the application rod equipped with a pressure control device to prevent higher pressures) outside slab and post and pier type structures;

e. Post-construction coarse spray surface treatment (maximum 50 psi) and low-pressure (maximum 25 psi) vertical rodding (with the application rod equipped with a pressure control device to prevent higher pressures) under the slab of slab type structures.

The agreement classified one use, the protection of underground cables, as an "unaffected use".

In addition to this classification of the uses of Velsicol's termiticide products, the agreement included, *inter alia*, the following provisions:

- The retained uses were converted to restricted uses as provided for in sections 3(d) and 4 of FIFRA;
- The registrations of the retained uses were amended to conditional registrations, with no sale or distribution by Velsicol allowed until certain conditions set forth in the Conditions of Registration are met.
- No further sale or distribution by Velsicol of end-use products labeled for deleted uses was allowed.
- Velsicol amended the label of its manufacturing-use products to provide that such products could not be used to manufacture any end-use product (other than Velsicol products) for sale and distribution in the United States that is labeled for use as a subterranean termiticide.

The agreement became effective immediately on August 11, 1987. In return for the conditions accepted by Velsicol, EPA agreed, *inter alia*, that it would take no action against existing stocks of Velsicol's products then in the hands of applicators and distributors. EPA estimated that a volume equal to approximately two-months average use of chlordane and heptachlor termiticides (or approximately 110,000 gallons) was in the hands of applicators and distributors as of August 11th.

Portions of the agreement between Velsicol and EPA have been challenged in a federal court action brought by a number of environmental groups (*NCAMP v. EPA*, Civil Action No. 87-1089-LFO, D.D.C.). The court in that action has expressed concerns that EPA may have substantially underestimated the amount of existing stocks as of August 11th or that some individuals may have large stockpiles of chlordane products. While EPA continues to believe that its earlier estimate of existing stock was an accurate one, EPA contacted Velsicol (as well as the plaintiffs in the federal litigation) to discuss possible amendments to the August 11 agreement in order to resolve the court's concern. Velsicol agreed to amend the agreement, and on October 1, 1987, Velsicol and EAP ratified a Supplement to the Memorandum of Understanding (a copy of which is attached hereto).

Under the terms of this Supplement, Velsicol's chloradane termiticide registrations have been split into product registrations containing the deleted uses and product registrations containing the retained uses. Velsicol and EPA have agreed to the voluntary cancellation of certain product registrations, including those containing the deleted uses (but not those containing the retained uses), and have further agreed to the placement of a two-tiered cap on the use of existing stocks of Velsicol's products outside of its control before August 11. These existing stocks may be sold, distributed, and used in any manner consistent with their labeling until November 30, 1987. From December 1, 1987 until April 15, 1988, these stocks may be sold, distributed, and used only in accordance with the conditions of use prescribed in Appendix A of this Order. No use will be permitted after April 15, 1988.

EPA believes the terms of this Supplement will allow for an orderly and efficient phase-out of chloridane use. The Supplement provides sufficient time for the use of the volume of existing stocks estimated by EPA to exist in August of 1987, but will prevent unlimited use of such stocks if EPA was substantially incorrect in its estimate or if individuals possess large stockpiles. EPA favors a two-tiered approach because it encourages the use of application methods that are believed to pose less potential for misapplication and are believed less likely to result in indoor exposure than the uses that will be discontinued after November 30, 1987.

EPA finds that implementation of this Supplement is consistent with the purposes of FIFRA and will not have unreasonable adverse effects on the environment. EPA has previously determined that the agreement entered into on August 11, 1987, which contained no limitations on the use of existing stocks, was consistent with the purposes of the Act. The limitations contained in this Order will not permit any greater use of stocks than that which the Agency has already found to be acceptable.

The Agency considers the dates set forth herein, which were the product of an agreement between Velsicol and EPA, to be appropriate for several reasons. First, the Agency believes the dates chosen satisfy the concerns that the Agency may have substantially underestimated the amount of stocks in the possession of applicators and distributors as of August 11, 1987 or that individuals may have large stockpiles, by establishing a cap on use that would prevent the use of significantly larger quantities than the amount estimated to exist by EPA. Second, these dates allow for an orderly transition away from the deleted uses (with such uses not being permitted after November 30, 1987), and eventually from all other uses (after April 15, 1988). In particular, they provide EPA, Velsicol, and the National Pest Control Association with an adequate opportunity to notify applicators and state enforcement agencies of the terms of this Order; the dates will not encourage a hurried use of existing stocks which could lead to misapplication and greater indoor exposures; and they will allow for the certification of applicators (use of the

existing stocks will be a restricted use as set forth in FIFRA sections 3(d) and 4 after November 30, 1987). Finally, the dates reflect information provided to EPA that, even though there may well have been only 110,000 gallons of existing stocks in the hands of applicators and distributors on August 11, 1987, the rate of chlordane use has decreased since that date, and will of necessity decrease even further after November 30, 1987 when certain uses will no longer be permitted.

Based on all the foregoing, pursuant to FIFRA section 6(a)(1):

1. The following registrations of Velsicol's End Use Products are hereby cancelled:

A. The End Use Product described in Section II.A.2 of the attached Supplement (that product currently assigned EPA Registration Number 876-233 bearing all uses of Gold Crest Termide other than the retained uses).

B. The End Use Product described in Section II.B.2 of the attached Supplement (that product currently assigned EPA Registration Number 876-63 bearing all uses of Gold Crest C-100 other than the retained uses).

C. The End Use Product described in Section II.C.2 of the attached Supplement (that product currently assigned EPA Registration Number 876-104 bearing all uses of Chlordane 8EC Termite other than the retained uses).

D. Gold Crest C-50 (EPA Reg. No. 876-86).

E. Gold Crest H-60 (EPA Reg. No. 876-85).

F. California SLN for crawlspace perimeter spray (Termide) (CA-810012).

G. California SLN for crawlspace perimeter spray (C-100) (CA-810011).

H. Hawaii SLN for crawlspace perimeter spray (C-100) (HI-850003).

2. The sale, distribution, and use of existing stocks of any products in the possession of persons other than Velsicol on or after August 11, 1987 bearing Registration Numbers 876-63, 876-85, 876-86, 876-104, 876-233, CA-810011, CA-810012, or HI-850003 is subject to the following conditions:

A. Such products may be sold, distributed, and used in any manner consistent with their labeling until November 30, 1987.

B. Such products may be sold, distributed, and used from December 1, 1987 until April 15, 1988 only in accordance with the provisions contained in Appendix 1 to this Order.

C. Such products may not be sold, distributed, or used after April 15, 1988.

D. Any such products that have not been used on or before April 15, 1988 must be disposed of in accordance with applicable federal, state and local laws.

It is so ordered this 1st day of October, 1987.

Douglas D. Campt,

Director, Office of Pesticide Programs.

Appendix I—Voluntarily Cancelled Subterranean Termite Control Products Directions for Use Between December 1, 1987, and April 15, 1988

Restricted use Pesticide

For Retail Sale to and use Only by Certified Applicators or Persons Under Their Direct Supervision

It is a violation of Federal law to use this product in a manner inconsistent with these Directions. This product may not be used against any pests not named in these Directions. Apply only to establish subsurface termite control barriers specified in these Directions.

Contamination of public and private water supplies must be avoided by following these precautions: Use anti-backflow equipment or procedures to prevent siphonage of pesticide back into water supplies. Do not treat soil beneath structures that contain cisterns or wells. Do not treat soil that is water saturated or frozen. Consult state and local specifications for recommended distances of treatment areas from wells, and refer to Federal Housing Administration Specifications on new construction for further guidance.

Preconstruction Subterranean Termite Treatment

Effective preconstruction subterranean termite control requires the establishment of an unbroken vertical and/or horizontal chemical barrier between wood in the structure and the potential or existing termite colonies in the soil. To meet FHA termite proofing requirements, follow the latest edition of the Housing and Urban Development (HUD) Minimum Property Standards.

Dilution Instructions for Gold Crest Termide

Use a .75% water emulsion for subterranean termites other than *Coptotermes* spp. Mix 1 gallon of Gold Crest Termide in 99 gallons of water to produce a 0.75% water emulsion. Use a 0.75–1.5% water emulsion for *Coptotermes* spp. where necessary. Mix 1–2 gallons of Gold Crest Termide in 99 gallons of water to produce a 0.75–1.5% water emulsion.

Dilution Instructions for Gold Crest C100 and Chlordane 8EC/Termite

Use a 1% water emulsion for subterranean termites other than *Coptotermes* spp. Mix 1 gallon of product in 95 gallons of water to produce a 1% water emulsion. Use a 1–2% water emulsion for *Coptotermes* spp. where necessary. Mix 1–2 gallons of product in 95 gallons of water to produce a 1–2% water emulsion.

Dilution Instructions for Gold Crest H-60

Use a .5% water emulsion for subterranean termites other than *Coptotermes* spp. Mix 1 gallon of product in 59 gallons of water to produce a .5% water emulsion. Use a 1% water emulsion for *Coptotermes* spp. where necessary. Mix 2 gallons of product in 59 gallons of water to produce a 1% water emulsion.

Dilution Instructions for Gold Crest C-50

Use a 1% water emulsion for subterranean termites other than *Coptotermes* spp. Mix 1 gallon of product in 47 gallons of water to produce a 1% water emulsion. Use a 2% water emulsion for *Coptotermes* spp. where necessary. Mix 2 gallons of product in 47 gallons of water to produce a 2% water emulsion.

Do not apply to soil beneath structures which will contain subslab or intra-slab air ducts. Do not apply to any area intended as a plenum air space. Check with builder or contractor or determine if the design of the structure includes these ducts or a plenum.

Do not apply to any area inside the foundation wall which will not be covered by a concrete slab (e.g., bath traps, inside surfaces of concrete or block walls above the level of the slab). Cover these areas during application with polyethylene or similar material. Do not treat into or through hollow masonry voids.

Slab Construction

Horizontal Barriers

Before footings are poured, horizontal barriers may be established in footing trenches. Treatment of the footings through hollow masonry voids is prohibited. Then, after interior grading is completed and prior to the pouring of concrete slabs, horizontal barriers may be established on soil which will be covered by concrete floor, entrance platforms, and in other critical areas which will be covered by concrete slabs.

In the case of a single-pour, monolithic slab which does not have a separate foundation or footing, an overall horizontal barrier would be created before the concrete is poured.

To produce a horizontal barrier, apply the emulsion at the rate of 1 gallon per 10 square feet to fill dirt. If fill is washed gravel or other coarse material, apply at 1½ gallons per 10 square feet.

UNITED STATES ENVIRONMENTAL
WASHINGTON, D.C

FEB 9 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Chlordimeform - Stocks at Dealer/Distributor Level

FROM: Phyllis E. Flaherty *Phyllis E Flaherty*
Acting Director
Policy and Grants Division
Office of Compliance Monitoring

TO: Addressees

Recently, I received a question regarding chlordimeform. The question was: "Would a dealer/distributor be in violation of the Cancellation Order for Chlordimeform if a farmer pays for chlordimeform prior to February 19 but does not physically receive the product until after February 19, 1989?"

Based on discussions with the Office of General Counsel and the Office of Pesticide Programs, this action would be a violation of the Cancellation Order. The Cancellation Order states that no one may sell or distribute chlordimeform after February 19. Under the FIFRA 88 amendments, the definition of the term "sell or distribute" includes "deliver". In addition, the intent of the Order was to require the recall of all stocks in the possession of distributors and retailers.

Please forward a copy of this memorandum to States within your Region in order to make sure everyone understands that this is the Agency's position.

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

JUN 19 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Final Compliance Strategy for the Cancellation of Chlordimeform

FROM: John J. Neylan III, Director
Policy and Grants Division (EN-342)
Office of Compliance Monitoring

TO: Addressees

Attached is the Final Compliance Strategy for the Cancellation of Chlordimeform. The Cancellation Order became effective on February 19, 1989.

This strategy is effective immediately and calls for compliance monitoring of the cancellation order through inspection of producing establishments, distributors, dealers/retailers, and users of chlordimeform products. Inspections of distributors, dealers, and users will be conducted by States with Cooperative Enforcement Agreements, as part of their routine inspections. In those States in which the producing establishments are located, inspections are to be conducted in order to monitor the recall provision of the Cancellation Order. Also, in Regions/States where substantial use has occurred, States are to specifically target and conduct inspections at the distributor/dealer level for purposes of assuring compliance with the Cancellation Order.

We appreciate the comments submitted on the February 15, 1989 draft of this strategy. We have incorporated most of these comments into the final document. Attached is a summary of these comments and OCM's responses. For your information, we have also attached a copy of the February 8, 1989 FEDERAL REGISTER Notice entitled, "Final Decision Not to Initiate a Special Review and Decision and Order of Cancellation." Included as appendices to the Strategy are a list of chlordimeform pesticide registrants, products, and producing establishments and a summary of the chlordimeform actions.

If you have any questions regarding the attached strategy, please contact Steve Howie of my staff at FTS 475-7786.

Attachments

ADDRESSEES

Douglas D. Campt (H7501C)
Edwin F. Tinsworth (H7505C)
Anne Lindsay (H7505C)
Frederick F. Stiehl (LE-134A)
Mark Greenwood (LE-132A)
A. E. Conroy II (EN-342)
Connie Musgrove "
Mike Wood "
Jerry Stubbs "
Sherry Sterling "
David Dull "
Ken Kanagalingam "
Bob Zisa "
John J. Neylan III "
Phyllis E. Flaherty "
Maureen Lydon "

Jake Mackenzie
Western Regional Compliance Director

I	Louis F. Gitto, Director Air Management Division	Marvin Rosenstein, Chief Pesticides & Toxic Substances Br
II	Barbara Metzger, Director Environmental Services Division	Ernest Regna, Chief Pesticides & Toxic Substances Br
III	Stephen R. Wassersug, Director Hazardous Waste Management Div	Larry Miller, Chief Toxic & Pesticides Branch
IV	Winston A. Smith, Director Air, Pest. & Toxics Mangt. Div	Richard DuBose, Chief Pesticides & Toxic Substances Br
V	William H. Sanders III, Director Environmental Services Division	Phyllis Reed, Chief Pesticides & Toxic Substances Br
VI	William B. Hathaway, Director Air, Pesticides & Toxic Division	Robert Murphy, Chief Pesticides & Toxic Substances Br
VII	William A. Spratlin, Director Air and Toxics Division	Carl Walter, Acting Chief Pesticides & Toxic Substances Br
VIII	Irwin L. Dickstein, Director Air and Toxics Division	Alvin Yorke, Chief Toxic Substances Branch
IX	David P. Howekamp, Director Air Management Division	Davis Bernstein, Chief Pesticides & Toxics Branch
X	Gary O'Neal, Director Air and Toxics Division	Kenneth Feigner, Chief Pesticides & Toxic Substances Br

cc: Michael Walker (LE-134P)
Jim Roeloffs (TS-788)
John Tice (TS-769C)
Al Heier (A-107)

RESPONSE TO COMMENTS RECEIVED RELATED TO CHLORDIMEFORM STRATEGY

COMMENT 1: One Region was concerned how the cancellation order treats the end-user who wants to "give away" a small quantity of chlordimeform to another end-user.

Another Region wanted to know if a dealer/distributor would be in violation of the Cancellation Order if a farmer paid for the chlordimeform prior to February 19, 1989 but did not receive the product until after that date.

RESPONSE 1: The Cancellation Order states that no one may sell or distribute chlordimeform after February 19, 1989. Under the FIFRA 88 amendments, the term "sell or distribute" includes "deliver." Therefore, such a transfer without exchange of monies or a prior payment and subsequent distribution would both be considered a "delivery" and are prohibited by the Cancellation Order. Please refer to the memorandum sent to the Regions on February 9, 1989 from Phyllis E. Flaherty entitled, "Chlordimeform - Stocks at Dealer/Distributor Level," for further discussion on this subject.

COMMENT 2: One Region suggested that OCM develop a "Compliance Monitoring Summary" which would present all EPA cancellations, etc, in a concise booklet which would list cancellation dates, effective dates for discontinuation of sales, final date for use of existing stocks, and any other pertinent facts.

RESPONSE 2: We have added a summary (see Appendix B) for chlordimeform which addresses this issue.

COMMENT 3: One Region felt that the strategy should require chlordimeform inspections to be targeted instead of allowing the states to set their own priorities in relation to ongoing state work. The commenters suggested that specific reporting of inspections or findings should be required to be submitted to EPA. The commenter suggested that more responsibility be placed on the states for some reporting response since inspections, except for tips and complaints, are routine.

RESPONSE 3: We have incorporated this suggestion into the strategy by adding requirements for producing establishment inspections and affirmative inspections in States with a history of substantial use of chlordimeform.

COMMENT 4: One commenter suggested that the States be required to check the recall provision of the Order at the registrants production facilities and distributors, and to conduct random inspections at a specified number of RUP dealers/distributors.

RESPONSE 4: We have incorporated this into the Strategy. Since the two registrants are required to conduct a recall down to the dealer/distributor level, the States should monitor the recall provision of the cancellation order according to Section 14 of the Pesticides Inspection Manual (dated August 1987). Furthermore, the recall action is to be followed up by a visit to the companies to check their records to determine if the recall was successful.

FINAL COMPLIANCE STRATEGY FOR THE CANCELLATION OF CHLORDIMEFORM

OVERVIEW

Chlordimeform is present as the active ingredient in pesticide products registered for use to control the egg and larvae stage of Heliothis spp. on cotton. Chlordimeform products are also registered as yield enhancers for all cotton growing areas based on increased cotton yields above that expected from insect control alone.

In 1985, the two chlordimeform registrants, Ciba-Geigy Corporation (Ciba-Geigy) and Nor-Am Chemical Company (Nor-Am) were notified of the Agency's intention to commence a Special Review of pesticide products containing chlordimeform. In January 1986, the draft Registration Standard, which was made available for public comment, stated that the Agency intended to put chlordimeform in the Special Review process. Studies with the unmetabolized parent chlordimeform indicated that the compound was not mutagenic; however, metabolism of the parent compound produced one metabolite considered moderately mutagenic and another one considered to be strongly mutagenic.

On January 6, 1989, the Acting Assistant Administrator for the Office of Pesticides and Toxic Substances signed a FEDERAL REGISTER Notice entitled: "Chlordimeform: Final Decision Not to Initiate a Special Review and Decision and Order of Cancellation." The Agency's decision is based on the proposal, in February 1988, by Ciba-Geigy and Nor-Am, to voluntarily cancel all chlordimeform registrations effective February 19, 1989. The registrants indicated that they intended to terminate sale and distribution after the 1988 cotton-growing season. Furthermore, the Order cancels all registrations of pesticide products containing chlordimeform as the active ingredient and prohibits all sale and distribution of existing stocks of chlordimeform in the possession of registrants, retailers, and distributors after February 19, 1989. Additionally, the registrants are required, by the Order of Cancellation, to recall all existing stocks down to the dealer/distributor level, consistent with their earlier proposal to the Agency.

The Agency conducted a short term risk/benefit analysis of the use of existing stocks of chlordimeform in the hands of end-users and has concluded that the benefits of one additional year of limited use outweigh the risks of such use. Therefore, the Order allows use of existing stocks in the possession of end users until October 1, 1989.

Compliance with the Cancellation Order will be determined through inspections of registrants, distributors, dealers, and users of canceled products. Inspections are to be conducted by States with Cooperative Enforcement Agreements and EPA in States without Cooperative Enforcement Agreements, as part of their current routine inspections. In Regions/States where substantial use of chlordimeform has occurred, States will specifically target and conduct inspections at the distributor/dealer level for purposes of assuring compliance with the Cancellation Order. If States receive tips, complaints, or other information indicating that use is occurring after October 1, 1989, they should target specific inspections at the user level.

REGULATED INDUSTRY

All registrants, producers, distributors, and users of chlordimeform are subject to the Cancellation Order. At the time of the voluntary cancellation, there were two registrants, eight registrations, and two producer establishments. A list of these can be found in Appendix A.

CONDITIONS OF CANCELLATION

All pesticide products containing chlordimeform were automatically canceled on February 19, 1989.

Recall

The Order requires the two registrants to conduct a recall down to the dealer/distributor level consistent with their earlier proposal to the Agency, in order to ensure that no further quantities of chlordimeform become available to end users.

Existing Stocks

Sale and distribution of existing stocks now in the possession of retailers and distributors is not permitted. Such sale and distribution was prohibited as of February 19, 1989. Please note that section 2(gg) of the FIFRA 88 Amendments defines the term "to distribute or sell" to mean: to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver.

Ciba-Geigy and Nor-Am have indicated that they have not marketed chlordimeform after the 1988 cotton growing season. Both registrants are required to recall all existing stocks of chlordimeform down to the dealer/distributor level. The

registrants have also indicated that they will accept for disposal any stocks of chlordimeform turned in by end users. Persons holding existing stocks of canceled products must dispose of them in accordance with the applicable requirements of the Resource Conservation and Recovery Act (RCRA). Noncompliance with the Cancellation Order or its terms is a violation of FIFRA sections 12(a)(1)(A) and 12(a)(2)(K).

The use of chlordimeform stocks in the possession of end users will be allowed until October 1, 1989; however, such use must be in accordance with the terms of the cancellation order and any label restrictions.

COMPLIANCE MONITORING

Producing establishments will be asked to verify by mail that production and sale for distribution within the U.S. has ceased. Compliance with the Cancellation Order will be determined during inspections at producing establishments.

During routine inspections of dealers and users, inspectors are to ensure that the canceled products are no longer being sold or distributed or, if after October 1, 1989, used. Tips and complaints are to be investigated as appropriate. If a State/EPA has reason to suspect violations, then inspections should be specifically targeted and conducted to address any potential violations.

Producer establishments are located in Regions 3 and 4; therefore Regions 3 and 4 have their lead responsibility for monitoring the efforts of Nor-Am and Ciba-Geigy, respectively, to recall all existing stocks and to ensure that the results of the recall are forwarded to EPA Headquarters. Recall monitoring of existing stocks will also be performed by Regions working in conjunction with the States, with priority placed on areas where substantial use has occurred.

ALLOCATION OF RESPONSIBILITIES

Office of Pesticide Programs

Will develop and provide OCM with a list of products affected by the Notice and their registration status.

Office of Compliance Monitoring

Will develop and transmit the Compliance Monitoring Strategy to the Regions.

Will distribute a list of registrants, producing establishments, and products affected by the Notice to the Regions.

Regions

Will provide copies of the Compliance Monitoring Strategy to the States.

Will distribute a list of registrants, producing establishments, and products affected by this Notice to the States.

Will conduct inspections in States without Cooperative Enforcement Agreements as specified in this Strategy.

Will take enforcement actions as appropriate.

Will report information to States which indicates possible non-compliance with the Cancellation Order, including information on tips and complaints received.

Will specify recall monitoring provisions to the States.

Will report results of the recall and any violations to EPA headquarters as where specified in this strategy.

States

Will conduct inspections and submit reports as agreed upon with the Regions.

Will monitor the recall provisions of the Cancellation Order as required by the Strategy.

Will investigate tips and complaints as received. If States receive information which indicates possible noncompliance with the Cancellation Order, they should investigate to ensure compliance.

Will take enforcement actions, as appropriate.

In addition, States should address the chlordimeform Cancellation Order in their priority setting process for FY 90, as appropriate.

APPENDIX B

COMPLIANCE STRATEGY SUMMARY FOR CHLORDIMEFORM CANCELLATION

AFFECTED ENTITY	REQUIREMENTS	EFFECTIVE DATE	AUTHORITY
Registrants/Retailers/ Distributors	Existing Stocks (Sale and Distribution)	2/19/89	Order
Registrants	Recall	*	Order
Registrants	Disposal	*	**
Users	Existing Stocks (Use)	10/1/89	Order
Users	Disposal	10/1/89***	**

* No effective date mentioned in the FR Notice.

** Applicable Federal, State, and Local laws

*** Must be disposed of after this date but no time frame in FR Notice.

ENVIRONMENTAL PROTECTION AGENCY

[OPP-30000/52A; FRL-3618-7]

Chlordimeform; Final Decision Not To Initiate a Special Review and Decision and Order of Cancellation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; final decision not to initiate a special review and decision and order of cancellation.

SUMMARY: On September 19, 1988, the Agency proposed not to initiate a Special Review of chlordimeform (53 FR 36422) because chlordimeform registrations had been amended, at the registrants' request, to terminate on February 19, 1989. The September 19 notice also proposed not to allow sale, distribution, and use of chlordimeform after February 19, 1989. In response to the notice, EPA received numerous comments from users, state officials, and researchers to allow use of remaining stocks in 1989. After conducting a risk/benefit analysis of the use of existing stocks for one more season, EPA has decided to allow use of existing stocks of chlordimeform in the possession of end users until October 1, 1989. Sale and distribution of existing stocks now in the possession of registrants, retailers, and distributors will not be permitted after February 19, 1989; registrants are required to recall those stocks in the hands of distributors and retailers.

FOR FURTHER INFORMATION CONTACT:

By mail: Paul Parsons, Registration Division (TS-767C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

Office location and telephone number: Rm. 1008, CM #2, 1921 Jefferson Davis Highway, Arlington, VA. (703-557-0064).

SUPPLEMENTARY INFORMATION: This Notice has six units. Unit I is the Introduction. Unit II summarizes the Agency's risk concerns about chlordimeform. Unit III discusses the comments received in response to the proposed notice not to initiate a Special Review of chlordimeform. Unit IV sets forth the Agency's final decision not to initiate the Special Review of chlordimeform and the Agency's risk/benefit analysis of allowing the use of existing stocks of chlordimeform in 1989. Unit V describes the comment opportunities and announces the availability of the public docket. Unit VI sets forth the Order of Cancellation.

I. Introduction

A. Description of Chlordimeform

Chlordimeform is the common name for N'-(4-Chloro-o-tolyl)-N, N-dimethylformamidine. Chlordimeform hydrochloride is the common name for N'-(4-Chloro-o-tolyl)-N,N-dimethylformamidine hydrochloride. The two most common trade names are Galecron® (Ciba-Geigy Corporation) and Fundal® (Nor-Am Chemical Company). Both Ciba-Geigy and Nor-Am are registrants of technical chlordimeform and chlordimeform hydrochloride. Chlordimeform, an insecticide, is used on cotton to control *Heliothis spp.*

B. Legal Background

A pesticide product may be sold or distributed in the United States only if it is registered or exempt from registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136 *et seq.*). Before a product can be registered it must be shown that it can be used without "unreasonable adverse effects on the environment." (FIFRA section 3(c)(5)). The term "unreasonable adverse effects on the environment" is defined in FIFRA section 2(bb) as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefit of the use of any pesticide." The burden of proving that a pesticide meets this standard for registration is, at all times, on the proponent of initial or continued registration. If at any time the Agency determines that a pesticide no longer meets this standard, the Administrator may cancel this registration under section 6 of FIFRA.

The Special Review process provides a mechanism to permit public participation in EPA's deliberations prior to issuance of any Notice of Final Determination describing the regulatory action which the Administrator has selected. The Special Review process, which was previously called the Rebuttable Presumption Against Registration (RPAR) process, is described in 40 CFR Part 154, published in the Federal Register of November 27, 1985 (50 FR 49015).

The Special Review process is commenced by the issuance of a preliminary notification to registrants and applicants for registration pursuant to 40 CFR 154.21 that the Agency is considering commencing a Special Review. If the Agency determines, after issuance of a notification pursuant to 40 CFR 154.21, that it will not conduct a Special Review, it is required under 40 CFR 154.23 to issue a proposed decision to be published in the Federal Register. That regulation requires that a period of not less than 30 days be provided for public comment on the proposed decision not to conduct a Special Review. Subsequent to receipt and evaluation of comments on the proposed decision not to conduct a Special Review, the Administrator is required by 40 CFR 154.25 to publish in the Federal Register his final decision regarding whether or not a Special Review will be conducted.

C. Regulatory History

Chlordimeform was first registered in 1966 for use on apples. Between 1966 and 1976 use on several more crops was authorized, including cotton. In 1976 the registrants voluntarily withdrew chlordimeform from the market based on results of a chronic mouse study showing that chlordimeform caused malignant tumors.

Chlordimeform was reintroduced to the market in 1978 with only the cotton use on the label. At that time, extensive protective clothing measures were required as well as requirements for mixing and loading in closed systems, reduced application rates, restricted use classification, and training for workers. Registrants were also required to implement a worker urine monitoring program. Following the reintroduction of chlordimeform, the Agency received additional positive mouse cancer studies on chlordimeform and its metabolites.

On September 15, 1985, the Agency issued a preliminary notification to the registrants of chlordimeform, pursuant to 40 CFR 154.21, based on evidence that chlordimeform caused tumors in laboratory animals. On January 15, 1986, a draft Registration Standard for chlordimeform was issued for public comment. This document notified the public that the Agency would initiate a Special Review and invited comments from registrants and other interested parties. Public comment on the draft Registration Standard was initiated because there was a substantially complete chronic health and teratology data base for chlordimeform (40 CFR 158.34). The Agency decided not to issue a Federal Register notice merely announcing initiation of a Special Review but to proceed directly to a combined Notice of Initiation of Special Review and Preliminary Determination. A Notice of Preliminary Determination sets forth both the risks and the benefits of the chemical, analyzes the risks and benefits, discusses regulatory options for reducing risk, and proposes a regulatory action. The Agency was preparing a combined Notice of Initiation of Special Review and

Preliminary Determination when, prior to formal initiation of a Special Review, on February 19, 1988, Ciba-Geigy and Nor-Am, the only registrants of chlordimeform, requested voluntary cancellation of all products containing chlordimeform, effective February 19, 1989. Both companies announced their intent to discontinue sale and distribution after the 1988 cotton-growing season, about October 1, 1988; they indicated that they expected existing stocks, about the same amount as they sold in 1987, to be used up in the 1988 growing season. Both companies also stated that they would recall any unused stocks down to the user level, and would dispose of these recalled stocks. Both companies requested immediate withdrawal of all tolerances except for cotton; they requested the withdrawal of the cotton related tolerances effective December 31, 1988. The Agency has approved amendments submitted by both companies which place a termination date of February 19, 1989 on their chlordimeform registrations.

The Agency has also discussed with the National Institute of Occupational Safety and Health (NIOSH) and various State health agencies, a possible program to contact agricultural and factory workers exposed to significant levels of chlordimeform in the past. The purpose of such notification would be to inform workers of their increased risk of bladder cancer, and to encourage them to seek medical attention, such as cancer screening tests, which would allow early detection and treatment. No decision has been made yet to pursue a notification program.

This Notice announces that, for the reasons explained in the September 19, 1988, Federal Register Notice (53 FR 36422) and summarized in Unit IV of this Notice, the Agency will not initiate the Special Review based on the companies' voluntary cancellations. The Agency has cancelled Ciba-Geigy's and Nor-Am's chlordimeform registrations, effective February 19, 1989. The September 19, 1988, proposed notice contained a prohibition against the sale, distribution, and use of existing stocks after February 19, 1989. This notice announces EPA's decision to prohibit sale and distribution after February 19, 1989, but to allow the use of existing stocks in the possession of end users, until October 1, 1989, based on comments and information received from users, state officials, and researchers, which the Agency used in a risk/benefit analysis of the short term use of chlordimeform until October 1, 1989. The reasons for granting this provision are also discussed in Unit IV.

II. Risk Concerns

A. Oncogenic Risks

A private notification, issued pursuant to 40 CFR 154.21, which began the pre-Special Review process, was sent to chlordimeform registrants because of Agency concerns that chlordimeform exceeded the risk criterion for oncogenicity now specified in 40 CFR 154.7(a)(2). This concern was specifically based on four mouse oncogenicity studies which demonstrate significant dose-related increases in tumor rates in male and female mice. These studies are discussed at length in the draft Chlordimeform Registration Standard, which can be obtained from the address given above for "FURTHER INFORMATION."

After the private notification to registrants, the Agency received preliminary findings from a retrospective mortality study of German production workers which suggests 4-chlor-o-toluidine (5-CAT), a metabolite of chlordimeform which has been detected in the urine of exposed agricultural workers, may induce bladder cancer in humans. The metabolite 5-CAT belongs to a class of organic chemicals, the substituted anilines, many members of which have been identified as carcinogenic.

Based on animal data, EPA had previously concluded that there is sufficient experimental evidence to classify chlordimeform as a B_2 or probable human carcinogen, pursuant to Agency carcinogen assessment guidelines. The human data from the epidemiological study of workers support the classification of chlordimeform as a probable human carcinogen.

B. Exposure

Exposure estimates for chlordimeform were developed using data from Ciba Geigy/Nor-am urine monitoring studies and the Agency's surrogate data base. The estimated values for absorbed dose varied by little more than an order of magnitude. The variations in values are not viewed as significant and in fact represent a reasonable agreement between the dermal surrogate data and urine data and support the level of confidence in the exposure determinations. A detailed exposure analysis is contained in the public docket and was summarized in the September 19 notice.

C. Applicator Risk

The Agency concluded that the most appropriate potency value for the parent compound with regard to mixer/loader/applicator risk is 0.94 $(mg/kg/day)^{-1}$. This value was chosen because it represents the geometric mean of cancer potency for malignant hemangioendotheliomas observed in the mouse oncogenicity studies.

After considering the data related to exposure and oncogenicity, the Agency developed risk estimates for agricultural workers. The following Table 1 summarizes the risk estimates for workers, mixer/loaders, and scouts:

TABLE 1—LIFETIME CANCER RISKS FOR APPLICATORS EXPOSED TO CHLORDIMEFORM

	EPA surrogate data	Urine data agency corrected
Mixers/loaders	10^{-3}	10^{-3}
Pilots	10^{-4}	
Flaggers	10^{-4}	
Scouts	10^{-4}	

The exposure value used in the risk calculation for mixer/loaders (0.023 mg/kg/ working day) was the absorbed dose value calculated by the Agency based on adjustments to the urine data base. Risk estimates for mixer/loaders based on the Ciba-Geigy/Nor-Am urine data are 10^{-3}, and are consistent with those risk estimates based on the Agency's surrogate dermal data base. The risk estimates are for the upper 95 percent confidence level. For the purposes of conducting risk assessments, the Agency traditionally assumes a life expectancy of 70 years. In addition, the Agency traditionally assumes agricultural workers have a 35-year working lifetime.

III. Comments on Proposed Notice Not To Initiate Special Review

Virtually all comments received concerned the Agency's proposal to prohibit the use of existing stocks of chlordimeform after the date of cancellation, February 19, 1989. The Agency's response to these comments appears in the following Unit III.A. In making the proposal, the Agency assumed that all stocks of chlordimeform would be used up in 1988, and so there would be no stocks remaining in 1989; in addition, the registrants had agreed to recall any unused stocks down to the end user level. However, drought and low pest pressure in 1988 combined to reduce the usage of chlordimeform to about 75 to 80 percent of usage in more typical years. Based on limited surveys and estimates by State agricultural officials and the registrants, the Agency believes that

there are significant stocks of chlordimeform (thought to be within a range of 10 to 25 percent of a normal year's supply; that is, 100,000 to 250,000 pounds) remaining in the hands of end users. Therefore, in light of the larger than expected stocks of chlordimeform in the hands of end users and in light of the comments of State pesticide officials and user groups, the Agency has conducted a risk/benefit analysis of allowing the use of existing stocks of chlordimeform in 1989. This risk/benefit analysis appears in the following Unit III.B.

A. Agency's Response to Comments

Comments were received from the following organizations and state regulatory agencies:

Arizona Agricultural Chemical Association (1)
Arizona Commission of Agriculture and Horticulture (2)
Arizona Cotton Growers Association (3)
Arizona Farm Bureau Federation (4)
Agricultural Council of Arkansas (5)
Arkansas State Plant Board (6)
Association of America Pesticide Control Officials (7)
Georgia Agricultural Chemical Association (8)
Georgia Cooperative Extension Service (9)
Georgia Department of Agriculture (10)
Helena Chemical Corporation (11)
Louisiana Agricultural Aviation Association (12)
Louisiana Cooperative Extension Service (13)
Louisiana Farm Bureau Federation (14)
Mississippi Cooperative Extension Service (15)
Mississippi Department of Agriculture and Commerce (16)
National Agricultural Aviation Association (17)
National Cotton Council (18)
North Carolina Farm Bureau Federation (19)
Sundance Farms (20)
Trans-Pecos Cotton Association (21).

In addition, numerous comments were received from individual cotton growers and pesticide applicators. These latter comments are substantially the same as those comments made by state regulatory officials, and are answered in the responses to the state regulatory officials.

1. *Comment:* One commenter (3) states that the Agency does not have legal authority to prohibit use of a voluntarily canceled pesticide, and that the Agency's proposal to not allow use of existing stocks is not consistent with an earlier proposal to allow use with restrictions.

Agency's Response: In determining the status of stocks of pesticides voluntarily canceled pursuant to section 6(f), the Administrator may or may not permit the sale and use of existing stocks. The Agency is not prevented from changing its position on use of existing stocks, where such can be justified under FIFRA, especially when new conditions become relevant.

2. *Comment:* Several commenters (6, 7, 8, 9, 14, and 17) stated that it would be difficult to locate any remaining stocks of chlordimeform, especially if these stocks are in the hands of end users.

Agency's Response: The Agency does not agree that it will be particularly difficult to locate existing stocks of chlordimeform. Both registrants have already contacted their dealer/distributor networks about the recall of chlordimeform, and have agreed to publicize the recall in appropriate newspapers and agricultural journals in order to reach end users. In addition, the Agency notes that chlordimeform is a restricted use pesticide, and that therefore records of chlordimeform sales have been required to be kept.

3. *Comment:* Several commenters (1, 2, 3, 5, 6, 7, 10, 12, 13, 15, 17, 18, and 21) stated that there is no means by which to dispose of chlordimeform, or that use of existing stocks of chlordimeform would pose less risk than transportation and disposal, or that allowing use of chlordimeform would allow it to remain in the hands of people trained in proper safety procedures.

Agency's Response: The Agency agrees that disposal of existing stocks of chlordimeform is a serious matter; however, the Agency does not agree that there is no method available to dispose of chlordimeform. It is possible to incinerate chlordimeform, and it is this method of disposal that registrants have agreed to use, not burial in landfills. The Agency also does not believe that allowing personnel employed by the registrants to ship and handle chlordimeform in order to dispose of it is intrinsically riskier than allowing it to be used up; through many years of registered use, personnel trained in proper safety procedures have shipped and handled chlordimeform in quantities larger than those expected to be involved in the recall. Appropriate protective clothing and other safety measures can be employed to mitigate risks.

4. *Comment:* One commenter (11) states that there are no funds set aside to indemnify users who have remaining stocks of chlordimeform.

Agency's Response: Section 15 indemnification provisions are not involved in this situation. A voluntary cancellation occurred here. There was no imminent hazard suspension as is required as one of the prerequisites for section 15 to be triggered.

5. *Comment:* Some commenters (4, 5, 10, 13, and 16) expressed concern that stocks of chlordimeform remaining in the hands of end users are not likely to be turned in for disposal; as a result, there will be illegal use of chlordimeform, probably by ground application, which poses higher risks than the aerial applications that would occur if existing stocks of chlordimeform were to be used up. Furthermore, they comment that aerial applicators will have to turn away customers who want to have chlordimeform applied aerially.

Agency's Response: The Agency is aware of the possibility that not all remaining stocks of chlordimeform may be returned, and then, in the absence of an existing stocks provision, these stocks may be diverted to riskier ground application. However, the Agency believes that the efforts of the registrants to publicize the recall would result in at least some stocks being returned by users. If use after the date of cancellation were illegal, the Agency would expect states to vigorously enforce the prohibition against use of existing stocks. The Agency agrees with the commenters that aerial applicators, because of their extensive licensing procedures, are more likely to comply with the prohibition against continued use of chlordimeform, and that this would possibly lead to less business for affected aerial applicators during 1989. If the aerial applicators were not to refuse such business and undertook illegal applications, in addition to possible penalties, such illegal activity would jeopardize such aerial applicator's license and certification.

6. *Comment:* Several comments (2, 3, 4, 13, 14, 16, 17, 18, and 20) concerned the benefits of chlordimeform, arguing that there are no alternative pesticides with which to replace chlordimeform, or that use of chlordimeform will delay development of resistance to the pyrethroid insecticides.

Agency's Response: The Agency agrees that chlordimeform does have benefits, and that these benefits will be foregone if use of existing stocks is not permitted. However, the Agency notes that there are alternative pesticides registered for ovicidal control of *Heliothis spp.* (methomyl and thiodicarb). The Agency further notes that no data have been provided to show that chlordimeform delays resistance to the pyrethroid insecticides.

7. *Summary of Comments:* Comments generally concerned the practicality of

retrieving and disposing of remaining stocks of chlordimeform, the risks of disposal and of misuse of these stocks, and the benefits of these stocks. The Agency does not find any of the comments to be compelling in allowing or disallowing the use of remaining stocks. However, in consideration of the concern for the use or nonuse of remaining stocks as expressed in these comments, EPA has conducted an analysis of the short-term risks and benefits regarding the possible use of existing stocks of chlordimeform in 1989.

B. Risk/Benefit Analysis of Allowing Use of Existing Stocks

1. Risks of Use of Existing Stocks of Chlordimeform

In order for the Agency to allow the use of existing stocks of products cancelled as a result of a risk/benefit finding, EPA must determine that the benefits of the use of any existing stocks outweigh the risks of such use for the period of use. Chlordimeform registrations were not cancelled as a result of an Agency risk/benefit finding, but instead were cancelled voluntarily by the registrants. Nevertheless, the Agency believes a risk/benefit analysis for existing stocks is appropriate in this case because the Agency had issued a Preliminary Notification to the registrants and was in the process of preparing a Notice of Initiation of Special Review and a Preliminary Determination at the time the voluntary cancellation was filed. The incremental risk of allowing an additional year of use of the existing stocks of chlordimeform is calculated by dividing the lifetime risk by 70, and by dividing this result by some factor representing the reduced amount of chlordimeform to be used. The lifetime risk already includes an adjustment for 35 years of exposure during an assumed lifespan of 70 years, because occupational exposures are assumed to be 35 years. This calculation assumes that risk is directly proportional to the total amount of pesticide handled over time.

In a typical year, about 1 million to 2 million pounds of chlordimeform are reportedly used. Based on specific information received through the public comments, the Agency believes that from 10 to 25 percent of this amount of chlordimeform remains available for use in 1989. These assumptions are based on a limited survey of Alabama pesticide distributors, which confirm earlier estimates by State regulatory officials and the registrants. However, comments and other information available to the Agency indicate that there may be much larger stocks of chlordimeform remaining in the hands of end users; the Agency cannot fully evaluate the accuracy of any of these estimates, because insufficient information has been submitted on the design of the surveys used to reach these estimates. Therefore, the Agency has calculated risks and benefits not only for the 10 percent and 25 percent remaining stocks assumption, but also on the worst case assumption, that is, that there is an entire typical year's supply of chlordimeform remaining in the hands of end users. The Agency has received little specific information on how leftover stocks are divided between end users and distributors/retailers, but the registrants have indicated that virtually all remaining stocks are in the hands of end users.

Two different scenarios can be proposed concerning the number of workers exposed to chlordimeform. In the first scenario, it would be assumed that, at most, the same number of workers will be exposed to chlordimeform in 1989 as were exposed in earlier years, but that they will individually be exposed to less chlordimeform in proportion to the decrease in the supply of chlordimeform (the "constant number/reduced poundage" assumption). This is believed to be a reasonable assumption because chlordimeform, a restricted use pesticide, would be applied only by air in 1989 (as most current labeling requires and as most chlordimeform has been applied in the past), and because chlordimeform is applied in many cotton-growing areas; in brief, there are very few people qualified and equipped to apply chlordimeform, and they are widely scattered.

The second scenario would assume that a smaller number of individual workers, smaller in proportion to the decrease in the supply of chlordimeform, will apply the same amount of chlordimeform as in previous years (the "reduced number/constant poundage" assumption). This may also be a reasonable assumption, since the decline in chlordimeform stocks may be regionally distributed, such that some regions may have no chlordimeform and others may have nearly as much as in any other year. The reduced number/constant poundage assumption results in higher individual risk to a smaller number of applicators, when compared to the results of the reduced poundage/constant number assumption. However, aggregate risk, the total number of cases of cancer arising from an additional year's use of chlordimeform, calculated by multiplying individual risk by the total number of exposed workers, is the same regardless of which assumption about the number of applicators is used. There are no data to support one assumption over the other, so risk numbers have been calculated for both assumptions.

Using the constant number/reduced poundage assumption, and assuming only 10 percent (the low end of available estimates) of the 1988 chlordimeform supply remains in the hands of end users, the individual oncogenic risk from an additional year's exposure to chlordimeform would be:

Risk (as cited in the exposure analysis) X 1/10 X 1/70. Risk estimates for the other assumptions were adjusted accordingly. The following Table 2 shows the individual risks to various groups of exposed workers, using the 10 percent, 25 percent and 100 percent available stock assumptions:

TABLE 2.—RISK FROM AN ADDITIONAL YEAR OF CHLORDIMEFORM USE [1]

Exposed group	35-Year [2] exposure risk	No. at [3] risk	1-Year exposure		
			10% stocks	25% stocks	100% stocks
A: Constant Number of Applicators/Reduced Poundage per Applicator:					
Mixer/Loaders	6×10^{-6}	124	10^{-6}-10^{-6}	10^{-5}	10^{-5}-10^{-5}
Applicators	1×10^{-4}	204	10^{-4}	10^{-4}-10^{-3}	10^{-3}
B: Reduced Number of Applicators/Constant Poundage per Applicator:					
Mixer/Loaders	6×10^{-6}	12.4 or 81	10^{-6}-10^{-6}	10^{-6}-10^{-6}	10^{-6}-10^{-6}
Applicators	1×10^{-4}	20.4 or 61	10^{-4}	10^{-4}	10^{-4}

[1] Additional risk has been rounded to the nearest order of magnitude.
[2] Individual risk cited in exposure analysis and used in rounded form in Notice of Intent Not to Initiate Special Review.
[3] From exposure analysis.

2. Benefits of Use of Existing Stocks of Chlordimeform

The possible benefits from chlordimeform accrue indirectly from its contribution to reducing insect resistance to the pyrethroid insecticides, and directly from its effects on cotton yields, through its control of *Heliothis* spp. The available data do not allow a definitive estimate of the magnitude of yield losses that could result from not using chlordimeform in 1989. Limited data indicate possible yield reductions of 5 to 10 percent, or an average of 7.5 percent on treated acres, about the same as the loss estimate developed by USDA in its preliminary benefits assessment, if other pesticides are used in place of chlordimeform.

Using a range of 0 to 7 percent loss on 28 percent of the harvested cotton acreage (that is, 100 percent of the annual usage before cancellation), the loss in benefits ranges from $10 to $220 million. Using a range of 0 to 7 percent yield loss on 7 percent of the harvested cotton acreage (that is, 25 percent of the annual usage before cancellation), the loss in benefits ranges from $3 million to $54 million. Using a range of 0 to 7 percent yield loss on 2.8 percent of the harvested cotton acreage (that is, 10 percent of the prior annual usage), the loss in benefits ranges from $1 million to $22 million. The low end of the range reflects the greater cost of alternative pesticides, most likely to be methomyl or thiodicarb in this case. The upper end of the range reflects the possible greater efficacy of chlordimeform over alternatives. These benefit estimates are based on the small amount of data on yield losses, and may over or underestimate actual benefits.

3. Risk/Benefit Analysis of Use of Existing Stocks of Chlordimeform

Making the worst case assumption that 100 percent of a normal year's supply of chlordimeform remains in the hands of users, that is, 1 million pounds, the incremental risk from one additional year's use of chlordimeform to mixer/loaders is in the 10^{-4} to 10^{-5} range, and to applicators is 10^{-6}. As shown in Table 2, individual risks from one more year of use under any of the probable use scenarios are low. The incidence of cancer in the exposed group, as predicted by this assessment, would be negligible, because of the small number of applicators and mixer/loaders who handle chlordimeform. Benefits under the various scenarios range from $1 to $220 million. Given the minimal risk and the possible substantial benefits, the Agency concludes that the use of existing stocks of chlordimeform in the 1989 growing season does not pose unreasonable risks. However, because cancer risk from 35 years of occupational exposure is high, estimated to be 1 in a 1000, and because epidemiological data suggest a correlation between exposure to the 5-CAT metabolite of chlordimeform and excess incidence of bladder cancer, the Agency believes long term risks would be unacceptable.

The Agency is requiring the registrants, Ciba-Geigy and Nor-Am, to conduct their recall programs down to the dealer/distributor level, in order to be sure that no further quantities of chlordimeform become available to end users.

As mentioned previously, the EPA has held discussions with other Federal and State agencies regarding the possibility of notifying factory and agricultural workers who were exposed to significant levels of chlordimeform over long periods of time of their elevated risk of bladder cancer. EPA believes that factory workers' level of exposure to chlordimeform was substantially higher than that to mixer/loaders or applicators, possibly resulting in as much as two orders of magnitude greater risk. Thus, EPA believes it is reasonable to allow limited exposure of mixer/loaders and applicators for an additional year. Nevertheless, EPA supports the voluntary urine monitoring program offered by the registrants to mixer/loaders and applicators.

IV. Agency's Final Decision Regarding Special Review

All chlordimeform registrations have been amended so that they terminate February 19, 1989. The Agency received no comments objecting to its proposed decision not to initiate a Special Review of chlordimeform. Therefore, the Agency will not initiate a Special Review of the use of chlordimeform on cotton. The only issue resulting from the Agency's proposal was the objection to the prohibition of the use of existing stocks in 1989.

The agency has conducted a short term risk/benefit analysis of the use of existing stocks of chlordimeform in the hands of end users and concluded that the benefits of one additional year of limited use outweigh the risks of such use. Therefore, the use of chlordimeform stocks in the possession of end users will be permitted until October 1, 1989. Such use must be in accordance with all label restrictions. Any further sale or distribution of existing stocks or recalled stocks by registrants, distributors, or retailers is prohibited after February 19, 1989. All use of chlordimeform after October 1, 1989, is prohibited. Both registrants indicated they have not marketed chlordimeform after the 1988 cotton season, around the beginning of October 1988. Both registrants also indicated that they will recall all existing stocks of chlordimeform down to the dealer/distributor level, and will accept for disposal any stocks of chlordimeform turned in by end users.

While the Agency has serious concerns about the long-term risks associated with chlordimeform use on cotton, it will not initiate a Special Review of chlordimeform because all use, and therefore exposure, will end at the end of the 1989 cotton-growing season. The cancellations will become effective automatically on February 19, 1989. The Agency has acted in reliance on the voluntary cancellation by proposing revocation of non-cotton tolerances and by not initiating a Special Review.

The Agency has other tools that may be available to it under FIFRA to take regulatory action regarding chlordimeform, including initiation of Special Review and subsequent initiation of cancellation proceedings, immediate initiation of cancellation proceedings, suspension, and emergency suspension. As compared with initiation of Special Review followed by initiation of cancellation proceedings, or immediate initiation of cancellation proceedings, the action announced here reduces risks faster than would occur under those other more time-consuming approaches. Finally, the Agency does not believe that the appropriate tests for either suspension or emergency suspension have been met.

V. Public Record

The Agency has established a public record (public docket #30000/52) for the chlordimeform Special Review. This public record includes:

1. This Notice.

2. The draft Registration Standard.

3. Any other notices pertinent to the chlordimeform Special Review.

4. Documents and copies of written comments submitted to the Agency in response to the pre-Special Review registrant notification, the draft Registration Standard, this Notice, and any other notice regarding chlordimeform submitted at any time during the chlordimeform Special Review process by any person outside government.

5. Analysis of comments received in response to the draft Registration Standard and the preliminary notification to registrants.

6. Memoranda describing each meeting between Agency personnel and any person outside government which concerns a chlordimeform Special Review decision.

7. Comments, documents, proposals or other materials concerning the chlordimeform Special Review submitted by any person or party outside government.

8. A current index of materials in the public docket.

Information for which a claim of confidentiality has been asserted will not be put in the public docket. The docket and index will be available for inspection and copying from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays, at the following location: Public Docket and Freedom of Information Section, Field Operations Division (TS-767C), Rm. 236, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

VI. Order of Cancellation

By this order, the voluntary cancellations are accepted; cancellation is hereby ordered according to the terms contained herein. Any further sale or distribution of chlordimeform products is prohibited as described herein and any use must be in accordance with the terms set forth herein and any label restrictions.

Dated: January 6, 1989.

Victor J. Kimm,

Acting Assistant Administrator for Pesticides and Toxic Substances.

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

JUL 25 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Final Compliance Monitoring Strategy for Compound 1080 Livestock Protection Collars

FROM: A. E. Conroy II, Director
Office of Compliance Monitoring (EN-342)

TO: Addressees

Attached is the final Compliance Monitoring Strategy for Compound 1080 Livestock Protection (LP) Collars. This document reflects the strategy for monitoring compliance with the provisions of the labeling for registered Compound 1080 LP Collars.

Note that only one federal pesticide registration has been issued (EPA Registration Number 6704-85) for Compound 1080 LP Collars, that being to the U. S. Department of the Interior, Fish and Wildlife Service (FWS). The registration was issued conditionally under section 3(c)(7) of the Federal Insecticide, Fungicide and Rodenticide Act. To date, FWS does not intend to train or certify LP Collar applicators, or to distribute LP Collars to rancher applicators. The FWS will assist in State training programs, but expects most LP Collar use to proceed without FWS involvement. Wyoming is currently seeking a separate registration for the LP Collars. Copies of the Cancellation Order and the subsequent documents are available upon request.

The Office of Compliance Monitoring (OCM) received the following comments on the draft strategy.

One Regional Office suggested that when state governmental agencies are the registrants of LP Collars, EPA should maintain the responsibility for producing establishment and agent inspections so the States are not placed in a position of having to regulate themselves. OCM agrees with this and has modified the strategy accordingly.

One Regional Office requested that the Regions submit annual rather than quarterly inspection/violation reports to OCM because quarterly reports are not necessary. OCM has considered this comment and has retained the quarterly Regional reporting. This reporting is needed due to the sensitivity of the issue and the new approach to pesticide use imposed by the courts. Therefore, we need to closely monitor the use of the LP Collars during the period of conditional registration.

One Regional Office requested that each appropriate group notify OCM/Regions/States when any registrations change including changes in the registrants and agents thereof. OCM has considered this comment and has modified the strategy accordingly.

One Regional Office suggested that the strategy include a statement for States to develop amendments to State plans to include LP Collar certification and coordinate the activity with the Regional Office. OCM agrees with this comment and has modified the strategy so that States shall develop such amendments when it is appropriate.

Thank you for your comments on the draft strategy. If you have any questions concerning this strategy, please call Richard Green of my staff at (FTS) 382-5567.

Attachment

Addressees

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cc: Regional Pesticides and Toxic Substances Branch Chiefs

FIFRA COMPLIANCE MONITORING STRATEGY

FOR

COMPOUND 1080 LIVESTOCK PROTECTION COLLARS

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

OFFICE OF COMPLIANCE MONITORING

FIFRA COMPLIANCE MONITORING STRATEGY FOR COMPOUND 1080 LIVESTOCK PROTECTION COLLARS

FIFRA COMPLIANCE MONITORING STRATEGY FOR COMPOUND 1080 LIVESTOCK PROTECTION COLLARS

OVERVIEW

The following points highlight the inspection activities and major new requirements.

- State/EPA inspectors will conduct annual inspections of producing establishments, registrants, and agents thereof as long as registrations are conditional and thereafter according to the routine pesticide inspection scheme.
- State/EPA inspectors will conduct use and records inspections of applicators according to the schedule herein.
- Specific certification is required to use Compound 1080 LP Collars. States must amend their State plans to include specific Compound 1080 LP Collar certification in order for the LP Collars to be used within the State.
- Applicators are required to keep records and report certain information. Applicators are required to inspect each LP Collar in use on a weekly basis.
- Warning signs are required to be posted.
- Registrants and agents thereof are required to keep records.

BACKGROUND

The Livestock Protection (LP) Collar (also called the "toxic collar") for protecting sheep (Ovis spp.) and goats (Capra spp.) from depredating coyotes consists of a flat rubber container holding a liquid toxicant which is attached with straps around the throat of a sheep or goat. Sodium Monofluoroacetate, commonly called Compound 1080, is the only pesticide registered in the United States (U.S.) for use in LP Collars. Compound 1080, once ingested (or absorbed through open wounds) in lethal doses, causes loss of cardiac or respiratory function and eventually, death.

On March 18, 1972 (37 FR 5718) the use of Compound 1080 for predator control was cancelled and suspended.

Administrative Law Judge Spencer T. Nissen, in a 1982 decision and Lee M. Thomas, who was designated by the Administrator to rule on his behalf in a 1983 decision/1, allowed for applications for registration of Compound 1080 in LP Collars subject to certain restrictions described herein. These decisions constitute modifications of the terms and conditions of the 1972 Cancellation Order.

/1 Initial (FIFRA Docket No. 502, October 22, 1982) and final decision (49 FR 4830, February 4, 1984) in the matter of "Notice of Hearing on the Applications to Use Sodium Fluoroacetate (Compound 1080) to Control Predators."

On July 11, 1985 the Office of Pesticide Programs (OPP) issued the first registration (EPA Registration Number 6704-85) for Compound 1080 LP Collars to the Fish and Wildlife Service.

REQUIREMENTS

Federal Registration Requirements under FIFRA Section 3

The requirements listed below (numbers 1-18) appear verbatim in the technical bulletin which are part of the accepted labeling. Only the numbers with asterisks appear in Judge Nissen's initial decision which are part of the Cancellation Order. In comparing attachment C of the initial decision (affirmed by the final decision) with the asterisked numbers below, note that some of the language in the initial decision is less restrictive. However, Judge Nissen indicated that to effect a practical program, EPA could use its discretion to impose more stringent modifications to his requirements if it was deemed appropriate. Please note that these requirements reflect the label on the one registered product and that other products registered for this use in the future may not have the same requirements.

1.* Use of Livestock Protection (LP) Collars shall conform to all applicable Federal, State and local regulations.

2.* LP Collars shall be sold or transferred only by registrants or their agents/2, and only to certified LP Collar applicators. LP Collars may be used only by specifically certified LP Collar applicators or persons under their direct supervision.

The certified applicator is responsible for assuring compliance with all restrictions. The certified applicator will determine, in accordance with label directions, when and under what circumstances LP Collars will be used. The certified applicator will either apply LP Collars or be physically present where collars are applied by a noncertified person. However, the noncertified person who has received instructions from the certified applicator may store LP Collars, check LP Collars in the field, remove LP Collars, repair or dispose of damaged LP Collars in accordance with use restrictions, retrieve LP Collars lying in the field, and properly dispose of contaminated material and animal carcasses.

/2 As a condition of registration, the registrant must submit to OPP the names of agents.

3.* Certification of applicators shall be performed by appropriate regulatory agencies. Prior to certification, each applicator shall receive training which will include, but not limited to:

(a) training in safe handling and placement of LP Collars;
(b) training in disposal of punctured LP Collars, contaminated animal remains, and contaminated vegetation and soil;
(c) instructions for practical treatment of Compound 1080 poisoning in humans and domestic animals;
(d) instructions in recordkeeping.

4.* At their address of record, registrants or their agents shall keep records of all LP Collars sold or transferred. Records shall include name, address, and state where LP Collar certification was issued, certification number of each recipient, and dates and numbers of LP Collars sold or transferred.

5.* Each certified applicator shall keep records of use and the results of use in accordance with State and Federal regulations for a period of not less than two years following disposal or loss of LP Collars. The records shall include, but are not limited to:

(a) the number of LP Collars attached on livestock;
(b) the pasture(s) where collared livestock were placed;
(c) the dates of each inspection, attachment, and removal;
(d) the number and locations of livestock found with ruptured or punctured LP Collars and the apparent cause of damage;
(e) the number, dates, and approximate location of LP Collars lost;
(f) the species, locations, and dates of all suspected poisonings of humans, domestic animals or nontarget wild animals resulting from LP Collar use.

6.* Any suspected poisoning of threatened or endangered species must be reported within 3 days to EPA as must each accident or injury to humans, domestic animals, or nontarget wild animals from LP Collar use.

7.* Only the registrant or the manufacturer is permitted to fill LP Collars with Compound 1080 solution. Compound 1080 solution may not be removed from LP Collars and used for any other purpose.

8.* LP Collars shall only be used to take coyotes within fenced pastures no larger than 2,560 acres (4 square miles). But where average annual precipitation does not exceed 20 inches and vegetation is sparse, consisting only of short to mid-height grasses and scattered shrubs, collars may be used up to a maximum of 10,000 acres (16 square miles) in size.

Fenced pastures include the grazing land that is enclosed by livestock fencing. This includes wire or other man-made fences such as rock walls, and natural barriers such as escarpments, lakes, and large rivers that will prevent escape of livestock. Collars shall not be used on unfenced, open range.

In no case shall the applicator place collared livestock in any pasture where compliance with other use restrictions such as monitoring is impossible; in fenced pastures larger than 10,000 acres; or unfenced open range.

9. LP Collars shall be used only where losses of sheep or goats due to predation by coyotes are occurring or, based upon experience, where coyote predation can reasonably be expected to occur.

10.* Where LP Collars are in use, each logical point of access (i.e., roads, gates, and trails) shall be conspicuously posted with a bilingual (English/Spanish) warning sign not less than 8" x 10" in size. Such signs shall be inspected weekly to insure their continued presence and legibility, and will be removed when LP Collars are removed. The signs will have a minimum type size for DANGER-POISON of 24 point (1/4 inch) with remaining text at least 18 point (3/16 inch).

11.* Each LP Collar in use shall be inspected by the applicator at least once every seven days and LP Collars adjusted if needed.

If any collared animal is not located in two consecutive checks, an intensive search for the animal is required.

In addition, if more than three collared animals cannot be located during any one check, an intensive search for the animals is required.

If more than nine collared animals cannot be located during any 60 day period, remove all LP Collars from animals and terminate use of collars. Do not resume use until adequate steps are taken to prevent further excessive loss of LP Collars.

12.* Damaged, punctured, or leaking LP Collars shall be removed from the field for repair or proper disposal. Damaged LP Collars shall be placed individually in leakproof containers while awaiting repair or proper disposal. Authorized LP Collar repairs are limited to minor repairs of straps or fastenings. Leaking or punctured LP Collars must be properly disposed.

13.* Dispose of Compound 1080 wastes (punctured, leaking, or otherwise irreparable, damaged LP Collars; contaminated leather clothing, animal remains, wool, hair, vegetation, water, and soil) under three feet of soil, at a safe location, preferably on property owned or managed by the applicator and at least 1/2 mile from human habitations and water supplies. No more than 10 LP Collars may be buried in any one hole. If buried in a trench, each group of 10 LP Collars must be at least 10 feet apart.

Alternatively, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance in disposing of wastes at approved hazardous waste disposal facilities.

When snow or frozen ground make on site disposal impractical, up to one cubic foot of wastes may be stored in a leakproof container, in a dry, locked place for up to 90 days.

Triple rinse metal and plastic containers with water. Then puncture and dispose of container and rinsate as above.

14.* All persons authorized to possess and use LP Collars shall store them under lock and key in a dry place away from food, feed, domestic animals, and corrosive chemicals and in outbuildings or outdoor storage areas attached to, but separate from, human living quarters.

15. The number of LP Collars used shall be the minimum necessary for effective livestock protection. For pastures of the following size classes, do not use more LP Collars than the number indicated:

Size (acres)	Number of Collars
up to 100	20
101 to 640	50
641 to 10,000	100

16. Each applicator shall have a 1-ounce bottle of syrup of ipecac available when attaching, inspecting, removing, or disposing of LP Collars.

17. No contaminated animal shall be used for food or feed.

18. The use of 1080 LP Collars may not be used in the following areas due to potential adverse effects to endangered species.

State	Counties
CA	Fresno, Kern, King, Los Angeles, Monterey, San Benito, San Luis Obispo, Santa Barbara, Tulare, and Ventura

The 1080 LP Collar may not be used in the following areas without written approval from the nearest U.S. Fish and Wildlife Service (FWS) Office (Endangered Species Specialists). If the FWS or the user determines that the use of the LP Collar may adversely impact an endangered species in the specific areas requested, the collar may not be used in these areas. Written approval must be obtained annually.

State	Counties	Nearest FWS Office and Phone Number
CA	Alameda, Contra Costa, Merced, San Joaquin, Santa Clara, and Stanislaus	Sacramento, CA 916-484-4935
ID	Bonner, Boise (north of State Highway 21), Boundary, Clearwater, Custer (north of local road running from Sun Valley to Chilly and a corresponding line running northeast from Chilly to Patterson), Fremont, Idaho, Lemhi, Shoshone, and Valley	Boise, ID 208-334-1806
MT	Beaverhead, Carbon, Flathead, Gallatin, Glacier, Lake, Lewis and Clark, Lincoln, Madison, Missoula, Park, Pondera, Powell, Sanders, Stillwater, Sweet Grass, and Teton	Helena, MT 406-449-5225
WA	Pend Oreille, Okanogan, (Nat'l Park and Forest Land), Skagit, and Whatcom	Boise, ID 208-334-1806
WY	Fremont, Hot Springs, Park, Sublette, Teton and Yellowstone Nat'l Park	Helena, MT 406-449-5225

Because of possible adverse impacts on the Eastern Timber Wolf, the nearest FWS Endangered Species Office must be notified before LP Collars are used in these areas.

MI	Keweenaw (Isle Royal) and entire upper peninsula	Twin Cities 612-725-3576
MN	Aitkin, Becker, Beltrami, Carlton, Cass, Clearwater, Cook, Crow Wing, Hubbard, Itasca, Kittson, Koochiching, Lake, Lake of the Woods, Mahnomen, Marshall, Pennington, Pine, Roseau, and St. Louis	Twin Cities 612-725-3576
WI	Douglas, Florence, Lincoln, Oneida, and Price	Twin Cities 612-725-3576

REGULATED INDUSTRY

- Registrants of federally registered LP Collars containing Compound 1080.

- Agents under the control of registrants described above which sell or transfer Compound 1080 LP Collars - (registrants are required to submit names and addresses of their agents to OPP after registration is issued).

- Certified applicators and persons under their direct supervision.

NEUTRAL ADMINISTRATIVE INSPECTION SCHEME

For each Compound 1080 Collar registration issued, State/EPA inspectors will inspect annually all producing establishments, registrants, and agents thereof which distribute, sell, offer for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver the products.

In States where Compound 1080 LP Collars certification is issued, State/EPA inspectors will conduct use and records inspections of applicators who have received certification for Compound 1080 LP Collars during that year and who have also purchased LP Collars. State/EPA inspectors can obtain information regarding applicators' purchases from registrants or their agents. These inspections should cover as many applicators as possible so long as the annual number of inspections does not exceed a maximum of 10% of the annual resources allocated for use inspections. Any applicators which were not inspected during the year they were certified shall be targetted for inspection the following year until all applicators are eventually inspected. Use on federal property shall be incorporated into the targetting scheme.

These inspections shall continue annually as long as any registrations remain conditional for the submission of data described in the original registration notice. Thereafter, inspections will be performed upon request from OPP and as part of the Region/State routine pesticide inspection scheme. Tips and complaints will receive highest priority for inspections.

PROGRAM MANAGEMENT & ALLOCATION OF RESPONSIBILITY

Office of Pesticide Programs (OPP)

OPP's Registration Division (RD) shall:

- Provide OCM with copies of labels for each Compound 1080 LP Collar registration and names and addresses of registrants and agents thereof. Also, OPP will provide OCM a copy of the original registration notice including any conditions of registration and will provide OCM with any changes in registrations changes in registrants or agents thereof.

Office of Compliance Monitoring (OCM)

OCM will:

- Provide copies of labels for each Compound 1080 LP Collar registration, registration notices, and names and addresses of registrants and agents thereof to the Regions for distribution to the States.

- Notify Regions when any Compound 1080 LP Collar registrations change including changes in registrants and agents thereof.

Regions

The EPA Regions will:

- Assure that States participating in the FIFRA Cooperative Enforcement Agreement Program conduct producing establishment, agent, and use inspections for compliance with the labeling requirements.

- When State governmental agencies are the registrants of Compound 1080 LP Collars, EPA will conduct establishment and agent inspections for those products (i.e., Wyoming).

- Conduct use and records inspections of certified applicators (who have received Compound 1080 LP Collars), registrants, and agents thereof for compliance with the labeling requirements in States without primacy.

- Provide copies of labels for each Compound 1080 LP Collar registration, registration notices, and names and addresses of registrants and agents thereof for distribution to the States or field inspection offices.

- Distribute list of establishments which produce Compound 1080 LP Collars to the States.

- Conduct import inspections (if appropriate).

- Develop a list of registered Compound 1080 LP Collar producing establishments and distribute to the States.

- Report lists of EPA/State inspections/violations for Compound 1080 LP Collars to OCM quarterly.

- Take appropriate enforcement action for violations in States without primacy and in response to State referrals.

- Submit to OPP any reports of suspected poisoning of threatened or endangered species immediately after the report is received.

- Take the lead in the development of the EPA programs to certify Compound 1080 LP Collar applicators.

- Refer any Compound 1080 LP Collar incident reports to the States for followup action. Allegations or indications of Compound 1080 LP Collar misuse shall be tracked as significant cases under FIFRA §27.

- Review any changes in State plans to include Compound 1080 LP Collars and solicit assistance as needed from OPTS.

Office of Training and Technical Support (in OPTS)

- Provide assistance to Regions in amending State plans to include certification of Compound 1080 LP Collar applicators.

States

Participating States will:

- Develop amendment to State plans to include certification of Compound 1080 LP Collar applications in coordination with the EPA Regional office, as appropriate.

- Conduct certification and training for LP Collar applicators provided State plan for certification is approved, as appropriate.

- Develop a training program for LP Collar applicators coordinated with U.S. Department of Agriculture, Science and Education Administration (SEA), and the Regional EPA Offices.

- Conduct use and records inspections of agents* of registrants and certified applicators (who have received Compound 1080 LP Collars) for compliance with the labeling requirements and any SSURO issued within the State.

- Conduct producing establishment inspections*.

- Take enforcement actions for violations or refer violations to EPA.

- Conduct import inspections as requested by the Regional EPA office.

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* EPA will conduct producing establishment and agent inspections for Compound 1080 LP Collar registrations when State governmental agencies are the registrants.

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

OCT 20 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Final Compliance Monitoring Strategy
for Daminozide

FROM: A. E. Conroy II, Director
Office of Compliance Monitoring (EN-342)

TO: Addressees

Attached is the final Compliance Monitoring Strategy for the plant growth regulator daminozide (ALAR). The preliminary strategy was transmitted for comment in November 1985. This final strategy reflects data call-in and label modification requirements but does not include a notice of intent to cancel as was originally described in the preliminary strategy.

The Assistant Administrator for the Office of Pesticides and Toxic Substances stated on January 22, 1986 that the continued use of daminozide would be permitted provided the registrant (Uniroyal) submitted certain data, modified the labeling for one product, and agreed to a production limit for a newly registered product for use on grapes only.

Uniroyal has submitted and the Agency has accepted the revised labeling (attached). The Agency has also registered a new product for grapes. Uniroyal has agreed to provide data which are based upon an established schedule which is tracked by the Office of Compliance Monitoring (OCM).

Thank you for your comments on the preliminary strategy. If you have any questions concerning this strategy, please call Richard Green of my staff at (202) 382-5567.

Attachments

DATA CALL-IN SCHEDULE

DATA TYPE	SCHEDULED DUE DATE
Plant Metabolism Study	08/31/87
Livestock Metabolism Study	08/31/87
Livestock Feeding Study	08/31/87
Crop Feeding Trials	05/31/87
Storage Stability Study	08/31/87
Degradation of UDMH to Daminozide	08/31/87
Isotope Dilution Method for UDMH	08/31/86
UDMH Analytical Method * 4 months extra time provided to Uniroyal if data cannot be evaluated by the round robin method	11/30/86*
Daminozide Analytical Method	11/30/86
Comparison of UDMH Methods of Analysis	05/31/86
Market Basket Surveys	07/15/86, 10/15/85, 02/15/87
Greenhouse Worker Exposure Study	12/31/86
Dislogable Residue Study	12/31/86
Glove Permeability Study	12/31/86
Metabolism Study	02/14/87
Dermal Absorption Study	12/15/86
Mammalian Cell Gene Mutation Study	12/15/86
Mammalian Cell Chromosomal Aberration Study	12/15/86
Bacteria DNA Repair Study	12/15/86
UDMH Rat 12 Month Sacrifice Data Final Report	01/15/88 05/15/89
" Mouse 8 Month Sacrifice Data " Mouse 12 Month Interim Report " Mouse Final Report	07/15/87 01/15/88 05/15/89

NOTE: Dates may change due to OPP/OCM approved requests for schedule modification

Addressees

James Lamb (TS-788)
Terrell Hunt (LE-134A)
Deeohn Ferris (LE-134P)
Stan Abramson (LE-132A)
Ken Shiroishi (EN-342)
John J. Neylan III "
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Regional Pesticides and Toxic Substances Branch Chiefs

FIFRA COMPLIANCE MONITORING STRATEGY

FOR

DAMINOZIDE (ALAR)

OFFICE OF COMPLIANCE MONITORING

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FIFRA COMPLIANCE MONITORING STRATEGY FOR DAMINOZIDE (ALAR)*

REQUIREMENTS

FEDERAL REGISTRATIONS UNDER FIFRA §3

EPA required the Uniroyal Chemical Company to:

- Delete grapes from the ALAR 85 product label (EPA Registration Number (Reg. #) 400-79, amended label accepted February 24, 1986). A new product with a production volume limit was registered on January 30, 1986, for use only on Concord like grapes (grapes not intended for raisins) under EPA Reg. # 400-430.

- Amend EPA Reg. # 400-79 to reduce the application rate on apples from 8 lbs/acre to 4 lbs/acre for spring treatment and 3 lbs/acre for later treatment. However, the 8 lbs/acre rate was permitted for trees not expected to bear fruit that year provided apples produced from the treated trees are not harvested (included in February 24, 1986 EPA approval).

- Amend EPA Reg. # 400-79 to contain an advisory cautioning against the use of daminozide treated apples in apple sauce (advisory accepted by OPP as part of labeling on 2/24/86).

- Comply with FIFRA §3(c)(2)(B) data requirements or have its products subject to suspension/cancellation. Uniroyal is the sole registrant of the active FIFRA §3 registrations (see attached data call-in schedule).

EXISTING STOCKS PROVISIONS FOR THE REGISTRANT AND OTHER PERSONS

Uniroyal may not legally distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver product containers bearing EPA Reg. # 400-79 which are owned by, controlled by, or in the custody of Uniroyal after February 24, 1986, unless the product bears the EPA approved amended label accepted on that date with grapes deleted and apple dosages amended. Noncompliance with this provision is considered a violation of FIFRA §12(a)(1)(B) or §12(a)(1)(E).

Other persons may legally distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver product containers bearing EPA Reg. # 400-79 which conform to the last label accepted by EPA (with apples and grapes) prior to the February 24, 1986 amended label until supplies are exhausted.

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* Butanedioic acid mono 2,2-dimethylhydrazide is commonly called daminozide and also recognized under the trade name ALAR.

REGULATED INDUSTRY

Number of federal registrants with active daminozide products - 1 (Uniroyal Chemical Co.)

Number of Producer Establishments - 1 (1984 FIFRA §7 reporting information)

EPA Establishment Number 7874-LA-001
Uniroyal Chemical Co.
Geismar, LA 70734

Number of products affected by this regulatory action - 2

Product Name	EPA Registration Number
ALAR 85	400-79
ALAR for Grapes	400-430

NEUTRAL ADMINISTRATIVE INSPECTION SCHEME

The Region will negotiate with the the State of Louisiana to conduct in FY 87 an establishment inspection for EPA Registration Number 400-430. Thereafter, they will conduct an establishment inspection every two years for EPA Reg. No. 400-430 until the production volume limitation is removed from the registration requirements. Because Louisiana will not know the production volume limitation, information obtained on quantities produced/distributed is to be forwarded to the Regional office for review. EPA will review the FIFRA §7 annual reporting information and FIFRA §8 data regarding movement of pesticides to assure compliance with this limitation. If needed for CBI reasons, EPA inspectors will conduct establishment inspections upon request to verify compliance with this limitation. OPP will notify OCM when the production volume limitation is removed. OCM will inform Region 6 who will in turn notify the State of the same information.

Note: A production volume limit has been imposed on EPA Registration Number 400-430 (ALAR 85 for Grapes) as a condition of registration. This limitation appears in the FIFRA §3(c)(7) registration notice for the product. Such information is considered confidential under FIFRA §7.

For EPA Reg. No. 400-79, the Region will negotiate with the State of Louisiana to conduct an establishment inspection once in FY 87 and thereafter according to the routine pesticide inspection scheme.

EPA/State inspectors will conduct use inspections according to the routine pesticide inspection targetting scheme.

Tips and complaints will receive highest priority for inspections.

SUPPLEMENTARY ALAR PRODUCT INFORMATION

° Number of active FIFRA §3 registrations for daminozide - 7

Product Name	EPA Registration Number
B-Nine	400-069
ALAR 85	400-079
ALAR a Plant Growth Regulator	400-099
KYLAR 85 a Plant Growth Regulator	400-103
B-Nine SP	400-110
ALAR Technical	400-117
ALAR for Grapes	400-430

NOTE: SAD 85 a Plant Growth Regulator, EPA Registration Number 2749-191 (Aceto Chemical Co., suspended 5/18/84)

° Number of FIFRA §24(c) registrations for daminozide - 1

ALAR 85 (FIFRA §24(c) SLN Number CA-800035 using EPA Registration Number 400-79)

The FIFRA §24(c) registration is subject to suspension or cancellation if the FIFRA §3 registration is suspended or cancelled. The only FIFRA §24(c) registration uses a FIFRA §3 product registered under Uniroyal.

° Intrastate Products - 3

Product Name	EPA Intrastate Registration Number
ALAR 85	400-6461
ALAR 85	400-6466
KYLAR 85	400-6533

The intrastate products are subject to denial if Uniroyal fails to comply with the FIFRA §3(c)(2)(B) data requirements. Uniroyal is the sole submitter of the intrastate applications for FIFRA §3 registration.

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

JUN 14 1989

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Compliance Strategy for the Agreement to Voluntarily Halt Sales of Food-Use Pesticides Containing Daminozide

FROM: John J. Neylan III, Director
Policy and Grants Division
Office of Compliance Monitoring (EN-342)

TO: Addressees

Attached is the Compliance Strategy for the Agreement to Voluntarily Halt Sales of Food-Use Pesticides Containing Daminozide signed on June 2, 1989, by Uniroyal, Inc. and EPA. The strategy sets forth the terms of the agreement, the dates by which certain activities must be carried out by Uniroyal and the Agency, and how the Agency intends to monitor compliance with the terms of the agreement. Compliance monitoring will be directed at Uniroyal to determine compliance with the terms of the agreement and at distributors and dealers to ensure that amended labeling has been placed on those products which may be relabeled. Growers may be visited in order to determine if they are aware of the recall and their rights under the recall and reimbursement program.

If you have any questions concerning the strategy, please contact David Stangel of my staff at 382-3477.

Attachment

ADDRESSEES

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Anne Lindsay (TS-767C)
Frederick F. Stiehl (LE-134A)
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IX	David P. Howekamp, Director Air Management Division	Davis Bernstein, Chief Pesticides & Toxics Branch
X	Gary O'Neal, Director Air and Toxics Division	Kenneth Feigner, Chief Pesticides & Toxic Substances Br

cc: Michael Walker (LE-134P)
Jim Roeloffs (TS-788)
John Tice (TS-769C)

COMPLIANCE STRATEGY FOR THE AGREEMENT TO VOLUNTARILY HALT SALES OF FOOD-USE PESTICIDES CONTAINING DAMINOZIDE

JUN 14 1989

OVERVIEW

Daminozide is the active ingredient of Alar, a product produced by Uniroyal Chemical Company, Inc. The chemical is a plant growth regulator and affects vegetative growth, flower bud initiation, fruit set and maturity, preharvest fruit drop and market quality of fruit at harvest and during storage. The main use for Alar is on apples. However, it is also registered for use on pears, peaches, nectarines, prunes, sweet and sour cherries, grapes , brussels sprouts, cantaloupes, tomato transplants, peanuts and non-food uses. Uniroyal is the sole registrant for daminozide and holds 6 registrations.

Daminozide is under Special Review by EPA because certain oncogenicity studies indicated that the chemical and its breakdown product UDMH (unsymmetrical dimethylhydrazine) may pose a carcinogenic risk.

On June 2, 1989, Uniroyal and EPA entered into an agreement whereby Uniroyal agreed in writing to voluntarily halt sales of food-use products and conduct a recall of all products down to the user level. Uniroyal will submit an application for amended registration of all products. The amendment will place a condition on the registration that until there is a final determination on daminozide, Uniroyal will sell no daminozide food-use products and will conduct a voluntary recall of all daminozide products. EPA will issue an export notification describing the status of daminozide registrations. EPA agreed to postpone the Science Advisory Panel's consideration of the Agency's draft Notice of Intent to Cancel in July 1989, until the Panel's next meeting in December, 1989, in part, in order to assess an interim report on the studies Uniroyal is conducting. The agreement is in effect until a final determination on daminozide has been made and any hearings requested have been completed.

REQUIREMENTS OF THE AGREEMENT

- On June 2, 1989, Uniroyal will halt all sales of daminozide products bearing food uses.

- By June 7, 1989, Uniroyal will submit an application for the amendment of all daminozide registrations. Uniroyal will amend both its B-Nine daminozide labels to delete the tomato transplant use, thereby making it a non-food use product and to relabel all B-Nine stocks in its possession.

- By June 9, 1989, Uniroyal will notify all dealers and distributors of the recall and reimbursement program.

- By June 21, 1989, EPA will approve Uniroyal's application to amend its B-Nine and B-Nine SP labels.

- EPA will issue a Stop Sale, Use or Removal Order (SSURO) to Uniroyal, pursuant to the agreement, for all registrations with food uses.

- By June 16, 1989, Uniroyal will notify all persons on their grower mailing list of the recall and reimbursement program.

- By July 12, 1989, Uniroyal will provide labeling stickers for B-Nine and B-Nine SP products to dealers and distributors. Uniroyal will instruct dealers and distributors to relabel all stocks by August 20, 1989.

- Uniroyal will provide to EPA, pursuant to FIFRA §3(c)(2)(B), records demonstrating compliance with the provisions and schedule of the recall and reimbursement program.

COMPLIANCE MONITORING

Inspections

- Compliance monitoring of this agreement will be directed mainly at Uniroyal and its efforts to comply with the terms of the agreement.

- The Office of Pesticide Programs (OPP), OCM, and Region I will monitor the recall and reimbursement program and Uniroyal's adherence to the terms of the program.

- States are to inspect, within 4 months after the date this strategy is issued, any establishment which produced Daminozide within the past 3 years. Followup inspections are to be conducted upon request.

- As part of routine comprehensive inspections, Regions and States should assure compliance with the terms of the agreement and monitor the relabeling of the B-Nine products.

- In those States where Daminozide has been used in the past, inspections will be specifically targeted for the purpose of determining if relabeling of B-Nine products has occurred. These inspections may also be comprehensive in nature to address compliance with other sections of FIFRA. The number of inspections to assure compliance with the agreement will be determined by the States and Regions. When lists of Uniroyal distributors and dealers become available, these will be provided to the Regions and States.

- The Compliance Division of OCM will be requesting inspections at sites where the product is being consolidated as a result of the recall. The number and frequency of inspections will be determined from information the Agency receives related to the recall. Inspections at sites where Daminozide has been consolidated should verify compliance with FIFRA section 17(a)(1) regarding export labeling requirements, storage conditions, and FIFRA section 8 records. Inspectors should document the destination and amount of exports. States are to report this information to the Regional Office.

- States may conduct inspections of growers to determine if they are holding any daminozide products, and if they are, whether they had been contacted by Uniroyal and made aware of their options for recall and reimbursement of the stocks they are holding.

- Tips and complaints will be priority inspections.

Compliance

- The Office of Compliance Monitoring (OCM) will issue a Stop Sale, Use or Removal Order (SSURO) to Uniroyal pursuant to the agreement. The SSURO will allow Uniroyal to move stocks of daminozide products only for the purposes of recalling or relabeling them.

- After August 20, 1989, Regions and States will issue SSURO's for those B-Nine and B-Nine SP products which do not bear amended labeling and take action against those distributors selling such misbranded products. In addition, States and Regions will notify Region I when this occurs so that they may take appropriate action against Uniroyal.

- The name and address and telephone number of any grower who has not been contacted by Uniroyal should be forwarded to Uniroyal and the Chief, Compliance Branch, OCM so that Uniroyal can contact the grower and OCM can followup.

- When Regions and States encounter a distributor or dealer who has continued to sell products rather than participate in the recall and reimbursement program, the inspector should determine the reason why they are continuing to sell and the Region will forward this information to the Chief, Compliance Branch, OCM for consideration in evaluating the effectiveness of the recall program.

Reports

- States are to report within two weeks of discovering any violations of the agreement to the Regional Office.

- States are to include information on the number of Daminozide inspections and violations found as part of their quarterly reports to the Regions.

- Regions are to send information on inspections and violations to the Director of the Compliance Division quarterly. Violations of the agreement should be reported immediately along with supporting documentation.

LIST OF UNIROYAL DAMINOZIDE PRODUCTS

EPA Reg. No.	Name
400-69	B-Nine
400-79	Alar 85
400-99	Alar
400-103	Kylar 85
400-110	B-Nine SP
400-117	Alar Technical - Not affected by the Agreement

Intrastates

400-06461	Alar 85
400-06466	Alar 85
400-06533	Kylar 85
CA 800035	California State Registration

Uniroyal intends to relabel both B-Nine and B-Nine SP products.

OPP believes that all the Intrastates are now cancelled.

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

STOP SALE, USE, OR REMOVAL ORDER

JUN 13 1989

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Mr. James A. Wylie, Jr.
Vice President and
General Manager
Crop Protection Division
Uniroyal Chemical Co., Inc.
74 Amity Rd.
Bethany, CT 06525

Reference: DAMINOZIDE - Food Use Products Including But Not Limited To
EPA Reg. Nos. 400-69,-79,-99,-103, and -110

By the authority vested in me pursuant to Section 13(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. §136k(a)), and in accordance with the enclosed June 2, 1989, "Agreement Between Uniroyal Chemical Company, Inc., and the United States Environmental Protection Agency For Voluntary Halt of Sales of Food-Use Pesticides Containing Daminozide", hereinafter referred to as the "Agreement", you are hereby ordered not to distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, receive and (having so received) deliver or offer to deliver, remove, or use the pesticide(s) listed above, or any other pesticides under your control, ownership, or custody that are subject to the "Agreement".

This order pertains to all quantities of the above-mentioned pesticide(s) within the control, ownership, or custody of your company, wherever located, and thus prohibits the sale of daminozide registered for food uses in the United States by Uniroyal and any Uniroyal subregistrant. The pesticide(s) may not be sold, offered for sale, held for sale, shipped, delivered for shipment, received and (having so received) delivered or offered for delivery, removed or used other than in accordance with the provisions of this order or of further Stop Sale, Use, of Removal Orders as may be issued in connection with the pesticide(s).

Notwithstanding the provisions of this Stop Sale, Use, or Removal Order, you may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, receive and (having so received) deliver or offer to deliver, remove, or use the pesticide(s) affected by this order which are under your control, ownership, or custody provided it is for purposes of consolidation in one or more locations, in order to implement a product recall. Specifically, in accordance with the aforementioned June 2, 1989 "Agreement", Uniroyal will recall from all distributors, dealers and subregistrants all stocks and inventories of daminozide products registered for food uses, including stocks returned by growers.

In addition, the information cited on page 5, paragraph 4, Review of Records, of the "Agreement" must be reported in writing to the EPA Representative listed below beginning on July 1, 1989 and quarterly thereafter until such time as Uniroyal has demonstrated to the Agency that the recall has been completed or the "Agreement" terminates as stated on page 8, paragraph 8, Duration of Agreement.

EPA Representative: Ms. Sherell A. Sterling (EN-342)
U.S. Environmental Protection Agency
Office of Compliance Monitoring
401 M Street, S.W.
Washington, DC 20460
Phone # 382-7835

Any person violating the terms or provisions of this order shall be subject to the civil or criminal penalties prescribed in Section 14 of the Act (7 U.S.C.§136l).

Michael F. Wood

Michael F. Wood, Director
Compliance Division (EN-342)

Enclosure

AGREEMENT BETWEEN UNIROYAL CHEMICAL COMPANY, INC.
AND THE UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
FOR VOLUNTARY HALT OF SALES OF
FOOD-USE PESTICIDES CONTAINING DAMINOZIDE

WHEREAS, on May 12, 1989, the U.S. Environmental Protection Agency ("EPA") issued a Notice announcing the Agency's preliminary determination pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") to cancel all food-use registrations for daminozide, and indicating that a draft Notice of Intent to Cancel had been forwarded with appropriate supporting documents to the FIFRA Scientific Advisory Panel ("SAP") for its review; and

WHEREAS, following the SAP's review and the evaluation of comments on the Notice of Intent to Cancel by the U.S. Department of Agriculture and public comments, the Agency will issue a Final Determination whether the registration should be cancelled; and

WHEREAS, the SAP is tentatively scheduled to review such matters at its July, 1989 meeting; and

WHEREAS, the SAP is to consider at such meeting, among other materials, interim results of a two-year drinking water oncogenicity study of the daminozide metabolite UDMH on mice and rats which EPA required Uniroyal Chemical Company, Inc. ("Uniroyal") to perform pursuant to a FIFRA § 3(c)(2)(B) Data Call-In Notice issued in 1986 the final report of which is due in September, 1989, and interim results of an additional

oncogenicity study on mice which EPA required Uniroyal to perform on March, 1987, the final report on which is due in January, 1990; and

WHEREFORE, in order to allay public confusion and concern regarding the safety of daminozide food-use products and the consumption of apples and other foodstuffs caused by publicity related to daminozide and this regulatory action, Uniroyal hereby voluntarily agrees, on the terms described below, to halt the sale of food-use pesticides containing daminozide, and to treat such food-use registrations as "suspended" within the meaning of FIFRA § 12(a)(1)(A), pending the full review of the matter by the SAP and the completion of the Agency's Special Review process, including any FIFRA § 6 cancellation hearing.

Terms of Agreement

1. Immediate Halt to Sales. Uniroyal agrees voluntarily to halt all sales of all its products containing daminozide for all food uses. In order to implement this Agreement, Uniroyal and EPA agree that all food-use registrations of pesticides containing daminozide shall be treated as "suspended" for purposes of FIFRA § 12(a)(1)(A). To accomplish this, Uniroyal will submit, within five days of the execution of this Agreement, an application for an amendment to all such registrations. The amendment will place a condition on the registrations requiring

that from the date on which the application is granted until the date on which EPA issues a Notice of Final Determination of Intent to Cancel the Daminozide Registrations, or the termination of any FIFRA § 6 cancellation hearing challenging such action, whichever occurs later: (1) no daminozide food-use products will be sold by Uniroyal for use in the United States; and (2) Uniroyal will conduct a voluntary recall, as described in paragraph 2 below, of all such daminozide products. Simultaneous to its issuance of the amended conditional registration, EPA will issue a "Stop-Sale, Use or Removal" Order to Uniroyal regarding all food-use registrations of daminozide, and Uniroyal agrees not to challenge the validity of such "Stop Sale, Use or Removal" Order.

It is the understanding of EPA and Uniroyal that the above measures will prohibit the sale of daminozide registered for food uses in the United States by Uniroyal and any Uniroyal subregistrants.

2. Voluntary Product Recall. Uniroyal voluntarily will recall from all distributors, dealers and subregistrants all stocks and inventories of daminozide products registered for food uses, including stocks returned by growers. (See paragraph 5.) Uniroyal specifically agrees as part of its voluntary recall effort to notify by letter, to be mailed within one week of the execution of this Agreement, all distributors and dealers known

by Uniroyal to be direct Uniroyal daminozide customers, and any subregistrants. Uniroyal agrees in such letters to indicate that Uniroyal has agreed voluntarily to halt all food-use sales of daminozide, and to recall all outstanding stocks and inventories from any source through distributors and dealers and to reimburse the owners of such products at the invoice price or, if no invoice is available, the prevailing price at time of purchase. In addition, Uniroyal agrees to mail to all persons on its grower mailing list (to be provided to EPA pursuant to paragraph 4 below), within two weeks of the execution of this Agreement, letters indicating that Uniroyal has agreed voluntarily to halt all food-use sales of daminozide, and that Uniroyal has agreed voluntarily to recall all outstanding stocks and inventories from any source through distributors and dealers and to reimburse the owners of such products at the invoice price or, if no invoice is available, the prevailing price at the time of purchase. Uniroyal agrees to allow EPA to review and approve the text of these letters prior to their release. Uniroyal also agrees as part of such recall to pay all reasonable costs of transporting the stocks and inventories to a site or sites, to be designated later, where the product will be repackaged and/or relabeled for subsequent sale (or storage for subsequent sale) for non-food uses, or for export as otherwise permitted by law. Uniroyal agrees to implement the recall and reimbursement program described in this Agreement as expeditiously as possible.

3. Amendment of Uniroyal's "B-Nine" Label. In conjunction with the provisions of paragraph 2 above, Uniroyal agrees to amend its B-Nine daminozide label, which is primarily a non-food-use product, to delete the tomato transplant use from the label, and to relabel (with a sticker or other means) any B-Nine stocks in Uniroyal's possession to delete the tomato transplant use. With respect to any stocks or inventories in the possession of distributors or dealers, Uniroyal agrees to issue to such distributors and dealers within three weeks of EPA's approval of the amendment appropriate labeling stickers for the deletion of the tomato transplant use, and agrees to inform the distributors and dealers that such labels should be affixed to all B-Nine products within the channels of trade no later than 60 days after EPA's approval of the amendment. EPA agrees that it will act promptly on Uniroyal's application to so amend the registration, and in any event to grant permission to delete the use no less than three business days from EPA's receipt of Uniroyal's application.

4. Review of Records. In recognition of the needs and benefits of EPA's ability to monitor progress of Uniroyal's voluntary recall efforts, Uniroyal agrees that, for purposes of this matter, the following are "data" within the meaning of FIFRA § 3(c)(2)(B) and are subject to call-in by EPA pursuant to that provision: records demonstrating daminozide sales by Uniroyal

directly to distributors, dealers and subregistrants in 1988 and 1989, including such records as necessary to determine the identity of all purchases and the amounts purchased; records demonstrating compliance with the provisions and schedule of the recall and reimbursement program, including details of the recall of such products from all direct Uniroyal customers (which may include distributors, dealers and subregistrants) and such records as necessary to determine the identity of all parties returning daminozide products to Uniroyal and the amounts returned; records indicating the amounts of daminozide products relabeled as B-Nine; and records regarding all sales of B-Nine products, including quarterly reports of current and future B-Nine sales, records demonstrating historical sales for B-Nine products and the approximate levels of B-Nine stocks and inventories presently available in the distribution chain in June, 1989, as well as such prospective records as necessary to demonstrate the identities of all Uniroyal direct cu omers purchasing B-Nine and the amounts purchased. The quarterly reports are being provided to allow EPA to monitor B-Nine sales in order to ensure that persons not a party to this Agreement do not divert B-Nine unlawfully to food use.

Uniroyal further agrees that all records indicating satisfaction of the recall requirements under this Agreement

shall be considered "reports" within the meaning of FIFRA § 12(a)(2)(N).

5. User Notification. In addition to the notification described in paragraph 2 above, Uniroyal agrees within two weeks of the execution of this Agreement, to send to the organizations listed below a letter, for distribution to their members, indicating that Uniroyal has agreed with EPA voluntarily to halt all food-use sales of daminozide and to recall all outstanding stocks and inventories from any source through distributors and dealers and to reimburse the owners of such products at the invoice price or, if no invoice is available, the prevailing price at the time of purchase. The letters will explain the reasons for this action and urge the growers to cease using the product immediately.

The associations to which Uniroyal agrees to send this letter will include at least the following: (1) International Apple Institute; (2) New York - New England Apple Institute; (3) Processed Apple Institute; (4) National Food Processors Association; (5) Washington State Apple Commission; and (6) the National Peanut Council. In addition, Uniroyal agrees to send the same or a similar letter to the lead land grant university in each major apple-growing state within the same two-week period. Uniroyal agrees to allow EPA to review and approve the text of

the letters required by this paragraph or to use the same letter described in paragraph 2.

6. Export Notification. EPA will issue an export notification regarding the status of daminozide registrations. The export notifications will explain that Uniroyal has agreed voluntarily to halt sales, and that in order to implement this Agreement, EPA and Uniroyal have agreed to treat the food-use registrations as "suspended" for enforcement purposes. EPA agrees to provide Uniroyal by telecopy with the text of such notifications, after they have been finalized and cleared for issuance, but five days prior to their issuance, in order that Uniroyal may notify affected customers. This is expressly understood not to imply a right to edit or change the text of such notifications, which will be drafted independently by the Agency.

7. SAP Review. EPA agrees to postpone the SAP's consideration of the Agency's Draft Notice of Intent to Cancel until the SAP's December, 1989 meeting. EPA further agrees to suspend the "five-minute rule" which ordinarily limits to five minutes a registrant's opportunity to make oral presentations to the SAP. Instead, both EPA and Uniroyal shall receive thirty minutes to make oral presentations, as supplemented by written materials, with the further understanding that the decision to extend the period for oral presentations is in the sole

discretion of the SAP. In addition, the Agency agrees to reserve at least one full day for the SAP's consideration of daminozide.

8. Duration of Agreement. This Agreement shall not expire and will remain enforceable until the completion of the SAP review and EPA's issuance of a Final Notice of Determination to Cancel the Daminozide Registrations, and any FIFRA § 6 cancellation hearing initiated as a challenge thereto, or a decision by the Agency upon its review of the SAP comments to withdraw its Draft Notice of Intent to Cancel, except that Uniroyal and EPA hereby agree that either party can request reconsideration of this matter upon the completion of the SAP review and as a result of any such reconsideration may mutually agree to terminate the Agreement earlier. EPA and Uniroyal anticipate that the SAP review and the decision whether to issue a Final Notice of Determination to Cancel or to withdraw the Draft Notice of Intent to Cancel will be accomplished by the Agency no later than March, 1990, and that any FIFRA § 6 cancellation hearing initiated by Uniroyal as a challenge thereto will be completed by September, 1991, and that the Agency will use its best efforts to accomplish these goals within the spirit and intent of this Agreement.

9. Limited Purpose of Agreement. Uniroyal by this Agreement does not admit or concede that daminozide or its metabolities present a significant risk of cancer, or an

unreasonable adverse risk to health or the environment within the meaning of FIFRA § 3(c)(5), or that any tolerances for daminozide established under the Federal Food, Drug and Cosmetic Act are inappropriate or should be reduced or revoked.

EPA by this Agreement does not modify or in any way recant its preliminary determinations concerning daminozide or its metabolities as expressed in the Preliminary Determination to Cancel Certain Daminozide Product Registrations published at 54 Fed. Reg. 22,558 (May 24, 1989). In addition, EPA specifically reserves the right to take any appropriate action under the Federal Food, Drug and Cosmetic Act.

10. Change in Circumstances. Uniroyal agrees that nothing in this Agreement limits EPA's authority to take appropriate regulatory action against daminozide or its metabolites under any of its statutory or regulatory authority if, in EPA's judgment, changed circumstances or new information indicate that such additional measures are necessary. EPA agrees that nothing in this Agreement limits the rights of Uniroyal to challenge such additional actions.

11. Enforceability. Uniroyal acknowledges the enforceability of this Agreement pursuant to FIFRA §§ 3(c)(2)(B), 12(a)(1)(A), 12(a)(1)(I) and 12(a)(2)(N), and agrees that it will

not challenge or encourage or assist any party to challenge the validity of this Agreement in any forum.

James A. Wylie, Jr.
Vice President and
General Manager
Crop Protection Division
Uniroyal Chemical Co., Inc.

(Date)

Victor J. Kimm
Acting Assistant Administrator
for Pesticides & Toxic
Substances
United States Environmental
Protection Agency

June 2, 1989
(Date)

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

NOV 7 1979

OFFICE OF ENFORCEMENT

MEMORANDUM

SUBJECT: DBCP Suspension Order Enforcement Strategy

TO: Enforcement Division Directors
Pesticides Branch Chiefs

Background

On September 8, 1977, the Administrator announced his intention to take two separate suspension actions with respect to pesticide products containing dibromochloropropane (DBCP). These actions were taken pursuant to his authority under Section 6(c) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended (FIFRA). On October 27, 1977, because no registrants invoked their right to a hearing pursuant to Section 6(c)(2), the Administrator issued a Suspension Order concerning DBCP products. The order was based on the findings that DBCP is carcinogenic and also found to damage human reproductive functions and may cause sterility in males. The October 27, 1977, Suspension Order therefore proposed two separate actions: (1) the "Unconditional" or "Specific Food Use" Suspension of all products registered for use on nineteen (19) specific food crops in which DBCP residues occurred, or appeared likely to occur in the edible portion of the treated crop; and (2) A "Conditional" Suspension of DBCP products registered for all other end uses. The conditionally suspended uses were: cotton, soybeans, citrus, grapes, pineapples, peaches, nectarines, plums, almonds, commercial okra, commercial lima beans, commercial snap beans, commercial southern peas, berries (blackberries, blueberries, loganberries, dewberries, boysenberries, raspberries), strawberry nursery stock, apricots, cherries, figs, walnuts, bananas, turf (commercial and residential) and ornamentals (commercial and residential). For the conditionally registered uses it was thought that risks to applicators could be sufficiently reduced on an interim basis by placing restrictions on the product, such as, limiting use to certified applicators using respirators and protective clothing.

On July 18, 1979, the Administrator announced his intention to suspend all remaining uses of pesticide products containing dibromochloropropane (DBCP). This Notice of Intent to Suspend is based on additional information showing that the conditional suspension is not adequate to reduce the risks associated with continued use of DBCP, and in turn prevent an imminent hazard during the time required to complete full scale cancellation proceedings which are now pending pursuant to Section 6(b) of FIFRA. The new findings reveal that DBCP residues may occur even in crops which are not grown in contact with or in close proximity to treated soil; that treatment with DBCP may result in contamination of water supplies, including drinking water sources; and that application of DBCP may result in ambient air levels of DBCP at sites outside the application area and may result in ambient air levels of DBCP at the site of application several days after application.

Pursuant to Section 6(c)(2) of FIFRA, each registrant of a DBCP product was given the opportunity to request an expedited hearing on the question of whether an imminent hazard existed. Three registrants requested such a hearing and following these proceedings the Administrative Law Judge presiding on the issue, ruled that an imminent hazard did in fact exist and recommended to the Administrator that all remaining uses of pesticide products containing dibromochloropropane be suspended.

On October 29, 1979, the Administrator issued a Suspension Order suspending all products containing dibromochloropropane with the exception of those products bearing directions for use on pineapples. This usage was strictly limited to the State of Hawaii.

A copy of the Notice of Intent to Suspend, the Recommended Decision by Administrative Law Judge, Gerald Harwood, the Suspension Order, a copy of the recall letters sent to registrants of DBCP products, and a list of registrants and registered DBCP products are enclosed.

This memorandum represents EPA's Enforcement Strategy to be used in relation to this Suspension Action.

Enforcement Policy

The Agency intends to ensure that the Administrator's Order is strictly complied with by all affected persons, including manufacturers, formulators, registrants, wholesalers, retailers and users.

On November 5, 1979, the Pesticides and Toxic Substances Enforcement Division notified by certified mail all registrants and/or producers of products containing DBCP requesting that they:

a. remove from sale down to and including the retail level all existing stocks of products bearing suspended uses;

b. recall those products which do not bear directions for use on pineapple;

c. relabel with interim or amended labeling those products bearing directions for use on pineapple.

The interim labeling we proposed would bear the statement "For Sale for Use on Pineapples in Hawaii Only". No product may be legally shipped after March 1, 1980, without approved amended labeling. Those products in the state of Hawaii bearing directions for use on pineapples shall be removed from sale until they have been relabeled with interim or approved amended labeling. Under no circumstances shall relabeled products be sold at the retail level in any state other than Hawaii.

Enforcement Procedures

1. After initial contact with the registrant, an inspector from the Regional Office or State should visit affected registrants to discuss the recall action and monitor the steps taken to comply with the recall. Proper storage of recalled products should be stressed. See Section 14 of the Pesticides Inspection Manual for information on procedures to be followed in monitoring the recall.

2. If a firm refuses to recall its products, the Regional Office in cooperation with the States shall issue Stop Sale, Use or Removal Orders and/or seizures to effect removal of the products from the channels of trade.

3. When necessary the Regional Offices and States will take appropriate enforcement action against those persons found in violation of the DBCP Suspension Order.

Regional Offices shall request States to identify and recall products bearing intrastate labels since intrastate products represent a major share of those registrations which are currently active. The Regions should also inform the States that only products bearing federal registrations were sent recall letters by PTSED. Those Hawaiian intrastate products bearing directions for use on pineapples may be relabeled if the state so wishes.

Use of Existing Stocks and Disposal

As stated in the Administrator's Suspension Order, the use of existing stocks of DBCP (except those products bearing directions for use on pineapples in Hawaii) is prohibited and would be in violation of the Suspension Order and subject to enforcement action. Persons desiring to dispose of stocks of DBCP products should be apprised that they may arrange with the appropriate regions to ship their products for disposal. This may include returning the product to the supplier, or disposal in accordance with directions provided by the Office of Solid Waste. Disposal questions may be referred to Mr. Ray Krueger (202-472-9403).

Export

DBCP products may be exported. Exportation must be in accordance with FIFRA Section 17(a) which includes a requirement that the product must bear specific labeling. Registrants exporting DBCP products affected by the Suspension Order should also be cautioned in relation to the stipulation signed by the Department of State concerning the utilization of U.S. funds for U.S. AID regulation entitled "Pest Management Program, Interim Pesticides Procedures", published in the Federal Register on January 7, 1976. The notice states that AID will not provide assistance for the procurement or use of a pesticide which has been finally suspended or cancelled by EPA.

Indemnification

The Office of Enforcement has been advised by the Office of General Counsel that registrants of DBCP products would not be eligible to make any claim for an indeminity payment until the registration of their pesticide is canceled, (See section 15(a) of FIFRA). Any questions concerning indemnities should be directed to Mr. Mitchell Bernstein, Office of General Counsel (202-426-9448).

Inquiries

Should you have any questions concerning any facet of this memorandum and the DBCP Suspension Order, please contact the appropriate Regional Coordinator.

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

Enclosures

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

OCT 7 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Compliance Strategy for the Emergency Suspension of Dinoseb

FROM: A. E. Conroy II, Director
Office of Compliance Monitoring

TO: Addressees

On October 7, 1986, the Administrator of the Environmental Protection Agency (EPA) signed an Emergency Suspension Order immediately suspending the registrations of pesticide products containing dinoseb or any of its four salts. This Emergency Suspension Order prohibits the continued sale, distribution and use of all dinoseb products after October 7, 1986. On the same day, the Administrator signed a Notice of Intent to Cancel and Notice of Intent to Deny the registrations of all dinoseb products.

Attached is the Final Compliance Strategy for the Emergency Suspension and Cancellation of Dinoseb. Please transmit a copy of this Strategy to the States. Please note that because of the nature of this action, this Compliance Strategy is immediately effective. If you have any questions or comments regarding the Strategy, contact Dan Helfgott (EN-342, FTS 382-7847) of my staff.

Thank you for your cooperation.

Attachment

ADDRESSEES

Douglas D. Campt (TS-766C)
Victor Kimm (TS-788)
Jim Lamb (TS-788)
Terrell Hunt (LE-134A)
Stanley Abramson (LE-132A)
John Seitz (EN-342)
Ken Shiroishi "
Phyllis Flaherty "
John Martin "
John J. Neylan III "
Ralph Turpin "
Mike Wood "
Dexter Goldman "

Jake Mackenzie
Western Regional Compliance Director

A. Charles Lincoln
Eastern Regional Compliance Director

I	Louis F. Gitto, Director Air Management Division	Gerald M. Levy, Chief Office of Pesticides & Toxic Sub.
II	Barbara Metzger, Director Environmental Services Div.	Ernest Regna, Chief Pesticides & Toxics Sub. Branch
III	Stephen R. Wassersug, Director Hazardous Waste Management Div.	Larry Miller, Chief Toxic & Pesticides Branch
IV	Winston A. Smith, Director Air, Pest. & Toxic Mgmt Div.	H. Kirk Lucius, Chief Pesticides & Toxic Subs. Branch
V	William H. Sanders III, Director Environmental Services Div.	Phyllis Reed, Chief Pesticides & Toxic Subs. Branch
VI	William B. Hathaway, Director Air, Pesticides & Toxics Div.	Norman E. Dyer, Chief Pesticides & Toxics Subs. Branch
VII	William A. Spratlin, Director Air & Toxics Division	Leo Alderman, Chief Toxics & Pesticides Branch
VIII	Irwin L. Dickstein, Director Air & Toxic Subs. Division	Alvin Yorke, Chief Toxic Substances Branch
IX	Jeffrey Zelikson, Acting Director Toxics & Waste Management Div.	Richard Vaille, Chief Pesticides & Toxics Branch
X	Gary O'Neal, Director Air & Toxic Division	Anita Frankel, Chief Pesticides & Toxic Subs. Branch

Sue Vogt (TS-788)
Deeohn Ferris (LE-134P)

OCT 7 1986

COMPLIANCE STRATEGY FOR THE EMERGENCY SUSPENSION OF DINOSEB

OVERVIEW

On October 7, 1986, the Administrator of the Environmental Protection Agency (EPA) signed an Emergency Suspension Order immediately suspending the registrations of pesticide products containing dinoseb (2 sec-butyl-4,6-dinitrophenol) or any of its four salts. This Emergency Suspension Order prohibits the continued sale, distribution and use of all dinoseb products after October 7, 1986. At the same time, the Agency also issued a Notice of Intent to Cancel and Notice of Intent to Deny all registrations of pesticide products containing dinoseb. These actions are also applicable to intrastate products for which an application for federal registration has been submitted and FIFRA §24(c) Special Local Needs Registrations.

Both of the October 7, 1986 regulatory actions are based on data which shows that dinoseb exposure causes developmental toxicity (including frank teratogenic effects), reproductive toxicity, acute toxicity, cataractogenic potential, immunotoxicity and oncogenicity (from parent compound and nitrosamine contaminants). The developmental toxicity effects are the largest concern since data indicate an immediate risk potential for fetuses of pregnant women exposed to dinoseb.

The Agency and States will assure compliance with the Emergency Suspension Order and Cancellation Order by issuing and monitoring Stop Sale, Use or Removal Orders (SSURO) and Formal Recall requests, conducting inspections at the producer, retail and user levels as well as investigating tips and complaints. The inspections are to assure that suspended or cancelled products are not being used or moved in commerce.

REQUIREMENTS

The October 7, 1986 Emergency Suspension Order states that, effective immediately, no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver, offer to deliver, or use all dinoseb products.

The Emergency Suspension of dinoseb products is effective immediately regardless of whether or not the registrant requests an expedited hearing. The Order will remain in effect until completion of the hearing and issuance of a final order on the issue of suspension.

If the Agency does not receive a timely and valid request for a hearing concerning the Agency's determination that an imminent hazard exists, the suspension of a dinoseb product will become final by operation of law, will not be reviewable by any court, and will remain in effect until a final order is issued concerning the proposed cancellation of that product.

The Agency also issued on October 7, 1986, a Notice of Intent to Cancel the registrations of all pesticide products containing dinoseb. The Notice allowed affected registrants 30 days to request a hearing on the proposed cancellation or have their dinoseb product cancelled. Submission of a request for an expedited hearing concerning the emergency suspension of a particular dinoseb product will not prevent cancellation of that product in the event no cancellation hearing is requested by the registrant.

Regulated Industry

The Emergency Suspension Order affects all pesticide products containing dinoseb or any of its four salts, including those in the possession of registrants, distributors, and users. There are 64 registrants located in 25 States, including one importer. There are 181 products (100 federally registered products, 81 intra-state products), made from 6 formulations of dinoseb. Current FIFRA and TSCA Enforcement System (FATES) data indicate there are 15 establishments which produced a pesticide product containing dinoseb in 1985. Appendix I contains a list of registrants and producers. Appendix II contains a list of producer establishments.

Dinoseb (including the four salts of dinoseb: alkanolamine, triethanolamine, ammonium and sodium) is registered as a herbicide, desiccant, fungicide, and insecticide. The principal use is to control broadleaf weeds as a contact herbicide at preemergence and postemergence.

The major use sites by volume include: soybeans (40 percent), cotton (15 percent), potatoes (16 percent), peanuts (2 percent), alfalfa (4 percent), snap beans (2 percent), peas (2 percent), grapes (2 percent), and almonds (1 percent). Other use sites include: forage legumes, small grains, fruit and nut orchards, berries, cucurbits, hops, onions, garlic, ornamentals, conifers, and noncrops (such as rights-of-way and aquatic drainage ditches).

The common trade names of dinoseb are: DNBP, DNOSBP, "dinitro", dinoseb (F-ISO), Caldon, Sinox, Vertac General and Selective Weed Killer, Basanite, Chemox General and PE, Chemsect, Dinitrex, Dinitro-3, Dinitro General, Drexel Dynamite 3, Dynamite, Elgetol 318, Gebutox, Hel-Fire, Kiloseb, Nitropone C, Subitex, Unicrop DNBP, Vertac Dinitro Weed Killer 5, Dynanap, Premerge Plus with Dinitro, and Klean Krop.

OUTREACH

The Office of Pesticide Programs will contact affected groups as outlined in the attached Communication Strategy.

COMPLIANCE MONITORING

The Agency sent each registrant a package, by certified mail, containing the Emergency Suspension Order, Notice of Intent to Cancel, SSURO, and a Formal Recall letter. The Formal Recall letter requested the registrants to determine the locations of affected products and amount at each location, effect the return of the recalled products to their company and inform the Agency of their inventory of all dinoseb products. In the event that the certified mailing is returned to the Agency and subsequent attempts to deliver the package are unsuccessful, OCM will ask the Regions to locate the registrant and deliver the package.

Neutral Administrative Inspection Scheme (NAIS)

Regions/States will conduct inspections of registrants and producer establishments within 30 days of the suspension action. Producer establishment inspections (PEI's) are conducted to assure that producers and registrants are not using, distributing, selling, offering for sale, holding for sale, shipping, delivering for shipment, or receiving and (having so received), delivering or offering to deliver, to any person suspended or cancelled dinoseb products. During PEI's, inspectors are to collect information from the producers on the names and addresses of all consignees of their product within the last 18 months, if this information has not already been obtained as part of the response to the Recall. Information on the names and locations of dinoseb dealers may also be obtained by contacting the registrant's main business office. Regions should provide States with a list of dealers based on the information obtained through the response to the Formal Recalls and the PEI's.

Regions/States will also conduct dealer and user inspections in order to determine compliance with the emergency suspension order, cancellation order, and SSURO's. Assuring geographic distribution, Regions/States are to randomly inspect 10 percent of the dealers. These inspections should be completed within 90 days of the suspension. States should issue SSURO's under State authority, or have Regions issue SSURO's, to dealers found holding or selling suspended products as well as taking enforcement actions as appropriate.

Users of dinoseb may be identified through the major uses of dinoseb as outlined in the Regulated Industry section of this Strategy. Inspectors should examine records of sale, if they are available, in order to further identify users. Regions/States will conduct use inspections based on this information.

Regions/States should respond to all tips and complaints regarding possible violations of the dinoseb suspension/cancellation order as soon as possible.

Regions will follow-up and track the Formal Recall following the procedures outlined in section 14 of the Pesticides Inspection Manual.

ALLOCATION OF RESPONSIBILITIES

Office of Pesticide Programs/Registration Division (OPP/RD)

° Will mail copies of the Emergency Suspension Order and Notice of Intent to Cancel to trade associations, and other Federal and State Agencies.

° Will maintain a list of registrants affected by the Emergency Suspension Order and provide this information to OCM.

° Will send copies of certified mail receipts, or a list of the dates they were received by the registrants, to OCM and OGC.

° Will contact OCM regarding undeliverable or missing certified mail receipts within 15 working days from the date of the mailing.

Office of Compliance Monitoring (OCM)

° Will prepare Stop Sale, Use or Removal Orders (SSURO).

° Will prepare Formal Recall letters.

° Will send by certified mail a package to each affected registrant containing:

1) A copy of the Emergency Suspension Order.

2) A copy of the Notice of Intent to Cancel.

3) A SSURO for the products covered by the October 7, 1986 Emergency Suspension Order.

4) A Formal Recall letter.

° Will prepare and transmit the Compliance Monitoring Strategy to the Regions.

° Will notify the Regions regarding undeliverable or missing certified mail receipts.

° Will provide a list of all registrants and user groups affected by the Emergency Suspension Order, those persons issued SSUROs, those registrants with cancelled dinoseb products, and additional pertinent information to the Regions.

° Will keep the Assistant Administrator of OPTS informed on the status of the Formal Recall, inspections, and enforcement actions for one year. These reports will be based on monthly status reports from the Regions for the first three months, and quarterly reports for the next three quarters.

Regions

° Will provide to OCM the name of a Regional Contact person.

° Will coordinate with States in the implementation of this Strategy.

° Will provide a list of producer establishments of dinoseb products to the States.

° Will provide States with copies of materials received from OCM.

° Will conduct inspections in States without Cooperative Enforcement Agreements.

° Will issue SSURO's for any suspended stocks found.

° Will take enforcement action as appropriate.

° Will follow-up and track the Formal Recall.

° Will report to OCM for one year on the status of the Formal Recall, the number and type of inspections, and the number and type of violations found by the Regions/States. This reporting will be monthly for the first three months and quarterly for the remaining three quarters.

° Will attempt to deliver the Emergency Suspension Order to those registrants that Headquarters was unable to notify by certified mail.

States

° Will conduct inspections.

° Will issue SSURO's under State authority, or have Regions issue SSURO's, for any suspended or cancelled stocks found.

° Will take enforcement action, as appropriate, provided they have the authority.

° Will report to the Regions on actions taken under the emergency suspension.

° Will report to the Regions for one year on the number and type of inspections and violations found by the State. This reporting will be monthly for the first three months and quarterly for the remaining three quarters.

APPENDIX 1

DINOSEB REGISTRANTS AND PRODUCTS

REGION I (2)

Staples C W Inc.
PO Box 328
Presque Isle, Me 04769
EPA Reg. No: 1345-004

Uniroyal Chemical
Division of Uniroyal, Inc.
74 Amity Rd.
Bethany, Ct 06525
EPA Reg. No: 400-075,-100,-138,-139,-140,-147,-153,-158,-174,-190,-235,
-302,-327

REGION II (6)

Agway, Inc.-Crop Services
Chemical Division
PO Box 4741
Syracuse, NY 13221
EPA Reg. No: 8590-026

American Hoechst Corporation
Rt. 202-206 N.
Summerville, NJ 08879
EPA Reg. No: 8340-010

Blue Spruce Company
50 Division Avenue
Millington, NJ 07946
EPA Reg. No: 1439-175,-190,-231,-235

N.Y.S. College of Agriculture and Life Science
Cornell University
Attn.-Dr. Dewey
Ithaca, NY 14853
EPA Intrastate Accession No: 38655-10431

Trans Chemical Industries, Inc.
150 Meadowlands Parkway
Secaucus, NJ 07094
EPA Reg. No: 9618-013

White House Company
8 Kingstand Ave.
Harrison, NJ 07027
EPA Reg. No: 3951-112

REGION III (4)

BFC Chemicals
PO Box 7495
3509 Silverside Rd.
Wilmington, De 19803
EPA Reg. No: 45639-118

FMC Corp.
Agricultural Chemical Group
2000 Market St.
Philadelphia, Pa 19103
EPA Reg. No: 279-1841,-1854,-1855,-1859,-2836,
EPA Interstate Accession No: 279-3898,-4037

Royster Company
PO Drawer 1940
Norfolk, Va 23501
EPA Reg. No: 4904-334

S.N.P.E. Stevens Et Al
1911 Jefferson Davis Hwy.
Suite 600, Crystal Mall #1
Arlington, Va 22202
EPA Reg. No: 35134-001

REGION IV (17)

Cedar Chemical
Suite 2414 Clark Tower
5100 Poplar Ave.
Memphis, Tn 38137
EPA Reg. No: 56077-003,-004,-005,-011,-012,-013,-014,-015,-016,
-021,-023,-024,-025

Cleveland Chemical Company
PO Box 820
Cleveland, Miss. 38732
EPA Reg. No: 8867-025

Drexel Chemical Company
2487 Pennsylvania St.
PO Box 9306
Memphis, Tn 38109
EPA Reg. No: 19713-023,-028,-033,-078,-082,-110,-203

Griffin Corporation
Attn.-Linda C. Elliot
PO Box 1847
Valdosta, Ga 31601
EPA Reg. No: 1812-118

Helena Chemical Company
Clark Tower Suite
5100 Poplar Ave.
Memphis, Tn 38137
EPA Reg. No: 5905-217,
EPA Intrastate Accession No:-7584,-7585,-7586,-7587, -7588,
-7593,-7599,-7600,-7601,-7602,-7887,-7888,-7889,-7890, -7891,
-7892,-7893,-7894,-7895

IDA, Inc.
PO Box 9483
2487 Pennsylvania St.
Memphis, Tn 38109
EPA Reg. No: 45115-028,-047,-052

Landia Chemical Company
P.O. Drawer AO
Lakeland, Fl 33802
EPA Intrastate Accession No: 9859-5637

Laroche Inc.
1100 Johnson Ferry Rd. NE
Atlanta, Ga 30342
EPA Reg. No: 3442-669

Micro-Flo Company
Rt. 1-Box 190
Sparks, Ga 31647
EPA Reg. No: 51036-054,-068

Riverside Chemical Company
Riverside Terra Corp.
PO Box 171376
Memphis, Tn 38117
EPA Reg. No: 9779-001,-186

Security Chemical Company
PO Box 938
Fort Valley, Ga 31030
EPA Reg. No: 769-365

Southern Agricultural-Insecticides Inc.
PO Box 218
Palmetto, Fl 33561
EPA Reg. No: 829-197

Stevens Industrial Inc.
N. Main St.
PO Box 272
Dawson, Ga 31742
EPA Reg. No: 2459-213

Superior Fertilizer and Chemical Company
PO Box 1021
Tampa, Fl 33601
EPA Intrastate Accession No: 3122-7195

Union Carbide Agricultural Products Co.
Office of Regulatory Affairs
PO Box 12014
T. W. Alexander Dr.
Research Triangle Park, NC 27709
EPA No: 264-363

Valley Chemical Company
PO Box 1317
Greenville, Ms 38702
EPA Intrastate Accession No: 1063-3299

Vertac Chemical Company
Suite 2414 Clark Tower
5100 Poplar Ave.
Memphis, Tn 38137
EPA Intrastate Accession No: 39511 -6817,-6818,-6819,-r820,-6821,
-6822,-6823, -6824,-6825,-6826,-6827,-6828,-6829,-6830,-6831,-6832,
-6833, -6834,-6835,-6836,-6837,-6838,-6839,-6849,-6850,-6851,-6853

REGION V (1)

Universal Cooperatives Inc.
Farm Chemical Division
PO Box 460
7801 Metro Parkway
Minneapolis, Mn 55440
EPA Reg. No: 1386-478,-582

REGION VI (7)

Ag-Chemical Services, Inc.
PO Box 1263
McAllen, Tx 78501
EPA Reg. No: 37790-8343

Ansul Chemical Company
P.O. Drawer 1165
Weslaco, Tx 78596
EPA Intrastate Accession No: 6308-3010,-3011,-3012,-3013,-3014

Apollo Enterprises Inc.
Route 1
Alteimer, Ar 72004
EPA Reg. No: 13166-013

DH Industrial Supply Company
PO Box 472
Bowie, Tx 76230
EPA Reg. No: 3797-004

Micro Chemical Company
PO Box 711
Winnsboro, La 71295
EPA Reg. No: 4841-050

Retzloff Chemical Company
PO Box 45296
Houston, Tx 77045
EPA Reg. No: 7472-007

Wilson Lee & Company
Wilson, Ar 72395
EPA Reg. No: 9220-001

REGION VII (4)

The Cropmate Company
320 Embassy Plaza
Omaha, Ne 68114
EPA Reg. No: 1145-095

Hi-Plains Sprayers, Inc.
710 S. Smokey Hill
Oakley, Ks 67748
EPA Accession Number No: 35965-3007

Kaw Valley, Inc.
1801 South 2nd St.
Leavenworth, Ks 66048
EPA Reg. No: 44215-087,-088,-089,-90,-125

Platte Chemical Company
150 South Main
Fremont, Ne 68025
EPA Reg. No: 34704-176,-244,-245,-246,-253
EPA Intrastate Accession No: 34704-3860

REGION VIII (1)

Schall Chemical Inc.
120 N. Broadway
Montevista, Co 81144
EPA Reg. No: 3468-010

REGION IX (18)

AFC Company
PO Box 207
Edison, Ca 93220
EPA Intrastate Accession No: 37177-8221

Arizona Agrochemical Company
Chemical Distributors
PO Box 21537
Phoenix, Az 85036
EPA Reg. No: 1526-480,-494

Bakersfield Ag Chemical Inc.
Rt. #1 Box 858
Bakersfield, Ca. 93308
EPA Intrastate Accession No: 11369-8775,-8793

Britz Inc.
PO Box 9050
Fresno, Ca 93790
EPA Intrastate Accession No: 10951-9810

Brown & Bryant Inc.
PO Bin T
Shafter, Ca 93263
EPA Intrastate Accession No: 11373-6981

Gowan Company
PO Box 5696
Yuma, Az 85364
EPA Reg. No: 10163-028
EPA Intrastate Accession No: 10163-6122

J.R. Simplot Co.
Agriculture Chemical Dept.
PO Box 198
Lathrop, Ca 95330
EPA Reg. No: 7001-077,-327
EPA Intrastate Accession No: 7001-4378,-7746

Newell Chemical Company
IBA Brea Agricultural Service
1905 N. Broadway
Stockton, Ca 95205
EPA Intrastate Accession No: 36998-4464

Puregro Company
1276 Halyard Drive
West Sacramento, Ca 95691
EPA Reg. No: 1202-205,-244

Rockwood Chemical Company
PO Box 34
Brawley, Ca 92227
EPA Intrastate Accession No: 10226-3751

Russell Chemical Company
PO Box 939
Brawley, Ca 92227
EPA Intrastate Accession No: 11159-7329
Dinoseb

Santa Paula Chemical Company
18115 E. Telegraph Rd.
Santa Paula, Ca 93060
EPA Intrastate Accession No: 43906-7330

Simplot, J.R. Company
Minerals and Chemical Division
PO Box 198
Lathrop, Ca 95330
EPA Reg. No: 11682-011,-012

Soil Service, Inc.
PO Box 1817
Salinas, Ca 93901
EPA Intrastate Accession No: 6973-3597

Stauffer Chemical Company
1200 S. 47th St.
Richmond, Ca 94804
EPA Reg. No: 476-1971

Van Waters & Rogers
Agricultural Dept. (Namco)
2256 Junction Ave.
San Jose, Ca 95131
EPA Reg. No: 550-070

Western Farm Services, Inc.
C/O Shell Chemical Co.
3075 Citrus Circle, Suite 195
Walnut Creek, Ca 94598
EPA Reg. No: 11656-001
EPA Intrastate Accession No: 11656-5767

Wilbur Ellis Company
191 W. Shaw Ave., Suite 107
Fresno, Ca 93704
EPA Reg. No: 2935-353,
EPA Intrastate Accession No: 2935-6592,-6593,-6594,-6636,-6661

REGION X (3)

Feed Services Inc.
PO Box 430
Caldwell, Id 83605
EPA Intrastate Accession No: 10914-9304,-9326

Pacific Supply Cooperative
1200 SW Main
Portland, Or 97205
EPA Reg. No: 483-142

Wood Industries
PO Box 1016
Yakima, Wa 98907
EPA Intrastate Accession No: 682-5596

FOREIGN PRODUCERS (1)

Marks & Company Ltd. A H
Wyke Bradford Rd. 12-9EJ
Yorkshire, England
EPA Reg. No: 15440-001

APPENDIX II

DINOSEB PRODUCER ESTABLISHMENTS*

REGION I (0)

REGION II (0)

REGION III (0)

REGION IV (4)

Drexel Chemical Co
Tunica Industrial Park
Tunica, MS 38676
Produces: Sodium dinoseb, Triethanolamine dinoseb, Dinoseb

Platte Chemical Company, Inc.
North Raceway Road
Greenville, MS 38701
Produces: Alkanolamine dinoseb, Dinoseb

Uniroyal Chemical
214 West Ruby Ave.
Gastonia, NC 28053
Produces: Sodium Dinoseb

Vertac, Inc., Vicksburg Plant
PO Box 3, Rifle Range Road
Vicksburg, MS 39180
Produces: Alkanolamine dinoseb, Ammonium dinoseb, Dinoseb

REGION V (3)

ADI Distributors Inc.
430 West Carmel Drive
Carmel, IN 46032
Produces: Sodium dinoseb

ADI Distributors Inc.
8558 Industry Park Drive
Piqua, OH 45356
Produces: Sodium dinoseb

Sweetser Service Cr., Inc.
215 W. Franklinn St., PO Box 188
Sweetser, IN 46987
Produces: Sodium dinoseb

* According to 1985 FATES data.

REGION V (0)

REGION VI (0)

REGION VII (2)

Macon Exchange Bulk Fert Plant
Highway 63 North
Macon, MO 63552
Produces: Sodium dinoseb

SCF, Inc.
PO Box 101
Levasy, MO 64066
Produces: Sodium dinoseb

REGION VIII (0)

REGION IX (5)

Arizona Agrichem - Kyrene Prod. Plant
6751 W. Galveston
Chandler, AZ 85224
Produces: Dinoseb

FMC Corp., ACG, Attn.: Delia D. McGoey
Box 1669 2501 Sunland Ave.
Fresno, CA 93717
Produces: Ammonium dinoseb

Helena Chemical Company
1075 S. Vineland (PO Box 305)
Kerman, CA 93630
Produces: Dinoseb

Occidental Chemical Company
16777 S. Howland Avenue
Lathrop, CA 95330
Produces: Dinoseb

United Agri Products
PO Box 2357 (3173 So. Chestnut)
Fresno, CA 93745
Produces: Dinoseb

REGION X (1)

J.R. Simplot Company DBA Sim-Chem
E of Boise, Exit 74, Simco Rd.
Mountain Home, ID 83647
Produces: Dinoseb

COMMUNICATIONS STRATEGY
FOR DINOSEB

BACKGROUND:

The Agency has been reviewing all available dinoseb data as part of the reregistration process. In conjunction with this review, a Data Call In Notice (DCI) requesting ground water and toxicology studies was issued on June 13, 1984. In response to this DCI, two teratogenicity studies were submitted in May, 1986 which demonstrated that dinoseb causes developmental toxicity in laboratory animals and may pose a risk of birth defects in pregnant women. This risk is greatest for those women exposed at the dinoseb application site.

EPA has also reviewed reproduction studies which indicate that dinoseb has the potential to cause male sterility.

Dinoseb is a contact herbicide widely used to control broadleaf weeds. Cotton, potatoes, and soybeans comprise 71% of the chemical use. Additional uses include: alfalfa, almonds, grapes, peanuts, peas, snap beans, and ornamentals.

ACTION BEING TAKEN:

After considering a range of regulatory options to mitigate exposure to dinoseb, the Agency has decided to emergency suspend all registrations. In conjunction with this action, a Notice of Intent to Cancel all dinoseb registrations is being issued.

The Administrator has determined that continued registration of dinoseb poses an imminent hazard during the period in which administrative hearings could delay the effectiveness of the cancellation of these registrations.

MESSAGE:

The Agency has determined that use of products containing dinoseb is an imminent hazard to human health due to significant exposure to applicators, particularly pregnant women. This regulatory decision will eliminate all risks to applicators, bystanders, and field workers. There is no dietary exposure of concern.

Numerous alternatives exist for most use sites of dinoseb. Paraquat and diquat are considered to be the two major alternatves. ICI Plant Protection Division (Great Britian) is the major producer of these two chemicals.

Dinoseb
Telephone Notification List

RESPONSIBLE PARTY	PERSON TO BE CALLED	PHONE#
	WITHIN EPA	
Mike McDavit	Jim Lamb (OPTS)	382-2892
"	Jan Peck (OPTS)	382-2906
"	Cathleen McInerney (OPP)	557-7102
"	Jill Collins (OPA)	382-4355
"	Larry Cook (OGC)	382-7505
"	Al Jennings (OPPE)	382-4005
"	Gus Conroy (OCM)	382-3807
"	Joy Wilson (AA/OEA)	382-5654
"	Alan Seilen (OIA)	382-4875
"	Richard Longmire (OPP)	557-9351
Jill Collins	Bill Prendergast (OCL)	382-5200
"	Al Heier (OPA)	382-4374
"	Andy Robart (OPPSL)	382-4454
"	Priscilla Flattery (OPA)	382-4387
Cathleen McInerney	Phil Gray (OPP)	557-7096
"	John Ulfelder (OA)	382-7960
	EPA REGIONS	
	(to be called two days prior to announcement)	
Susan Wayland	Regional Division Directors (conference call; OCM to attend)	
Priscilla Flattery	Regional Public Affairs Officers	
	OMB	
Cathleen McInerney	Carlos Tellez, OMB	395-7340

RESPONSIBLE PARTY	PERSON TO BE CALLED	PHONE #
	CONGRESS	
Bill Prendergast	Gary Mitchell,	225-2342
"	Tim Galvin,	225-4452
"	Skip Stiles, House Agriculture Subcommittee Staff	--------
"	Mario Castillo, House Agriculture Committee Staff	225-2171
"	Chuck Connor, Senate Agriculture Committee Staff	224-6901
"	Ron Outen, Senate Environment & Public Works Committee Staff	224-7814
	STATES (to be called one day prior to announcement)	
Phil Gray	L.O. Nelson, SFIREG/AAPCO Indiana	-------
"	Bob Ehart, Wisconsin	-------
"	Rodney Awe, Idaho	(208) 334-3243
"	Robert McCarty, Mississippi	--------
"	Art Losey, Washington	--------
Mike McDavit	Clare Berryhill, CA Dept. of Food & Agriculture	(916) 322-6315
"	Bob Batteese Maine	(207) 289-2731
	Kay Evans Maine	(207) 289-3871
"	Jeffrey Carlson, Massachusetts	(617) 727-2863

RESPONSIBLE PARTY	PERSON TO BE CALLED	TELEPHONE #
Mike McDavit	Van Kozak, Texas Dept. of Ag.	(512)463-7545
Region I	Vermont	--------
"	New Hampshire	--------
"	Connecticut	--------
"	Rhode Island	--------
Region II	New York	---------
"	New Jersey	---------
"	Puerto Rico	---------
Region III	Pennsylvania	---------
"	West Virginia	---------
"	Virginia	---------
"	Maryland	---------
"	Delaware	---------
Region IV	North Carolina	---------
"	South Carolina	---------
"	Georgia	---------
"	Florida	---------
"	Alabama	---------
"	Tennessee	---------
"	Kentucky	---------
Region V	Ohio	---------
"	Michigan	---------
"	Illinois	---------
"	Minnesota	---------
Region VI	Arkansas	---------
"	Louisiana	---------
"	Oklahoma	---------
"	New Mexico	---------
Region VII	Iowa	---------
"	Missouri	---------
"	Kansas	---------
"	Nebraska	---------
Region VIII	North Dakota	---------
"	South Dakota	---------
"	Montana	---------
"	Wyoming	---------
"	Colorado	---------
"	Utah	---------
Region IX	Arizona	---------
"	Nevada	---------
"	Hawaii	---------
Region X	Oregon	---------
"	Alaska	---------

RESPONSIBLE PARTY	PERSON TO BE CALLED	TELEPHONE #
	STATES	
Andy Robart	J.B. Grant, NASDA	628-1566
"	Bob Jackson, ASTHO	--------
"	Jim Solyst, NGA	-------
	INDUSTRY and USER GROUPS	
Mike McDavit	John Baize, American Soybean Association	554-7804
"	Dr. James Brown, National Cotton Council	901/274-9030
"	Harold Collins, National Agriculture Aviation Association	546-5722
"	Jack Early, National Agriculture Chemicals Association	296-1585
"	Ralph Engle, Chemical Specialties Manufacturers Association	872-8110
"	Tom Ford, National Potato Council	303/589-4787
"	David Hamilton American Association of Nurserymen	789-2900
"	Robert Keeney United Fruit and Vegetable Association	836-3410
"	Robert Kirshner National Forest Products Association	797-5800
"	Dave Lambert American Seed Trade Association	-------
	Michael Hodge American Frozen Food Institute c/o Collier Shannon Rill & Scott [illegible] Tower Ct. NW	342-8002

RESPONSIBLE PARTY	PERSON TO BE CALLED	TELEPHONE #
	INDUSTRY	
Mike McDavit	Denise Larr, Pesticide Producers Association	429-8405
"	Mark Maslyn, American Farm Bureau	484-2268
	FARMWORKER/LABOR/AGRICULTURE/ENVIRONMENTAL GROUPS	
Richard Longmire	Fernando Cuevas, Farm Labor Organizing Committee	305/887-2949
"	Rebecca Harrington, United Farm Workers (AFL-CIO)	512/474-5010
"	Chip Hughes, East Coast Farm Worker Support Network	919/682-3818
"	Ralph Lightstone, California Rural Legal Assistance	916/446-1416
"	Dr. Marion Moses, United Farm Workers (AFL-CIO)	415/731-6569
"	Baldemar Velasquez, Farm Labor Organizing Committee	419/243-3456
"	David Cavenaugh, National Association of Community Health Centers	833-9280
Andy Robart	Maureen Hinckle, National Audubon Society	547-9009
"	Diane Baxter, National Coalition Against the Misuse of Pesticides	543-5450

RESPONSIBLE PARTY	PERSON TO BE CALLED	PHONE #
	AGRICULTURE/ENVIRONMENTAL GROUPS	
Andy Robart	Lawrie Mott, Natural Resources Defense Council, SF	415/421-6561
"	Ellen Silbergeld, Environmental Defense Fund	387-3500
"	Norm Dean, National Wildlife Federation	797-6800
"	Neil Fitzpatrick, Audubon Naturalist Society of the Central Atlantic States, Inc.	652-9198
"	Shirley A. Briggs, Rachel Carson Council, Inc.	652-1877
"	---------- National Parks and Conservation Assn.	---------
"	Geoffrey Webb, Friends of the Earth	---------
"	Michael Clark, Environmental Policy Institute	547-5330
"	Lucky Wentworth, Izaak Walton League of America	528-1818
"	Douglas Wheeler, Sierra Club	--------
"	Bob Fredrick, National Grange	628-3507
"	Paul Sacia, National Farmers Union	554-1600
"	Pat Quinn, National Council of Agricultural Employers	554-6400

RESPONSIBLE PARTY	PERSON TO BE CALLED	PHONE #
	AGRICULTURE/ENVIRONMENTAL GROUPS	
Andy Robart	Randy Jones, National Council of Farmer Cocperatives	659-1525
"	Larry Silverman, American Clean Water Association	--------
"	Lois Ellison, American Lung Assn.	--------
"	Katherine McCarter, American Public Health Association	--------
"	Bambi Young, Center for Science in the Public Interest	--------
"	---------- Consumer Federation of America	--------
"	Rose Audette, Environmental Action	---------
"	Phillip Reed, Environmental Law Institute	---------
"	Sydney Wolf, Health Research Group	---------
"	Nancy Neuman, League of Women Voters	---------
"	---------- Migrant Legal Action Program	---------
"	Nat Williams, Nature Conservancy	---------
"	Joan Claybrook, Public Citizen	---------

RESPONSIBLE PARTY	PERSON TO BE CALLED	TELEPHONE #
Andy Robart	Dianne Barzman, Public Voice for Food and Health Policy	----------
"	Paul Portney, Resources for the Future	----------
"	Larry Jahn, Wildlife Management Institute	----------
"	Debbie Berkowitz, Food and Allied Services Union	737-7200
"	George Koch, Grocery Manufacturers Association	337-9400
"	Charlie Mack, Food Industry Assoc. Executives	296-8951
"	Harry Sullivan, Food Marketing Institute	452-8444
"	Robert Fersh, Food Research and Action Center	393-5060
"	Melanie Miller, National Peanut Council	775-0450
"	Robert Keaney, United Fruit Growers	836-3410
"	---------- Florida Fruit & Vegetable Assn.	(305) 984-1351
"	Jack Cooper, National Food Processors Association	639-5900
"	Erik Jansson, National Network to Prevent Birth Defects	543-5450

RESPONSIBLE PARTY	PERSON TO BE CALLED	TELEPHONE #
	OTHER FEDERAL AGENCIES	
Phil Gray	Charles Smith, Pesticide Assessment Program/USDA	447-4751
"	Jim Parochetti, Cooperative Extension Service/USDA	447-6506
"	Ken Williams, Office of Migratory Birds, Fish and Wildlife Service,	--------
"	John Wessel, FDA USDI	-------
Cathleen McInerney	Larry Kline, Office of Endangered Species, UDSI	235-2760
"	Sanford Miller, Bureau of Foods/HHS	245-8850
"	John Wood, APHIS/USDA	436-8896
	INTERNATIONAL AGENCIES and FOREIGN GOVERNMENTS	
Alan Seilen	Pep Fuller, U.S. Trade Representative	--------
"	Tom Wilson, U.S. State Department	--------
"	Carroll Collier, Agency for International Development	--------
Cathleen McInerney	Wayne Ormrod, Plant Products and Quarantive Directorate, Agriculture Canada	613-995-7900
"	Pierre Mineau, Canadian Wildlife Service	819-997-6121

MAILINGS:

The Registration Division (RD) will mail copies of the document to pesticide registrants (the FR notices will be mailed prior to publication). RD will also mail the document to trade organizations, EPA Regions, other Federal agencies, State officials and key EPA employees. The Office of External Affairs will send copies to Congress, environmental groups, and intergovernmental groups, as appropriate.

Federal Register

Friday
February 17, 1989

Part IV

Environmental Protection Agency

Dinoseb Pesticide Products; Procedures for Submission of Claims for Indemnification and Requests for Disposal; Amended and Final Notice

ENVIRONMENTAL PROTECTION AGENCY

[OPP-150003A; FRL-3523-3]

Dinoseb Pesticide Products; Procedures for Submission of Claims for Indemnification and Requests for Disposal; Amended and Final Notice

AGENCY: Environmental Protection Agency.

ACTION: Final notice; procedures for requesting indemnification and disposal for pesticide products containing Dinoseb.

SUMMARY: This Notice amends an April 15, 1987, Federal Register Notice by announcing that EPA is again accepting claims for indemnification and/or requests for disposal for all suspended and cancelled dinoseb-containing pesticides under sections 15 and 19 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 m and q (prior to the FIFRA amendments of 1988). On June 9, 1988, the EPA Administrator issued a Final Order which concluded the cancellation hearing on dinoseb, cancelled the registrations of all remaining dinoseb products, and provided for limited use of existing stocks under certain specified conditions. This Notice provides information on eligibility and procedures to owners of dinoseb stocks who may wish to seek indemnification for losses suffered as a result of regulatory actions taken by EPA and/or Federal disposal assistance.

DATES: Claims and requests filed in response to this Notice for products which may not be used on caneberries in Washington and/or Oregon, must be submitted by June 19, 1989, to be considered. Claims and requests for products which may be used on caneberries in Washington and/or Oregon should not be submitted until after June 15, 1989. These latter claims/requests must be submitted before August 15, 1989, to be considered.

ADDRESS: All claims and requests filed in response to this Notice should be mailed to: Resource Management and Evaluation Branch (TS-757C), Office of Pesticide Programs, Environmental Protection Agency, 401 M Street SW., Washington, DC 20460, Attention: Stanley Cook.

FOR FURTHER INFORMATION CONTACT:

By mail: Stanley Cook, Resource Management and Evaluation Branch (TS-757C), Office of Pesticide Programs, Environmental Protection Agency, 401 M Street SW., Washington, DC 20460

Office location and telephone number: Room 1002, CM#2, 1921 Jefferson Davis Highway, Arlington, VA, 1-800-DIN-OSEB (in Maryland call 1-800-331-3704).

SUPPLEMENTARY INFORMATION: EPA is issuing this amended Notice because all suspended dinoseb registrations have now been cancelled, and holders of stocks of these products may be eligible for indemnification and/or Federal disposal assistance. This Notice discusses how claims for indemnification and requests for Federal disposal should be prepared and submitted to EPA. It also instructs persons who responded to the April 15, 1987, Notice how to affirm, amend, or withdraw a previously submitted claim and/or request, or to submit a claim for indemnification and/or request for disposal assistance for previously ineligible products.

This Notice establishes two time periods with separate deadlines for owners to submit claims for indemnification and/or requests for disposal. Owners of products which may not be used in 1989 on caneberries must file claims/requests during the first time period. Owners of products which may be used on caneberries must file claims/requests during the second time period. Procedures for filing claims/requests are discussed in Unit II. of this Notice. Unit II. B. lists products for which claims/requests may be submitted during one of these two time periods.

This Notice also discusses the interim storage, transportation, and disposal of dinoseb stocks. EPA has awarded contracts to two waste management firms for the disposal of dinoseb. It is the responsibility of the holder to store the dinoseb safely and transport it to EPA's designated facility when EPA is ready to receive the stocks.

I. Background

A. Legal Standard

Section 6 of FIFRA authorizes the EPA Administrator to take certain actions to prohibit sale, distribution, and use of pesticide products that pose unreasonable adverse effects to human health or the environment. If use of a pesticide poses a risk that outweighs the benefits of continued use, the pesticide's registration may be cancelled and/or suspended. If action is necessary to prevent an imminent hazard to human health or the environment, the Administrator may announce his intent to suspend a pesticide registration at the same time he issues a Notice of Intent to Cancel. If an emergency exists which does not permit the Administrator to hold a hearing before suspending a pesticide registration, he may issue an Emergency Suspension Order which immediately halts all use, sale, and distribution of the pesticide. Adversely affected persons may request, within certain time frames, a hearing to challenge EPA's suspension. After an opportunity for a expedited hearing, a Final Suspension Order can be issued. Also in accordance with section 6 of FIFRA, a Notice of Intent to Cancel and deny registrations provides that a pesticide product would be cancelled 30 days after publication of the cancellation notice or its receipt by the registrant unless the registrant or other adversely affected person requests a hearing to contest the cancellation of that registration.

Prior to its amendment in December 1988, section 15 of FIFRA required the Administrator to make indemnity payments to owners of pesticides suspended and cancelled under section 6 who suffered losses by reason of the Agency's actions. The statute provided that indemnification is payable to any person under the following conditions:

1. The Administrator suspended the registration to prevent an imminent hazard.

2. The registration was subsequently cancelled.

3. The person owned some quantity of the pesticide immediately before the suspension.

4. The person suffered losses by reason of the suspension or cancellation.

Under section 15(b), the amount of indemnity payment was to be determined on the basis of the cost of the pesticide owned by the person immediately before the suspension, but could not exceed the pesticide's fair market value at that time.

Also prior to the 1988 amendments, section 19(a) of FIFRA and the regulations promulgated pursuant to it at 40 CFR Part 165 required Administrator to accept at convenient locations for safe disposal those pesticides the registrations of which have been suspended and cancelled as specified in section 6(c), if requested by the owner of the pesticide. However, before the owner of a pesticide requests such acceptance, he/she must make every reasonable effort to return the material to the manufacturer, distributor, or other agents capable of relabeling, recovering, recycling, or reprocessing the material (See 40 CFR 165.4).

Both sections 15 and 19 of FIFRA were substantially amended by Pub. L. 100-532, the FIFRA Amendments of 1988, which was given into law by the President on October 25, 1988. EPA does

not believe that the 1988 amendments are applicable to its current dinoseb indemnification and disposal program. Accordingly, all references in this Notice to sections 15 and 19 of FIFRA refer to the law as it existed prior to the 1988 amendments.

B. Dinoseb History

Based on information about the adverse human health and environmental risks posed by dinoseb-containing pesticide products, on October 7, 1986, the Administrator issued an Emergency Suspension Order for all registrations of pesticides containing the active ingredient dinoseb. It immediately prohibited all further sale, distribution, and use of dinoseb products. Notice of this action was published in the **Federal Register** of October 14, 1986 (51 FR 36634). Although four registrants requested a hearing concerning whether the suspension of dinoseb products should remain in effect, these requests were withdrawn on October 30, 1986, resulting in immediate entry of a Final Suspension Order.

Also on October 7, 1986, the Administrator issued a Notice of Intent to Cancel and deny registrations of all dinoseb-containing pesticide products, published in the **Federal Register** of October 14, 1986 (51 FR 36650). Upon the expiration of the applicable 30-day period, many dinoseb registrations were cancelled by operation of law. However, several registrants requested hearings contesting the EPA's cancellation action. These registrations were suspended, but not cancelled, pending the outcome of an administrative hearing.

Prior to issuance of a Final Cancellation Order, certain actions were taken which resulted in modification of the Suspension Order on dinoseb. First, EPA was petitioned under Subpart D of 40 CFR Part 164 to modify the Final Suspension Order to permit use of dinoseb on certain crops. Following an administrative hearing, on March 30, 1987, the Administrator issued a Decision and Final Order Modifying the Final Suspension of Pesticide Products which Contain Dinoseb. This order and the FIFRA section 18 emergency exemptions which implemented it allowed limited use of FIFRA during the 1987 and 1988 growing seasons on dry peas, lentils, and chickpeas in Washington and Idaho. A subsequent order permitted use on the same crops in certain counties of Oregon.

Second, following a complaint filed in the U.S. District Court for the District of Oregon by a number of user groups, the Suspension Order on dinoseb was enjoined on April 15, 1987, with respect to certain crops in the Pacific Northwest. *Love v. Thomas*, 668 F. Supp. 1143 (D. Oregon 1987), *affirmed in part* 838 F. 2d 1059 (9th Cir. 1988). In particular, the District Court ruling enjoined the Suspension Order as it applied to dinoseb use on caneberries, cucurbits, green peas, and snap beans in the States of Idaho, Oregon, and Washington.

On June 9, 1988, the Administrator issued a Final Cancellation Order on dinoseb, cancelling all remaining registrations. However, the Order provided for limited use of existing stocks of dinoseb on specific crops in the Pacific Northwest during the 1988 and 1989 growing seasons. The Order permitted existing stocks of all cancelled dinoseb products which were previously labeled for use on peas, lentils, or chickpeas to be sold, distributed, and used for weed control in dry peas, lentils, chickpeas, and green peas in the States of Idaho, Oregon, and Washington during the 1988 use season. In addition, the Order permitted existing stocks of all cancelled dinoseb products previously labeled for use on caneberries (blackberries, boysenberries, loganberries, and raspberries) to be sold, distributed, and used for cane control in these crops in the States of Oregon and Washington for the 1988 and 1989 use seasons. The 1989 caneberry use in Washington and Oregon is the only allowable use remaining at this time.

The Final Cancellation Order was challenged in the same District Court of Oregon, which initially issued a preliminary injunction partially staying the Order. However, the Court ultimately concluded it did not have jurisdiction to review the Order and, in the alternative, entered judgment sustaining the Administrator's decision. *Northwest Food Processors* v. *Thomas*, N-88-641-RE (D. Oregon Sept. 25, 1988). The Northwest Food Processors Association previously filed a petition in the Ninth Circuit Court of Appeals seeking review of the cancellation order and has also appealed the Federal District Court decision to the Ninth Circuit Court.

C. April 15, 1987 Federal Register Notice

EPA issued a notice, published in the **Federal Register** on April 15, 1987 (52 FR 12352), announcing that pursuant to sections 15 and 19 of FIFRA it was accepting claims for indemnification and/or requests for disposal assistance for dinoseb pesticide products that were suspended and cancelled. The April 15, 1987 Notice described procedures and set a deadline of July 14, 1987 for filing claims and/or requests for eligible products. As described in the April 15, 1987 Notice, eligibility did not extend to suspended dinoseb registrations which had not been cancelled (i.e., those registrations for which registrants had requested a cancellation hearing). Although such products were not eligible for indemnification and disposal assistance at that time, EPA requested holders of these ineligible products to provide the Agency with certain basic information, such as location and quantity of their stock. EPA requested this information to be able to estimate the total quantity and location of all dinoseb products which could become eligible for indemnification and disposal assistance if the registrations of such products were eventually cancelled.

In response to the April 15, 1987 Notice, EPA received over 1200 submissions. About one-third of these were for products eligible at that time for indemnification and disposal assistance, and the others were for products that were not eligible. All submissions were assigned claim or file numbers and information from the aggregate was used to estimate the total amount and location of dinoseb stocks. EPA has been reviewing these submissions and has contacted some people regarding their claims/requests. EPA has made a number of offers to pay indemnification to owners, and is processing these claims as the acceptance agreements are returned by the owners. The Agency will be contracting all other people who responded to the April 15, 1987 Notice regardless of whether their products were eligible or ineligible for indemnification or disposal at the time of their initial submission. EPA appreciates the cooperation of holders of suspended-only products who responded to the April 15, 1987 Notice. The information helped expedite the dinoseb indemnification and disposal program.

After the publication of the April 15, 1987 Notice, and prior to issuance of a Final Cancellation Order, several registrants who had requested a cancellation hearing withdrew their requests and, in so doing, their dinoseb registrations were cancelled by operation of law. Once cancelled, owners of such products were eligible to seek indemnification and disposal assistance. For example, the registrations of Uniroyal Chemical Company dinoseb products were cancellations on June 19, 1987 when Uniroyal withdrew from the hearing. At that point, dinoseb products registered by Uniroyal became eligible for indemnification and disposal assistance. However, many owners of Uniroyal

products may not have been aware of the cancellation and their subsequent eligibility. This Notice serves, in part, to announce that owners of Uniroyal products registered by other companies who withdrew from the hearing after the April 15, 1987 Notice was issued are now eligible to file claims for indemnification and requests for disposal and must file claims/requests as outlined in Unit II. of this Notice.

II. Requirements for Indemnification and Disposal

A. Who is Eligible to File Claims for Indemnification and Requests for Disposal?

1. General

All federally registered dinoseb products, including products with Special Local Need registrations (under section 24(c) of FIFRA), have been suspended and cancelled. Accordingly, owners of these cancelled dinoseb products including registrants, manufacturers, distributors, retailers, and users may submit claims for indemnification and requests for disposal, provided that the cancellation occurred after the October 7, 1986 Emergency Suspension Order and the other conditions specified in this Unit are met.

2. Effect of Intrastate Registration

At the time of the October 7, 1986 Emergency Suspension Order, certain products containing dinoseb were being marketed under State pesticide registrations with applications for Federal registrations pending before EPA in accordance with EPA regulations at 40 CFR 162.17. Applications for these intrastate products were pending on October 7, 1986, when EPA issued a concurrent Notice of Intent to Deny all pending applications for Federal registration of these products.

The denial of Federal registration for these intrastate products was analogous to cancellation. A U.S. Claims Court decision in *Gro-Green Products, Inc.* vs. *United States*, 3 Cl. Ct. 639 (1983), held that in similar circumstances a claimant who held stocks of an intrastate pesticide product containing silvex was entitled to indemnification. Accordingly, persons with dinoseb products that were previously marketed under pending intrastate applications may also be eligible for indemnification and disposal, and must submit any claim during the first time period established in Unit II. E.

3. Effect of Section 18 Emergency Exemptions, the District Court Rulings and the Final Cancellation Order

The Final Cancellation Order superceded all sale, distribution, and use of dinoseb under the section 18 emergency exemptions or the District Court rulings. However, as discussed above, the Final Cancellation Order permitted the sale, distribution, and use of dinoseb for certain crops in 1988 and 1989. Persons who used dinoseb under the section 18 emergency exemptions, the District Court rulings, or the existing stocks provision (for uses other than on caneberries) in the Cancellation Order, and who have not submitted a claim for indemnification, must now do so. Further, if they have previously submitted a claim/request or information they must now affirm, amend, or withdraw it. Such amended claims/requests must reflect any product that was used or sold for one of these uses. However, if a dinoseb product may be used on caneberries during the 1989 use season, they should not submit a claim or amend a claim until the second time period as discussed in Unit II. E.

Owners/holders of dinoseb should remember that products for which existing stocks may still lawfully be sold or used under the Cancellation Order include *any* products labeled for caneberry uses, whether or not they were cancelled prior to issuance of the Order. Such products must be used only in full compliance with all of the stringent use restrictions required under the Order, and supplemental labeling containing all of the use restrictions must accompany the product when it is sold or distributed. Holders of these products may use, sell, or distribute their dinoseb stocks in Oregon and/or Washington during the 1989 caneberry use season in conformity with the Cancellation Order. Owners/holders who previously submitted claims/requests on these products and who subsequently use, sell, or distribute some or all of their stock must amend their claim accordingly and notify EPA during the second time period as discussed in Unit II. E.

4. Ownership requirement

Any person who owned some quantity of a registered dinoseb pesticide product immediately before the registration of that product was suspended, or who subsequently received a permissible assignment of the original owner's claim or a power of attorney from the original owner to file the claim, may claim indemnification for the product. Claims/requests may be filed by persons representing, in some legal capacity, the product owners at the time of suspension or cancellation.

A "power of attorney" is a document which appoints someone other than the actual product owner (the registrant, for example) as an agent of the product owner. In this instance, such a document merely gives an agent the authority to submit an indemnification claim and receive payment on the owner's behalf. The claim remains that of the pesticide owner.

EPA encouraged registrants to recall their products from distributors and retailers, so that the dinoseb products would be consolidated. If a registrant recalled its products, the registrant could obtain assignment of the original owner's claim. The document of assignment transfers the pesticide owner's right of indemnification to the other person. The pesticide owner thereafter has no legal interest in the claim. Samples of a "power of attorney" and assignment documents are provided in an Appendix to the Dinoseb Claim Form. Forms are available from the regional offices listed in Unit II. D. of this Notice.

The Federal Anti-Assignment of Claims Act would ordinarily bar an assignment of a claim that occurred before the claim was allowed. As st[illegible] in the April 15, 1987 Notice, EPA pla[illegible] to waive this prohibition against "early" assignments with regard to otherwise valid claims for indemnification under section 15 of FIFRA. However, EPA intends to waive this prohibition only with respect to an assignee who took back the product as part of a recall or a seller who subsequently accepted returned stocks from purchasers.

Owners such as end-users and dealers/distributors who have acquired stocks of dinoseb products since October 7, 1986, will not be eligible for indemnification for such stocks even if the products were acquired in a lawful manner because these people did not own the product on the date of suspension. EPA will not waive the Anti-Assignment of Claims Act prohibition against assignment of indemnification claims for these products because waiver of this prohibition would not be consistent with the purposes of the Act. Claims for indemnification belong only to the person who owned such stocks on October 7, 1986 and may not be assigned to anyone else unless such assignment is part of a recall or return of stocks to suppliers.

EPA suggests that any dealer or u[illegible] who acquired stocks of dinoseb products after October 7, 1986, which

he/she cannot or does not intend to lawfully sell or use should attempt to return such stocks to the party who owned them on October 7, 1988. Only that party is eligible to receive any indemnity payment for remaining stocks. Likewise, any person who intends to acquire dinoseb for the lawful use permitted under the Final Cancellation Order should be cautioned that he/she would not be eligible for indemnification for that particular stock, if any is unused at the end of the 1989 use season, because he/she was not its owner on October 7, 1988. However, even if it is not possible to return remaining stocks of a cancelled pesticide product to the original owner, the new holder may submit a request for Federal disposal assistance if the stocks are otherwise eligible.

EPA requires information from the claimant on the current ownership and location of the product, as well as the ownership at the time of suspension. For purposes of determining who owned the product at the time of suspension, the operative date is October 7, 1988.

5. Loss Requirement

The amount of indemnity payment is to be determined on the basis of the cost of the pesticide owned by the person immediately before suspension, but can not exceed the pesticide's fair market value at that time. Owners can recover indemnification only for losses suffered. Therefore, anyone who legally sold or used any dinoseb products after October 7, 1988 (e.g., as legally permitted under section 18, the District Court injunctions, or the Final Cancellation Order) must make appropriate adjustments on his/her claim. The total amount of "loss" sustained by the owner for a given amount of a dinoseb product must be reduced by the proceeds of any sale or distribution of that product. Any owner who uses a given amount of a dinoseb product has eliminated those "losses" that might otherwise have been sustained as a result of suspension and cancellation of the amount of product. A claimant is not entitled to an indemnity payment for any amount of dinoseb product for which losses were recovered through sale or use.

B. What Products Are Eligible for Indemnification and Disposal?

The following lists include all dinoseb products that are now eligible for indemnification and Federal disposal assistance. List A contains products for which no caneberry uses are permitted, and for which EPA is now accepting claims/requests. Claims/requests for products in List A must be submitted during the first time period specified in Unit II. E. List B contains products which may be used on caneberries in Washington and/or Oregon during the 1989 caneberry season. Claims/requests for products on List B should not be submitted to EPA until the second time period specified in Unit II. E.

Most pesticide product labels contain an EPA registration number (usually designated as "EPA Reg. No. 999999-9999") and an EPA establishment number (usually designated as "EPA Est. No. 99999"). The owner should locate the EPA registration number and use that for identifying his/her product(s) and for completing the form. The owner should not use the EPA establishment number for identifying his/her product(s). That number is not sufficiently specific to be useful for the dinoseb indemnification and disposal program. Some product labels list a registration number that begins with the letters "SLN" and then a two letter State abbreviation, followed by a 6-digit number. These are called section 24(c) or Special Local Need registrations and are legitimate EPA registration numbers. In rare cases, pesticide product labels do not contain an EPA registration number. These are probably "intrastate" products that have never received a Federal registration number. For these, the owner should use the State registration number provided on the label to identify the product(s) and note on the form that no EPA registration number is present on the label.

LIST A—PRODUCTS THAT MAY NOT BE USED ON CANEBERRIES IN WASHINGTON AND/OR OREGON

Company Name/ Registration No.	Product Name
AFC Company:	
037177-6221	AFC Contact Weed Killer.
AG-Chem:	
037790-0343	Salvo.
Agway:	
008590-26	Agway Toxi-Fum Premerge.
A.H. Marks and Company, Ltd.:	
015440-1	Technical DNBP.
Ansul:	
006308-3010	Ancrack Herbicide
006308-3011	Ancrack Herbicide.
006308-3012	Ancrack Herbicide.
006308-3013	Ancrack Herbicide.
006308-3014	Ancrack Herbicide.
Apollo Enterprises:	
013166-13	Dinitro 3.
Baird and McGuire, Inc.:	
SLN NV-810005	Baird's Contact Weed Killer.
Bakersfield AG:	
011369-8775	Bac Dinitro Weed Killer.
011369-8793	Bac Contact Weed Killer.
SLN CA-780171	Bac Weed Killer.
BFC Chemicals:	
045639-119	Tuco Enide Dinitro E.C.
Blue Spruce:	
001439-175	Chemox PEG.
001439-190	Chemox PE-R Pre-merge Type.
001439-231	Chemox PE Pre-merge Type.
001439-235	Chemox 289.
Brea AG Service:	
036998-4454	Brea Contact Weed Killer.
Britz Fertilizer:	
010951-9810	Britz Contact Weed Killer.
Brown & Bryant:	
011373-6981	Beebee Weed Killer-D
Cedar Chemical Corporation:	
056077-3	Dinoseb Technical.
056077-4	Dinitro Weed Killer.
056077-11	Selective Weed Killer.
056077-13	Premerge 3.
056077-14	Premerge.
056077-15	Dinitro 3 Weed Killer
056077-16	Premerge Plus.
056077-21	Technical DNBP.
056077-23	General Weed Killer (Technical).
056077-24	DN-289.
056077-25	Dinoseb.
Cleveland Chemical:	
008267-25	Premerge Dinitro Weed Killer.
Cornell University:	
038655-10431	NYS—Dewey—(DNBP) Premerge.
Cropmate Company:	
001145-95	Amoco Premerge Dinitro.
Crystal Chemical Company:	
SLN CA-780085	Dinitro NCS.
DH Industries:	
003797-4	Right-A-Way Weed Killer Semi-Concentrate.
Dow Chemical U.S.A.:	
SLN AZ-770033	Dow Selective Weed Killer.
SLN AZ-800032	Dow Selective Weed Killer.
SLN AR-800013	Premerge 3 Dinitro Amine Herb.
SLN CA-780160	Premerge 3 Dinitro Amine Herb.
SLN FL-790016	Premerge 3 Dinitro Amine Herb.
SLN IN-770002	Premerge 3 Dinitro Amine Herb.
SLN MD-790014	Premerge 3 Dinitro Amine Herb.
Drexel Chemical Company: (*New No./ Old No.*)	
019713-33/006308-73.	Ancrack.
019713-28/006308-79.	Dynamyte 300.
019713-33/006308-89.	Dynamyte T.
019713-82/ inapplicable.	Dynamyte 3.
019713-110/ inapplicable.	DNBP Technical.
SLN AR-830013	Ancrack Herbicide.
SLN DE-830001	Ancrack Herbicide.
SLN ID-830012	Drexel Dynamyte 3.
SLN LA-840004	Ancrack Herbicide.
SLN OK-830016	Ancrack Herbicide.

LIST A—PRODUCTS THAT MAY NOT BE USED ON CANEBERRIES IN WASHINGTON AND/OR OREGON—Continued

Company Name/ Registration No.	Product Name
SLN TN-840001	Antrack Herbicide.
SLN WA-830016	Orchard Dynamyte 3
Feed Service:	
010914-9304	R-15 Concentrate.
010914-9305	R-15 Dessicant.
FMC Corporation:	
000279-1641	Niagara Sinox-W Code C.
000279-1654	Sinox G 100.
000279-1659	Niagara Sinox PE Code 10.
000279-0859	Sinox Plus.
SLN WA-770043	Niagara Sinox Plus Code 31213
Gowan:	
010163-28	Prokil General WS Premerge
010163-6122	Prokil General Weed Killer.
Griffin:	
001812-118	Premerge Dinitro Weed Killer.
Helena:	
005905-7584	Spark.
005905-7585	Spark.
005905-7586	Spark.
005905-7587	Spark.
005905-7588	Spark.
005905-7593	Spark.
005905-7599	Spark.
005905-7600	Spark
005905-7601	Spark.
005905-7602	Spark.
005905-7887	Spark.
005905-7888	Spark.
005905-7889	Spark.
005905-7890	Spark.
005905-7891	Spark.
005905-7892	Spark.
005905-7893	Spark.
005905-7894	Surge Growth Stimulant.
005905-7895	Spark.
Hi-Plains:	
035965-3007	Spur 440.
Ida Incorporated:	
045115-47	Dinitro 3 Dinitro Weed Killer.
J.R. Simplot Company:	
007001-4378	Contact Weed Killer.
007001-7745	Contact Weed Killer.
011682-11	Sim-Chem Dinitro Weed Killer.
Kaw Valley:	
044215-87	Miller Dinitro Weed Killer.
044215-88	Chemox General Weed Killer.
044215-89	Tide Weed Pre-merge Type.
044215-90	Baird's N-D Herbicide.
044215-125	AGSCO Skin-Set A Herbicide for Potato Vine Killing.
SLN CA-790013	Tide Weed-Aside Pre-Emerge Type.
Landia Chemical Company:	
009359-5037	Scathe Peanut Herbicide.
Larochc Incorporated:	
000442-669	USS Premerge Dinitro.
Micro Chem. Company:	
004841-50	Premerge Dinitro Weed Killer.
Micro-Flo:	
051036-68	Premerge Dinitro Weed Killer.

LIST A—PRODUCTS THAT MAY NOT BE USED ON CANEBERRIES IN WASHINGTON AND/OR OREGON—Continued

Company Name/ Registration No	Product Name
Mid America Chemical Company, Inc.:	
SLN CA-790227	Dinitro Contact Weed Killer.
SLN CA-790228	Fireball Dinitro Weed Killer.
Pacific Supply:	
000769-142	Dinitro P.E.
Platte Chemical:	
034704-176	Clean Crop Dinitro-GS 3 Weed Killer.
034704-244	Clean Crop Dinitro 3-B Herbicide.
034704-245	Clean Crop Dinitro 5-B Herbicide.
034704-246	Clean Crop Technical DNBP.
034704-253	Clean Crop Contact Weed Killer.
034704-3860	Clean Crop Top-Kill.
Puregro:	
001202-244	Puregro Preharvest Desiccant.
SLN CA-780043	Puregro Contact Weed Killer.
SLN ID-840013	Puregro Preharvest Desiccant.
Retzloff:	
007472-7	DNBP-3s Horbicide.
Riverside/Terra:	
009779-1	Dinitrol.
009779-186	Brand Premerge.
Rockwood:	
010226-3751	Rockwood Brand Desiccant.
Royster Company:	
004904-334	Chem-Pest Dinitro Weed Killer.
Russell Chemical:	
011159-7329	Dynitox 300.
Santa Paula:	
043906-7330	Russell Chemical Contact WK.
SLN CA-760016	Santa Paula Chemical Contact.
Schall:	
003468-10	Schall Contact Weed Killer.
Security Lawn:	
000769-305	Premerge Dinitro Weed Killer.
S.N.P.E.:	
035134-1	Dinoseb.
011682-12	Sim-Chem Vine Killer.
Soil Service:	
006973-3597	Super Contact Weed Killer.
Southern Agric. Ins.:	
000829-197	Dinitro General Weed Killer.
Staples CW Incorporated:	
001345-4	Premerge Dinitro.
Stauffer:	
000476-1971	Dinitro P.E. Weed Killar.
Steven Industries:	
002459-213	Master Brand Premerge.
Superior:	
000122-7195	Superior Yellow Top.
Thompson-Hayward Chemical Company:	
SLN CA-760177	Contact Weed Killer.
Toxo Spray Dust, Inc.:	
SLN CA-790209	Toxo Contact Weed Killer.

LIST A—PRODUCTS THAT MAY NOT BE USED ON CANEBERRIES IN WASHINGTON AND/OR OREGON—Continued

Company Name/ Registration No.	Product Name
Trans Chemic:	
000618-13	TCI-DNBP
Uniroyal Chemical Company, Inc.:	
000400-75	Dyanap.
000400-100	Dyanap (H.W.).
000400-135	Uniroyal Dinoseb-1.
000400-139	Uniroyal Dinoseb-3.
000400-147	Ethyl DNBP.
000400-153	DNBP.
000400-190	TH Dinitro Technical.
000400-295	DE Pestor Dinitro Weed Killer
000400-302	Klean Krop
000400-327	Salvage Dinitro Weed Killer.
SLN AL-810028	Uniroyal Dinoseb 3.
SLN AR-830018	Uniroyal Dinoseb 3.
SLN AR-840004	Uniroyal Dinoseb 3.
SLN ID-830010	Uniroyal Dinoseb 3.
SLN ID-830013	Uniroyal Dinoseb 3.
SLN ID-840003	Uniroyal Dinoseb 3.
SLN ID-840006	Uniroyal Dinoseb 3.
SLN LA-800034	Uniroyal Dinoseb 3.
SLN MS-800045	Uniroyal Dinoseb 3.
SLN MO-810021	Uniroyal Dinoseb 3.
SLN OR-830002	Uniroyal Dinoseb 3.
SLN OR-830031	Uniroyal Dinoseb 3.
SLN OR-840004	Uniroyal Dinoseb 3.
SLN TN-810014	Uniroyal Dinoseb 3.
SLN WA-830014	Uniroyal Dinoseb 3.
SLN WA-830015	Uniroyal Dinoseb 3.
SLN WA-840021	Uniroyal Dinoseb 3.
SLN WA-840045	Uniroyal Dinoseb 3.
SLN WA-840046	Uniroyal Dinoseb 3.
Universal Cooperative:	
001386-478	Unico Dinitro PE Weed Killer.
001386-502	Unico Dinitro T.
Valley Chemical:	
001063-3299	Beanweda.
Van Waters and Rogers:	
000550-70	Guardsman Premerge Dinitro.
Vertac Chemical:	
039511-4	Dinoseb Technical.
039511-10	Dinitro Weed Killer.
039511-85	Selective Weed Killer
039511-87	Premerge 3.
039511-88	Premerge.
039511-89	Dinitro 3 Weed Killer
039511-90	Premerge Plus.
039511-112	Technical DNBP.
039511-114	General Weed Killer (Technical).
039511-115	DN-289.
039511-116	Dinoseb.
039511-6817	Selective Weed Killer.
039511-6818	Selective Weed Killer.
039511-6819	Selective Weed Killer.
039511-6820	Selective Weed Killer.
039511-6821	Selective Weed Killer.
039511-6822	Selective Weed Killer.
039511-6823	Premerge.
039511-6824	Premerge.
039511-6825	Premerge.
039511-6826	Premerge.
039511-6827	Premerge.
039511-6828	Premerge.
039511-6829	Premerge.
039511-6830	Premerge.
039511-6831	Premerge.
039511-6832	Premerge.
039511-6833	Premerge.
039511-6834	Premerge.
039511-6835	Premerge.

LIST A—PRODUCTS THAT MAY NOT BE USED ON CANEBERRIES IN WASHINGTON AND/OR OREGON—Continued

Company Name/ Registration No.	Product Name
039511-6836	Premerge.
039511-6837	Premerge.
039511-6838	Premerge.
039511-6839	Premerge.
039511-6849	General Weed Killer
039511-6850	General Weed Killer
039511-6851	General Weed Killer.
039511-6853	General Weed Killer
SLN AL-820004	Premerge 3 Dinitro Amine Herb.
SLN AR-820026	Premerge 3 Dinitro Amine Herb.
SLN CA-810014	Premerge 3 Dinitro Amine Herb.
SLN CA-820107	Premerge 3 Dinitro Amine Herb.
SLN IL-820020	Premerge 3 Dinitro Amine Herb.
SLN IN-820005	Premerge 3 Dinitro Amine Herb.
SLN MO-820007	Premerge 3 Dinitro Amine Herb.
SLN NC-820004	Premerge 3 Dinitro Amine Herb.
SLN NC-820017	Premerge 3 Dinitro Amine Herb.
SLN VA-820007	Premerge 3 Dinitro Amine Herb.
SLN VA-820026	Premerge 3 Dinitro Amine Herb.
Western Farm Service:	
011656-5767	Contact Weed Killer.
SLN CA-790094	Contact NCS.
[illegible]A-760122	Western Farm Service Contact Weed Killer
[illegible]CA-790137	Western Farm Service Contact Weed Killer.
White House:	
003951-112	Eagle River DNBP Technical.
Wilbur Ellis:	
002935-353	Red Top Weed Killer.
002935-6592	Red Top Weed Killer.
002935-6593	Red Top Weed Killer.
002935-6594	Red Top Weed Killer.
002935-6636	Red Top Dinitro Weed Killer.
002935-6661	Red Top Dinitro Weed Killer.
SLN CA-760004	Red Top Contact Weed Killer.
SLN ID-770024	Red Top Contact Weed Killer.
SLN ID-820004	Red Top Contact Weed Killer.
SLN MT-810021	Red Top Contact Weed Killer.
SLN OR-760012	Red Top Contact Weed Killer.
SLN OR-780048	Red Top Contact Weed Killer.
SLN OR-810044	Red Top Contact Weed Killer.
SLN WA-760013	Red Top Contact Weed Killer.
SLN WA-770043	Red Top Contact Weed Killer.
SLN WA-800068	Red Top Contact Weed Killer.
SLN WA-830025	Red Top Contact Weed Killer.
Wilson Lee and [illegible]pany:	
[illegible]0-1	Dinitro (DNBP) Weed Killer.

LIST A—PRODUCTS THAT MAY NOT BE USED ON CANEBERRIES IN WASHINGTON AND/OR OREGON—Continued

Company Name/ Registration No.	Product Name
Woods:	
000682-5596	Crop King Dy-All.

The names of products which may be used on caneberries in Washington and/or Oregon during the 1989 caneberry season are provided on List B. Claims for products on List B should not be submitted to EPA until the second time period specified in Unit II.E.

As noted in the footnote to List B, owners of dinoseb products previously registered under FIFRA section 24(c) for use in only one State on any crop other than caneberries may or may not be permitted to submit claims/requests during the first period discussed in Unit II. E., depending on whether the product also bears general labeling for use on one or more caneberry crops. If a product is registered under section 24(c) and does not bear any labeling for use on a caneberry crop, the owner may submit a claim during the first period.

LIST B—PRODUCTS THAT MAY BE USED ON CANEBERRIES IN WASHINGTON AND/OR OREGON

Company name/ registration no.	Product name
Arizona Agro:	
001526-480	GWK.
001526-494	Dinitro Weed Killer.
Cedar Chemical Corp.:	
056077-5	Dinitro Weed Killer 5.
056077-12	General Weed Killer
056077-17	Dinitro General.
Crystal Chemical Co.:	
SLN CA-770538 [1]	Dinitro General Herbicide.
SLN CA-780056 [1]	Do.
SLN CA-780200 [1]	Do.
Dow Chemical U.S.A.:	
SLN CA-760132 [1]	Dow General Weed Killer.
SLN CA-780137 [1]	Do.
SLN CA-790043 [1]	Do
SLN ME-780004 [1]	Do.
SLN NY-780026 [1]	Do.
SLN PA-790017 [1]	Do.
SLN WA-790071 [1]	Do.
Drexel Chemical Co. (new No./old No.):	
019713-29/ 006308-80.	Dynamyte 5.
019713-78/ inapplicable.	Dynamyte 2.5.
019713-203/ 001022-442.	Premerge Dinitro Weed Killer.
SLN ID-860020 [1]	Dynamyte 5.
SLN NV-860008 [1]	Do.
SLN WA-840062 [1]	Dynamyte 5 Dinitro Weed Killer.
FMC Corp.:	
000279-1855	Niagara Sinox General.
000279-2836	Niagara Sinox Plus Code 31218.
000279-4037	Sinox General.
SLN CA-760199 [1]	Sinox 0.5 E.C.
SLN OR-780053 [1]	Niagara Sinox Plus Code 31218.
SLN WA-790079 [1]	Sinox General Contact Weed Killer.
Helena:	
005005-217	Helena Hel-Fire.
SLN SC-820002 [1]	Do.
Ida Inc.:	
045115-28	Dinitro 2.5.
045115-52	IDA Inc. Dinitro 5.
J.R. Simplot Co.:	
007001-77	Best Contact Weed Killer.
007001-327	Oxy Dinitro Weed Killer.
011682-11	Sim-Chem Dinitro Weed Killer.
SLN CA-760034 [1]	Best Contact Weed Killer.
SLN CA-780137 [1]	Do.
SLN OR-810072 [1]	Do.
SLN OR-790023 [1]	Do.
SLN WA-790038 [1]	Do.
Micro-Flo:	
051036-54	Fasco Dinitro Weed Killer.
Puregro:	
011202-205	Puregro General Weed Killer.
Union Carbide:	
000264-363	E Z Flow Vega-Kill.
Uniroyal:	
000400-140	*Uniroyal Dinoseb-5.*
000400-158	Uniroyal Dinoseb-3.3.
000400-174	Dinitro Weed Killer #5.
SLN ID-830031 [1]	Uniroyal Dinoseb 5
SLN ID-830032 [1]	Do.
SLN OR-830028 [1]	Do.
SLN OR-830029 [1]	Do.
SLN OR-840003 [1]	Do.
SLN WA-790068 [1]	Do.
SLN WA-810102 [1]	Do.
SLN WA-820042 [1]	Do.
SLN WA-820066 [1]	Do.
Vertac Chemical:	
033511-11	Dinitro Weed Killer 5.
039511-86	General Weed Killer.
039511-91	Dinitro General.
SLN CA-860038 [1]	Vertac General Weed Killer.
SLN IL-820019 [1]	Dow General Weed Killer
SLN ME-820001 [1]	Do.
SLN OR-820022 [1]	Do.
SLN OR-820023 [1]	Do.
SLN OR-820024 [1]	Do.
SLN OR-820025 [1]	Do.
SLN PA-820012 [1]	Do.
SLN WA-810075 [1]	Dinitro Weed Killer 5
SLN WA-820006 [1]	Dow General Weed Killer.
SLN WA-820007 [1]	Do.
SLN WA-820008 [1]	Dinitro Weed Killer 5
SLN WA-820009 [1]	Do.
Western Farm Service:	
11656-1	Contact Weed Killer.

[1] Owners of dinoseb products previously registered under FIFRA section 24(c) for use in only one State on any crop other than caneberries may or may not be permitted to submit claims/requests during the first period discussed in Unit II. E., depending on whether the product also bears general labeling for use on one or more caneberry crops. If a product is registered under section 24(c) and does not bear any labeling for use on a caneberry crop, the owner may submit a claim during the first time period.

Using these lists, the person filing the claim should find the product(s) for

which he/she is claiming indemnification and/or requesting disposal assistance, and complete the claim form (including the product registration number) as described in Unit II. C. If the registration number on the product label is not present on this list, and the owner is sure he/she has a dinoseb product, he/she should file the claim or request using whatever number is present on the label. The absence of a product registration number may be explained by a registration transfer from one company to another. In such a case, the new registration legally encompasses all former registrations and, as long as the registration was transferred to another company and was subsequently suspended and cancelled under section 6(c) of FIFRA, the owner may be entitled to an indemnity payment and/or disposal assistance with respect to that product even though the product now goes by another EPA registration number.

C. What Information Must be Submitted?

1. Claim Form and Supporting Documentation

EPA has prepared an updated form for filing claims/requests and an instruction sheet to accompany it. The form and instructions distributed in conjunction with the April 15, 1987 Notice have been revised to reflect changes in the eligibility and labeling of certain products that have occurred since the April 15, 1987 Notice. The revised materials can be obtained from the EPA regional offices listed in Unit II. D. of this Notice.

It is the responsibility of the person submitting an indemnity claim to submit the required documentation to support the claim. The instructions accompanying the claim form indicate what type of supporting documentation is acceptable for each element of the claim. For example, all individuals filing claims must submit evidence of the cost to the claimant in either producing or acquiring the product. The cost is limited to the direct cost of the product and does not include such incidental items as transport or storage costs. For registrants/manufacturers holding inventories of a labeled and packaged product that could not be sold, production records showing cost of production, or invoices showing the purchase cost will be acceptable. Distributors, wholesalers, retailers, and users should submit purchase invoices, purchase receipts, or notarized affidavits.

If disposal or reprocessing has already occurred, evidence of legal disposal is also required. Records to be used as such evidence should be kept in sufficient detail so that EPA could track the history of individual dinoseb products for which indemnification is being sought. Such evidence must include invoices or waste manifests from facilities permitted to handle dinoseb wastes. In such a case, indemnity payments may be granted for the cost of the product but not for the cost of disposal or reprocessing.

The form also provides a way to request disposal of a product, whether or not indemnification is requested. All information requested on the form regarding quantity, unit number and size, and other facts pertinent to disposing of excess product must be submitted in order for the product to be eligible for Federal disposal.

A claimant is not entitled to an indemnity payment for a dinoseb product for which he/she has already recovered losses through sale or use. If an owner of a dinoseb product has sold or used any existing stocks (for example, for use consistent with the Final Cancellation Order, for other lawful uses during past use seasons, for a non-pesticidal purpose, for use in another country, or other purposes), the owner must reflect the effect of this sale or use in completing the claim form, since it will lower the amount of indemnification for which he/she is eligible. Any claim against the Federal government must be offset by the amount received from sale or use of the dinoseb product because the owner has eliminated those "losses" he/she might otherwise have sustained as a result of suspension and cancellation of that amount of product.

Any person submitting a claim as a legal representative of another person must submit evidence which establishes his/her authority to file the claim and receive payment in satisfaction of the claim on behalf of the owner of the product. A person submitting a claim as an assignee must submit evidence of assignment of the claim and demonstrate that such assignment occurred as part of a recall of the products in question.

If at any time a claimant decides to withdraw a claim and/or request, he/she must certify in writing that the product has been properly disposed of; lawfully sold, distributed, or used in accordance with the Cancellation Order, emergency exemptions, or the injunctions by the District Court of Oregon; recycled; or exported.

2. Business Records Verification

Manufacturers, registrants, distributors, and any other claimants that normally maintain business records are permitted to consolidate the supporting information required to accompany the claim form and to verify the contents of the claim by submitting an auditor's report or a schedule supported by an independent certified accountant's statement verifying the validity of the schedule. Each element of the claim, such as cost per unit of product or quantity of product owned at the time of suspension, must be reviewed and verified by the independent auditor if verification for the complete contents of the claim is being provided through the report or statement. If the independent review is being conducted for only one element of the claim, such as a manufacturer's cost of production per unit of product, supporting documentation must be submitted for all other elements of the claim. EPA retains the right to request submission of the information that formed the basis for the audits or reports in order to verify the validity of the information submitted.

3. Composite Claim Lists

Registrants or suppliers who have recalled a product from their customers and who are assignees or representatives of those customers may submit composite lists for separate elements of the claim form identifying the product, product owner, quantities and units of pesticides, and other pertinent information indicated on the claim form. Documentation of the assignment, power of attorney, or other legal authorization from each original owner of the product listed in such composite list must be submitted. The legal documentation should identify the parties and product involved. If the pesticide is still owned by anyone other than the person completing the claim form, proof of each element of the claim must be submitted on behalf of the owner. For example, if a registrant has recalled material and is filing the claim by power of attorney for the owner, the registrant must submit verification of ownership at the time of suspension, the quantity of product returned to the registrant by the owner, and the cost of the product to the owner. If, on the other hand, the registrant is filing the claim as an assignee, the registrant should provide the information and verification required by the claim form.

4. *Confidential Business Information*

As a general matter, businesses may assert claims of business confidentiality covering part of the information submitted through the claim form, in the manner described in 40 CFR 2.203(b).

...h assertions of confidentiality of ...s information must be supported ...mentation of the reasons why ...ure of the information is likely to ...substa... harm to the ...titive p... ...ion of the business. ...formation covered by the ...n will be disclosed by EPA only ...xtent allowed by FIFRA section ...by means of the procedures set ...40 CFR Part 2. If no such ...on and supporting documentation ...pany the information when it is ...d by EPA, it may be made ...ble to the public by EPA without ...notice to the business (See 40 ...2(a)(2)). EPA has determined ...will not afford confidential ...ent to certain information ...ed on the claim form because it ...be disclosed to contractors to ...ge for disposal of the dinoseb ...des. Confidentiality claims should ...applied to: the type, composition, ...antity of pesticide product, the ...ze of containers, and the product's ...on. If EPA receives any ...ntiality claims for this ...ation, the claim for ...nification and/or request for ...sal will not be considered and will ...turned to the claim...

...Investigations

...A plans to conduct random ...igations of claims/requests ...ed ... the purpose of ...thi... their veracity. In verifying ...requests, EPA may seek to enter ...ises to examine any dinoseb ...cide products being stored pending ...sal to assure that they are being ...appropriately (i.e., in ...mance with the regulations and ...lines described in Unit III.), to ...mine records relevant to the claim, ...conduct whatever other ...inations are necessary to audit the ...

...ning Claim Required

...claimant or authorized ...entative must sign the claim form. ...ng the form constitutes agreement ...following:

...That all statements made and ...tion provided in the claim are ...nd correct to the best of the ...nt's knowledge, and that the ...nt of the claim is an accurate ...ment of the cost of the product.

...That the claimant had no ...wledge of facts which, in ...selves, showed that the dinoseb ...cide did not meet Federal ...tration requirements.

...That acceptance by the claimant of ...payment made by EPA constitutes full satisfaction and final settlement of the claim.

...d. That by submission of the claim, the claimant grants permission to authorized agents of the Federal government to enter premises where records or products are retained to conduct whatever inspections, audits, or examinations are necessary to verify the contents of the claim.

e. That by submission of the claim, the claimant waives any claim for confidential treatment of certain types of information, including the type, composition, and quantity of pesticide product, the unit size of containers, and the product's location.

f. That the claimant has received no other payment for the cost of the pesticides for which indemnification is claimed and that should claimant receive such other payment, claimant agrees to promptly reimburse the Federal government, in such amount up to and including the full amount of the indemnification payment made under this program.

g. That ownership of and responsibility for pesticide products for which indemnification payments are made under this program remains with the claimants and/or holders of the material unless and until EPA accepts the material for disposal under section 19 of FIFRA.

h. That neither payment of indemnification under section 15 of FIFRA nor acceptance of pesticides for disposal under section 19 of FIFRA in any way constitutes a finding or warranty by the United States with respect to the proper or safe storage, packaging, handling, transport, or disposal of such products by the owners or holders of the products or by agents, employees, or other persons acting in their behalf.

i. That if the claim is filed by an assignee, the United States may assert against the assignee any defenses, or right of set-off or counterclaim, applicable against the person who assigned the claim.

D. Where Can a Claim Form be Obtained?

Copies of the claim form can be obtained from EPA regional offices. The regional office contact person for dinoseb indemnification and disposal information/claim forms, addresses, telephone numbers, and the States located within each EPA region are as follows:

EPA Regional Offices

1. Region I, Dr. Harold Kazmaier, John F. Kennedy Federal Building, Rm. 2311, Boston, MA 02203 (617-565-3276) (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont).

2. Region II, Ernest Regna, Woodbridge Avenue, Edison, NJ 08837 (201-321-6765) (New Jersey, New York, Puerto Rico, and the Virgin Islands).

3. Region III, Donald Lott, 841 Chestnut Building, Philadelphia, PA 19107 (215-597-9370) (Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, and West Virginia).

4. Region IV, Bill Pfister, 345 Courtland St., NE., Atlanta, GA 30365 (404-347-2222) (Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee).

5. Region V, John Ward, 230 Dearborn St., Chicago, IL 60604 (312-353-2192) (Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin).

6. Region VI, Van Kozak, 1445 Ross Ave., Dallas, TX 75202 (214-655-7239) (Arkansas, Louisiana, New Mexico, Oklahoma, and Texas).

7. Region VII, James R. McDonald, 726 Minnesota Ave., Kansas City, KS 66101 (913-236-2835) (Iowa, Kansas, Missouri, and Nebraska).

8. Region VIII, Ed Stearns, 999 18th St., Suite 500, Denver, CO 80202-2405 (303-293-1745) (Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming).

9. Region IX, Thomas Broz, 215 Fremont St., San Francisco, CA 94105 (415-974-8019) (Arizona, California, Hawaii, Nevada, American Samoa, and Guam).

10. Region X, Jon Heller, 1200 6th Avenue, Seattle, WA 98101 (206-442-1970) (Alaska, Idaho, Oregon, and Washington).

E. Where and When Must the Claim/Request be Filed?

All claims for indemnification and requests for disposal for any dinoseb products whose registration is listed in this Notice as having been suspended and cancelled must be submitted to EPA in Washington, DC at the address listed under the "ADDRESS" section at the beginning of this Notice. Because the Final Cancellation Order permits the limited sale, distribution, and use of existing stocks of certain dinoseb products for vegetative cane control in caneberries (blackberries, boysenberries, loganberries, and raspberries) in the States of Washington and Oregon during the 1989 use season, the Agency is establishing two time periods for submission of indemnification claims and requests for disposal assistance.

EPA is not accepting claims/requests for products that can be used on caneberries until after the 1989 season because it would be unable to compute the losses suffered by owners until these opportunities for sale and use of the products have expired. Therefore, owners of products that can legally be used on caneberries should not submit claims and/or requests for disposal until the beginning of the second time period.

The first time period extends from February 17, 1989 to June 19, 1989. Owners of dinoseb products which may not be used on caneberries in Washington and Oregon must submit claims for indemnification and requests for disposal assistance during this period. The second time period extends from June 15, 1989 to August 15, 1989, and owners of dinoseb products which may be used on caneberries in Washington and Oregon during the 1989 use season must submit claims for indemnification and requests for disposal assistance during this second time period. Unit II. B. of this Notice lists products according to whether or not they are labeled for use on caneberries.

Claims submitted by owners of products that were eligible for indemnification at the time of the April 15, 1987 Notice but which may be used on caneberries in Washington and/or Oregon will not be processed until after June 15, 1989.

As explained previously, EPA will be contacting all people who submitted information on their dinoseb products, but whose products were ineligible at the time of the April 15, 1987 Notice. If none of the information has changed, the owners will be able to affirm the information in their prior submission and formally submit their claims/requests by returning a signed summary claim sheet and certification form during the first or second time period, depending on whether their products may be used on caneberries.

In addition, EPA has decided to afford owners of products eligible at the time of the April 15, 1987 Notice but who failed to submit a claim and/or request for disposal assistance in response to the April 15, 1987 Notice, a second opportunity to do so now. These people should determine whether their product may be used on caneberries, and thus whether to respond during the first or second period. All claims/requests must be submitted by August 15, 1989. All claims/requests received after August 15, 1989 will be denied. EPA does not plan to provide another opportunity to file or submit claims for indemnification or requests for disposal assistance for dinoseb stocks.

If a claim/request is filed within the prescribed time period, but EPA requests supporting documentation not included with the original claim/request, an appropriate period will be allowed for submission of the additional information required for consideration of the claim/request.

A claim/request may be amended at any time before final action by EPA. All amendments must be submitted in writing and signed by the claimant or his/her authorized agent or legal representative.

Further, in order to expedite the disposal of dinoseb products, EPA requests persons who will be submitting requests for disposal assistance during the time period June 15, 1989 through August 15, 1989, but who have not yet submitted information or a request for disposal assistance to so notify EPA Headquarters disposal staff immediately by telephone (1-800-DIN-OSEB (in Maryland call 1-800-331-3704)).

F. How Will Claims be Processed?

Upon receipt of a claim, EPA will assign it a claim number and all correspondence regarding the claim will reference that number. All claimants will be notified of any additional information or verification required for consideration of the claim. If a claimant is unable to provide the documentation required for consideration of his/her claim within the prescribed time period, the claim will be denied. EPA plans to conduct random audits of claims, including field inspections, and may reject claims if investigators are not permitted to enter the claimant's premises or are otherwise impeded in conducting an audit.

EPA's determinations regarding eligibility of claims and amounts of indemnity payable shall be administratively final.

III. Interim Storage, Transportation And Disposal of Dinoseb Stocks

EPA encourages all registrants and manufacturers that are capable of recalling or reprocessing their dinoseb pesticide products to do so. However, if the product is reprocessed, the amount of indemnity to which that person is entitled may be affected.

EPA has awarded contracts to two waste management firms for the disposal of dinoseb. It is the responsibility of the holders to handle and store the material safely. The conditions required for proper handling of dinoseb pesticides may be governed by FIFRA or the Resource Conservation and Recovery Act (RCRA), as well as by pertinent state and local laws and requirements. The determination of whether FIFRA or RCRA applies depends on the intent of the holder (see 40 CFR 261.2(a)(2)(i) and 261.33, 40 FR 637 (Jan. 24, 1985)). Simply stated, if unused dinoseb pesticide stocks are being held with the intent of legally using, recycling, selling, or distributing them, then they may still be considered pesticide products and should be stored in accordance with FIFRA. However, once the stocks are being held with the clear intent of disposing of them, then they may be considered solid or hazardous wastes and must be stored, transported, and disposed of in accordance with RCRA and any other applicable laws and regulations governing wastes. The procedures for handling, storing, and disposing of dinoseb under FIFRA and RCRA are described in more detail in the following units.

A. Interim Storage

In general, the FIFRA procedures for storage described in 40 CFR 165.10 recommend that the material be stored on pallets or similar raised platforms in a dry, well-ventilated, and separate room, building, or covered area with a concrete floor, where fire protection is provided. Movement or handling should be kept to an absolute minimum.

Containers should be stored with the label plainly visible. Containers should be checked regularly for corrosion and leaks. If a dinoseb container is found to be leaking or damaged, the container should be transferred to a sound, suitable, larger container (preferably a steel salvage drum) and the overpack container should be properly relabeled. Alternately, the contents of the damaged container may be transferred to a new container (i.e., repackaged) and then properly labeled. Before repackaging however, the owner/holder should contact the appropriate EPA regional office to learn of any applicable State or local requirements. Overpacking or repackaging will not generally jeopardize the award of a claimant's indemnity payment, provided that the claimant or holder adequately documents such repackaging and the outside of the package is clearly marked with information to identify the contents. Additional guidance is provided in a short document on overpacking and repackaging dinoseb, available from the pesticide disposal staff at EPA headquarters (1-800-DIN-OSEB (in Maryland call 1-800-331-3704)).

However, if a person is holding unused stocks with the clear intent of disposing of the stocks, he/she must comply with the requirements under

Subtitle C of RCRA as specified in 40 CFR [illegible] 24, 261 through 266, and 270. These requirements may differ from the storage requirements of FIFRA. Additionally, a storage permit may be required (See 40 CFR 270.13 through 270.15).

In general, the dinoseb storage area must be maintained to mitigate the threat or the potential threat of release. In case of an emergency (several leaking containers or a spill), the owner/holder should immediately contact the appropriate EPA regional office listed in Unit II. D. In the event of a release, the released product becomes a waste (unless it is capable of being recycled) which is subject to regulation under Subtitle C of RCRA. In particular, the person storing the dinoseb product that has been spilled must clean up the spill and properly store, treat, or dispose of any resultant materials in accordance with the appropriate hazardous waste rules. Dry, absorbent materials such as absorptive clay, sand, sawdust, vermiculite, oil-dry, kitty litter, dry rags, or paper should be kept on hand for use as appropriate for the emergency cleanup of spills or leaks. Materials that are used for this purpose and become contaminated with dinoseb may themselves be hazardous wastes and must be managed as such. If the holder of the product takes no action after a spill or release, EPA will take appropriate action, including any enforcement action. In addition, the holder of the product may also be subject to liability under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA).

EPA may perform inspections of materials in storage to determine if the above conditions have been met. Further technical advice may be obtained from the EPA regional office contacts listed in Unit II. D of this Notice. In addition, information on the storage provisions under FIFRA are available from the pesticide disposal staff at EPA headquarters at 1-800-DIN-OSEB (in Maryland call 1-800-331-3704), and on the storage requirements under RCRA from the RCRA Hotline at 1-600-424-346 or (202) 382-3000.

B. Disposal

Disposal of certain unused pesticide products may be subject to regulation as hazardous waste under RCRA. Under the existing hazardous waste rules, unused dinoseb product that has become a "waste" is regulated when discarded in commercial grade, technical grade, or off-specification form or if dinoseb is the sole active ingredient in the formulation (hazardous waste designation "P020") (See 40 CFR 261.33(e)). Discarded formulations containing dinoseb as one of a number of active ingredients are presently not considered to be hazardous wastes unless they exhibit a characteristic of hazardous waste. A formulation is considered hazardous if it has one or more of the following characteristics:

1. It is easily combustible.

2. It dissolves metals or other materials, or burns the skin.

3. It shows Extraction Procedure toxicity (contains high concentrations of heavy metals or specific pesticides that could be released into ground water).

4. It is unstable or undergoes rapid or violent chemical reaction with water or other materials. (See 40 CFR 261.20 through 261.24 for additional information about these characteristics).

Persons accumulating or possessing dinoseb in less than the quantities specified in these regulations (1 kilogram or about 2 pounds per month) may be conditionally exempt from RCRA regulation. However, State hazardous waste storage and disposal requirements may still apply.

Under the hazardous waste rules, empty containers with minimal dinoseb residues as defined in 40 CFR 261.7 are exempt from regulation under RCRA. Specifically, containers that once contained dinoseb are considered to be empty if they are triple-rinsed with an appropriate solvent (or cleaned by a method of equivalent effectiveness) or the container's inner liner has been removed (See 40 CFR 261.7(b)(3)). However, the rinsate that is generated from this operation may be considered a hazardous waste under RCRA and must be managed in accordance with the appropriate management standards unless the person conducting the operation is a farmer. Specifically, a farmer disposing of such rinsate from a dinoseb container that was used on his/her own farm is not subject to regulation under RCRA for those wastes provided he/she triple rinses each emptied dinoseb container and disposes of the dinoseb residues on his/her own farm in a manner consistent with the disposal instructions on the product label (See 40 CFR 262.70). Additional information can be obtained from the RCRA Hotline (1-800-424-9346 or (202) 382-3000).

C. Transportation of Dinoseb Stocks

EPA has awarded contracts to two waste management firms for the disposal of dinoseb. It is the responsibility of the holder to handle and store the material safely and transport it to EPA's designated facility when the Agency is ready to receive the stocks. EPA is preparing guidance for dinoseb owners/holders on transportation requirements. Holders should note, however, that proper transportation to EPA's acceptance site is the responsibility of the holder and that transportation costs will be borne by the holder (See 40 CFR 165.5). Information obtained from holders responding to the April 15, 1987 Notice has facilitated much progress on certain technical and procedural issues including the recent award of contracts for disposal. Such early progress should expedite the ultimate disposal of all dinoseb stocks for which EPA will be responsible. Additional information on scheduling shipments and transporting stocks to the EPA-designated acceptance site is forthcoming. Any disposal of dinoseb independent of the federal disposal program must be conducted in accordance with all relevant local, State and Federal requirements. Documentation must be provided by submitting certificates of destruction or other proof of proper disposal to the pesticide disposal staff at EPA headquarters.

Dated: February 13, 1989.

Victor J. Kimm,

Acting Assistant Administrator, Office of Pesticides and Toxic Substances.

[FR Doc. 89-3817 Filed 2-16-89; 8:45 am]

BILLING CODE 6560-50-M

[OPTS-00049D; FRL-3522-2]

Biotechnology; Request for Comment on Regulatory Approach

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is soliciting comments on the direction of its program under the Toxic Substances Control Act (TSCA) to ensure that products of biotechnology are tested, manufactured, processed, and used in a manner that does not present an unreasonable risk of injury to human health and the environment. This notice does not change the Policy which was published in the June 26, 1986 Federal Register (51 FR 23313). EPA has been developing a proposed rule to address matters discussed in that policy statement of the regulations of certain products of biotechnology under TSCA. During this process comments have been received from our own science advisory committees and other Federal agencies. A number of issues have arisen and EPA is requesting comment on several issues. Commenters are requested to review the issues in this notice and provide their comments.

DATES: Written comments should be submitted by May 16, 1989.

ADDRESS: Comments on issues raised in this notice must bear the docket control number OPTS-00049C, and must be submitted to the following address: TSCA Document Processing Center (TS-790), Office of Toxic Substances, Environmental Protection Agency, Room L-100, 401 M Street SW., Washington, DC, 20460.

A docket will be available for public inspection in the TSCA Public Docket Office, Room NE-G004, at EPA Headquarters, 401 M Street SW., Washington, DC, from 8:00 a.m. to 4 p.m., Monday through Friday, except legal holidays. The docket includes all documents relevant to the issues raised in this Notice and will contain all public comments that are received. These documents containing confidential business information will be placed in a separate, confidential file.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Room EB-44, 401 M Street SW., Washington, DC, 20460. In the USA: (202) 554-1404. TDD: (202) 554-1551.

SUPPLEMENTARY INFORMATION:

I. Background

On December 31, 1984, the White House Office of Science and Technology Policy issued in the **Federal Register** a "Proposal for a Coordinated Framework for Regulation of Biotechnology" (49 FR 50880, December 31, 1984). In that proposal, EPA stated that the definition of "chemical substance" under section 3(2) of TSCA includes all microorganisms except those excluded from TSCA jurisdiction (i.e., those microorganisms manufactured, processed or distributed in commerce for use as pesticides, foods, food additives, drugs, cosmetics, or other related items are excluded).

After reviewing comments on the 1984 Proposal, EPA issued in 1986, as part of the "Coordinated Framework for Regulation of Biotechnology" (51 FR 23313, June 26, 1986), a "Statement of Policy" describing how EPA was addressing certain microbial products of biotechnology under TSCA. In the 1986 Policy, EPA interpreted the new chemical substance premanufacture notification (PMN) provisions of TSCA section 5 to cover new (inter-generic) microorganisms used for commercial purposes. This interpretation became effective immediately. EPA also requested voluntary submission of other information until final rules were in place, and described its intentions to develop, under TSCA, a significant new use rule for pathogenic microorganisms; a rule modifying the PMN research and development exemption so that small scale field testing of microorganisms for TSCA purposes is subject to PMN; a section 8(a) reporting rule for other microorganisms prior to release in the environment; and section 5(h)(4) exemptions as appropriate.

In developing a regulatory framework to implement the 1986 policy statement, EPA received advice and a "concept paper" from other federal agencies, as well as unsolicited suggestions from some nongovernmental organizations. EPA discussed proposals with the interagency biotechnology Science Coordinating Committee (BSCC) and received its comments. On December 21, 1988, EPA convened a public meeting of the Subcommittee on the Proposed Biotechnology Rule under TSCA of the EPA Biotechnology Science Advisory Committee (BSAC), EPA's independent science advisory group. A draft proposed rule was provided to the Subcommittee. This group was asked to examine scientific issues associated with EPA's approach, as well as the utility of using groups of independent experts to determine whether research and development (R&D) proposals should be exempt from the premanufacture notification requirements of section 5 of TSCA. Several members of the public requested and received permission to address the Subcommittee. Included among the commenters was the Chairperson of the BSCC who described inter-agency discussions over the proposed TSCA rulemaking.

A number of basic issues have arisen during the course of the development of a proposed rule which EPA has concluded need to be addressed before a specific rule is developed and proposed.

These include:

1. What should be the scope of the microorganisms subject to EPA's review?

2. What should be the scope of EPA's review of R&D activities involving release of microorganisms to the environment?

3. Since TSCA only allows EPA to review those microorganisms developed for "commercial purposes", how broadly or narrowly should EPA define "commercial purposes" in the context of research conducted at educational and reseerch facilities?

4. If the definitions of "release to the environment" and "contained facility" are to be used to determine whether there is EPA review of specific uses of microorganisms, how should these terms be defined? To what extent should EPA rely on the definition of "contained facility" found in the guidelines of the National Institutes of Health (NIH)?

5. To what extent should EPA establish independent expert review groups (i.e., Environmental Biosafety Committees (EBCs)), similar to the NIH Institutional Biosafety Committees (IBCs), to assist in the review of potential environmental releases of microorganisms? What should be the scope of review by those groups?

To aid EPA in addressing these issues, this notice requests comment on them from all interested persons. For commenters who wish additional information concerning the background for these issues, materials in the public docket are available on request from the address in FOR FURTHER INFORMATION CONTACT. These include: letters from other Federal agencies commenting on the draft approach, the recommendations of the BSAC Subcommittee on the Proposed Biotechnology Rule under TSCA following their December 21, 1988 meeting, the draft proposed rule they discussed at that meeting, and the comments of the members of the public and the BSCC chairperson at the BSAC

Subcommittee meeting. All other information in the docket is available in the TSCA public docket Office at the address in **ADDRESSES.**

Elsewhere in this **Federal Register** a similar notice appears soliciting comments on a proposed regulatory approach for the products of biotechnology under the Federal Insecticide, Fungicide, and Rodenticide Act.

Dated: February 3, 1989.

John A. Moore,

Acting Administrator.

[FR Doc. 89-3620 Filed 2-14-89; 8:45 am]

BILLING CODE 6560-50-M

ENVIRONMENTAL PROTECTION AGENCY

[OPP-50668; FRL-3522-3]

Microbial Pesticides; Request for Comment on Regulatory Approach

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is soliciting comments on issues that have arisen in the development of an amendment to its Experimental Use Permit (EUP) regulations under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The amendment would require notification before initiation of small-scale testing of certain genetically modified microbial pesticides. Each notification will be reviewed by EPA and a determination made as to whether an EUP will be required. This notification scheme is intended to provide sufficient oversight of the early testing of these microbial pesticides to mitigate any adverse human health or environmental effects. During the development of a draft proposed regulation, comments have been received from EPA science advisory committees and other Federal agencies. Comments are now being solicited from all interested persons on issues arising during the course of development of the proposed regulation.

DATE: Comments identified by the docket control number [OPP-50668] must be received on or before May 16, 1989.

ADDRESS:

Written comments by mail to: Public Information Branch, Field Operations Division (TS-787C), Environmental Protection Agency, 401 M Street SW., Washington, DC 20460

In person, bring comments to: Room 246, CM #2, 1921 Jefferson Davis Highway Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: Frederick Betz, Science Integration and Policy Staff, Environmental Fate and Effects Division (TS-769C), Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. (703-557-9307).

A public docket has been established and will be available for public inspection at the Virginia address given above from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays. Comments received in response to this Notice, except those containing confidential business information, will be included in the public docket.

SUPPLEMENTARY INFORMATION:

I. Introduction

Section 5 of FIFRA, 7 U.S.C. 136 *et seq.*, and 40 CFR 172.2 provide for issuance by EPA of EUPs for the testing of new pesticides or new uses of existing pesticides. Such permits are generally issued for large-scale testing of pesticides involving terrestrial application to more than ten acres of aquatic application to more than one acre. It has been generally presumed that smaller experiments would not require EUPs. However, EPA recognizes that small-scale studies with some microbial pesticides that have been genetically modified may raise many of the same concerns as more extensive uses of conventional pesticides. Accordingly, EPA is in the process of modifying its existing regulatory program to address these concerns.

II. Background

Based on the conclusion that there is a need to evaluate small-scale tests of certain microbial pesticides prior to their release in the environment, EPA issued its "Interim Policy on Small-Scale Field Testing of Genetically Altered and Nonindigenous Microbial Pesticides" (49 FR 40659, October 17, 1984). This policy stated that the 40 CFR Part 172 presumption would not automatically apply for certain microbial pesticide products and that EPA should be notified before initiation of any such small-scale testing in order to determine whether an EUP would be required. The Interim Policy was subsequently republished for review and comment in December 1984 in conjunction with the "Proposal for a Coordinated Framework for Regulation of Biotechnology" (49 FR 50880, December 31, 1984) issued by the Office of Science and Technology Policy.

After reviewing the public comments on the 1984 Proposal, in June 1986, EPA published a final policy statement entitled "Applicability of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to Microbial Products" as part of the Office of Science and Technology Policy's Coordinated Framework for Regulation of Biotechnology (51 FR 23313, June 26, 1986). The 1986 Policy stated EPA's concern about the potential risks associated with small-scale testing of certain microbial pesticides. To address these potential risks, the Policy specified that EPA be notified prior to initiation of small-scale testing of all nonindigenous and genetically modified microbial pesticides. The notification allows EPA to make a determination as to whether the test should be carried out under an EUP. In addition, the 1986 Policy set forth EPA's plan for future rulemaking to codify the interpretation set out in the Policy Statement.

EPA received public comment on the 1986 Policy and began to revise the existing Part 172 EUP rule to incorporate the major elements of the Policy. In the summer of 1988, the Agency provided a draft of the proposed rule to Congress, the U.S. Department of Agriculture (USDA) and the U.S. Food and Drug Administration. In November 1988, a revised draft was reviewed and commented on at a public meeting of a Subpanel of the FIFRA Scientific Advisory Panel (SAP Subpanel). The SAP Subpanel and Federal agencies provided written comments.

A number of issues have arisen during the course of the development of this regulation which EPA has concluded need to be addressed before a rule is proposed, including: (1) Scope of genetically modified microbial pesticides subject to notification; (2) Review of nonindigenous microbial pesticides at small-scale; (3) Establishment of independent expert review groups (Environmental Biosafety Committees) patterned after the National Institutes of Health's Institutional Biosafety Committees. To aid EPA in addressing these issues, this Notice requests comment on them from all interested parties to help facilitate development of the rule.

For commenters who wish additional information concerning the background for these issues, materials in the public docket are available on the request, including the recommendations of the SAP Subpanel following their November 22, 1988 meeting, the draft regulation discussed at that meeting, comments received from the public and other Federal agencies on the draft proposed regulation, the transcript from the EPA Biotechnology Scientific Advisory Committee's January 12, 1989 meeting where a recommendation regarding the FIFRA proposal was adopted, and EPA's most recent draft which includes responses to the SAP Subpanel recommendations and many of the comments received to date.

Elsewhere in this Federal Register, a notice appears soliciting comments on regulatory approaches being considered for products of biotechnology under the Toxic Substances Control Act.

Dated: February 3, 1989.

John A. Moore,

Acting Administrator.

[FR Doc. 89-3619 Filed 2-14-89; 8:45 am]

BILLING CODE 6560-50-M

Commodities	Parts per million
• • • • •	
Cabbage	1.0
• • • • •	

[FR Doc. 89-3192 Filed 2-14-89; 8:45 am]
BILLING CODE 6560-50-M

40 CFR PART 180

[PP 7E3464/R1005; FRL-3518-7]

Pesticide Tolerance for Prometryn

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes a tolerance for residues of the herbicide prometryn in or on the raw agricultural commodity dill. The Interregional Research Project No. 4 (IR-4) petitioned for this tolerance.

EFFECTIVE DATE: February 15, 1989.

ADDRESS: Written objections, identified by the document control number, [PP 7E3464/R1005], may be submitted to: Hearing Clerk (A-110), Environmental Protection Agency, Rm. 3708, 401 M Street SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: By mail:

Hoyt Jamerson, Emergency Response and Minor Use Section (TS-767C), Registration Division (TS-767C), Environmental Protection Agency, 401 M Street SW., Washington, DC 20460.

Office location and telephone number: Rm. 716, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703)-557-2310.

SUPPLEMENTARY INFORMATION: EPA issued a proposed rule, published in the Federal Register of December 12, 1988 (53 FR 50262), in which it was announced that the Interregional Research Project No. 4 (IR-4), New Jersey Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, NJ 08903, had submitted pesticide petition 7E3464 to EPA on behalf of Dr. Robert H. Kupelian, National Director, IR-4 Project, and the Agricultural Experiment Station of California.

The petition requested that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act, propose the establishment of a tolerance for the residues of the herbicide prometryn (2,4-bis(isopropylamino)-6-methylthio-*s*-triazine) in or on the raw agricultural commodity dill at 0.25 part per million (ppm). The petition was later amended to propose a tolerance of 0.3 ppm.

The petitioner proposed that this use of prometryn on dill be limited to use in California base on the geographical representation of the residue data submitted. Additional residue data will be required to expand the area of usage. Persons seeking geographically broader registration should contact the Agency's Registration Division at the address provided above.

There were no comments or requests for referral to an advisory committee received in response to the proposed rule.

The data submitted in the petition and all other relevant material have been evaluated and discussed in the proposed rule. Based on the data and information considered, the Agency concludes that the tolerance will protect the public health. Therefore, the tolerance is established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the Federal Register, file written objections with the Hearing Clerk, at the address given above. Such objections should specify the provisions of the regulation deemed objectionable and the grounds for the objections. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 27, 1989.

Douglas D. Campt,

Director, Office of Pesticide Programs.

Therefore, 40 CFR Part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for Part 180 continues to read as follows:

Authority: 21 U.S.C. 346a.

2. Section 180.222 is amended by designating the current paragraph and list of tolerances as paragraph (a) and by adding new paragraph (b), to read as follows:

§ 180.222 Prometryn; tolerances for residues.

• • • • •

(b) Tolerances with regional registration, as defined in § 180.1(n), are established for residues of the herbicide prometryn (2,4-bis(isopropylamino-6-methylthio-*s*-triazine) in or on the following raw agricultural commodity:

Commodity	Parts per million
Dill	0.3

[FR Doc. 89-3193 Filed 2-14-89; 8:45 am]
BILLING CODE 6560-50-M

40 CFR Part 704

[OPTS-82013D; FRL-3520-5]

Comprehensive Assessment Information Rule; Extension of Notification and Reporting Deadlines

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; extension of notification and reporting deadlines.

SUMMARY: EPA has received two requests for a 60-day extension of either the effective date of the Comprehensive Assessment Information Rule (CAIR), or, in the alternative, an extension of all notification and reporting deadlines for the CAIR. EPA has evaluated these requests, and has decided to grant a 30-day extension for all CAIR notification and reporting deadlines for the 19 substances to the CAIR.

DATES: The notification and reporting deadlines are extended to the following dates:

1. Submission of a CAIR reporting form by manufacturers, importers, and processors under § 704.223(a) is extended to June 7, 1989.

2. Submission of a CAIR reporting form by persons who process a CAIR listed substance under a tradename under § 704.223(b) is extended to July 6, 1989.

3. Notification of customers who process a CAIR listed substance under a tradename under § 704.208(a)(3) is extended to April 7, 1989.

4. Submission to EPA of a list of tradenames under which a person

distributes a CAIR listed substance under § 704.208(a)(1) is extended to March [illegible], 1989.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. EB-44, 401 M Street SW., Washington, DC 20460, Telephone: (202) 554-1404, TDD (202) 554-0551.

SUPPLEMENTARY INFORMATION: EPA issued the CAIR (40 CFR Part 704) in the Federal Register of December 22, 1988 (53 FR 51380), under section 8(a) of the Toxic Substances Control Act (TSCA). EPA received two requests for a 60-day extension of either the effective date of the CAIR, or, in the alternative, an extension of all notification and reporting deadlines for the CAIR. These requests were received from the National Paint and Coatings Association (NPCA) and The Society of the Plastics Industry (SPI). EPA has evaluated these requests, and has decided to grant a 30-day extension for all CAIR notification and reporting deadlines for the 19 substances subject to the CAIR to the above dates.

EPA realizes that the extension granted for the submission of [illegible]es under which a person distributes a CAIR listed substance under § 704.208(a)(1) is extended to a date that is more than 30 days after the original notification deadline of February 7, 1989. This was necessary because the extension requests submitted by NPCA and SPI were granted on February 7, 1989, and the publication of the Federal Register document announcing these extensions was not possible until after February 7. Therefore, EPA extended this deadline to 30 days after EPA's expected publication date of this Federal Register document. Note that the new notification deadline will be March 20, 1989, even if this date is more than 30 days after the publication date of this Federal Register document.

Individual companies may request a reasonable extension beyond these new deadlines on a substance-by-substance basis through the mechanisms set forth in the CAIR. Failure to comply with the new extension deadlines, or any further extension deadlines granted by EPA to individual companies, will constitute a violation of TSCA section 15(3), and may subject the violator to the penalties described in TSCA section 16.

List of Subjects in 40 CFR Part 704

[illegible]icals, Environmental protection, Hazardous materials, Reporting and recordkeeping requirements.

Dated: February 8, 1989.

Joseph J. Merenda,

Director, Existing Chemical Assessment Division, Office of Toxic Substances.

[FR Doc. 89-3530 Filed 2-14-89; 8:45 am]

BILLING CODE 6560-50-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Public Land Order 6708

[OR-943-09-4214-10; GP9-064; OR-19673(WASH), OR-19854(WASH)]

Partial Revocation of Powersite Classifications No. 349 and No. 400; Washington

AGENCY: Bureau of Land Management, Interior.

ACTION: Public Land Order.

SUMMARY: This order revokes one Secretarial order and one U.S. Geological Survey order insofar as they affect 153.40 acres of lands withdrawn for Bureau of Land Management's powersite purposes. This action will remove restrictions or open the lands to surface entry on 145 acres. Of the balance which is within Power Project No. 2145, 3.40 acres remain open subject to section 24 of the Federal Power Act and 5 acres remain closed to surface entry and mining. All the lands have been and will remain open to mineral leasing.

EFFECTIVE DATE: March 10, 1989.

FOR FURTHER INFORMATION CONTACT: Champ Vaughan, BLM Oregon State Office, P.O. Box 2965, Portland, Oregon 97208, 503-231-6905.

By virtue of the authority vested in the Secretary of the Interior it is ordered as follows:

1. The Secretarial Order dated June 22, 1944, which established Powersite Classification No. 349, is hereby revoked insofar as it affects the following described lands:

Willamette Meridian

T. 23 N., R. 23 E.;
Sec. 26, lots 7 and 8, and NW¼SE¼.

The areas described aggregate 113.40 acres in Chelan and Douglas Counties.

2. The U.S. Geological Survey Order dated February 15, 1949, which established Powersite Classification No. 400, is hereby revoked insofar as it affects the following described land:

Willamette Meridian

T. 23 N., R. 23 E.;
Sec. 26, SW¼NE¼.

The area described contains 40 acres in Douglas County.

3. The State of Washington has waived its preference right for public highway rights-of-way or material sites as provided by the Federal Power Act of June 10, 1920, as amended, 16 U.S.C. 818.

4. That portion of lot 7 inside the boundary of Power Project No. 2145 remains closed to operation of the public land laws, including the mining laws.

5. That portion of lot 8 inside the boundary of Power Project No. 2145 has been and continues to be open to operation of the public land laws, including the mining laws, subject to the provisions of section 24 of the Federal Power Act of June 10, 1920.

6. That portion of Lot 8 outside the boundary of Power Project No. 2145 has been open to operation of the public land laws, including the mining laws, subject to the provisions of section 24 of the Federal Power Act of June 10, 1920, and will be relieved of the section 24 restriction at 8:30 a.m., on March 10, 1989.

7. At 8:30 a.m., on March 10, 1989, the land described in paragraphs 1 and 2, except as provided in paragraphs 4, 5, and 6, will be open to operation of the public land laws generally, subject to valid existing rights, the provisions of existing withdrawals and reservations, and to requirements of applicable law. All valid applications received at or prior to 8:30 a.m., on March 10, 1989, shall be considered as simultaneously filed at that time. The land has been and continues to be open to the mining and mineral leasing laws.

Rick Ventura,

Assistant Secretary of the Interior.

February 3, 1989.

[FR Doc. 89-3489 Filed 2-24-89; 8:45 am]

BILLING CODE 4310-33-M

43 CFR Public Land Order 6709

[AK-932-09-4214-10; F-025943]

Modification of Public Land Order No. 3708; Transfer of Administrative Jurisdiction From the National Aeronautics and Space Administration to the National Oceanic and Atmospheric Administration; Alaska

AGENCY: Bureau of Land Management, Interior.

ACTION: Public Land Order.

SUMMARY: This order modifies Public Land Order No. 3708 to transfer jurisdiction of 8,500 acres of land withdrawn for a tracking station near Fairbanks, Alaska, from the National Aeronautics and Space Administration to the National Oceanic and

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

APR 9 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Amendment to the Compliance Strategy for the Emergency Suspension of Dinoseb

FROM: A. E. Conroy II, Director
Office of Compliance Monitoring

TO: Addressees

On March 30, 1987, the Administrator of the Environmental Protection Agency (EPA) signed a decision to modify his October 7, 1986 Emergency Suspension Order of pesticide products containing dinoseb. Pursuant to this decision, on April 1, 1987, the Agency issued a FIFRA Section 18 Emergency Exemption which granted a specific exemption to the States of Washington and Idaho for the use of dinoseb to control broadleaf weeds in dry peas, chickpeas and lentils.

Attached is an amendment to the October 7, 1986 Compliance Strategy for the Emergency Suspension of Dinoseb, pursuant to the April 1, 1987 Agency actions. Please transmit a copy of this document to the States. Please note that because of the nature of this action, this amendment is immediately effective. If you have any questions or comments regarding this amended strategy, please contact Dan Helfgott of my staff at FTS 382-7825 (EN-342).

Attachment

ADDRESSEES

Douglas D. Campt (TS-766C)
Frederick F. Stiehl (LE-134A)
Stanley Abramson (LE-132A)
Ken Shiroishi "
Phyllis Flaherty "
John Martin "
John J. Neylan III "
Ralph Turpin "
Jerry Stubbs "
Mike Wood "
Dexter Goldman "

Jake Mackenzie
Western Regional Compliance Director

A. Charles Lincoln
Eastern Regional Compliance Director

I	Louis F. Gitto, Director Air Management Division	Gerald M. Levy, Chief Office of Pesticides & Toxic Sub.
II	Barbara Metzger, Director Environmental Services Div.	Ernest Regna, Chief Pesticides & Toxics Sub. Branch
III	Stephen R. Wassersug, Director Hazardous Waste Management Div.	Larry Miller, Chief Toxic & Pesticides Branch
IV	Winston A. Smith, Director Air, Pest. & Toxic Mgmt Div.	H. Kirk Lucius, Chief Pesticides & Toxic Subs. Branch
V	William H. Sanders III, Director Environmental Services Div.	Phyllis Reed, Chief Pesticides & Toxic Subs. Branch
VI	William B. Hathaway, Director Air, Pesticides & Toxics Div.	Norman E. Dyer, Chief Pesticides & Toxics Subs. Branch
VII	William A. Spratlin, Director Air & Toxics Division	Leo Alderman, Chief Toxics & Pesticides Branch
VIII	Irwin L. Dickstein, Director Air & Toxic Subs. Division	Alvin Yorke, Chief Toxic Substances Branch
IX	Jeffrey Zelikson, Acting Director Toxics & Waste Management Div.	Richard Vaille, Chief Pesticides & Toxics Branch
X	Gary O'Neal, Director Air & Toxic Division	Anita Frankel, Chief Pesticides & Toxic Subs. Branch

cc: Jim Lamb (TS-788)

APR 2 1987

AMENDMENT TO THE COMPLIANCE STRATEGY FOR THE EMERGENCY SUSPENSION OF DINOSEB

OVERVIEW

On March 30, 1987, the Administrator of the Environmental Protection Agency (EPA) signed the Decision and Final Order Modifying Final Suspension of Pesticide Products Which Contain Dinoseb. In this document, the Administrator modified his October 7, 1986 Emergency Suspension Order of Dinoseb to allow emergency exemptions to be granted under FIFRA Section 18 to the States of Washington and Idaho during 1987. Pursuant to the Administrator's decision, the Agency issued the FIFRA Section 18 Emergency Exemption on April 1, 1987, which granted a specific exemption to the Washington and Idaho Departments of Agriculture for the use of dinoseb to control broadleaf weeds in dry peas, chickpeas and lentils.

Under the Section 18 Notice, the Washington and Idaho Departments of Agriculture are responsible for ensuring that all the provisions of the Emergency Exemption are met within their States. These States are responsible for conducting inspections at the dealer and user levels to assure compliance with the terms and conditions of the April 1, 1987 Emergency Exemption. Regions will monitor compliance with the amended federal SSURO in accordance with the Pesticides Inspection Manual.

REQUIREMENTS

The April 1, 1987 FIFRA Section 18 Emergency Exemption permits dinoseb pesticide products which were federally registered for use on peas, chickpeas or lentils prior to October 7, 1986, to be shipped, sold and used (this includes dinoseb products which were cancelled as a result of the October 7, 1986 Notice of Intent to Cancel). Shipment is allowed under the previously federally-registered product label, and under the terms and conditions specified in the Section 18 Emergency Exemption and the Amendment to the SSURO (see attached). Sale and use is allowed only under the terms of the Section 18 Exemption.

COMPLIANCE MONITORING

The Agency will modify, upon request by the registrant, the October 7, 1986 Stop Sale, Use or Removal Order (SSURO) to permit registrants to distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, receive and (having so received) deliver or offer to deliver, remove, or use pesticide products containing dinoseb pursuant to the terms and conditions of the April 1, 1987 FIFRA Section 18 Emergency Exemption for dinoseb pesticide products. Registrants who have not requested and been granted an amended federal SSURO may not sell or distribute their dinoseb products.

Registrants are required to submit to EPA Regional representatives listed in the amended SSURO the following information within five working days of transporting affected dinoseb products: 1) the product name and registration number of transported product(s); 2) the date, name and location from where the product(s) were transported as well as the name and location of state-licensed dealer(s) in Washington or Idaho to whom the product(s) were shipped; and 3) the quantity of product(s), by registration number, being transported. The EPA Regional representative will transmit this information to Region X within five working days. Region X will further transmit this same information to the States of Washington and Idaho, within five working days, for use by the States in targetting inspections. The Regions will report monthly to the Office of Compliance Monitoring (OCM) on the location and quantities of dinoseb stocks transported to and from their Regions until August 31, 1987. OCM will compile a summary of dinoseb movement between Regions and transmit monthly reports to the Regions.

EPA Region X and the States of Washington and Idaho are directed to amend any SSUROs issued at the dealer and user levels to permit sale and use of pesticide products containing dinoseb pursuant to the terms and conditions specified in the April 1, 1987 FIFRA Section 18 Emergency Exemption.

Under the Section 18 Exemption, the Washington and Idaho Departments of Agriculture are responsible for ensuring that all the provisions of the Emergency Exemption are met within their States. These States are responsible for conducting inspections at the dealer and user levels to assure compliance with the terms of the April 1, 1987 Exemption. The specific number of inspections will be negotiated by EPA Region X with the States of Idaho and Washington. Regions will monitor compliance with the amended federal SSUROs according to the Pesticide Inspection Manual.

Any distribution or use of pesticide products containing dinoseb not in accordance with the FIFRA Section 18 Exemption is considered a violation of the FIFRA Section 6 Suspension/ Cancellation Order, as modified by the Administrator on March 30, 1987.

Accession 254786

EPA1451
B. Prendergast

EPA9401
Jon Heller

WA/DOA
EPX5675
ATTN: Mr. C. Alan Pettibone, Director

/ZIP
Regional Director HFR-01
Food and Drug Administration
909 1st Avenue Room 5009
Seattle WA 98174,
/ZIP
Branch Chief HFF-314
FDA/CFSAN
200 C Street S.W.
Washington DC 20204,
/ZIP
John A. Beare M.D.
Health Services Division
Mail Stop LJ-18
Olympia WA 98504+

Washington Department of Agriculture

Attention: Mr. C. Alan Pettibone - Director

The Environmental Protection Agency hereby grants a specific exemption, in accordance with the Administrator's Decision and Final Order Modifying Final Suspension of Pesticides which Contain Dinoseb and section 18 of the Federal Insecticide, Fungicide and Rodenticide Act, as amended, to the Washington Department of Agriculture for use of dinoseb to control broadleaf weeds in dry peas, chickpeas and lentils. The Washington Department of Agriculture is responsible for ensuring that all provisions of this specific exemption are met. It is also responsible for providing information in accordance with 40 CFR 166.32. This specific exemption is subject to the following conditions, restrictions, and warnings:

FORMULATION

1. This specific exemption authorizes the use of any 3 lb. a.i. per gallon formulation of dinoseb which was federally-registered for use on peas, chickpeas, or lentils prior to October 7, 1986, subject to the terms and conditions set forth below.

2. Only that product which was formulated prior to October 7, 1986, is permitted to be shipped and used under this exemption. Shipment is allowed under previously federally-registered product labeling.

LABELING TO USED UNDER THE SPECIFIC EXEMPTION

The provisions of this specific exemption constitute supplemental labeling to the labels of previously registered dinoseb products which are authorized for use under this exemption. Therefore, the state must ensure that this supplemental labeling accompanies the dinoseb product at the time of sale. The state must also ensure that growers with dinoseb supplies already in their possession be supplied a copy of this supplemental labeling prior to use. All appropriate precautions and restrictions of the registered product labels must be observed. The following precautions and restrictions take precedence over those contained on the registered labeling.

1. Due to developmental toxic effects in laboratory animals, resulting from exposure to dinoseb, the following precautions will be observed:

Women of childbearing age may not use the product; all reasonable efforts should be made to minimize indirect exposures to women of child-bearing age; the product also poses risks to male reproduction; is acutely toxic and the product may be applied only by certified applicators.

2. All use must be made by certified applicators; other persons, even if they are operating under the direct supervision of a certified applicator, may not use dinoseb.

3. Women of childbearing age, i.e., under the age of 45, may not be involved in mixing, loading, or any aspect of dinoseb application.

4. Mixing and loading of dinoseb must be carried out in a closed system.

5. Mixer/loaders and applicators must wear chemical resistant disposable coveralls (Tyvek® suits) and chemically resistant gloves when mixing or loading dinoseb. Applicators or other personnel must remove such protective clothing immediately before entering the tractor cab to avoid cab contamination, but must carry an unused set of gloves and coveralls in their cabs, to be used in the event of spraying equipment malfunction and repair during application.

6. Aerial application is prohibited.

7. Ground application is prohibited except by the "barrel sucker"/ground boom/tractor system. Ground application is restricted to a closed-cab tractor with a positive pressure ventilation system.

8. Ground application is prohibited when wind conditions exceed ten miles per hour.

9. Application is limited to a maximum of 80 acres treatment per day per certified applicator.

10. One preemergent or early post emergent application of dinoseb at a maximum application rate of 1.5 lb. a.i. per acre on lentils and 3.0 lb. a.i. per acre on dry peas or chickpeas is authorized.

11. EPA recommends that growers should make every reasonable effort to return unused dinoseb product to the manufacturer, distributor, or other agents capable of relabeling, recovering, recycling, or reprocessing the pesticide. Product which is not returned should be stored in accordance with recommended procedures described in 40 CFR 165.10. In short, these procedures for storage recommend that the material be stored on pallets or similar raised platforms in a dry, well-ventilated, and separate room, building or covered area with a concrete floor, where fire protection is provided.

SPECIFIC EXEMPTION REQUIREMENTS

1. Dinoseb may only be sold to growers of dry peas, lentils and/or chickpeas in the state of Washington.

2. Growers may purchase in a quantity not to exceed that required to treat his dry pea, chickpea, and/or lentil acreage at the maximum application rates specified in this authorization. All stocks of dinoseb already in a grower's possession must be taken into account when determining this quantity.

3. Only state-licensed dealers are authorized to sell or ditribute dinoseb under this specific exemption.

4. Dealers authorized to sell or distribute dinoseb under this specific exemption must obtain and report the following information from growers prior to sale or distribution:

a) grower's name, address, and grower's license number,
b) number of acres and type(s) of pulse crop to be treated,
c) the product name(s) and registration number(s),
d) the quantity of dinoseb sold or distributed,
e quantity of dinoseb previously in grower's possession, and
f) the name, address and certification number of the certified applicator to apply dinoseb.

This information will be forwarded by the dealer to the Washington Department of Agriculture and the EPA Region X Office within five days of sale or distribution.

5. Certified applicators applying dinoseb under this specific exemption will record and report the following information:

a) name, address and certification number,
b) name and address of dry pea, lentil and/or chickpea grower,
c) date of application,
d) type of pulse crop and number of acres treated,
e) number of gallons applied,
f) registration number(s) of product(s) applied, and
g) sex of certified applicator (if female, specify age).

This information will be forwarded to the certified applicator within five days of use to the Washington Department of Agriculture and the EPA Region X Office.

6. The Washington Department of Agriculture will conduct a monitoring program of use of dinoseb under the specific exemption to insure compliance with the conditions and restrictions set forth in this exemption. The specifics concerning this monitoring are to determined by the Washington Department of Agriculture and EPA Region X.

7. A final report summarizing the results of this exemption must be submitted by January 15, 1988. If use of dinoseb is required again for the 1988 growing season, an interim report containing all information available at time of filing, must be submitted with the new specific exemption request.

8. The Washington Department of Agriculture will immediately report any adverse effects resulting from the use of dinoseb under this specific exemption to the EPA, Office of Pesticide Programs.

9. This specific exemption expires on July 15, 1987.

The Agency will not consider any emergency exemption application for the 1988 use season unless the Idaho or Washington Department of Agriculture, the American Frozen Food Institute, or the American Dry Pea and Lentil Association conduct or sponsor adequate tests on alternative pesticides during the 1987 season. EPA's consideration of any emergency exemption application for the 1988 use season will be influenced by evidence of the extent to which there is good faith compliance with the conditions and restrictions herein.

Douglas D. Campt, Director
Office of Pesticide Programs

Date APR 1

SSS

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

AMENDMENT
TO THE SSURO OF OCTOBER 7, 1986

APR 1 1987

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

FILE COPY

Cedar Chemical
Suite 2414 Clark Tower
5100 Poplar Ave.
Memphis, TN 38137

Reference: DINOSEB

By the authority vested in me pursuant to Section 13(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. §136k(a)), you are hereby ordered not to distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, receive and (having so received) deliver or offer to deliver, remove, or use the pesticide(s) listed above, or any other pesticides under your control, ownership, or custody that were suspended by the Administrator's Emergency Suspension Order of October 7, 1986.

This order pertains to all quantities of the above-mentioned pesticide(s) within the control, ownership, or custody of your company, wherever located. The pesticide(s) may not be sold, offered for sale, held for sale, shipped, delivered for shipment, received and (having so received) delivered or offered for delivery, removed or used other than in accordance with the provisions of this order or of further Stop Sale, Use, of Removal Orders as may be issued in connection with the pesticide(s).

Notwithstanding the provisions of this Stop Sale, Use, or Removal Order, you may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, receive and (having so received) deliver or offer to deliver, remove, or use the pesticide(s) affected by this order which are under your control, ownership, or custody provided it is for purposes of consolidation in one or more locations, e. g., implementing a product recall and/or it meets all the requirements of the enclosed Section 18 Emergency Exemption Order and that it is being shipped to a licensed, authorized dealer in the States of Washington or Idaho.

In addition, the following information must be reported in writing to the EPA representative listed below within five working days of transporting this material: 1) the product name and registration number of the transported products(s); 2) the date, name and location from where the product(s) were transported as well as the name and location of distributors in Washington or Idaho to whom the product(s) were shipped; and 3) the quantity of product(s) by registration number being transported.

Mr. Kirk Lucius, Chief
Pesticides and Toxic
Substances Branch
EPA Region IV
345 Courtland Street, NE
Atlanta, GA 30365
404-257-3621

Any person violating the terms or provisions of this order shall be subject to the civil or criminal penalties prescribed in Section 14 of the Act (7 U.S.C.§136l).

Ralph M. Turpin, Acting Director
Compliance Division (EN-342)

Enclosure

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

APR 17 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Dinoseb

FROM: for A. E. Conroy II, Director
Office of Compliance Monitoring

TO: Regional Division Directors

On April 16, 1987, District Court Judge Redden of the District of Oregon granted a preliminary injuction which stayed the dinoseb Suspension Order, in the States of Idaho, Oregon, and Washington, pending EPA's final decision with respect to the cancellation of dinoseb. Further, Judge Redden's order permits the use of dinoseb on green peas, snap beans, cucurbits (cucumbers, squash and zucchini) and caneberry crops in these States.

The above uses are only permitted under certain restrictions set out in the Judge's order, provided that the aforementioned States will agree to enforce these restrictions. The Court Order has been magnafaxed to you separately.

While the Court's decision is not abundantly clear, it is OCM's opinion that the scope of the decision is limited to the States of Idaho, Oregon and Washington only. Therefore, the following guidance should apply to enforcing the October 14, 1986 dinoseb suspension order:

1) The Section 18 Emergency Exemption is not affected by the Court's decision.

2) The Court Order applies only to the States of Idaho, Oregon and Washington, and permits the use of dinoseb only on the crops listed above. In these three States, the Court Order shall take precedence over the Agency's suspension order, and the Agency's Stop Sale Orders (SSURO) should not be enforced in those States.

3) Any sale, distribution and use of dinoseb, in the three States, not in accordance with the restrictions found in the Court Order or the Section 18 Emergency Exemption is a violation of the suspension order.

4) The Suspension Order is still in effect outside of the three States.

5) OCM has amended five SSURO's, previously issued to registrants with stocks of dinoseb, solely for permitting these five registrants to ship dinoseb to Washington and Idaho for use under the Section 18 Emergency Exemption. No product can be shipped lawfully unless the product is registered for use on peas, lentils or chickpeas, and labelled accordingly. The recent section 18 Emergency Exemption extended allowable uses to Oregon and the five SSURO's are hereby amended to include this State.

6) No other shipments of dinoseb (other than from the five registrants that received amended SSURO's) to the three States from outside of the three States are lawful. Shipments of dinoseb by anyone other than the five registrants would be in violation of the Suspension Order (Section 12(a)(2)(J).

7) We have contacted the States of Oregon, Washington, and Idaho concerning this matter. If additional stocks of dinoseb are needed in these States for uses covered by the Court Order, EPA will expedite vacation of SSURO's using the following procedure:

   - o Registrants must contact the appropriate state department of agriculture and obtain agreement that the product may be shipped into the subject state for an allowable use. Registrants should obtain an agreement from the state regarding the quantity of dinoseb product that may be shipped into the state.

   - o Contact EPA [telephone 1) Charles Auer at 202-382-3807; Dr. Jake Mackenzie at 415-974-7279; or call 202-382-3807 and request dinoseb coordinator] with the following information:

     - State contact and amount approved for shipment.

- Registration number of product(s) and labeled uses.

- name and location of where product(s) are shipped from and name and location of person receiving the product(s)

- Date of shipment or proposed shipment and quantities of product in each shipment.

- Name, title, address, and phone number of company contact.

EPA will verbally vacate SSURO's using the above procedure. Companies should follow-up with EPA in writing. EPA Headquarters will provide information regarding vacation of SSURO's to the appropriate regions.

You should immediately discuss this matter with your State counterparts to inform them of the Agency's position concerning the Court decision. In addition, the appropriate Regions should contact the five registrants with amended SSURO's to inform them of this position. The five registrants are:

1.	Uniroyal Chemical Bethany, CY	Region 1
2.	Cedar Chemical Memphis, TN	Region 4
3.	Drexel Chemical Memphis, TN	Region 4
4.	Platte Chemical Greeley, CO	Region 8
5.	Wilbur Ellis Company Fresno, CA	Region 9

We will keep you informed of further developments in this matter and we will discuss this during the April 22 OPP conference call. If you have any questions, please call Jack Neylan or Dan Helfgott at FTS 382-7835.

cc: Dr. John Moore, OPTS
Jim Lamb, OPTS
Doug Campt, OPP
Stan Abramson, OGC
Jake Mackenzie
Chuck Lincoln
Regional Branch Chiefs

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

MAR 14 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: FIFRA Section 18 for Dinoseb

FROM: John J. Neylan III, Director *Phyllis Flaherty for J Neylan*
Policy and Grants Division
Office of Compliance Monitoring

TO: Addressees

On March 14, 1988, the Agency issued FIFRA Section 18 Emergency Exemptions which granted a specific exemption to the States of Washington, Idaho, and Oregon to allow the use of all dinoseb products labeled for use on dry peas, lentils, and chickpeas to control broadleaf weeds on these crops (this includes dinoseb products which were cancelled as a result of the October 7, 1986 Notice of Intent to Cancel). Sale, distribution, and use of these dinoseb products are only allowed under the terms and conditions specified in the attached Section 18. Additionally, the April 16, 1987 District Court Order which permitted the use of dinoseb on green peas, snap beans, cucurbits (cucumbers, squash and zucchini) and caneberries, pursuant to the terms and conditions specified in that order, is still in effect. The States of Washington, Idaho, and Oregon have promulgated emergency regulations which implement the 1987 District Court Order.

Under existing Stop Sale, Use, or Removal Orders (SSUROs), Cedar Chemical and Drexel Chemical Company were permitted to ship dinoseb products for purposes of consolidating stocks for the formal recall. Additionally, after notifying EPA and obtaining approval from the State of Washington, Idaho or Oregon, Cedar and Drexel were permitted to sell and distribute dinoseb for the uses allowed under the District Court Order (green peas, snap beans, cucurbits, and caneberry crops). Under existing SSUROs, other registrants were permitted to ship dinoseb only for purposes of consolidating stocks for formal recall. Registrants may no longer sell or distribute dinoseb pursuant to last year's Section 18 Exemptions because these exemptions expired on July 15, 1987.

In order to implement the new FIFRA Section 18 Emergency Exemptions and continue to implement the District Court Order, the Agency will amend existing dinoseb SSUROs to permit the sale, distribution, and uses specified in the Section 18 Exemptions and the State regulations which implement the 1987 District Court Order, using the following procedures:

° Registrants must contact the appropriate State Departments of Agriculture and obtain agreement that the product may be shipped into the subject State for an allowable use. Registrants must obtain an agreement from the State regarding the quantity of dinoseb product that may be shipped into the State.

° Registrants must contact EPA by telephone [1) John Mason at 202-382-7835; 2) Jake Mackenzie at 415-974-7279; or (3) call 202-382-3807 and request the dinoseb coordinator] and provide the following information:

- State contact and amount approved for shipment.

- Registration number of product(s) and labeled uses.

- Name and location of product(s) to be shipped and name and location of person receiving the product(s).

- Date of shipment or proposed shipment and quantities of product in each shipment.

- Name, title, address, and phone number of company contact.

Companies must also provide the above information to the EPA Office of Compliance Monitoring (OCM) in writing subsequent to their initial phone call which requested the amendment to the SSURO. OCM will provide those registrants that request permission to ship dinoseb with a written amended SSURO. OCM will also provide information regarding the amended SSUROs to the appropriate Regions and EPA personnel involved in handling dinoseb indemnification claims. Registrants who have not requested and been granted an amended federal SSURO may not move or ship their dinoseb products, except for purposes of consolidating stocks for the formal recall.

The following guidance will apply for enforcing the October 7, 1986 dinoseb suspension order and subsequent cancellations:

1) Any sale, distribution, and use of dinoseb, in the three States, not in accordance with the restrictions found in the 1988 FIFRA section 18 Emergency Exemptions, or the 1987 District Court Order, as implemented by the regulations of the States of Washington, Idaho, and Oregon, is a violation of the FIFRA section 6 Suspension/Cancellation Order.

2) No product can be shipped lawfully for use under the Section 18 unless: (1) the product was registered, packaged, and labeled on October 7, 1986, or (2) the product was manufactured from stocks of a registered technical dinoseb product which were packaged and labeled, and in the possession of the manufacturer, on or before October 7, 1986.

3) No product can be shipped lawfully for use under the State regulations which implement the District Court Order unless: (1) the product was registered, packaged, and labeled on October 7, 1986, or (2) the product was manufactured from stocks of a registered technical dinoseb product which were packaged and labeled, and in the possession of the manufacturer, on or before October 7, 1986, and (3) has not yet been cancelled pursuant to the October 7, 1986 Cancellation Order.

4) No dinoseb product may be distributed or sold for use on dry peas, lentils, chickpeas, green peas, cucurbits, snap beans, or caneberries, unless the product was previously labeled for these uses.

5) Registrants that did not receive an amended SSURO, who ship dinoseb to the three States, will be in violation of the FIFRA Section 6 Suspension/Cancellation Order and in violation of the SSURO issued under FIFRA Section 13.

6) Only pesticide dealers licensed by the State of Washington, Idaho, and Oregon may sell or distribute dinoseb products for use under the FIFRA Section 18 or the State regulations which implement the 1987 District Court Order.

7) Distributors, dealers, and retailers located in other States may ship dinoseb stocks to licensed, authorized dealers in the State of Washington, Idaho, and Oregon for use consistent with the FIFRA Section 18 Emergency Exemptions or the State regulations which implement the 1987 District Court Order, provided the distributor, dealer, retailer has obtained approval from the State. Distributors, dealers, retailers who have previously been issued a State or Federal SSURO must have that SSURO amended before such shipment may occur. Further, such shipment must be in accordance with U.S. Department of Transportation regulations.

8) Use of dinoseb product in the three States for broadleaf control of dry peas, lentils, and chickpeas must be in accordance with the use limitations specified in the attached March 14, 1988 FIFRA section 18.

9) Use of dinoseb product in the three States on green peas, snap beans, cucurbits, and caneberry crops must be in accordance with the use limitations specified in the State regulations implementing the April 16, 1987, District Court Order.

10) Use of dinoseb in the three States not in accordance with the Section 18 or State regulations implementing the District Court Order is a violation of the FIFRA section 6 Suspension/Cancellation Order.

11) No dinoseb products may be used outside the three States. Use of dinoseb outside the three States is a violation of the FIFRA section 6 Suspension/Cancellation Order.

EPA Region X and the States of Washington, Idaho, and Oregon are directed to amend any SSUROs issued at the dealer and user levels to permit sale and use of pesticide products containing dinoseb pursuant to the terms and conditions specified in the March 14, 1988 FIFRA Section 18 Emergency Exemptions and the State regulations implementing the 1987 District Court Order, if this has not already been done.

Under the Section 18 Exemptions and the District Court Order the States of Washington, Idaho, and Oregon are responsible for ensuring that all the provisions of the Emergency Exemptions and District Court Order are met within their States. These States are responsible for conducting inspections at the distributor, dealer, retailer and user levels to assure compliance with the terms of the March 14, 1988 FIFRA Section 18 Emergency Exemptions and the State regulations implementing the 1987 District Court Order. These States are also responsible for assuring that products sold and distributed for use under the FIFRA Section 18 Exemption are not used for the uses allowed under the State regulations which implement the 1987 District Court Order (only Cedar and Drexel's dinoseb products will be allowed for use on green peas, snap beans, cucurbits, and caneberry crops). The specific number of inspections will be negotiated by EPA Region X with the States of Washington, Idado, and Oregon. Regions will monitor compliance with the amended federal SSUROs according to the Pesticides Inspection Manual.

Please note, the FIFRA Section 18 Emergency Exemptions issued on March 14, 1988 will expire upon issuance of the final dinoseb cancellation order (which is expected shortly), or July 15, 1988, whichever comes first. Further, use under the 1987 District Court Order and State regulations must also cease after issuance of the final dinoseb cancellation order. Therefore, upon issuance of the final dinoseb cancellation order, sale, distribution, and use of dinoseb products will only be permitted consistent with the terms and conditions specified in that order.

You should immediately transmit a copy of this memorandum to the States and discuss these dinoseb actions with them. If you have any questions regarding this memorandum, please contact Dan Helfgott at FTS 382-7825.

Attachment

ADDRESSEES

John A. Moore	(TS-788)
Douglas D. Campt	(TS-766C)
Edwin F. Tinsworth	(TS-767C)
Frederick F. Stiehl	(LE-134A)
Mark Greenwood	(LE-132A)
A.E. Conroy II	(EN-342)
Connie Musgrove	"
Ken Shiroishi	"
Phyllis Flaherty	"
Mike Wood	"
Jerry Stubbs	"
Dexter Goldman	"
Jan Auerbach	(TS-767C)
Jane Hopkins	(TS-788)
Phil Gray	(TS-766C)

Jake Mackenzie
Western Regional Compliance Director

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II	Barbara Metzger, Director Environmental Services Div	Ernest Regna, Chief Pesticides & Toxic Substances Br
III	Stephen R. Wassersug, Director Hazardous Waste Management Div	Larry Miller, Chief Toxic & Pesticides Branch
IV	Winston A. Smith, Director Air, Pest. & Toxics Mangt. Div	Richard DuBose, Chief Pesticides & Toxic Substances Br
V	William H. Sanders III, Dir Environmental Services Div	Phyllis Reed, Chief Pesticides & Toxic Substances Br
VI	William B. Hathaway, Dir Air, Pesticides & toxic Div	Robert Murphy, Acting Chief Pesticides & Toxic Substances Br
VII	William A. Spratlin, Director Air and Toxics Division	Leo Alderman, Chief Pesticides & Toxic Substances Br
VIII	Irwin L. Dickstein, Director Air and Toxics Division	Alvin Yorke, Chief Toxic Substances Branch
IX	Jeffrey Zelickson, Director Toxics and Waste Management Div	Davis Bernstein, Chief Pesticides & Toxics Branch
X	Gary O'Neal, Director Air and Toxics Division	Anita Frankel, Chief Pesticides & Toxic Substances Br
	Chris Kirby Oregon Dept. of Agriculture	Rod Awe Idaho Dept. of Agriculture
	Art Losey Washington Dept. of Agriculture	Vivan Jennings U.S. Dept. of Agriculture

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MAR 2 8 1988

MEMORANDUM

SUBJECT: Dinoseb Stipulated Order

FROM: John J. Neylan III, Director
Policy and Grants Division
Office of Compliance Monitoring

TO: Addressees

On March 24, 1988, the counsel for the Environmental Protection Agency and the plaintiffs in Love V. Thomas, filed the enclosed stipulation in that case, which describes those activities which are lawfully permitted by the April 15, 1987 District Court Order and the State regulations implementing that Order. From the Agency's perspective, this stipulation merely reaffirms the situation as it existed prior to the filing of the stipulation.

To prevent any misunderstanding, I have also attached (1) a list of dinoseb products which are not cancelled and are labeled for uses subject to the April 15, 1987 District Court Order, and (2) a copy of the March 14, 1988 memorandum which provides information concerning the Agency's enforcement policy for dinoseb. If you have any questions regarding this letter, please contact Dan Helfgott of my staff at FTS 382-7825.

Attachments

Susan K. Eggum
McEWEN, GISVOLD, RANKIN & STEWART
1408 Standard Plaza
1100 SW Sixth Avenue
Portland, OR 97204
Telephone: (503) 226-7321

Phillip D. Chadsey
STOEL, RIVES, BOLEY, JONES & GREY
900 SW Fifth Avenue
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Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT

DISTRICT OF OREGON

JAMES M. LOVE, NORTHWEST FOOD PROCESSORS ASSOCIATION, a non-profit association, and TUALATIN VALLEY FRUIT MARKETING, INC., an Oregon corporation, Plaintiffs,	Civil No. 87-343-RE
DAVE FROHNMAYER, Attorney General for the State of Oregon, on behalf of the people of the State of Oregon, Intervenor,	
v.	STIPULATED ORDER
LEE M. THOMAS, Administrator Environmental Protection Agency, Defendant.	

On March 11, 1988, plaintiffs filed a Motion For Order To Show Cause Why The Defendant Should Not Be Held In Contempt For Violation Of This Court's Preliminary Injunction and Setting Hearing. In response to plaintiffs' motion, counsel for plaintiffs

and for defendant have agreed to the following terms of a stipulated order:

1. All dinoseb products which are not cancelled (including but not limited to products manufactured by Cedar and Drexel and their respective predecessors and affiliates) and which are the subject of this Court's April 15, 1987 injunction ("the injunction") may be shipped into the states of Washington, Idaho, and Oregon and sold, distributed, and used in those states for those crops (green peas, snap beans, cucurbits and caneberries) in accordance with the injunction and the state regulations implementing the injunction.

2. This stipulated order shall remain in effect throughout the 1988 growing season for the crops which are the subject of the injunction, or until the defendant issues a final order in the dinoseb cancellation proceeding, FIFRA Docket No. 590, et al., whichever occurs sooner.

3. EPA has notified the manufacturers of affected products of these facts and will provide the manufacturers, EPA regional offices, and state agencies responsible for enforcement of FIFRA with notice of this stipulation and a copy of this stipulated order.

4. Plaintiffs' Motion For Order To Show Cause Why Defendant Should Not Be Held In Contempt For Violation Of This Court's Preliminary Injunction is hereby withdrawn.

5. Each party shall bear its own costs and attorney fees

/ / /

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incurred in connection with the withdrawn motion.

March 18, 1988.

ROGER J. MARZULLA
Acting Assistant Attorney General
Land & Natural Resources Division

Susan L. Smith

SUSAN L. SMITH, Assistant Chief
Environmental Defense Section Land
& Natural Resources Division U.S.
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/s/ Phillip D Chadsey by SKE

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DINOSEB PRODUCTS WHICH ARE NOT CANCELLED
AND ARE LABELED FOR USES SUBJECT TO THE
APRIL 15, 1987 DISTRICT COURT INJUNCTION

This list consists of registered pesticide products containing dinoseb which are 1) not cancelled, and 2) labeled for use on crops which are subject to the April 15, 1987 injunction by the United States District Court in Oregon. As confirmed by the enclosed stipulation, these products may be shipped into the states of Washington, Idaho, and Oregon, and sold, distributed and used in those states in accordance with the April 15, 1987 injunction and the state regulations implementing the injunction. To the extent that any stop sale, use, or removal order previously issued by EPA represents an impediment to such activities, EPA will modify that order in accordance with the procedures set forth in the enclosed March 14, 1988 memorandum.

As of March 21, 1988, Cedar Chemical Corporation and Drexel Chemical Company were the only companies whose dinoseb registrations had not been cancelled. However, many of the registrations for dinoseb products currently held by Cedar and Drexel were previously held by one or more other companies, and then transferred to Cedar or Drexel. Remaining stocks of these transferred products which are labeled with the prior brand names and registration numbers are not cancelled. In addition, a number of additional companies have obtained supplemental registrations which permit them to distribute Drexel products under other brand names. These supplemental registrations are also not cancelled.

I. Cedar Chemical Corporation

A. Current Cedar Chemical Corporation Registrations Transferred From Vertac Chemical Corporation

Product Name	Vertac Chemical Corporation Reg. No.	Cedar Chemical Corporation Reg. No.
Dinitro Weed Killer	39511-10	56077-4
Dinitro Weed Killer 5	39511-11	56077-5
Selective Weed Killer	39511-85	56077-11
General Weed Killer	39511-86	56077-12
Premerge 3	39511-87	56077-13
Premerge	39511-88	56077-14
Dinitro 3 Weed Killer	39511-89	56077-15
Dinitro General	39511-91	56077-17

B. Current Cedar Chemical Corporation Registrations Previously Transferred from Other Companies

Product Name (company)	Former Reg. No.	Current Reg. No.
Selective Weed Killer (Dow)	464-10	56077-11
Dow General Weed Killer (Dow)	464-98	56077-12
Premerge (Dow)	464-146	56077-14
Premerge 3 Dinitro Amine Herbicide (Dow)	464-490	56077-13
Helena Brand Dinitro Weed Killer 5 (Helena)	5905-194	56077-5
Dinitro - 3 Weed Killer (Crystal)	9663-11	56077-15
Dinitro General Herbicide (Crystal)	9663-18	56077-17

II. Drexel Chemical Company

A. Current Drexel Chemical Company Registrations

Product Name	Reg. No.
Dynamyte T	19713-33
Dynamyte 2.5	19713-78
Dynamyte 3	19713-82
Dynamyte 300	19713-28
Dynamyte 5	19713-29
Premerge Dinitro Weed Killer	19713-203

B. Registrations Transferred To Drexel Chemical Company from Other Companies

Former Product Name (Company)	Former Reg. No.	Current Reg. No.
Dynamyte T Dinitro Weed Killer (Ansul)	6308-89	19713-33
Trounce 3 Dinitro Weed Killer (Ansul)	6308-79	19713-28
Dynamyte 5 Dinitro Weed Killer (Ansul)	6308-80	19713-29
Dinoseb Dinitro Weed Killer (Chapman)	1022-442	19713-203

C. Supplemental Registrations for Drexel Chemical Company Products

Product Name	Reg. No.
Hopkins Dinitro 3	19713-28-2393
Dinitro 5	19713-29-635
Pure Gro Dinoseb 5	19713-29-1202
Hopkins Dinitro 5	19713-29-1063
Dino - 5 Dinitro Weed Killer	19713-29-2935
Dinitro 5 Weed Killer	19713-29-3442
Terra Dinitro-5	19713-29-14774
Dinitro General	19713-29-44215
Schall Contact Weed Killer	19713-78-3468
Dinitro Contact Weed Killer	19713-78-44215
Valco Brand-Beanweda	19713-82-1063
Pure Gro Dinomerge 3	19713-82-1202
Dino - 3	19713-82-2935
USS Dinitro 3 Pre-Emergence Weed Killer	19713-82-3442
Riverside Dinitrol 3	19713-82-9779
Red Panther Dinitro 3	19713-82-42761
Dinitro PE	19713-82-44215

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

JUN 15 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Compliance Monitoring Strategy for the Final Cancellation of Dinoseb

FROM: John J. Neylan III, Director
Policy and Grants Division
Office of Compliance Monitoring

TO: Addressees

On June 9, 1988, the Administrator of the Environmental Protection Agency (EPA) signed the final Dinoseb Cancellation Order. This Order, which is effective June 10, 1988, cancels all pesticide products containing dinoseb, or any of its salts, which have not already been cancelled pursuant to the Notice of Intent to Cancel (NOIC) issued on October 7, 1986 (51 FR 36650: October 14, 1986).

Pursuant to this Order, the Agency has authorized sale, distribution, and use of dinoseb for certain crops for the 1988 and 1989 growing seasons in the States of Washington, Idaho, and Oregon. Also pursuant to the Cancellation Order, the State Departments of Agriculture of Washington, Idaho, and Oregon have agreed to enforce all the provisions of the June 10, 1988 final Dinoseb Cancellation Order. Finally, please note that all sale, distribution, and use of dinoseb permitted under the 1988 FIFRA section 18 emergency exemptions, the 1987 U.S. District Court Order, and amended federal Stop Sale, Use, or Removal Orders are now prohibited. All sale, distribution, and use of dinoseb must now be in accordance with the final Dinoseb Cancellation Order. Therefore, use of dinoseb on snap beans and cucurbits is now prohibited. Further, sale and distribution of dinoseb for use on snap beans and cucurbits is also prohibited.

Attached is the Compliance Monitoring Strategy for the Final Cancellation of Dinoseb. This Strategy calls for the State Departments of Agriculture of Washington, Idaho, and Oregon to conduct inspections at the distributor, dealer, retailer, and user levels to assure compliance with the final Dinoseb Cancellation Order. Further, the Office of Compliance Monitoring, the Regions, and the States are to amend Stop Sale, Use, or Removal Orders (SSUROs), as necessary, to allow sale, distribution, and use only in accordance with the final Cancellation Order. Procedures for amending SSUROs will be identical to those procedures outlined on page 2 of the attached March 14, 1988 memorandum from John J. Neylan III, entitled FIFRA Section 18's for Dinoseb. Regions are to monitor compliance with the amended Stop Sale, Use, or Removal Orders in accordance with Section 13 of the Pesticides Inspection Manual.

This attached Strategy is effective immediately, and supersedes previous Agency guidance on the enforcement of dinoseb actions, including the October 7, 1986 Compliance Strategy for the Emergency Suspension of Dinoseb. Please transmit a copy of this Strategy, and the attached June 10, 1988 final Dinoseb Cancellation Order to the States within your Region as soon as possible. If you have any questions regarding the attached Strategy, please contact Dan Helfgott of my staff (EN-342; FTS 382-7825).

Attachments

Douglas D. Campt	(TS-766C)
Edwin F. Tinsworth	(TS-767C)
Frederick F. Stiehl	(LE-134A)
Mark Greenwood	(LE-132A)
A.E. Conroy II	(EN-342)
Connie Musgrove	"
Ken Shiroishi	"
Phyllis Flaherty	"
Mike Wood	"
Jerry Stubbs	"
Maureen Lydon	"
Dexter Goldman	"
Jan Auerbach	(TS-767C)
Jane Hopkins	(TS-788)
Phil Gray	(TS-766C)

Jake Mackenzie
Western Regional Compliance Director

I	Louis F. Gitto, Director Air Management Division	Marvin Rosenstein, Chief Pesticides & Toxic Substances Br
II	Barbara Metzger, Director Environmental Services Division	Ernest Regna, Chief Pesticides & Toxic Substances Br
III	Stephen R. Wassersug, Director Hazardous Waste Management Div	Larry Miller, Chief Toxic & Pesticides Branch
IV	Winston A. Smith, Director Air, Pest. & Toxics Mangt. Div	Richard DuBose, Chief Pesticides & Toxic Substances Br
V	William H. Sanders III, Dir Environmental Services Division	Phyllis Reed, Chief Pesticides & Toxic Substances Br
VI	William B. Hathaway, Director Air, Pesticides & Toxic Div	Robert Murphy, Acting Chief Pesticides & Toxic Substances Br
VII	William A. Spratlin, Director Air and Toxics Division	Leo Alderman, Chief Pesticides & Toxic Substances Br
VIII	Irwin L. Dickstein, Director Air and Toxics Division	Alvin Yorke, Chief Toxic Substances Branch
IX	Jeffrey Zelickson, Director Toxics and Waste Management Div	Davis Bernstein, Chief Pesticides & Toxics Branch
X	Gary O'Neal, Director Air and Toxics Division	Anita Frankel, Chief Pesticides & Toxic Substances Br
	Chris Kirby Oregon Dept. of Agriculture	Rod Awe Idaho Dept. of Agriculture
	Art Losey Washington Dept. of Agriculture	Vivan Jennings U.S. Dept. of Agriculture

COMPLIANCE MONITORING STRATEGY FOR THE FINAL CANCELLATION OF DINOSEB

OVERVIEW

On June 9, 1988, the Administrator of the Environmental Protection Agency (EPA) signed the final Dinoseb Cancellation Order. This Order, which was effective on June 10, 1988, cancels pesticide products containing dinoseb, or any of its salts, which have not already been cancelled pursuant to the Notice of Intent to Cancel (NOIC) issued on October 7, 1986 (51 FR 36650; October 14, 1986). Stayed by Judge On June 17, 1988 this order was changed by the court.

Pursuant to the terms of the Cancellation Order, the Agency has authorized the sale, distribution, and use of existing stocks of dinoseb products for certain crops in the States of Washington, Idaho, and Oregon. Also pursuant to the Cancellation Order, the State Departments of Agriculture of Washington, Idaho, and Oregon have agreed to enforce all the procedures, terms, and conditions of the June 10, 1988 Cancellation Order. Therefore, the States of Washington, Idaho, and Oregon are responsible for conducting inspections at the distributor, dealer, retailer, and user levels to assure compliance with the terms and conditions of the June 10, 1988 Cancellation Order in their States.

All other Regions/States will conduct inspections at the registrant, producer, dealer, distributor, retailer, and user level, as part of their routine inspectional program, to assure that no dinoseb stocks are being sold, distributed, or used in violation of the final Dinoseb Cancellation Order.

Please note that all sale, distribution, and use permitted under the 1987 and 1988 FIFRA section 18 emergency exemptions, the 1987 District Court Order, and amended federal Stop Sale, Use, or Removal Orders (SSUROs) are now prohibited. All sale, distribution, and use of pesticide products containing dinoseb must now be in accordance with the final Dinoseb Cancellation Order. ~~Therefore, sale, distribution, and use of dinoseb on snap beans and cucurbits (cucumbers, squash and zucchini) are no longer permitted.~~ The Office of Compliance Monitoring (OCM) may amend federal SSUROs upon request of the dinoseb registrant to permit sale, distribution, and use in accordance with the final Dinoseb Cancellation Order. The procedures for amending these SSUROs will be the same as those outlined on page 2 of the attached March 14, 1988 memorandum from John J. Neylan, entitled FIFRA Section 18's for Dinoseb. The Agency will monitor compliance with the amended federal Stop Sale, Use or Removal Orders (SSUROs) in accordance with section 13 of the Pesticides Inspection Manual.

Additionally, OCM may authorize the sale, distribution, or shipment of existing stocks of cancelled dinoseb products by registrants, distributors, dealers, or users located in States other than Washington, Idaho, and Oregon to licensed dealers in these States, when sale of existing stocks by the recipient dealer is permitted pursuant to the Cancellation Order. Such authorization is contingent upon the registrant, distributor, dealer, or user obtaining permission from the State Department of Agriculture of the State to which the cancelled product is being shipped.

This Compliance Monitoring Strategy for the Final Cancellation of Dinoseb is effective immediately, and supersedes previous Agency guidance on the enforcement of dinoseb actions, including the October 7, 1986 Compliance Strategy for the Emergency Suspension of Dinoseb.

REQUIREMENTS

The June 10, 1988 final Dinoseb Cancellation Order permits the sale, distribution, and use of existing stocks of dinoseb pesticide products: (1) for weed control on dry peas, lentils, chickpeas, and green peas in the States of Washington, Idaho, and Oregon during the 1988 growing season, and (2) for vegetative cane control in caneberries (blackberries, boysenberries, loganberries, and raspberries) in Washington, and Oregon during the 1988 and 1989 growing seasons.

Regulated Industry

The June 10, 1988 final Cancellation Order specifically cancels the dinoseb pesticide products of Cedar Chemical Corporation (formerly registered under Vertac Chemical) and Drexel Chemical Company.

The existing stocks provisions of the final Cancellation Order affect: (1) all registrants of dinoseb products, including those registrants of products cancelled pursuant to the October 7, 1986 NOIC; (2) growers that use dinoseb on dry peas, lentils, chickpeas, green peas, and caneberries in the States of Washington, Idaho, and Oregon; (3) dealers who are licensed by the States of Washington, Idaho, and Oregon to sell cancelled dinoseb pesticide products; and (4) registrants, distributors, dealers, or users who sell, distribute, or ship cancelled dinoseb products to licensed dealers in Washington, Idaho, and Oregon.

Existing Stocks

Cancelled dinoseb products may only be sold, distributed, and used if: (1) the product was federally registered, packaged, and labeled on October 7, 1986, or (2) the end-use product was manufactured from stocks of a registered technical dinoseb product which was packaged and labeled and in the possession of the manufacturer, on or before October 7, 1986. Cancelled dinoseb products may only be sold and distributed for use on dry peas, lentils, chickpeas, green peas, or caneberries if the product was previously labeled for these crops. Pesticide dealers in Washington, Idaho, and Oregon must be licensed by their State in order to sell or distribute cancelled dinoseb products. These dealers must record and submit dinoseb sales information to the State Department of Agriculture and EPA Region X Office within 5 days of sale, distribution, or delivery of the cancelled dinoseb product to a grower in Washington, Idaho, or Oregon. The dinoseb products may be sold and distributed only when accompanied by supplemental labeling which includes the use restrictions and warning statements contained in the June 10, 1988 final Dinoseb Cancellation Order. Further, use of all dinoseb pesticide products may only be in accordance with the terms and conditions outlined in the supplemental labeling.

Please note that existing dinoseb Stop Sale, Use, or Removal Orders (SSUROs), including those that were previously amended pursuant to the 1987 and 1988 dinoseb FIFRA section 18 emergency exemptions and Judge Redden's 1987 District Court Order, will not permit registrants to legally sell, distribute, ship, etc., any dinoseb products upon issuance of the final Dinoseb Cancellation Order. Therefore, the Agency must amend any existing dinoseb SSUROs before a registrant may sell, offer for sale, hold for sale, ship, deliver for shipment, receive and (having so received) deliver or offer to deliver, or remove pesticide products containing dinoseb for uses permitted by the final Dinoseb Cancellation Order during the 1988 and 1989 growing season.

Upon request by the dinoseb registrant, the Agency may modify any existing SSUROs to permit the registrant to sell, offer for sale, hold for sale, ship, deliver for shipment, receive and (having so received) deliver or offer to deliver, and remove pesticide products containing dinoseb which meet the conditions of the final Dinoseb Cancellation Order. The exact procedures that will be used to amend federal SSUROs is identical to those procedures outlined on page 2 of the attached March 14, 1988 memorandum from John J. Neylan III, entitled FIFRA Section 18's for Dinoseb. Registrants who have not requested and been granted an amended federal SSURO may not sell or distribute their dinoseb products.

EPA Region X and the States of Washington, Idaho, and Oregon are directed to amend any SSUROs issued at the distributor, dealer, retailer, and user levels to permit sale and use of pesticide product containing dinoseb pursuant to the terms and conditions specified in the final Dinoseb Cancellation Order.

Other Regions and States are directed to amend any SSUROs at the distributor, dealer, retailer, and user level to permit the sale, distribution, and shipment of dinoseb to licensed dealers in the States of Washington, Idaho, and Oregon, provided the person has received permission from the subject State.

Finally, registrants, distributors, dealers, retailers, or users located in States other than Washington, Idaho, and Oregon must obtain authorization from the Office of Compliance Monitoring before they may ship existing stocks of cancelled dinoseb products to Washington, Idaho, and Oregon. Such authorization is contingent upon the registrant, distributor, dealer, retailer, or user obtaining permission from the State Department of Agriculture of the State to which the cancelled product is being shipped.

Any sale, distribution, or use of pesticide products containing dinoseb not in accordance with the final Dinoseb Cancellation Order is a violation of FIFRA sections 12(a)(2)(K) and 12(a)(1)(A).

COMPLIANCE MONITORING

Pursuant to the terms and conditions of the final Dinoseb Cancellation Order, the Departments of Agriculture of the States of Washington, Idaho, and Oregon are responsible for ensuring that all the provisions of the Cancellation Order are met within their State. These States are responsible for conducting inspections at the dealer, distributor, retailer, and user levels to assure compliance with the terms of the June 10, 1988 final Dinoseb Cancellation Order. These States are also responsible for responding to tips and complaints of violations of the Cancellation Order.

All Regions/States are to perform inspections at the registrant, producer, dealer, distributor, retailer, and user levels, as part of their routine inspections, to assure that no person is distributing, selling, offering for sale, holding for sale, delivering for shipment, receiving (and having so received) delivering, offering to deliver, or using pesticide products containing dinoseb in violation of the June 10, 1988 final Dinoseb Cancellation Order.* Regions will monitor compliance with the amended federal SSUROs in accordance with Section 13 of the Pesticides Inspection Manual.

* Please note that pursuant to the October 7, 1986 Compliance Strategy for the Emergency Suspension of Dinoseb, Regions/States were to have conducted inspections of registrants and producer establishments by November 7, 1986.

Neutral Administrative Inspection Scheme (NAIS)

Inspections by the States of Washington, Idaho, and Oregon are to be conducted at a minimum of 15 percent of the pesticide dealers licensed to sell dinoseb and 15 percent of the growers who are legally permitted to use dinoseb. In addition, Washington, Idaho, and Oregon should ensure that growers who were previously permitted to use dinoseb on snap beans and cucurbits are aware of the final Dinoseb Cancellation Order and that they may no longer lawfully use dinoseb on those crops.

ALLOCATION OF RESPONSIBILITIES

Office of Pesticide Programs (OPP)

Will develop and provide to OCM a list of dinoseb pesticide products that are registered for use on dry peas, lentils, chickpeas, green peas, and caneberries.

Office of Compliance Monitoring (OCM)

Will develop and transmit the Compliance Monitoring Strategy to the Regions.

Will transmit the list of dinoseb products registered for use on dry peas, lentils, chickpeas, green peas, and caneberries to the Regions.

Will amend federal SSUROs, upon request by the registrants to allow the sale, distribution, use, etc., of dinoseb products registered for use on dry peas, lentils, chickpeas, green peas, and caneberries in the States of Washington, Idaho, and Oregon.

Will authorize the sale, distribution, or shipment of dinoseb by registrants, distributors, dealers, and users located in States other than Washington, Idaho, and Oregon to licensed dealers in those States. Such authorization is contingent upon the registrant, distributor, dealer, or user obtaining permission from Washington, Idaho, or Oregon for shipment to their State.

Will notify the Regions of the registrants, distributors, dealer, retailers, and users that have been given authorization to ship dinoseb to Washington, Idaho, and Oregon.

Will notify Regions of all SSUROs that have been amended by OCM.

Regions

Will transmit the Compliance Monitoring Strategy to the States.

Will transmit the list of dinoseb products to the States.

Will amend federal SSUROs in Washington, Idaho, Oregon, and other States to allow sale, distribution, shipment, use, etc., consistent with the terms of the final Dinoseb Cancellation Order.

Will inform States as to which dinoseb products have amended federal SSUROs.

Will inform States of which registrants, distributors, dealers, retailers, and users have been given authorization to ship dinoseb to Washington, Idaho, and Oregon.

Will monitor compliance with the amended federal SSUROs in accordance with section 13 of the Pesticides Inspection Manual.

Will report to OCM any enforcement actions taken by the Regions and States in response to violations of the final Dinoseb Cancellation Order, quarterly through FY 1990.

Will conduct inspections to assure compliance with the final Dinoseb Cancellation Order at the registrant, producer, dealer, distributor, retailer, and user levels, in States without Cooperative Enforcement Agreements, as part of their routine inspectional program.

Will take enforcement action, including issuing SSUROs, as appropriate for violations of the Cancellation Order.

States

Washington, Idaho, and Oregon will conduct inspections and respond to reasonable tips and complaints to assure compliance with the final Dinoseb Cancellation Order.

Washington, Idaho, and Oregon will take enforcement action as appropriate.

Washington, Idaho, and Oregon will report to Region X on enforcement actions taken in response to violations of the final Dinoseb Cancellation Order, quarterly through FY 1990.

Washington, Idaho, and Oregon will amend any SSUROs, as necessary, issued on their authority to distributors, dealers, retailers, and users to permit the sale, distribution, and use of dinoseb products pursuant to the terms and conditions of the final Dinoseb Cancellation Order.

Washington, Idaho, and Oregon will provide permission, at their discretion, to registrants, distributors, dealers, retailers, and users located in other States to ship dinoseb to licensed dealers in their State for further sale, distribution, and use pursuant to the final Dinoseb Cancellation Order.

States other than Washington, Idaho, and Oregon are to amend State SSUROs, as necessary, at the distributor, dealer, retailer, and user level to permit the sale, distribution and shipment of dinoseb to licensed dealers in the States of Washington, Idaho, and Oregon.

States other than Washington, Idaho, and Oregon will conduct inspections to assure compliance with the final Dinoseb Cancellation Order at the registrant, producer, dealer, distributor, retailer, and user levels, as part of their routine inspectional program.

States other than Washington, Idaho, and Oregon will take enforcement action, including issuing SSUROs, as appropriate and provided they have the authority, for violations of the Cancellation Order.

BEFORE THE ADMINISTRATOR
U.S. ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C.

In the Matter of:	)	
	)	
Cedar Chemical Company et al.	)	FIFRA Docket Nos. 590 et al.
	)	

CANCELLATION ORDER

Pursuant to FIFRA section 6(b), 7 U.S.C. §136d(b), and 40 C.F.R. §§164.91 and 164.103, I hereby cancel all registrations for pesticide products containing dinoseb (2-sec-butyl-4,6-dinitrophenol) or any of its salts which have not already been cancelled pursuant to the Notice of Intent to cancel which I issued on October 7, 1986, and which was published at 51 FR 36650, October 14, 1986. Except as provided below, it shall be unlawful under FIFRA sections 12(a)(1)(A) and 12(a)(2)(K), 7 U.S.C. §§136j(a)(1)(A) and (a)(2)(K), for any person in any State to distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver to any person any pesticide product containing dinoseb or any of its salts.

Pursuant to FIFRA section 6(a)(1), 7 U.S.C. §136d(a)(1), I have decided to permit distribution, sale, and use of stocks of cancelled dinoseb products: (1) for weed control in dry peas, lentils, chickpeas, and green peas in the States of Washington, Idaho, and Oregon during the 1988 use season, and (2) for vegetative cane control in caneberries (blackberries,

boysenberries, loganberries, and raspberries) in the States of Washington and Oregon during the 1988 and 1989 use seasons. Such distribution, sale, and use will only be permitted in accordance with the following procedures, terms, and conditions. No cancelled dinoseb product shall be distributed, sold, or used for any crop in any State without express written authorization from the Assistant Administrator for Pesticides and Toxic Substances (or his delegate). The Assistant Administrator shall authorize distribution, sale, and use of existing stocks of dinoseb products for a particular crop in a particular State only if the State Department of Agriculture expressly requests in writing that such distribution, sale, and use be permitted, and agrees to accept and enforce all procedures, terms, and conditions set forth in, or adopted pursuant to, this Order.

The following mandatory use restrictions shall be observed by all persons using any cancelled dinoseb product pursuant to this Order, shall constitute supplemental labeling for all cancelled dinoseb products which may be used pursuant to this Order, and shall take precedence over any inconsistent restrictions or provisions on the prior labeling for such products:

(1) Dinoseb shall not be applied at an application rate exceeding three pounds of active (a.i.) per acre for dry peas, chickpeas, and green peas, one and one-half pound a.i. per acre for lentils, and two and one-half pounds a.i. per acre for caneberries.

(2) Dinoseb shall not be applied by any one individual on any single day to more than a total of eighty (80) acres of dry peas, lentils, chickpeas, and green peas, or to more than twenty (20) acres of caneberries.

(3) No individual shall mix and/or load in one day more than the quantity of dinoseb required to treat the maximum permissible daily acreage for one crop at the maximum permissible application rate.

(4) Only certified applicators may mix, load, or apply dinoseb; other persons, even if they are operating under the direct supervision of a certified applicator, shall not mix, load, or apply dinoseb.

(5) All mixing and loading of dinoseb products must be done utilizing a closed system.

(6) All persons must wear chemically resistant disposable coveralls and chemically resistant gloves and boots during mixing and loading of dinoseb, while adjusting or repairing dinoseb application equipment, and during application of dinoseb to caneberries.

(7) Closed tractor cabs equipped with positive pressure ventilization must be used for application of dinoseb to dry peas, lentils, chickpeas, and green peas. Applicators must remove protective coveralls and gloves worn during mixing and loading immediately before entering a closed tractor cab in order to avoid cab contamination, and must carry an unused set of coveralls and gloves in the cab, for use in the event in-field repair, maintenance, or adjustment of equipment is required.

(8) Aerial application of dinoseb is prohibited. Dinoseb may only be applied utilizing tractor drawn equipment.

(9) Dinoseb may only be applied to caneberries as a low-pressure directed spray for vegetative cane (primocane) control.

(10) Application of dinoseb is prohibited when wind conditions exceed ten miles per hour.

(11) No person shall re-enter any field treated with dinoseb for any purpose within one week of application unless that person is within a closed cab, or is wearing chemically resistant disposable coveralls and chemically resistant gloves and boots. Any person required to re-enter a field treated with dinoseb within one week of application shall be notified that the field was treated with dinoseb and advised to avoid dermal contact with treated foliage and soil.

The following mandatory restrictions shall govern any distribution or sale of cancelled dinoseb products pursuant to this Order:

(1) No cancelled dinoseb product may be distributed or sold for use on any crop unless: (1) the product was registered, packaged, and labeled on October 7, 1986, or (2) the product was manufactured from stocks of a registered technical dinoseb product which were packaged and labeled, and in the possession of the manufacturer, on or before October 7, 1986.

(2) No cancelled dinoseb product may be distributed or sold for use on dry peas, lentils, chickpeas, or green peas unless the product was previously labeled for use on peas, lentils, or chickpeas. No cancelled dinoseb product may be distributed or sold for use on caneberries (blackberries, boysenberries, loganberries, and raspberries) unless the product was previously labeled for use on one or more of these crops.

(3) Only pesticide dealers licensed by the State in question may distribute or sell cancelled dinoseb products.

(4) Each container of a cancelled dinoseb product which is distributed or sold must be accompanied by supplemental labeling including all of the use restrictions set forth above, and a warning stating (1) that the product poses a hazard to unborn children and that all reasonable efforts should be made to prevent exposure of women of child-bearing age, (2) that the product also poses hazards to male reproduction, (3) that the product is acutely toxic, and (4) that the product may only be applied by certified applicators.

(5) Dealers may sell dinoseb only to growers who may legally use the product pursuant to this Order, and no grower shall be permitted to purchase a quantity greater than that required to treat the grower's eligible crop acreage at the maximum permissible application rate. All stocks of dinoseb already in a grower's possession must be taken into account when determining the quantity of dinoseb a grower may lawfully purchase.

(6) Dealers must obtain and record the following information prior to selling, distributing, or delivering any dinoseb product:

(a) The grower's name, address, and certification number (if any),
(b) The type of crop and number of acres to be treated,
(c) The name, address, and certification number of the person(s) who will mix, load, and apply the dinoseb,
(d) The quantity of dinoseb already in the grower's possession,
(e) The product name(s) and registration number(s) of the dinoseb product(s),
(f) The quantity of the dinoseb product(s) to be sold, distributed, or delivered.

All such information shall be forwarded by the dealer to the State Department of Agriculture and the EPA regional office within five days following sale, distribution, or delivery.

The Assistant Administrator for Pesticides and Toxic Substances, in consultation with the Regional Administrator and the Departments of Agriculture of the States of Washington, Oregon, and Idaho, shall establish procedures for monitoring and enforcement by the States of the restrictions on sale, distribution, and use imposed pursuant to this Order. The Assistant Administrator (or his delegate) may also authorize (1) sale, distribution, or shipment of existing stocks of cancelled dinoseb products by registrants, distributors, dealers, or end-users located in other States to dealers in the States of Washington, Oregon, and Idaho, when sale of existing stocks by the recipient dealer is permitted pursuant to this Order, and (2) any shipments of any cancelled dinoseb product which are necessary to facilitate proper storage or disposal of such products. This Order constitutes final Agency action in the

above-captioned proceeding under FIFRA sections 6(b) and 16(b), 7 U.S.C. §§136d(b) and 136n(b), and is a final cancellation order under 40 C.F.R. §164.130.

Lee M. Thomas
Administrator

Dated: June 9, 1988

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

MAR 3 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Compliance Monitoring of the June 9, 1988 Dinoseb Cancellation Order for the 1989 Growing Season

FROM: Michael F. Wood, Director Michael F. Wood
Compliance Division

Phyllis E. Flaherty Phyllis E. Flaherty
Acting Director
Policy and Grants Division

TO: Addressees

The purpose of this memorandum is to clarify that the June 9, 1988 Final Dinoseb Cancellation Order and the June 15, 1988 Compliance Monitoring Strategy for the Final Cancellation of Dinoseb are in effect, and to provide you with the procedures for amending Stop Sale, Use, or Removal Orders (SSUROs).

The Office of Compliance Monitoring (OCM) issued a Compliance Monitoring Strategy for the Final Cancellation of Dinoseb on June 15, 1988. However, on June 17, 1988, the U.S. District Court Judge of Oregon, Judge Redden, issued an order which temporarily stayed the effectiveness of the June 9, 1988 Final Dinoseb Cancellation Order. As a result, OCM issued a memorandum on June 21, 1988 which instructed the Regions not to implement the June 15, 1988 Compliance Monitoring Strategy. On October 4, 1988, Judge Redden granted EPA's motion for a summary judgement and reversed his previous decision. The result of this ruling is that the June 9, 1988 Final Dinoseb Cancellation Order was reinstated. The Office of Compliance Monitoring will inform the Regions of any additional rulings that may affect the status of dinoseb products. However, since the June 9, 1988 Final Dinoseb Cancellation Order is currently in effect, Regions and States are to assure compliance with that order in accordance with applicable provisions of the June 15, 1988 Compliance Monitoring Strategy for the Final Cancellation of Dinoseb.

The June 9, 1988 Final Dinoseb Cancellation Order permits the sale, distribution, and use of existing stocks of dinoseb for vegetative control in caneberries (blackberries, boysenberries, loganberries, and raspberries) in the States of Washington and Oregon during the 1989 growing season. As stated in the June 15, 1988 strategy, the procedures for amending Stop Sale, Use, or Removal Orders (SSUROs) to allow sale, distribution, and use of cancelled dinoseb products in accordance with the cancellation order are found on page 2 of the March 14, 1988 memorandum from John J. Neylan III regarding FIFRA Section 18's for Dinoseb (attached). The procedures set out in the March 14, 1988 memorandum, that were used in the 1983 growing season, will be used this year as well (see Attachment A).

If you have any questions regarding this memorandum, or the attached June 15, 1988 Compliance Monitoring Strategy for the Final Cancellation of Dinoseb, please contact Dan Helfgott in the Policy and Grants Division at FTS 382-7825. Questions on the procedures for amending SSUROs may be directed to John Mason of the Compliance Division at FTS 382-7835.

Attachments

ADDRESSEES

Douglas D. Campt	(TS-766C)
Edwin F. Tinsworth	(TS-767C)
Anne Lindsay	(TS-767C)
Frederick F. Stiehl	(LE-134A)
Mark Greenwood	(LE-132A)
A.E. Conroy II	(EN-342)
Connie Musgrove	"
Ken Shiroishi	"
Jack Neylan	"
Phyllis Flaherty	"
Mike Wood	"
Jerry Stubbs	"
Maureen Lydon	"
Jan Bearden	"
Bob Zisa	"
Ken Kanagalingam	"

Jake Mackenzie
Western Regional Compliance Director

I	Louis F. Gitto, Director Air Management Division	Marvin Rosenstein, Chief Pesticides & Toxic Substances Br
II	Barbara Metzger, Director Environmental Services Division	Ernest Regna, Chief Pesticides & Toxic Substances Br
III	Stephen R. Wassersug, Director Hazardous Waste Management Div	Larry Miller, Chief Toxic & Pesticides Branch
IV	Winston A. Smith, Director Air, Pest. & Toxics Mangt. Div	Richard DuBose, Chief Pesticides & Toxic Substances Br
V	William H. Sanders III, Dir Environmental Services Division	Phyllis Reed, Chief Pesticides & Toxic Substances Br
VI	William B. Hathaway, Director Air, Pesticides & Toxic Div	Robert Murphy, Chief Pesticides & Toxic Substances Br
VII	William A. Spratlin, Director Air and Toxics Division	Leo Alderman, Chief Pesticides & Toxic Substances Br
VIII	Irwin L. Dickstein, Director Air and Toxics Division	Alvin Yorke, Chief Toxic Substances Branch
IX	David P. Howekamp, Director Air Management Division	Davis Bernstein, Chief Pesticides & Toxics Branch
X	Gary O'Neal, Director Air and Toxics Division	Kenneth Feigner, Chief Pesticides & Toxic Substances Br
	Chris Kirby Oregon Dept. of Agriculture	Rod Awe Idaho Dept. of Agriculture
	Art Losey Washington Dept. of Agriculture	Vivan Jennings U.S. Dept. of Agriculture

cc:	Michael Walker	(LE-134P)
	Jim Roeloffs	(TS-788)
	John Tice	(TS-766C)

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

MAR 12 1990

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EBDC Compliance Monitoring Strategy

FROM: John J. Neylan III, Director
Policy and Grants Division
Office of Compliance Monitoring (EN-342)

TO: Addressees

Attached is the Compliance Monitoring Strategy for the Cancellation and Registration Amendments for Pesticide Products Containing EBDCs. We appreciate the comments submitted on the December 18, 1989 draft of this strategy. We have incorporated most of these comments into the attached strategy. We have also incorporated the additional EBDC actions that have been requested by the registrants and accepted by the Agency since the draft strategy was sent out for comment.

The EBDC strategy calls for Regions/States to conduct compliance inspections at EBDC producing establishments to assure that affected EBDC fungicides are not being sold or distributed in violation of the cancellations and amended registrations. The strategy also calls for Regions/States to check for compliance with the EBDC actions in the marketplace as part of their routine inspections. A summary of the strategy is attached. We have also included an appendix which lists all of the affected products, the actions taken, and the existing stocks deadlines.

Please transmit the strategy and summary to the States within your Region. If you have any questions on the attached EBDC strategy, please contact Dan Helfgott of my staff at FTS 475-7376.

Attachments

ADDRESSEES

Douglas D. Campt (TS-766C)
Edwin F. Tinsworth (TS-767C)
Anne Lindsay (TS-767C)
Frederick F. Stiehl (LE-134A)
Mark Greenwood (LE-132A)
A. E. Conroy II (EN-342)
Connie Musgrove "
John J. Neylan III "
David Dull "
Mike Wood "
Phyllis Flaherty "
Jerry Stubbs "
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Ken Kanagalingam "
Bob Zisa "
Sherry Sterling "
Jan Bearden "

Jake Mackenzie
Western Regional Compliance Director

I Marvin Rosenstein, Chief
Pesticides & Toxic Substances Br

II Ernest Regna, Chief
Pesticides & Toxic Substances Br

III Larry Miller, Chief
Toxic & Pesticides Branch

IV Richard D. Stonebraker, Acting Chief
Pesticides & Toxic Substances Br

V Phyllis Reed, Chief
Pesticides & Toxic Substances Br

VI Robert Murphy, Chief
Pesticides & Toxic Substances Br

VII Leo Alderman, Chief
Pesticides & Toxic Substances Br

Valerie Jewett
TS-788

VIII Alvin Yorke, Chief
Toxic Substances Branch

IX Davis Bernstein, Chief
Pesticides & Toxics Branch

X Kenneth Feigner, Chief
Pesticides & Toxic Substances Br

cc: Michael Walker (LE-134P)
John Fleuchaus (TS-788)
John Tice (TS-769C)
Artie Williams (H-7508C)
Phil Ross (LE-132A)

SUMMARY OF THE EBDC COMPLIANCE MONITORING STRATEGY

- Ethylene bisdithiocarbamates (EBDCs) are a group of pesticides used to control fungi on a wide variety of fruits, vegetables, ornamental plants, turf grasses, and industrial sites. The EBDC fungicides include mancozeb, maneb, metiram, nabam, and zineb.

MANEB, METIRAM, AND MANCOZEB

- The four technical registrants of EBDCs (DuPont, Pennwalt, Rohm & Haas, and BASF) have amended the registrations for their maneb, metiram, and mancozeb products to delete 42 food crops from most of their technical and end-use labels. Thirteen crop sites will remain.

  - In separate actions, Rohm and Haas has cancelled its maneb registrations, and three other registrants have amended their EBDC registrations consistent with the actions taken by the four technical registrants.

- As of January 1990, the four technical registrants must relabel all of their affected technical and end-use maneb, metiram, and mancozeb products not in the possession of the growers to reflect the deletion of the 42 crops.

  - However, due to an error in the Federal Register Notice, EPA will not enforce label changes required on Pennwalt's maneb and mancozeb products until after the effective date of the revised Federal Register Notice.

NABAM

- Rohm and Haas (the sole registrant holding nabam agricultural food uses) has amended the registrations of their nabam product registrations to delete agricultural food uses. Remaining uses on nabam labels are for use on ornamental plants and industrial sites.

ZINEB

- Micro-Flo Company, the sole registrant of zineb technical product, has cancelled its zineb registrations. Sixteen other registrants have voluntarily cancelled their zineb products as well. Two other registrants have deleted zineb as an active ingredient. The effective dates for the zineb registration amendments and cancellations are listed in Appendix A of the strategy.

INSPECTIONS

- Regions/States are to conduct inspections at the EBDC pesticide producing establishments to assure compliance with the cancellations and to assure that the affected EBDC fungicides are being sold and distributed with the revised labeling required by the amended registrations.

- Inspections at the EBDC registrants' producing establishments are to be completed by June 1, 1990. Regions/States must report to HQ on registrant violations discovered.

  Regions/States are to check for compliance in the marketplace as part of their routine inspection targeting to assure compliance with the cancellations and amended registrations.

viewing at all EPA Libraries and in the EPA RCRA Docket (M2427), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460 from 9:00 a.m. to 4:00 p.m., Monday thru Friday, excluding Federal Holidays, by appointment only. Appointments can be made by calling (202) 475-9327. Copies cost 15 cents per page. In addition, this document is available for purchase through the National Technical Information Service (NTIS), U.S. Department of Commerce, Springfield, Virginia 22161, at (703) 487-4600: Guidance Document on the Statistical Analysis of Ground-Water Monitoring Data at RCRA Facilities. (NTIS # PB89-151-047).

FOR FURTHER INFORMATION CONTACT: For general information contact the RCRA/Superfund Hotline, Office of Solid Waste (WH-563C), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460, telepone (800) 424-9346, or (202) 382-3000.

For technical information contact Jim Brown, (202) 382-4858.

Dated: November 20, 1989.

Christian R. Holmes,

Assistant Administrator for the Office of Solid Waste and Emergency Response.

[FR Doc. 89-28287 Filed 12-1-89; 8:45 am]

BILLING CODE 6560-50-M

[FRL-3693-4]

Center for Environmental Learning Advisory Board; Meeting

AGENCY: EPA Region III.

ACTION: Center for Environmental Learning Advisory Board; Meeting.

SUMMARY: The Director of the Center for Environmental Learning announces a meeting of the Center for Environmental Learning Advisory Board, December 12, 1989, in Washington, DC.

The following agenda items will be discussed:

Review 1989-90 work plan
Discuss national environmental education developments
Review special emphasis projects
Meet new Center for Environmental Learning staff member.

DATE: The meeting will begin at 10 a.m., December 12, 1989, and conclude at noon of the same day.

ADDRESS: The meeting will be in the Capitol Room, Omni Shoreham Hotel, 2500 Calvert Street NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Bonnie Smith, Director, Center for Environmental Learning (C3100), U.S. EPA Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107 (phone [215] 597-9076).

SUPPLEMENTARY INFORMATION: The Center for Environmental Learning will review and modify its 1989-90 agenda based on discussion among Board Members and availability of staff and budget.

Daniel Ryan,

Acting Director, Congressional and Intergovernmental Affairs.

[FR Doc. 89-28288 Filed 12-1-89; 8:45 am]

BILLING CODE 6560-50-M

[OPP-30000/53A; FRL 3683-8]

Ethylene Bisdithiocarbamates: Receipt of Requests To Amend and Cancel Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of receipt.

SUMMARY: This Notice, pursuant to section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*, announces EPA's receipt of requests from registrants of certain technical and end-use EBDC pesticide products to amend their registrations to delete certain uses on food crops. Additionally, from certain other registrants, EPA has received requests that certain EBDC products be voluntarily cancelled. EBDC products affected by these requests contain the following active ingredients: maneb, mancozeb, metiram, nabam, and zineb. Certain of the requests include requests for provisions for the disposition of existing stocks of the affected products. Such provisions are described in the Notice. Additionally, this Notice announces that EPA intends to approve and give effect to these requests, thus as to the respective products, either cancelling such products or amending their registrations to delete certain food crop uses.

EPA's approval will be effective December 14, 1989. As of that date, all future distribution or sale, or use of affected EBDC products shall be in accordance with the terms and conditions described herein.

DATE: The cancellation or modification of registration shall be effective December 14, 1989.

FOR FURTHER INFORMATION CONTACT: Susan T. Lewis, Product Manager (PM) 21, Registration Division (H7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. Office location and telephone number: Room 227, CM #2, 1921 Jefferson Davis Highway, Arlington, VA, 703-557-1900.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Maneb, Metiram, and Mancozeb

As specifically discussed below, on September 6, 1989, the four major registrants of maneb, mancozeb, and metiram technical and end-use pesticide products submitted requests to EPA asking that 42 food crop uses of maneb, mancozeb and metiram be deleted from their product registrations. The registrants involved in these actions are Pennwalt Corporation (mancozeb and maneb), BASF Corporation (metiram), and Rohm and Haas Company, Pennwalt Corporation, and E.I. duPont de Nemours & Company (mancozeb).

In total, these registrants requested that their affected products be registered for no more than a total of 13 food uses. The crops which the registrants by their actions asked be deleted are listed below under each individual chemical.

Along with their requests, the registrants submitted amendments to labeling reflecting the deletion of uses. Additionally, the registrants submitted requests for labeling changes for technical products which would restrict the use of technical or manufacturing use products to formulation of end-use products for use only on one or more of the 13 remaining crops for which the particular parent EBDC continued to be registered.

Included in Unit II.A. is a summary of the text of the individual requests as relates to matters required to be included in this Notice pursuant to section 6(f)(1). Copies of each of the letters have been included in the public docket (OPP-30000/53) which is maintained for EBDC Special Review.

B. Nabam

In March, 1989, Rohm and Haas (the sole nabam registrant holding nabam agricultural uses) requested that all of their nabam food uses be voluntarily cancelled. A summary of the request appears in Unit II.A.; a copy of Rohm and Haas' letter is available through the EBDC Special Review Docket.

C. Zineb

In July, 1989, Microflo Company, the sole registrant of zineb technical product and the sole registrant supporting any uses of zineb, submitted a request to EPA that each of Microflo's zineb product registrations be voluntarily cancelled. A summary of Microflo's request appears below; a copy of the request has been placed in the docket

for the EBDC Special Review. As of this date, sixteen other zineb registrants have requested voluntary cancellation of additional 52 zineb products. Those requests have also been entered into the Special Review docket.

As discussed in Unit II.A., EPA expects to approve each of these requests to amend certain registrations to delete uses or to voluntarily cancel affected registrations and give effect to such actions on December 14, 1989. Additionally, EPA has considered the requests for existing stocks provisions following the effective date of these actions and its determinations are described below.

EPA is continuing its Special Review of the EBDC pesticides and will shortly issue a proposed decision affecting EBDC registered products and uses.

II. Summary of Requests

A. Maneb

On September 8, 1989, Pennwalt Corporation submitted requests to EPA that the following crops be deleted from its maneb product registrations and labels: Peppers, tomatoes, onions, beans, broccoli, cabbage, cantaloupes, watermelon, other melons, cucumbers, squash, apples, spinach, stone fruits, carrots, celery, turnips, cauliflower, Brussels sprouts, collards, mustard greens, kale, rhubarb, lettuce, and Chinese cabbage. As a result of Pennwalt's requests, the following food uses would remain on its maneb labels: almonds, bananas, potatoes, sugar beets, and sweet corn.

Pennwalt submitted applications for pesticide registration for each of its affected products and revised labeling. Revised labeling submitted for end-use products reflected the use deletions; revised labeling submitted for technical products included language that limited the use of the technical product into end-use product formulations for use only on one or more of the retained uses.

Along with its requests to delete uses, Pennwalt indicated that the new labeling would be used on all new products. Additionally, Pennwalt stated its intent not to relabel product currently released for shipment or in channels-of-trade until January 1, 1990. Pennwalt indicated that at that time, all remaining product would be relabled prohibiting the dropped uses. Pennwalt provided a confidential attachment which listed the amount of product in its control as of the date of the letter and an estimate of the amounts that might be used by January. Pennwalt asked that the EPA consider the status of growers near the end of the growing season in issuing a final order for the use deletion and label change.

Pennwalt additionally described a number of actions it intended to seek or undertake, pertaining to tolerance reductions and/or revocations, consumer and user awareness, and integrated pest management.

B. Metiram

BASF submitted similar requests to Pennwalt's on September 6, 1989. In its requests, BASF asked that use on apples be deleted from its metiram registrations and labeling. As a result of BASF's action, the only food use of its metiram products would be on potatoes.

BASF, like Pennwalt as noted above, submitted applications and revised labeling. It included similar language restricting the use of its technical products. BASF indicated that, as of January 1, 1990, "* * * all remaining product not in the hands of growers will be relabeled* * * *"

In other respects, the letters and other submitted materials were similar to the Pennwalt requests outlined above.

C. Mancozeb

On September 6, 1989, both duPont and Rohm and Haas submitted letters to EPA requesting that certain uses be deleted from their product mancozeb registrations and labels. On September 8, Pennwalt submitted similar requests for its mancozeb products. DuPont requested that the following food crop uses by deleted: Apples, crabapple, quince, pears, papayas, pineapple, carrots, celery, fennel, cucumbers, melons, squash (summer and winter), tobacco (plant bed and field), cotton (foliar), field corn, oats, barley, and rye. Rohm and Haas requested that the following crops be deleted: Apples, barley, cantaloupes, carrots, celery, corn (field, hybrid seedcorn), crabapple, cucumbers, fennel, melons, muskmelons, oats, papaya, pears, pineapples, quince, rye, squash, and watermelons. Pennwalt requested that the following food crops be deleted: cucumbers, melons, summer squash, field corn, celery, carrots, apples, pears, crabapple, and quince. As a result of these requests, the three registrants' mancozeb products remain registered for the following uses: asparagus, bananas, cranberries, figs, grapes, onions, peanuts, potatoes, sugar beets, sweet corn, tomatoes, and wheat.

Dupont stated that, as of January 1, 1990, "* * * all remaining saleable product will be relabeled* * * *" Rohn and Haas stated that, as of that date, "* * * all remaining product not in grower's hands will be relabeled* * * *"

In other respects, the letters were similar to the Pennwalt requests which are more fully described above.

D. Nabam

On March 13, 1989, Rohm and Haas submitted to the EPA a request that the food uses of its two registrations for end-use Nabam products be cancelled. Since these products have non-food uses as well, the EPA has interpreted Rohm and Haas's letter as a request that these registrations be amended to delete all food uses. Rohm and Haas indicated that it had not sold any of the product for several years. It indicated that the food uses should be immediately cancelled and did not request any existing stocks provision.

E. Zineb

On July 17, 1989, Micro-Flo Company submitted a request to the EPA that its five zineb product registrations be voluntarily cancelled. It choose this option rather than any which would have indicated an intent to reregister the pesticide products. Micro-Flo did not request an existing stocks provision for any of these products. As of this date, 16 other zineb registrants have requested voluntary cancellation for an additional 52 zineb products. Two of these zineb registrants requested existing stocks provisions.

III. Existing Stocks Determination

The EPA has reviewed the existing stocks and relabeling elements of the four technical registrants' actions and has concluded that registrants of affected maneb, metiram, and mancozeb products may proceed according to the plan they described in their requests for use deletion. The EPA has considered the amounts of stock represented to be in existence and under the control of these registrants and has determined that distribution and sale of these stocks until January 1, 1990, and their use would not be inconsistent with FIFRA. After that date, all product remaining which is not in growers' hands must be relabeled to reflect the use deletions.

Two zineb registrants, Universal Cooperatives and Dexol Industries, requested an existing stocks period. Because all uses of zineb were suspended in July, 1988, and remain suspended, no existing stocks provision is being granted.

Rohm and Haas did not request an existing stocks provision for their nabam product registrations.

IV. Conclusion

EPA has received and expects to approve each of the requests described above effective December 14, 1989, incorporating the requested actions and the decisions governing existing stocks provisions as described above.

V.—List of Affected Registrations

Active ingredient	Registrant	Product No.
Deleted Uses:		
mancozeb	du Pont	352-341
mancozeb	do	352-343
mancozeb	do	352-398
mancozeb	do	352-449
mancozeb	Rohm & Haas	707-078
mancozeb	do	707-093
mancozeb	do	707-102
mancozeb	do	707-156
mancozeb	do	707-162
mancozeb	do	707-179
mancozeb	do	707-180
maneb	Penwalt	4581-225
maneb	do	4581-355
maneb	do	4581-359
metiram	BASF Corp.	7969-70
metiram	do	7969-71
nabam	Rohm & Haas	707-003
nabam	do	707-070
Cancelled Registrations:		
zineb	Rohm & Haas	CT480003
zineb	do	FL780066
zineb	do	KY800015
zineb	do	MD800009
zineb	do	MN830011
zineb	do	MO820011
zineb	do	OR840036
zineb	do	PA790005
zineb	do	PA800015
zineb	do	SC800006
zineb	do	VA800016
zineb	do	707-002
zineb	do	707-072
zineb	Micro-Flo	51036-23
zineb	do	51036-25
zineb	do	51036-62
zineb	do	51036-63
zineb	do	51036-148
zineb	Agway	8590-49
zineb	Chem-Nut	37686-41
zineb	do	37686-57
zineb	Dexol Ind.	192-121
zineb	do	192-146
zineb	FMC Corp.	AZ81001900
zineb	do	GA80001100
zineb	do	KY80001100
zineb	do	MD80001600
zineb	do	OR76002800
zineb	do	OR77006300
zineb	do	PA80001700
zineb	do	KY80001100
zineb	do	MD80001600
zineb	do	OR76002800
zineb	do	OR77006300
zineb	do	PA80001700
zineb	do	SC80001100
zineb	do	VA80001300
zineb	Imperial	746-34
zineb	PBI Gordon	33955-456
zineb	Universal Coop.	1386-75
zineb	do	1386-316
zineb	Wilbur Ellis	OR81003700
zineb	do	WA82006000
zineb	HR McLane	47056-63
zineb	do	47056-78
zineb	do	47056-87
zineb	do	47056-89
zineb	do	47056-90
zineb	do	47056-92
zineb	Holden Corp.	1772-55
zineb	do	1772-74
zineb	Morgro Chem.	42057-73
zineb	Colusa Cnty. Ag.	CA79011101
zineb	do	CA79011102
zineb	Riverside Cnty. Ag.	CA83002900
zineb	The Land, Epcot	FL82006900
zineb	Penn State Univ.	PA76000100

Dated: November 28, 1989.

Linda J. Fisher,

Assistant Administrator for Pesticides and Toxic Substances.

[FR Doc. 89-28289 Filed 12-1-89; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL COMMUNICATIONS COMMISSION

[Gen Docket No. 89-97; DA 89-1433]

Southern California Public Safety Plan

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: The FCC is accepting the Southern California Area's (Region 5's) plan for public safety. By accepting this plan, the FCC enables the licensing of the 821–824/866–869 MHz spectrum for public safety to begin. The Southern California Region is the third of the 55 regions in the National Plan to be accepted.

EFFECTIVE DATE: November 21, 1989.

FOR FURTHER INFORMATION CONTACT: Maureen Cesaitis, Private Radio Bureau, Policy and Planning Branch, Washington, DC 20554, (202) 632-6497.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Order, adopted November 8, 1989, released November 21, 1989, accepting the Southern California Area's Plan for Public Safety. The full text of this Commission action is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street NW., Washington, DC. The complete text of the Order may also be purchased from the Commission's copy contractor, International Transcription Service, (202) 857-3800, 2100 M Street NW., Suite 140, Washington, DC 20037.

Summary of Order

The Chief, Private Radio Bureau and the Chief Engineer have accepted the regional public safety plan for the Southern California Region, Region 5. The Region 5 plan is the third of its kind to be accepted and it represents the culmination of the efforts of the many public safety organizations that participated in its development.

In accepting this plan, the Commission's staff noted that the Southern California Region represented a challenge because of its large growing population and unique terrain. It said it was pleased to see restrictions on antenna heights and transmitter outputs and encouragement of use of special antenna patterns to limit each system's coverage so as to reuse these channels. It said it was especially pleased to see how Region 5 has combined small users into larger, trunked, more efficient systems. The staff said it believed the Region 5 Plan represented a careful balance of the public safety and special emergency mobile communication needs throughout the area and will result in efficient use of the newly allocated spectrum.

In 1987, the Commission established policies and rules for a National Plan for public safety services to ensure that the new six megahertz of public safety spectrum (821–824/866–869 MHz) be used effectively and efficiently for important public safety functions. The Commission established 55 regions and instructed each region to develop a plan for use of the newly allocated spectrum to meet current and future mobile communications requirements of the public safety and special emergency entities operating in the area. After each plan is completed and approved by its regional planning committee, it must be submitted to the Chief, Private Radio Bureau, and the Chief Engineer. After the two Bureau Chiefs have formally accepted a plan, the individual public safety entities can begin applying for licensing in the new 800 MHz spectrum.

Upon release of the full text of the Order, the individual public safety entities in Region 5 may begin applying for licensing in the 821–824/866–869 MHz bands.

Action by the Chief, Private Radio Bureau and the Chief Engineer, November 8, 1989, by Order (DA 89-1433).

Ordering Clauses

It is ordered, That the Southern California Area Plan for Public Safety is accepted, subject to amendments contained in the Order. *It is further*

the risk of seismic activity, and teh effect that this may have on the demonstration. Further review shows that seismic activity is minimal near the Upjohn site, and will pose no danger. Several commentors questioned whether the injection and confining zones were adequate to contain the acidic waste. Review of the expected chemical interactions rock and the injected waste shows that the dissolution of rock will be minor compared to the thickness and amount of rock present. All comments have been considered in making the final decision. A responsiveness summary has been mailed to all commentors and included as part of the Administrative Record relating to this decision.

Conditions

Conditions relating to the exemption may be found in 40 CFR 148.23 and 148.24. In addition, the following conditions must be met:

(1) The combined annual injection volume for Well Numbers 3 and 4 must not exceed 20 million gallons;

(2) The injection zone shall be limited to the Munsing Formation; and

(3) Injection shall only occur into the Mt. Simon Member and into that portion fo the Eau Claire Member which is below 4750 feet.

The permits governing the use of these wells have been modified to impose these conditions on Upjohn.

DATE: This Action is effective as of February 27, 1990.

FOR FURTHER INFORAMTION CONTACT: David Werbach, Lead Petition Reviewer, USEPA—Region 5, telephone (312) 886-4242. Copies of the petition and all pertinent information relating thereto are on file and are part of the administrative record. It is recommended that you contact the lead petition reviewer prior to reviewing the administrative record.

Kenneth A. Fenner,

Acting Director, Water Division.

[FR Doc. 90-5048 Filed 3-5-90; 8:45 am]

BILLING CODE 6560-50-M

[OPTS-140129; FRL-3709-3]

Access to Confidential Business Information by the Cadmus Group, Inc.

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has authorized the Cadmus Group, Inc. (CAD), of Waltham, Massachusetts, and its subcontractor Booz-Allen & Hamilton, Inc. (BAH), of Bethesda, Maryland, for access to information which has been submitted to EPA under section 4 of the Toxic Substances Control Act (TSCA). Some of the information involved may be claimed or determined to be confidential business information (CBI).

DATES: Access to the confidential data submitted to EPA will occur no sooner than March 19, 1990.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Director, TSCA Environmental Assistance Division (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-545, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD: (202) 554-0551.

SUPPLEMENTARY INFORMATION: Under contract number 68-D8-0111, contractor CAD, of 135 Beaver Street, Waltham, MA, and its subcontractor BAH, of 4300 East West Highway, Bethesda, MD, will provide support for the Office of Toxic Substances (OTS) in identification of regulatory and non-regulatory alternatives, regulatory support, and negotiation support. The support may be in the form of conducting meetings, conferences, workgroups, TSCA implementation activities, and identification of emerging issues that could affect OTS programs. Also, CAD and its subcontractor may provide system development support and assist in the review, development of policies; strategies, and plans for EPA toxic substance responsibilities. In addition, CAD and its subcontractor will conduct a census of the toxicological testing in order to access the capacity for EPA under section 4 of TSCA.

In accordance with 40 CFR 2.306(j), EPA has determined that under contract number 68-D8-0111, CAD and its subcontractor will require access to CBI submitted to EPA under section 4 of TSCA to perform successfully the duties specified under the contract. Some of the information involved may be claimed or determined to be CBI.

EPA is issuing this notice to inform all submitters of information under section 4 of TSCA that EPA may provide CAD and its subcontractor access to these CBI materials on a need-to-know basis. All access to TSCA CBI under this contract will take place at EPA Headquarters and BAH's facility located at 4330 East West Highway, Bethesda, MD. CAD and its subcontractor BAH have been authorized access to TSCA CBI at BAH's facility under the EPA "Contractor Requirements for the Control and Security of TSCA Confidential Business Information" security manual. EPA has approved BAH's security plan and has found the facility to be in compliance with the manual.

Clearance for access to TSCA CBI under this contract is scheduled to expire on May 31, 1990.

CAD and subcontractor personnel will be required to sign nondisclosure agreements and will be briefed on appropriate security procedures before they are permitted access to TSCA CBI.

Dated: February 26, 1990.

Linda A. Travers,

Director, Information Management Division, Office of Toxic Substances.

[FR Doc. 90-5046; Filed 3-5-90; 8:45 am]

BILLING CODE 6560-50-D

[OPP-30000/53D; FRL 3712-8]

Ethylene Bisdithiocarbamates; Amendments and Cancellations of Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Amended notice and notice of receipt.

SUMMARY: In the Federal Register of December 4, 1989 (54 FR 50020), EPA issued a notice under section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq., which announced EPA's receipt of requests from registrants of certain technical and end-use ethylene bisdithiocarbamate (EBDC) pesticide products to amend their registrations to delete certain uses on food crops or to voluntarily cancel certain product registrations.

This notice amends the December 4 notice to include several additional crops in the list of those deleted from Pennwalt Corporation's affected maneb registrations and labels, to amend the list of affected product registrations by correcting a Pennwalt maneb registration number, to include affected Pennwalt mancozeb registration numbers which were omitted in the earlier notice, to delete an E.I. duPont de Nemours & Co. mancozeb product which was included by error, and to delete a Morgro zineb product from the list of cancelled registrations and to add it to the list of registrations with deleted uses. All other portions of the December 4 notice pertaining to these products and uses as well as all other products and uses affected by that notice remain the same. The December 4 notice is not amended or otherwise changed in any way for those products not affected by these changes.

In addition, this notice announces EPA's receipt of some additional

requests from registrants of end-use EBDC pesticide products to amend their registrations to delete uses and/or active ingredients or to voluntarily cancel their registrations. The affected registrations include the following: requests for deleted food crop uses for a Griffin Corp. maneb product and for a Ciba-Geigy mancozeb product, requests for voluntary cancellation of six Rohm and Haas Co. maneb products and one Agsco zineb product, and requests to delete the EBDC active ingredient and corresponding fungicidal uses for a Riverdale Chemical Co. maneb product and to delete the EBDC active ingredient from a Chas. H. Lilly zineb product.

The several EBDC products affected by the requests referenced in this notice contain the following active ingredients: maneb, mancozeb, and zineb. Pennwalt's requests include requests for provisions for the disposition of existing stocks of Pennwalt's affected maneb and mancozeb product registrations. Such provisions are described in this notice. This notice announces that EPA intends to approve and give effect to these requests by, as to the particular affected product, cancelling the affected registrations or amending those affected maneb, mancozeb, and zineb product registrations to delete the specified food crop uses or associated uses claims.

With the exception of the registrations of Riverdale Chemical Co. and Chas. H. Lilly Co., EPA expects to approve these requests effective March 16, 1990. As of that date, all future distribution, sale, or use of affected EBDC products shall be in accordance with the terms and conditions described herein. With respect to the Riverdale and Chas. H. Lilly registrations, EPA expects to approve these requests thereafter following completion of review of the companies' submissions.

DATES: The cancellations or modifications of registrations shall be effective March 16, 1990. In the case of the Riverdale and Chas. H. Lilly requests, EPA expects to approve these requests thereafter following completion of review of the companies' submissions.

FOR FURTHER INFORMATION CONTACT: Susan T. Lewis, Product Manager (PM) 21, Registration Division (H7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. Office location and telephone number: Rm. 227, CM #2, 1921 Jefferson Davis Highway, Arlington, VA, 703-557-1900.

SUPPLEMENTARY INFORMATION:

I. Introduction

On September 6 and 8, 1989, the four major registrants of maneb, mancozeb, and metiram technical and end-use pesticide products submitted requests to EPA asking that 42 food crop uses of maneb, mancozeb, and metiram be deleted from their product registrations. The registrants involved in these actions are Pennwalt Corp. (maneb), BASF Corp. (metiram), and Rohm and Haas Co., Pennwalt Corp. and E.I. duPont de Nemours & Co. (mancozeb).

In total, these registrants requested that their affected products be registered for no more than a total of 13 food uses.

Along with their requests, the registrants submitted labeling amendments reflecting the deleted uses. The registrants also submitted requests for labeling changes for technical products restricting the use of the technical or manufacturing use products to formulation of end-use products for use only on one or more of the 13 remaining crops for which the particular parent EBDC continued to be registered.

In March 1989, Rohm and Haas Co., the sole registrant holding registrations for nabam agricultural uses, requested that all of its nabam food uses be voluntarily cancelled.

In July 1989, Microflo Co., the sole registrant of zineb technical product and the sole registrant supporting any uses of zineb, submitted a request to EPA that each of Microflo's zineb product registrations be voluntarily cancelled. As of December 4, 1989, 15 other zineb registrants had requested voluntary cancellation of an additional 51 zineb products. The change in these numbers from the December 4 notice (which listed the numbers as 16 and 52, respectively) is due to the correction of Morgro's zineb product registration status from a cancelled registration to a product with deleted uses.

These requests were described in the **Federal Register** notice of December 4, 1989 (54 FR 50020). Copies of each of the letters have been included in the public docket (OPP-30000/53) which is maintained for the EBDC Special Review.

Several errors were made in the December 4 notice, and those errors are described and corrected below. Since the December 4 notice was published, some additional requests have been processed which are appropriate to be announced pursuant to section 6(f)(1) of FIFRA. This notice includes those requests as well. In all other respects, the December 4 notice remains in effect for the products not affected by this amended notice. Furthermore, the terms and conditions of the December 4 [illegible] are incorporated herein by referen[illegible]

II. Summary of Corrections and Additional Requests

A. Maneb

On September 8, 1989, Pennwalt Corp. submitted requests to EPA that the following crops be deleted from its maneb product registrations and labels: Peppers, tomatoes, onions, beans, broccoli, cabbage, cantaloupes, watermelon, other melons, cucumbers, squash, apples, spinach, stone fruits, carrots, celery, turnips, cauliflower, Brussels sprouts, collards, mustard greens, kale, rhubarb, lettuce, Chinese cabbage, eggplant, endive, grapes, and pumpkins. The latter four crops were inadvertently omitted from the list of deleted crops in the earlier notice. The notice correctly stated that, as a result of Pennwalt's requests, the following food uses would remain on its maneb labels: almonds, bananas, potatoes, sugar beets, and sweet corn. Pennwalt's affected maneb products are EPA Reg. Nos. 4581-255, 4581-355, and 4581-359.

The December 4 notice erroneously listed Pennwalt's EPA Reg. No. 4581-225 as one of the affected maneb products. EPA Reg. No. 4581-225 was cancelled, effective July 1, 1987. The correct product number for the product involved in Pennwalt's request is EPA Reg. No. 4581-255.

On January 8, 1990, Rohm and Haas submitted a request to voluntarily cancel its maneb products. Affected by that request are the following six maneb products: EPA Reg. Nos. 707-48, 707-83, 707-101, 707-103, 707-124, and 707-170. This notice includes these maneb products in the list of cancelled registrations.

On January 8, 1990, Riverdale Chemical Co. submitted a request to amend its product registration, EPA Reg. No. 228-188, by deleting maneb as an active ingredient and by removing claims for the product's use as a fungicide. That product has been registered for use as a miticide, insecticide, and fungicide. EPA construes Riverdale Chemical Co.'s request to remove maneb from its formulation and any associated claims as an amendment to delete the product's fungicidal uses and fungicidal claims while maintaining its registration as a miticide/insecticide. This notice announces EPA's receipt of Riverdale Chemical Co.'s request to amend its product registration and includes that end-use product in its list of affected product registrations. Approval of Riverdale Chemical Co.'s request to

amend its product registration is expected to occur following completion of EPA's review of its submission.

On January 24, 1990, Griffin Corp. (an end-use maneb product formulator) acknowledged that its maneb product, EPA Reg. No. 1812-231, would be affected by the deletion of food uses requested by the maneb technical registrants. Griffin Corp. requested an amendment to its registration deleting the following food uses: apples, grapes, beans, broccoli, cabbage, cantaloupes, watermelon, other melons, cucumbers, eggplant, endive, lettuce, peppers, pumpkins, spinach, squash, and tomatoes. As a result, the above-referenced Griffin Corp. product will remain registered for the following food uses: Almonds, potatoes, sugar beets, and sweet corn. This notice includes this Griffin Corp. maneb end-use product in its list of affected product registrations with deleted uses.

B. Mancozeb

The earlier notice indicated that on September 8, 1989, Pennwalt submitted a letter to EPA requesting that certain uses be deleted from its mancozeb product registrations and labels. Pennwalt requested that the following food crops be deleted: cucumbers, melons, summer squash, field corn, celery, carrots, apples, pears, crabapple, and quince. As a result of that request, Pennwalt's mancozeb products remain registered for the following uses: sugar beets, peanuts, wheat, potatoes, tomatoes, corn (sweet and popcorn), onions, asparagus, cranberries, and grapes. The earlier notice omitted the affected Pennwalt products from the list of affected registrations with deleted uses appearing at the end of the notice. Products included in this amended Notice which should have appeared in the December 4 notice are EPA Reg. Nos. 4581-358 and 4581-370.

The December 4 notice included E.I. duPont de Nemours & Co.'s EPA Reg. No. 352-343 among the list of affected mancozeb products. EPA Reg. No. 352-343 is currently registered for turf use only and was therefore erroneously included among affected products with food uses. That product remains unaffected by any of the requests announced in either this notice or the notice published on December 4, 1989.

On November 28, 1989, Ciba-Geigy (an end-use mancozeb product formulator) acknowledged that its mancozeb product, EPA Reg. No. 100-629, would be affected by the deletion of food uses requested by the mancozeb technical registrants. Ciba-Geigy requested an amendment to its registration deleting the following food uses: cucumbers, melons, and squash. As a result, the above referenced mancozeb Ciba-Geigy product will remain registered for the following food uses: potatoes, tomatoes, and onions. This notice includes this Ciba-Geigy mancozeb end-use product in its list of affected product registrations with deleted uses.

C. Zineb

On October 12, 1989, Agsco submitted a request to voluntarily cancel a zineb end-use product, EPA Reg. No. 554-72. This notice includes this additional zineb product in the list of cancelled registrations.

On August 9, 1989, Morgro submitted a request to amend its product registration, EPA Reg. No. 42057-73, by deleting zineb as an active ingredient and by removing claims for the product's use as a fungicide. That product has been registered for use as a miticide, insecticide, and fungicide. The earlier notice erroneously included Morgro's zineb product registration in its list of cancelled registrations. EPA construes Morgro's request to remove zineb from its formulation and any associated claims as an amendment to delete the product's fungicidal uses and fungicidal claims while maintaining its registration as a miticide/insecticide. This amended notice removes Morgro's zineb product from the list of cancelled registrations and includes it on the list of products with deleted uses.

On May 17, 1989, the Chas. H. Lilly Co. submitted a request to amend its product registration, EPA Reg. No. 802-474, by deleting zineb as an active ingredient. The product was a multiple-active-ingredient product and, therfore, the registration did not require deletion of its food crop uses and remains registered for the following food uses: carrots, corn, cucumbers, melons, summer squash, potatoes, and tomatoes. Although section 6(f) does not require EPA to publish notice of this request because it is neither a request to cancel nor a request to amend to remove uses, EPA has elected to include an announcement of this particular request in this notice. Therefore, this notice includes this Chas. H. Lilly end-use product in its list of affected product registrations. Approval of Chas. H. Lilly's request to amend its product registration is expected to occur following completion of EPA's review of its submission.

III. Existing Stocks Determination

For the purposes of this notice, existing stocks are defined as those stocks which are currently in the United States and which already had been packaged, labeled, and released for shipment, or were in the growers' possession before January 1, 1990. Of the above registrants, only Pennwalt Corp. requested an existing stocks provision for its maneb and mancozeb product registrations. Therefore, EPA was not requested to grant, nor is it granting, any existing stocks provisions for the continued sale and distribution of the other registrants' products. However, product already in the growers' possession may be used until those stocks are exhausted.

As described in the December 4 notice, EPA reviewed the existing stocks and relabeling elements of Pennwalt's request and concluded that Pennwalt could proceed according to the plan it described in its request for use deletions for its maneb and mancozeb products. EPA considered the amounts of stock represented to be in existence in the United States and under the control of this registrant and determined, as described in the December 4 notice, that distribution and sale of those stocks until January 1, 1990, and the use of those stocks in the growers' hands until the stocks were exhausted would not be inconsistent with FIFRA. Pennwalt previously has agreed to relabel, after that date, all product remaining which is not in growers' hands to reflect the use deletions. Therefore, EPA has not granted any additional existing stock provisions for the sale and distribution of Pennwalt EBDC pesticides which do not bear labeling reflecting the use deletions.

IV. Conclusion

Except as explained below, EPA has received and expects to approve each of the requests referenced above effective March 16, 1990, incorporating the requested actions and the decisions governing existing stocks provisions as described above. With respect to Riverdale Chemical Co.'s end-use maneb product registration and Chas. H. Lilly Co.'s end-use zineb product registration, EPA expects to approve the companies' requests to amend their registrations thereafter following completion of EPA's review of their submissions.

V. Amended List of Affected Registrations

Active Ingredient	Registrant	Product Number
Deleted Uses:		
Maneb	Pennwalt	4581 - 355
Maneb	do	4581 - 355
Maneb	do	4581 - 359
Maneb	Griffin	1812 - 251
Mancozeb	Pennwalt	4581 - 358
Mancozeb	do	4581 - 370
Mancozeb	Ciba-Geigy	100 - 629
Deleted Active Ingredient/Changed Uses:		
Maneb	Riverdale Chemical	228 - 188
Zineb	Morgro	42057 - 73
Deleted Active Ingredient/Same Uses		
Zineb	Chas. H. Lilly	802 - 474
Cancelled Registrations:		
Maneb	Rohm & Haas	707 - 48
Maneb	do	707 - 83
Maneb	do	707 - 101
Maneb	do	707 - 103
Maneb	do	707 - 124
Maneb	do	707 - 170
Zineb	Agsco	554 - 72
Registered Product/Status Unaffected:		
Mancozeb	duPont	352 - 343

Dated: February 26, 1990.

Linda J. Fisher,

Assistant Administrator for Pesticides and Toxic Substances.

[FR Doc. 90-5044 Filed 3-5-90; 8:45 am]

BILLING CODE 6560-50-D

[FRL-3729-9]

Further Extention of Time to Either Withdraw the Proposed Determination or Prepare a Recommended Determination for Two Forks Dam and Reservoir.

AGENCY: Environmental Protection Agency.

ACTION: Notice of a further extension of time.

SUMMARY: As announced in the February 6, 1990 Federal Register (55 FR 4009), the EPA extended the 404(c) process to either withdraw the Proposed Determination or prepare a Recommended Determination for the Two Forks Dam and Reservoir until February 28, 1990. Additional time is needed to catalog and review public comments and other documents relevant to the decision. Therefore, EPA has decided under its authority contained at 40 CFR 231.8 to further extend the 404(c) process to either withdraw the Proposed Determination or prepare a Recommended Determination until March 31, 1990.

FOR FURTHER INFORMATION CONTACT: Gene Reetz, Two Forks Team Leader or Mary Alice Reedy, Records Clerk, State Programs Management Branch, Water Management Division, EPA Region VIII, 999 18th Street, suite 500, Denver, Colorado 80202-2405 (303) 293-1570, FTS 330-1570.

Lee A. DeHihns,

Regional Decision Officer EPA Region VIII.

[FR Doc. 90-5047 Filed 3-5-90; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL MARITIME COMMISSION

Agreement(s) Filed

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, DC Office of the Federal Maritime Commission, 1100 L Street NW., room 10220. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the Federal Register in which this notice appears. The requirements for comments are found in § 572.603 of title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Title: Port of San Francisco/Evergreen Marine Corporation Terminal Agreement.

Parties:
Port of San Francisco (Port).
Evergreen Marine Corporation (Taiwan), Ltd. (EMC).

Synopsis: The Agreement provides for EMC to make San Francisco its published regularly-scheduled Northern California port of call. EMC guarantees the Port an annual minimum of 49 vessel calls and an annual minimum thruput of 23,000 20-foot equivalent units, excluding empty containers loaded/discharged from the vessels. In consideration thereof, EMC will pay to the Port discounted dockage and wharfage rates on a sliding scale based on the Port's Tariff No. 3-C.

Title: Virginia Port Authority/Sea-Land Service, Inc. Terminal Agreement.

Parties:
Virginia Port Authority
Sea-Land Service, Inc.

Synopsis: The Agreement revises Paragraph 4A of the basic agreement to indicate that if an option to renew the agreement is exercised, the option will be filed with the Commission as an amendment before it becomes effective.

By Order of the Federal Maritime Commission.

Joseph C. Polking,

Secretary.

Dated: February 28, 1990.

[FR Doc. 90-4957 Filed 3-5-90; 8:45 am]

BILLING CODE 6730-01-M

FEDERAL RESERVE SYSTEM

Robert Angus Connell, et al; Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

MAR 12 1990

COMPLIANCE STRATEGY FOR THE CANCELLATION AND REGISTRATION AMENDMENTS FOR PESTICIDE PRODUCTS CONTAINING ETHYLENE BISDITHIOCARBAMATE (EBDC)

OVERVIEW

Several registrants of ethylene bisdithiocarbamate (EBDC) pesticide products have either voluntarily cancelled their EBDC registrations, amended their registrations to delete a total of 42 crop sites, and/or deleted EBDC as an active ingredient (54 FR 50020; December 4, 1989, and 55 FR 7935; March 6, 1990).

This strategy calls for a limited number of inspections to take place by June 1, 1990, at the EBDC pesticide producing establishments listed in Appendix B to assure that EBDC products are not sold or distributed in violation of the EBDC cancellations and amended registrations. The Environmental Protection Agency (EPA) and States will also check for compliance with the EBDC actions in the marketplace as part of their routine inspections.

BACKGROUND

Ethylene bisdithiocarbamates (EBDCs) are a group of pesticides used to control fungi on a wide variety of fruits, vegetables, ornamental plants, turf grasses, and industrial sites. The EBDC fungicides include amobam, mancozeb, maneb, metiram, nabam, and zineb.

Amobam

In 1986, all amobam registrants voluntarily cancelled their registrations in response to the Agency's request to submit additional data under FIFRA section 3(c)(2)(B). Registrants were allowed to sell and distribute existing stocks of cancelled amobam for one year following the effective cancellation date. Other persons were permitted to sell or distribute existing stocks of amobam until those stocks were exhausted.

Nabam

All nabam agricultural food uses have been suspended since 1985 for failure to submit FIFRA section 3(c)(2)(B) data. In March 1989, Rohm and Haas (the sole registrant holding nabam agricultural food uses) requested that all of the suspended nabam agricultural food uses be deleted from its two nabam pesticide product registrations. The Agency accepted Rohm and Haas' request to delete agricultural food uses from their nabam pesticide registrations effective December 14, 1989 (products listed in Appendix A).

Since 1985, Rohm and Haas and their supplemental distributors have been prohibited from selling or distributing stocks of their suspended nabam. The Agency has not granted Rohm and Haas or their supplemental distributors any additional existing stocks provisions for the sale and distribution of those nabam products which are labeled for agricultural food uses as a result of the recent amended registrations. Persons other than Rohm and Haas and their supplemental distributors may sell and distribute existing stocks of Rohm and Haas' nabam pesticide products labeled for food uses until those stocks are exhausted.

Zineb

Since July 1988, all zineb uses have also been suspended under FIFRA section 3(c)(2)(B). In July 1989, Micro-Flo Company, the sole registrant of zineb technical product and the sole technical registrant supporting any uses of zineb, requested that each of its zineb registrations be cancelled. Sixteen other zineb registrants have since requested voluntary cancellation for an additional 52 zineb products, and two other registrants have deleted zineb as an active ingredient. The affected zineb products and the existing stocks deadlines of each zineb action are listed in Appendix A. The EPA is currently determining whether any of the remaining registrants of suspended end-use zineb products will attempt to support the continued registration of the products.

Since July 1988, registrants and supplemental distributors of suspended zineb have been prohibited from selling or distributing zineb pesticides labeled for agricultural food uses. The Agency has not granted any existing stocks provisions for zineb product which has been subsequently cancelled. Persons other than the zineb registrants and supplemental distributors may sell or distribute existing stocks of those zineb products until those stocks are exhausted.

Mancozeb, Maneb, and Metiram

In September 1989, Pennwalt, Rohm and Haas, BASF, and DuPont requested to delete 42 food crop uses from the registrations of most of their mancozeb, maneb, and metiram technical and end-use pesticide products. Since then, Rohm and Haas has requested to cancel the registrations of their maneb products, and three other registrants have amended their EBDC pesticide registrations consistent with the actions taken by Pennwalt, Rohm and Haas, BASF, and DuPont. The terms of these amended registrations and cancellations are described below in the section of this strategy entitled "Terms of the Maneb, Mancozeb, and Metiram Amended

Registrations and Cancellations." The list of affected products and the existing stocks provisions are summarized in Appendix A.

The only mancozeb, maneb, and metiram registrations which have been amended to delete use on 42 crop sites are products registered to the registrants listed in Appendix A. The supplemental distributors of affected EBDC products of those registrants are also affected by the amended registrations (see Appendix C). Other manufacturers of EBDC pesticide products are not directly required to delete the 42 uses from their product labels. However, Rohm and Haas, Pennwalt, BASF, and Dupont are the sole U.S. registrants of technical maneb, metiram, and mancozeb. The effect of relabeling the technical products is that it will become unlawful for downstream formulators to use the relabeled technical material in end-use products labeled for use on the deleted 42 crop sites.

On December 20, 1989 (54 FR 52158), EPA published a PD 2/3 Special Review document which proposed cancelling the 42 uses the registrants deleted from their EBDC registrations and labels, plus three additional food uses, and certain homeowner and industrial uses. Additionally, all uses of zineb were proposed for cancellation. However, since the PD 2/3 document is not a final cancellation action, this strategy does not call for any inspections to assure compliance with the PD 2/3 Special Review document. The Office of Compliance Monitoring will revise the EBDC Compliance Monitoring Strategy when the EPA publishes the PD 4 Special Review Document and finalizes its action on the EBDC pesticides (sometime in the Spring of 1991).

TERMS OF THE MANEB, MANCOZEB, AND METIRAM AMENDED REGISTRATIONS AND CANCELLATIONS

Under the terms of the amended registrations, Rohm and Haas, DuPont, Pennwalt, and BASF must revise labeling for their affected maneb, metiram, and mancozeb end-use and technical products to delete certain food crop uses. These labeling changes will be required on all new production as well as all existing stocks which are not in the possession of the grower. Further, the revised labeling for the technical products will restrict the formulation of the technical into end-use products registered for use on only one or more of the remaining 13 crops. Therefore, it would be a violation of FIFRA (misuse) for an end-use formulator who obtains an EBDC technical product bearing revised labeling to produce an end-use EBDC product which is labeled with any crop site other than those crop sites retained on the technical product. The registrants will be responsible for making sure that all maneb, metiram, and mancozeb products

released for shipment or in the channels of trade after January 1, 1990, bears appropriate labeling. However, due to the error in the December 4, 1989 Federal Register Notice, the label changes required on Pennwalt's maneb and mancozeb products should not be enforced until after the effective date of the revised Federal Register Notice (55 FR 7935; March 6, 1990).

In addition, Rohm and Haas has requested cancellation of the registrations of their maneb products. Riverdale Chemical Corporation has requested to delete maneb as an active ingredient from one of their products and to remove all associated fungicidal claims from the label of that product (no crop sites need to be deleted). Griffen Corporation has requested to delete certain food uses from its maneb end-use product consistent with the Pennwalt, Rohm and Haas, BASF, and DuPont action. Ciba-Geigy has also requested to delete certain food uses from its mancozeb end-use product consistent with the Pennwalt, Rohm and Haas, BASF, and DuPont action. The EPA has accepted these cancellations and registration amendments effective March 16, 1990 (55 FR 7935). The list of affected products and the existing stocks deadlines for each of these actions are listed in Appendix A.

Below is a summary of the crops which must be deleted from the maneb, metiram, and mancozeb product label and those crops which may be retained:

MANEB

REGISTRANT: Pennwalt Corporation, Riverdale Chemical Corporation, and Griffin Corporation.

DELETED CROPS:
Pennwalt: Peppers, tomatoes, onions, beans, broccoli, cabbage, cantaloupes, watermelon, other melons, cucumbers, squash, apples, spinach, stone fruits, carrots, celery, turnips, cauliflower, Brussels sprouts, collards, mustard greens, kale, rhubarb, lettuce, Chinese cabbage, eggplant, endive, grapes, and pumpkins.
Riverdale: No crops deleted, however, fungicidal uses and fungicidal claims must be deleted from label. Remains registered as a miticide/insecticide.
Griffen: Apples, grapes, beans, broccoli, cabbage, cantaloupes, watermelon, other melons, cucumbers, eggplant, endive, lettuce, peppers, pumpkins, spinach, squash, and tomatoes.

RETAINED CROPS:
Pennwalt: Almonds, bananas, potatoes, sugar beets, and sweet corn. Uses for seed treatment and ornamental crops.
Riverdale: Crops sites unchanged. Remains registered for the same crop sites as a miticide/insecticide.
Griffen: Almonds, potatoes, sugar beets, and sweet corn.

METIRAM

REGISTRANT: BASF Corporation.

DELETED CROPS: Apples.

RETAINED CROPS: Potatoes.

MANCOZEB.

REGISTRANT: Rohm and Haas, DuPont, Pennwalt, and Ciba-Geigy.

DELETED CROPS:
DuPont: Apples, crabapple, quince, pears, papayas, pineapple, carrots, celery, fennel, cucumbers, melons, squash (summer and winter), tobacco (plant bed and field), cotton (foliar), field corn, oats, barley, and rye.
Rohm and Haas: Apples, barley, cantaloupes, carrots, celery, corn (field and hybrid seedcorn), crabapple, cucumbers, fennel, melons, muskmelons, oats, papaya, pears, pineapples, quince, rye, squash, and watermelons.
Pennwalt: Cucumbers, melons, summer squash, field corn, celery, carrots, apples, pears, crabapple, and quince.
Ciba-Geigy: Cucumbers, melons, and squash.

RETAINED CROPS:
Rohm and Haas and Dupont: Asparagus, bananas, cranberries, figs, grapes, onions, peanuts, potatoes, sugar beets, sweet corn, tomatoes, and wheat.
Pennwalt: Sugar beets, peanuts, wheat, potatoes, tomatoes, corn (sweet and popcorn), onions, asparagus, cranberries, and grapes.
Ciba-Geigy: Potatoes, tomatoes, and onions.

EXPORTS

Cancelled EBDC products which are exported after the existing stocks deadlines must comply with the labeling requirements of FIFRA section 17(a)(1), and the export acknowledgement statement requirements of section 17(a)(2). Products which have had their registrations amended to delete crop uses are subject to FIFRA section 17(a)(1).

COMPLIANCE MONITORING

By June 1, 1990, the States, and Regions with States not operating under cooperative enforcement agreements, are to conduct at least one inspection at each of the pesticide producing establishments listed in Appendix B of this strategy to assure that cancelled EBDC products are not sold or distributed by those producers, to assure compliance with the FIFRA section 17 export requirements, and to assure that EBDC products which have had crop sites deleted from their registrations are sold and distributed with the revised labeling required by those amended registrations. Additionally, the Regions/States are to monitor compliance with the EBDC cancellations and amended registrations during routine inspections in the marketplace.

As part of routine inspections, and if not already completed under the FIFRA section 3(c)(2)(B) Compliance Monitoring Strategy, Regions/States should also conduct inspections at establishments that produced nabam, zineb, and amobam to assure that those EBDC pesticides are not sold or distributed in violation of the suspensions, and subsequent amended registrations or cancellations of those products, or export requirements.

The Regions should also check all Notices of Arrival of EBDC pesticides imported into the United States against the list of affected products in Appendix A of this strategy before releasing such products.

Violations

Persons that sell or distribute an EBDC product, which has had its registration amended to delete crop uses, without the revised labeling will be in violation of FIFRA section 12(a)(1)(B), for making claims for a registered pesticide that differ substantially from those made in connection with the pesticide's registration.

Formulators that use relabeled EBDC technical product to produce an end-use product which is labeled with any crop site deleted from the technical product label will be in violation of FIFRA section 12(a)(2)(G), for using a registered pesticide in a manner inconsistent with its labeling.

Any person that sells or distributes a cancelled EBDC product after the existing stocks deadlines is in violation of FIFRA section 12(a)(2)(K) for violation of a cancellation order.

ALLOCATION OF RESPONSIBILITIES

Office of Pesticide Programs

Will develop and provide OCM with a list of affected EBDC products which have had their registrations amended to delete the 42 food crop uses or have otherwise been amended or voluntarily cancelled.

Office of Compliance Monitoring

Will develop and transmit the EBDC Compliance Monitoring Strategy, including the list of affected EBDC products, to the Regions.

Will update the EBDC strategy in accordance with the revised Federal Register Notice.

Regions

Will transmit copies of the Compliance Monitoring Strategy, and any revisions to the strategy to the States.

Will conduct compliance inspections in States without Cooperative Enforcement Agreements as specified in this Compliance Monitoring Strategy, and as needed to respond to tips and complaints.

Will take enforcement actions as appropriate.

Will immediately send information regarding a registrant's violation of the EBDC actions to the Office of Compliance Monitoring/Compliance Division.

Will report to the Office of Compliance Monitoring/Compliance Division; attention Mike Calhoun, by August 1, 1990, on the total number of EBDC inspections, violations observed, and State or Federal actions taken since January 1, 1990.

Will check all Notices of Arrival of EBDC imported pesticides against the list of affected products in Appendix A of this strategy before releasing such products.

States

Will conduct inspections as specified in this Compliance Monitoring Strategy, and as needed to respond to tips and complaints.

Will take enforcement actions, as appropriate.

Will report to the Regions within two weeks of discovering a violation of the EBDC actions by a registrant or producing establishment.

Will report to the Regions, by July 1 1990, the total number of EBDC inspections and violations.

APPENDIX A

LIST OF AFFECTED REGISTRATIONS

ACTION: **Amended Registrations - Deleted Uses.** Products sold or distributed after existing stocks deadline must be relabeled to reflect the amended registration to delete crops.

Active Ingredient	Registrant	Product Number	Existing Stocks Deadline	
			Registrant	Distributor
maneb	Pennwalt	4581 - 255	3/16/90	3/16/90
maneb	Pennwalt	4581 - 355	"	"
maneb	Pennwalt	4581 - 35	"	"
maneb	Griffin	1812 - 25	"	"
mancozeb	Pennwalt	4581 - 358	"	"
mancozeb	Pennwalt	4581 - 370	"	"
mancozeb	Ciba Geigy	100 - 629	"	"
mancozeb	DuPont	352 - 341	12/31/89	12/31/89
mancozeb	DuPont	352 - 398	"	"
mancozeb	DuPont	352 - 449	"	"
nabam	Rohm & Haas	707 - 003	12/14/89	N/D
nabam	Rohm & Haas	707 - 070	12/14/89	N/D
mancozeb	Rohm & Haas	707 - 078	12/31/89	12/31/89
mancozeb	Rohm & Haas	707 - 093	"	"
mancozeb	Rohm & Haas	707 - 102	"	"
mancozeb	Rohm & Haas	707 - 156	"	"
mancozeb	Rohm & Haas	707 - 162	"	"
mancozeb	Rohm & Haas	707 - 179	"	"
mancozeb	Rohm & Haas	707 - 180	"	"
metiram	BASF Corp.	7969 - 70	"	"
metiram	BASF Corp.	7969 - 71	"	"

N/D = No Deadline

ACTION: **Cancelled Registrations.** Cancelled products may not be sold or distributed after the existing stocks deadline (NOTE: sale or distribution of zineb by registrant has been prohibited under a FIFRA section 3(c)(2)(B) suspension since July 1988). All exports after the effective date must comply with FIFRA section 17.

Active Ingredient	Registrant	Product Number	Existing Stocks Deadline Registrant	Distributor
maneb	Rohm & Haas	707 - 48	3/16/90	3/16/90
maneb	Rohm & Haas	707 - 83	"	"
maneb	Rohm & Haas	707 -101	"	"
maneb	Rohm & Haas	707 -103	"	"
maneb	Rohm & Haas	707 -124	"	"
maneb	Rohm & Haas	707 -170	"	"
zineb	Agsco	554 - 72	July 1988	N/D
zineb	Rohm & Haas	CT480003	July 1988	N/D
zineb	Rohm & Haas	FL780066	"	"
zineb	Rohm & Haas	KY800015	"	"
zineb	Rohm & Haas	MD800009	"	"
zineb	Rohm & Haas	MN830011	"	"
zineb	Rohm & Haas	MO820011	"	"
zineb	Rohm & Haas	OR840036	"	"
zineb	Rohm & Haas	PA790005	"	"
zineb	Rohm & Haas	PA800015	"	"
zineb	Rohm & Haas	SC800008	"	"
zineb	Rohm & Haas	VA800016	"	"
zineb	Rohm & Haas	707 -002	"	"
zineb	Rohm & Haas	707 -072	"	"
zineb	Micro-Flo	51036- 23	"	"
zineb	Micro-Flo	51036- 25	"	"
zineb	Micro-Flo	51036- 62	"	"
zineb	Micro-Flo	51036- 63	"	"
zineb	Micro-Flo	51036-148	"	"
zineb	Agway	8590 - 49	"	"
zineb	Chem-Nut	37686- 41	"	"
zineb	Chem-Nut	37686- 57	"	"
zineb	Dexol Ind.	192 - 121	"	"
zineb	Dexol Ind.	192 - 146	"	"
zineb	FMC Corp.	AZ81001900	"	"
zineb	FMC Corp.	GA80001100	"	"
zineb	FMC Corp.	KY80001100	"	"
zineb	FMC Corp.	MD80001600	"	"
zineb	FMC Corp.	OR76002800	"	"
zineb	FMC Corp.	OR77006300	"	"
zineb	FMC Corp.	PA80001700	"	"
zineb	FMC Corp.	KY80001100	"	"

Active Ingredient	Registrant	Product Number	Existing Stocks Deadline Registrant	Distributor
Cancelled Registrations (continued):				
zineb	FMC Corp.	MD80001600	July 1988	N/D
zineb	FMC Corp.	OR76002800	"	"
zineb	FMC Corp.	OR77006300	"	"
zineb	FMC Corp.	PA80001700	"	"
zineb	FMC Corp.	SC80001100	"	"
zineb	FMC Corp.	VA80001300	"	"
zineb	Imperial	746 - 34	"	"
zineb	PBI Gordon	33955-456	"	"
zineb	Universal Coop.	1386 - 75	"	"
zineb	Universal Coop.	1386 -316	"	"
zineb	Wilbur Ellis	OR81003700	"	"
zineb	Wilbur Ellis	WA82006000	"	"
zineb	HR McLane	47056 - 63	"	"
zineb	HR McLane	47056 - 78	"	"
zineb	HR McLane	47056 - 87	"	"
zineb	HR McLane	47056 - 89	"	"
zineb	HR McLane	47056 - 90	"	"
zineb	HR McLane	47056 - 92	"	"
zineb	Holden Corp.	1772 - 55	"	"
zineb	Holden Corp.	1772 - 74	"	"
zineb	Colusa Cnty. Ag.	CA79011101	"	"
zineb	Colusa Cnty. Ag.	CA79011102	"	"
zineb	Riverside Cnty. Ag.	CA83002900	"	"
zineb	The Land, Epcot	FL82006900	"	"
zineb	Penn State Univ.	PA76000100	"	"

ACTION: **Amended Registrations - Deleted Active Ingredient and Uses.** Products sold or distributed after the existing stocks deadline may not contain the deleted active ingredient, and must be relabeled to reflect the uses and active ingredient deleted from the registration.

maneb	Riverdale Chemical	228 - 188	3/16/90	N/D
zineb	Morgro	42057- 73	"	"

ACTION: **Amended Registrations - Deleted Active Ingredient, Uses Unchanged.** Products sold or distributed after the existing stocks deadline may not contain the deleted active ingredient, and must be relabeled to reflect the deleted active ingredient.

zineb	Chas. H. Lilly	802 - 474	3/00/90	N/D

APPENDIX B

LIST OF EBDC PRODUCING ESTABLISHMENTS

Region III

Agway Inc.
980 Locks Mill Rd.
York, PA 17402
mancozeb - #100-629 Ridomil MZ58

Central Chemical Corp.
PO Box 309
Elkton, MD 21921
mancozeb - #707-078 Dithane M45
#707-093 Dikar
maneb - #707-048 Dithane M22

Dragon Corp.
7033 Walrond Dr.
Roanoke, VA 24019
maneb - #707-048 Dithane M22

DuPont Co.
Agricultural Products Dept.
Wilmington, DE 19898
mancozeb - #352-449 Manzate 200 DF

Rohm & Haas Delaware Valley, Inc.
5000 Richmond St.
Philadelphia, PA 19137
mancozeb - #707-156 Dithane M45
maneb - #707-170 Dithane Flowable

Region IV

FMC Corp.
1200 Tallyrand Ave.
Jacksonville, FL 32206
mancozeb - #707-078 Dithane M45
maneb - #707-083 Dithane M22

Griffin Corp.
Rocky Ford Rd.
Valdosta, GA 31601
mancozeb - #352-398 DuPont Manzate 200
maneb - #1812-251 Manex Maneb Flowable

Micro Flo Co.
Highway 41 North
Sparks, GA 31647
zineb - #51036-062 Zineb 75WP

Red Panther Chemical Co.
PO Box 550
Clarksdale, MS 38614
zineb - #1386-075 Unico Garden Spray
#51036-062 Zineb 75WP

Sunniland Corp.
US Hwy. 17
Sanford, FL 32771
maneb - #707-170 Dithane Flowable

Sureco, Inc.
East Main St.
Fort Valley, GA 31030
zineb - #707-002 Staffel's Dithane 278
mancozeb - #352-449 Manzate 200 DF
maneb - #707-048 Dithane M22

Region V

Universal Cooperatives, Inc.
PO Box 471
Napoleon, OH 43545
zineb - #1386-316 Unico Garden Dust

Region VI

Central International Corp.
Farm Road 1101
Liberty, TX 77575
mancozeb - #707-093 Dikar

Pennwalt Corp.
201 W. Dodge St.
Bryan, TX 77801
maneb - #4581-359 Muneb 4F

Region VII

Imperial Inc.
West Sixth & Grass Sts.
Shanandoa, IA 51601
zineb - #746-034 New MFA Multi-Spray

PBI-Gordon Corp.
300 S. Third St.
Kansas City, KS 66118
zineb - #33955-456 Acme Tomato & Vegetable Dust

Region VIII

AGSO Inc.
Mill Rd.
Grand Forks, ND 58201
zineb - #554-072 AGSO Dustret

MorGro Chemical Corp.
145 W. Central Ave.
Salt Lake City, UT 84115
zineb - #42057-073 MorGro Soil & Bulb Dust

Region IX

Dexol Industries
1450 W 228th St.
Torrance, CA 90501
zineb - #707-002 Staffel's Dithane 278
#192-146 Dexol Zineb

Region X

Chas. H. Lilly Co.
7737 N.E. Killingsworth
Portland, OR 97218
zineb - #42057-073 MorGro Soil & Bulb Dust
#802-474 Lilly/Miller Vegetable Dust

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
SYSTEMS BRANCH
SUBJECT: DISTRIBUTOR MASTER IMAGE(S) FOR REQUESTED COMPANY

EPA REGISTRATION	PRODUCT DISTRIBUTOR NUMBER	ACCESSION NUMBER	PRODUCT NAME	DATE OF APPLICATION	DATE OF APPROVAL	DATE OF CANCELLATION	REASON CODE
000352-00341	034704	0164051	CLEAN CROP MANCOZEB 80WP FUNGICIDE	870409	000000	000000	
000352-00341	034704	0166382	CLEAN CROP MANCOZEB 80WP FUNGICIDE	870602	000000	000000	
000352-00398	001812	0170605	MANEX II	880201	000000	000000	
000352-00398	034704	0164050	CLEAN CROP MANCOZEB 4L FUNGICIDE	870409	000000	000000	
000352-00398	034704	0166383	CLEAN CROP MANCOZEB 4L FUNGICIDE	870602	000000	000000	
000352-00449	010404	0168287	LESCO MANCOZEB DG FUNGICIDE	871117	000000	000000	
000707-00002	000004	0031050	ZINEB 75%	770225	770315	000000	
000707-00002	000016	0069726	DRAGON ZINEB WETTABLE GARDEN FUNGICIDE	790810	790810	000000	
000707-00002	000192	0033902	DEXOL ZINEB GARDEN FUNGICIDE	770419	770428	000000	
000707-00002	000769	0022365	SECURITY ZINEB SPRAY	760630	760729	000000	
000707-00002	003286	0033901	STAFFEL'S DITHANE Z-78	770419	770426	000000	
000707-00002	009205	0060981	SKOOT	781026	781128	000000	
000707-00002	010873	0044771	TIFCHEM 75% ZINEB	771108	771130	000000	
000707-00078	000070	0079607	MANCOZEB AGRICULTURAL FUNGICIDE	800418	800418	000000	
000707-00078	009404	0074045	SUNNILAND DITHANE M-45	791120	800207	000000	
004581-00359	002935	0155330	WILBUR-ELLIS MANEB PLUS ZINC F4 FUNGICIDE	860521	860512	000000	
004581-00359	034704	0156167	CLEAN CROP MANEB 4L PLUS ZINC	860611	860527	000000	
007969-00070	034704	0184563	CLEAN CROP POLYRAM 80 DF	890606	000000	000000	

18 RECORDS PRINTED

LIST OF SUPPLEMENTAL REGISTRATIONS FOR THE EBDC PRODUCTS OF ROHM AND HAAS, PENNWALT, DUPONT, AND BASF

APPENDIX C

000004	BONIDE CHEMICAL CO. INC.	2 WURZ AVE.	YORKVILLE NY	13495
000016	DRAGON CORPORATION	PO BOX 7311	ROANOKE VA	24019
000070	WILBUR-ELLIS COMPANY	BOX 16458	FRESNO CA	93755
000192	DEXOL INDUSTRIES	1450 W 228TH ST	TORRANCE CA	90501
000769	SURECO, INC.	BOX 938	FORT VALLEY GA	31030
001812	GRIFFIN CORPORATION	BOX 1847	VALDOSTA GA	31603
002935	WILBUR ELLIS CO.	191 W SHAW AVENUE SUITE #107	FRESNO CA	93704
003286	ESCO DISTRIBUTOR INC.	301 1/2 STAPLES ST. BOX 6467	CORPUS CHRISTI TX	78411
009205	AGRO-CHEM INC	11150 W. ADDISON	FRANKLIN PARK IL	60131
009404	SUNNILAND CORPORATION	200 OAK AVENUE - P. O. BOX 1697	SANFORD FL	32771
010404	H. R. MCLANE, INC.	7210 S.W. 57TH AVENUE SUITE 212	MIAMI FL	33143
034704	PLATTE CHEMICAL COMPANY	419 18TH ST. (80631) BOX 667	GREELEY CO	80632

12 RECORDS PRINTED

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

Oct. 6, 1983

MEMORANDUM

OFFICE OF
GENERAL COUNSEL

SUBJECT: Indemnification Claims for Suspended EDB Products

FROM: Cara S. Jablon, Attorney
Marcia Mulkey, Attorney
Office of General Counsel
Pesticides and Toxic Substances Division

TO: William Miller
Product Manager
Registration Division
Office of Pesticide Programs

On September 28, 1983, the Administrator issued an emergency suspension order for the soil fumigation use of EDB, as well as a notice of intent to cancel registration of that use, and other major uses, of EDB. We expect that indemnification claims will be filed for the suspended products registered for the soil fumigation uses, pursuant to section 15 of FIFRA. The purpose of this memorandum is to provide you with information on procedures for filing such indemnification claims to enable you to respond to the requests for information regarding the filing of such claims.

Section 15 of FIFRA clearly provides that an indemnification claim following a suspension order does not ripen until the registration of the pesticide is cancelled "as a result of a final determination that the use of such pesticide will create an imminent hazard." Thus, until the cancellation becomes effective for the soil fumigation use of EDB (either at the end of the statutory 30-day period if no hearing request is received, or, in the event of cancellation hearings, when a final Agency cancellation order is issued following the hearings), no claims for indemnification are appropriate. Note that each registered product is treated independently regarding the issue of whether the cancellation is final, i.e., if a registrant does not contest the cancellation action for a given product, the cancellation is final for <u>that</u> product even though other registrants have requested a hearing to challenge the Agency's action for their registered products.

Furthermore, a claim may only be submitted on behalf of a person who owned the pesticide <u>before</u> the suspension order was issued, and who suffered losses by reason of the suspension or cancellation of the registration. To satisfy the loss criterion,

the claimant should establish that he made reasonable efforts to mitigate his losses, e.g., by attempting to resell his product for non-suspended uses. The statute also provides that the amount of the indemnification payment is based on the cost of the pesticide; thus the Agency is not necessarily bound to pay the full cost, but could pay some percentage of the cost. */ Finally, note that the Agency has previously taken the position that intrastate products do not qualify for indemnification under the statute.

Following is a check list of information to convey to potential claimants who inquire regarding indemnification procedures:

1. Explain that a claim for indemnification will not be reviewed by the Agency until the product has been cancelled, and that each registrant is on a separate track as to whether his product has been cancelled.

2. A claim must be submitted on behalf of the person who owned the pesticide before the suspension order was issued.

3. The indemnification claim should be sent to William Miller, Rm. 211, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, Virginia.

4. EPA does not have a specific indemnification form.

5. The claimant should submit a notarized affidavit which addresses the following:

   a. the fact that the claimant was the owner of the pesticide before the suspension order,

   b. the date of purchase and quantity of the pesticide for which indemnification is sought,

   c. the cost of the pesticide, including documentation to establish the basis for the alleged cost,

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*/ Note that the statute provides that the Agency has an affirmative defense against indemnification claims where the owner of the pesticide "had knowledge of facts which, in themselves, would have shown that such pesticide did not meet the requirements of section 3(c)(5) for registration", and "continued thereafter to produce such pesticide without giving timely notice of such facts to the Administrator".

d. the steps taken by the claimant to reduce his losses, e.g., efforts to sell his product for non-suspended/non-cancelled uses,

e. the fact that he did not have knowledge of facts, which, in themselves, would have shown that the pesticide did not meet the registration requirements of FIFRA section 3(c)(5), and

f. any trade secrecy claims which he wishes to make regarding the information contained in his affidavit.

We strongly advise you not to express any views on behalf of EPA regarding the circumstances under which the Agency is likely to pay indemnification or the amount of indemnification the Agency is likely to pay. Please refer all legal questions regarding indemnification to Alice Wegman in the Office of General Counsel at 382-7505.

cc. Edwin Johnson
Richard Johnson
Paul Lapsley
Barbara Paul
Louis True
William Wells

United States
Environmental Protection
Agency

Office of
Public Affairs (A-107)
Washington, DC 20460

EPA EDB Facts

February 3, 1984

EPA Decision 2/3/84

INTRODUCTION

The Environmental Protection Agency has concluded that the major uses of the pesticide ethylene dibromide (EDB) should halt, because the risks posed by continued use outweigh the benefits to society. The Agency began the process of removing EDB from the marketplace in September 1983 by issuing an emergency suspension of the sale and distribution of EDB for soil fumigation uses, and initiating cancellation for fumigation of stored grain, spot fumigation of milling machinery and quarantine fumigation of citrus and tropical fruits. At the same time, the Agency noted that the nonsuspended uses, such as grain fumigation, might pose unreasonable risks through dietary exposure, but that information to resolve that question was inadequate. Accordingly, EPA arranged for the U.S. Department of Agriculture and the Food and Drug Administration to sample a variety of food commodities for EDB residues. A number of states have reported residue findings in grainbased foods as have food industry and trade associations. EPA's Administrator wrote to governors requesting the States assistance in clarifying the extent of EDB use and the occurrance of residues in foods.

As a result of these sampling activities and an evaluation of the residue levels reported, on February 3, 1984, the Agency announced additional actions designed to hasten the elimination of public exposure to EDB through its use on food commodities. These actions will ensure adequate health protection during the interim period necessary to cancel uses and eliminate EDB residues from the food chain. These specific actions are:

ACTIONS

- An emergency suspension of EDB for fumigation of stored grain and grain milling machinery. The suspension order halts the sale, distribution and actual use of EDB products for these purposes.

- Announcement of recommended maximum acceptable levels of EDB residues in three categories of grain-based foods: raw grain intended for human consumption (900 ppb); consumer products requiring further preparation (150 ppb); and ready-to-eat products (30 ppb).

- Initiating actions to remove impediments to Federal enforcement of the recommended levels. These actions

include revoking the existing exemption from tolerance requirements for residues of EDB resulting from grain fumigation, and 2 revoking tolerances for inorganic bromi resulting from EDB fumigation of grain and other commodities.

The decisions on February 3 do not include further regulatory actions on the use of EDB fumigation of citrus and tropical fruits. The Agency has concentrated its information gathering and evaluation efforts on grain as the principal cause of nationwide concern about dietary exposure to EDB. The use of EDB to meet domestic and international quarantine requirements for fresh citrus and tropical fruit involves issues quite different from the grain uses. The Agency will be carefully studying the quarantine situation in the next several weeks, and further regulatory decisions on these uses of EDB may be necessary.

GRAIN

The use of EDB on stored grain and the "spot" fumigation of grain milling machinery both contribute residues to the American diet and EPA's objective is to eliminate this source of EDB exposure. The February 3 emergency suspension action immediately stops these uses and is designed to hasten the eventual elimination of EDB from the food chain. However, as a practical matter, EDB residues exist in grain at every production stage from stored grain on farms to products on store shelves, and may take several years to move through the channels of trade. Thus, recommended maximum acceptable levels of EDB in various foods are necessary during this interim period both to ensure adequate public health protection and to avoid unnecessary disruption of the food supply.

Risks

The primary concern about the dietary risks of EDB is for chronic effects of long term exposure, such as cancer, and not for an immediate or short term toxic effect. Because cancellation proceedings are already underway, the goal of immediate suspension is to minimize further exposure during the next several years.

EDB has been used as a grain fumigant for many years, and the population has been exposed from this source for several decades. Average consumption of EDB appears to have been decreasing in the past year because EPA's concerns about the chemical have prompted some voluntary movement to alternatives. The February 3 suspension will hasten the decline in exposure. The levels EPA is now recommending are designed to drive down the average dietary burden of EDB to near zero over a three year period.

Maximum Permissible Levels

The Agency is recommending maximum acceptable residue levels for three different kinds of grains and grain products to reflect the fact that commercial processing and cooking of foods reduce EDB residue levels. For example, analyses of cooked grain-based products show reductions of 80% to 95% of EDB residues. Thus, setting

the raw grain intended for human consumption acceptable level at 900 parts per billion (ppb) helps to ensure that processed foods requiring further cooking can be below the 150 ppb level, and that ready-to-eat products will be below the 30 ppb maximum acceptable level. These levels in foods pose acceptable low health risks for an interim exposure of 3 to 5 years and take into account the quantity of different foods in the average diet, as well as the quality, quantity and price of foods available. Consistent with the legal requirements for setting residue levels, the Agency has tried to strike the right balance between health protection and economic consequences affecting food consumption. There will be some economic impacts due to grain or food products with unacceptable levels of EDB being withdrawn from the market.

Enforcement

The Agency's recommended maximum acceptable levels for EDB are not presently enforceable at the federal level because there is an exemption from tolerance requirements for EDB in grains still in effect. This exemption dates from 1956 when by analytical standards of the day, no residue was expected or detected as a residue from EDB fumigation. The Agency is revoking this exemption through rulemaking procedures. Rulemaking can become effective in as little as 30 days, but requests for additional review can delay the process by as much as a year.

For Federal enforcement purposes, EPA establishes tolerances or recommends action levels. These levels are enforced by the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (for meat and poultry) which sample both domestic and imported produce and may withhold shipments of food which violate residue levels. In general, FDA attempts to conduct sampling at a point in the distribution system before products are dispersed to the retail level, and to sample batches representative of an entire lot rather than single product containers.

Individual states may have authority to enforce food quality standards of their own and they might use EPA recommended maximum acceptable levels or not. For example, the State of Florida has recently taken action against food products on the basis of any residues above 1 ppb, the limit of detection for EDB.

The emergency suspension of grain uses of EDB raises the related issues of what to do with grain already treated, and what to do with EDB grain fumigation products. We know that EDB residues dissipate over time. Therefore, EPA recommends that recently fumigated grain be held for at least 90 days before shipment, to help ensure meeting acceptable residue levels. Since the new suspension order includes a requirement to immediately halt the use of EDB, no further fumigation should occur on farm, in transit, in commercial storage or in milling operations.

EPA will request registrants of suspended EDB pesticides to identify and recall products down to the retail level of distribution. All owners of these suspended products, including end-users, may apply for indemnification upon final cancellation of the products.

Alternatives

The principal alternatives to EDB for grain fumigation are: carbon tetrachloride by itself, and in combination with carbon disulfide and ethylene dichloride (EDC); methyl bromide; and phosphide gas released by aluminum or magnesium phosphide. The phosphide products are toxic acutely and thus require extreme care in handling. They are restricted to use by certified applicators, but are not known to pose any chronic health hazards from dietary residues. Carbon tetrachloride is under EPA review as a potential carcinogen, although its risks do not appear to be as significant as EDB. Methyl bromide and EDC also have preliminary indications of adverse chronic effects such as genetic mutations. These three chemicals will be further evaluated by EPA for possible regulatory action.

CITRUS AND TROPICAL FRUITS

The Agency's September 1983 decision on EDB as a quarantine treatment for citrus and tropical fruits was to cancel the use effective September 1, 1984. This phase-out period reflects the fact that both the availability and acceptability of alternative quarantine treatments need to be clarified. The Agency feels that more information on residues, alternatives, and international trade must be carefully considered. The additional several weeks necessary to gather further information and consult with other agencies will not pose a signficant increment of risk to the public.

Both the purpose and amount of EDB used for quarantine treatment differ from the grain uses.

- Quarantine requirements for citrus and tropical fruits prevent the spread of potentially devastating infestations of several species of fruit flies. We require most fresh citrus and tropical fruits shipped into the mainland U.S. to be fumigated with EDB. Japan requires U.S. fresh citrus to be treated with EDB. Some fruits shipped within the U.S. to Texas, New Mexico, Arizona, and California must also be fumigated. Thus, decisions on EDB potentially affect imports from Latin American, Caribbean and Mediterranean nations, exports to Japan and interstate commerce.

- There will probably not be any single alternative to replac EDB. Alternatives being developed may prove acceptable and feasible for some, but not other quarantine requirements. Alternatives include: gamma irradiation; fumigation with methyl bromide or phosphine gas; cold treatment and heat treatment.

- Fresh citrus and tropical fruit comprise less than 2% of the average diet, compared to over 10% for grain.

- Only a small percentage of all citrus consumed in this country is treated with EDB. Of the 5.8 billion pounds citrus consumed, about 40 million pounds is imported fre fruit (most fumigated) and about 55 million pounds is fumigated for domestic interstate quarantine. This is about 2% of the total consumed.

- Unlike grain, ending the use of EDB on citrus and tropical fruit will result in a very fast elimination of residues from the food chain, because only fresh fruit is fumigated and it moves rapidly through the channels of trade.

- Use of methyl bromide on some domestic, interstate shipments and changes of U.S. crop estimates due to intense cold have greatly curtailed EDB use this year for domestic production.

- Citrus intended for processing into juice is not fumigated.

In the coming weeks, the Agency will be gathering further information from the Food and Drug Administration on EDB residues in imported citrus. We will also be consulting with USDA, the Department of State, the Department of Commerce, the Agency for International Development and the Office of the U.S. Trade Representative on the economic ramifications of alternative quarantine requirements for both imports and exports. The Agency will closely monitor EDB residues in citrus to determine further measures needed to reduce dietary exposure from this source.

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

FEB - 6 1984

OFFICE OF
PESTICIDES AND TOXIC SUBST

MEMORANDUM

TO: Addressees

SUBJECT: EDB Emergency Suspension of Products Registered for Use as a Grain Fumigant or Spot Fumigant of Grain Milling Machinery

On February 3, 1984, the Administrator signed an Emergency Order suspending the registrations of all EDB products registered for use as a grain fumigant and spot fumigant for grain milling machinery. This action follows the September 28, 1983 Notice of Intent to Cancel Registrations of Pesticide Products Containing EDB.

I am attaching the strategy document and other background materials to aid you and the States in operating the compliance monitoring/enforcement programs related to these two actions. Specifically these attachments are:

1. Emergency Suspension Order
2. Compliance Monitoring Fact Sheet
3. EPA Press Release
4. OPP Fact Sheet
5. Administrator's Statement
6. Enforcement Strategy
7. Indemnification Memo
8. List of Parties Appealing the September 28, 1983 Cancellation Order
9. List of active registrations for grain and spot fumigation
10. Copy of package sent to EDB users
11. Sample of letter sent to active registrants
12. Sample of letter sent to persons whose registrations were cancelled per September 28, 1983 Cancellation Order
13. Master list of all registrants prior to Cancellation

You should forward pertinent materials to the States and work closely with them to implement the EDB compliance/enforcement programs.

The enforcement and compliance monitoring of the Emergency Suspension order in particular, is a top priority of the Agency. Regions shall work with the states to readjust state priorities to ensure a vigorous enforcement presence in this area. David Stangel (FTS-382-7856) of my staff will answer any questions you or the States may have regarding the order or compliance program implementation.

A. E. Conroy II

A. E. Conroy II, Director
Compliance Monitoring Staff
Office of Pesticides and Toxic Substances

Attachments

2-6-84

STRATEGY FOR COMPLIANCE/ENFORCEMENT OF THE EMERGENCY SUSPENSION OF ETHYLENE DIBROMIDE (EDB)

Scope

On February 3, 1984, the Administrator of EPA signed an order immediately suspending the registrations of EDB for use in grain fumigation and spot fumigation of grain milling machines.

This Emergency Suspension Order has two effects:

(1) it prohibits the distribution, sale and movement of any EDB-containing pesticide product labeled for use as a grain fumigant or fumigant for grain milling equipment, and

(2) it prohibits the use by any person of a pesticide product containing ethylene dibromide on grain or grain milling equipment.*

Impact

The February 3, 1984 action does not affect the September 28, 1983 Emergency Suspension Order for EDB soil fumigant products.

The February 3, 1984 Emergency Suspension Order imposes restrictions beyond the September 28, 1983 Notice of Intent to Cancel EDB products for grain fumigation and spot fumigation of grain milling machines. The Emergency Suspension Order, unlike the Notice of Intent to Cancel, specifically prohibits persons from using stocks of EDB products in their possession for grain fumigation and spot fumigation of grain milling machines.

The Emergency Suspension Order does not affect the other EDB uses covered in the Notice of Intent to Cancel; i.e. post harvest quarantine fumigation, felled log fumigation, and specified minor uses.

Appendix I summarizes the status of various types of EDB products.

Regulated Industry

The Emergency Suspension Order dated February 3, 1984, involves 16 products and 7 registrants. The registrants are located in 4 States.

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*/ This prohibition, unlike the September 28, 1983 emergency suspension of EDB soil fumigation products, extends to products in the possession of end users .

The September 28, 1983 Notice of Intent to Cancel affected 54 EDB grain or grain machinery fumigation products of 23 registrants. Those registrants who appealed the Notice of Intent to Cancel retained registration of their products pending a hearing. The 16 products of 7 registrants now subject to the Emergency Suspension Order are the products whose cancellation was appealed. These products are subject to a formal recall and are eligible for indemnification.

Registrants who failed to appeal the Notice of Intent to Cancel had their product registrations cancelled. Their products will be subject to a voluntary recall but are not eligible for indemnification.

Appendix II contains a list of these registrants.

Information on the numbers of distributors and users affected by the Emergency Suspension Order will be sent to the Regions.

Enforcement

Objective

The primary objective of this compliance/enforcement strategy is to assure compliance with the emergency suspension order signed February 3, 1984.

The strategy, however, also addresses the voluntary recall of EDB products for use in grain fumigation and spot fumigation of grain milling machines whose registrations were voluntarily cancelled in response to the September 28, 1983 Notice of Intent to Cancel.

Violations Associated with Enforcement of the Emergency Suspension Order

Violation of the Emergency Suspension Order

Under Section 12(a)(2)(J) of FIFRA it is unlawful for any person to violate any Suspension Order issued under section 6. Variations of this violation include distribution/sale of any product labeled for any use covered by the Emergency Suspension Order and use of a product in violation of the Order.

Violation of a Stop Sale Use and Removal Order (SSURO)

Under section 12(a)(2)(I) of FIFRA it is a unlawful for any person to violate any SSURO issued under section 13.

Failure to Maintain Reports Required

Under section 12(a)(2)(B) of FIFRA, it is unlawful for a registrant to fail to maintain reports required by FIFRA. If a registrant does not have records required by section 8 of FIFRA regarding EDB products such as records on the movement of EDB products or the identity of the consignee, he is in violation of FIFRA.

Inspection Scheme

EPA attaches a high priority to enforcement of the EDB Emergency Suspension Order. Therefore, the States and the affected Regions should modify their established priorities to include inspections to monitor compliance with the Order.

The following ranking reflects the priority which should be given to inspections affected by the Order:

Priority 1 - Inspection of registered EDB producing establishments

Priority 2 - Inspection of EDB users

Priority 3 - Inspection of EDB distributors

Because of the small number of registrants, all registered EDB producing establishments should be inspected immediately.

Because the number of users is so large, the Regions should work with the States to develop an appropriate inspection targetting scheme.

The Regions should also work closely with the States to develop a targetting scheme for distributors after receiving information requested in both the formal and voluntary recalls.

Pertinent factors such as size or history of violation should be used to rank users and distributors for prior to random selection for inspection. The greater number of inspections should be targetted at users.

Roles and Responsibilities

Office of Pesticide Programs (OPP), EPA

° OPP will prepare a letter to each registrant citing the products affected by the Emergency Suspension Order dated February 3, 1984.

° OPP will review the current CMS list of registrants affected by the September 1, 1983 and February 1984 actions to assure its accuracy.

° OPP will provide CMS with a list of those products which are now finally cancelled because no hearing was requested in response to the Notice of Intent to Cancel of September 28, 1983.

Compliance Monitoring Staff (CMS)

° CMS will mail by certified mail a package to each registrant subject to the Emergency Suspension Order dated February 3, 1984. The package will contain:

1) OPP's letter to registrants

2) A copy of the Emergency Suspension Order

3) Stop Sale, Use, Removal Order (SSURO) for products covered by the Emergency Suspension Order dated February 3, 1984

4) A letter formally requesting that registrants recall their products

° CMS will send a letter to EDB users affected by the Emergency Suspension Order including a SSURO and a list of affected products.

° CMS will also send a letter requesting voluntary recall to registrants with EDB grain or grain machinery fumigant products cancelled because of failure to appeal the September 28, 1983 Notice of Intent to Cancel.

° CMS will send an informational package to the Regions containing:

1) A memorandum prepared by CMS transmitting to the Regions necessary background information for the February 3, 1984 Emergency Suspension compliance/enforcement program and information necessary to monitor the voluntary recall for products cancelled under the September 28, 1983 Notice of Intent to Cancel.

2) A copy of this Strategy.

3) A copy of the Emergency Suspension Order.

4) Fact Sheets prepared by OPP and CMS

5) Press release

6) Administrator's statement

7) OGC memo governing indemnification

8) List of parties appealing the September 1983 Notice of Intent to Cancel and subject to the Emergency Suspension Order

9) List of active registrations for grain and spot fumigation

10) Copy of package sent to EDB users

11) Sample of letter sent to active registrants

12) Sample of letter sent to persons whose registrations were cancelled per the September 28, 1983 Notice of Intent to Cancel

13) Master list of all registrants prior to cancellation

° CMS will send the Regions a preliminary list of users for further distribution to States as soon as it becomes available.

° CMS will also send the Regions a list of the establishments which produce the suspended and cancelled products.

° CMS will keep the Assistant Administrator of OPTS informed on the status of the recall based on weekly Status Reports from the Regions.

Regions/EPA

° Regions will coordinate with States in the implementation of this Strategy.

Outreach

° Regional offices in cooperation with State officials will be responsible for issuing news releases to inform the general public and users of the provisions set forth in the Order. The Regional Offices and State officials should also seek the cooperation of the appropriate extension, agricultural and user groups (co-op's, etc.) for further disseminating the information contained in the suspension order.

Recalls

° Regions will conduct the initial monitoring of both formal recalls for products suspended under the Emergency Order and voluntary recalls for products voluntarily cancelled in response to the Notice of Intent to Cancel. Monitoring should be done via telephone calls to registrants in their Region within 5 days of receipt of this Strategy. During this phone call, the Regional Office will:

1. Determine the management's response to EPA's Recall Request.

2. Offer to assist the firm in drafting a Recall Letter to its distributors. (Information on the ideal Letter of Recall is found in Section 14 of the FIFRA Inspection Manual.)

3. Determine the identity and amount, including size and number of containers, and location of EDB products affected by the Emergency Suspension Order or the Notice of Intent to Cancel under the control of the registrant. If unknown to the registrant, request that he submit the information to the Regional Office as soon as possible.

4. Request that the registrant submit the names and addresses of all consignees within the past two years to the Regional Office as soon as possible.

5. Request that the registrant provide the following information on affected EDB products at the distributor level as soon as possible: name and registration number of the product, distributors' names and addresses, location of the product, number and size of containers, and total amount of product.

° Regions will confirm all requests for information not provided during the telephone call in a letter to the registrant as soon as possible.

° In those cases where the Regional Office encounters or anticipates refusal by registrants to provide information as requested, the Regional Office/State should conduct an inspection of the registrant books and records and obtain such information as soon as possible.

° The Regional Office will maintain close contact, usually on a weekly basis, with the companies initiating the recall actions to assure that all necessary steps to remove the product from the market, are being taken as promptly as possible.

° Regions will provide Headquarters with a weekly status report on the recalls until all stocks are accounted.

° Regions will provide other Regions with information obtained as part of the recalls on distribution of EDB to a location.

Inspection Targetting

° Regions will notify States of EDB producing establishments/distributors of EDB within a particular State as determined from the recalls.

° Regions will send States a preliminary list of users as soon as it becomes available. The list will include grain elevators, grain millers, warehouses, and PCO's who service warehouses. The Regions should obtain the list of PCO's from their contacts with warehouses.

Enforcement Actions

° Regional offices in cooperation with State officials will be responsible for issuing SSURO's to distributors and retailers which have products not under the direct control of the registrant in the Regions and States for which they have jurisdiction.

° Regional offices and State officials will be responsible for issuing Stop Use Orders to any users not identified by CMS.

° Regions are responsible for lifting SSURO's issued in conjunction with the Suspension Order if appropriate (e.g., if a registrant decides to export the product).

° In those States with cooperative enforcement agreements, Regions are responsible for taking enforcement actions in cases referred to them by the States.

Federal Programs

° In States without cooperative enforcment agreements, the Regions are responsible for the entire compliance monitoring and enforcement program.

States

Inspections

° States will conduct establishment inspections to assure compliance with EPA's SSURO's and the EDB Emergency Suspension Orders and to confirm the amounts of existing stocks. States should forward information on existing stocks to the Regional Office. All EDB producing establishments should be inspected as soon as possible.

° States will conduct inspections at the distributor/retail and user level. The identity of most distributors will be determined from information from the recalls. (Regional offices will provide this information to States.)

° States may develop a list of EDB users affected by the Emergency Suspension Order who are not contained on the EPA user list and may issue State SSURO's to those users.

Enforcement

° States will be primarily responsible for enforcement actions. If a State cannot enforce the terms of the Emergency Suspension Order or Notice of Intent to Cancel, the State may refer the case to the Region for enforcement action.

° States and Regions are reminded that knowing and willful violations of the Suspension Order and/or SSURO's are likely candidates for criminal action.

° States should keep the Regional Office informed of all EDB violations/actions on a monthly basis for the next six months.

Appendix I - Status of EDB Uses

Stored Grain Fumigation Spot Fumigation of Grain Milling Machinery	Subject to Emergency Suspension Order of February 3, 1984, which prohibits sale, distribution and use. Also subject to September 28, 1983 Notice of Intent to Cancel. If registrants with products subject to notice did not appeal the action within required 30 days their products would already be cancelled.
Soil Fumigation	Subject to Emergency Suspension Order of September 28, 1983 against sale and distribution of products. Products in hands of users at time of suspension could be used until September 1, 1984 or final cancellation, whichever is later.
Felled Log Fumigation	Subject to September 28, 1983 Notice of Intent to Cancel. Registrants had 30 days to appeal or product was automatically cancelled. Products in hands of users prior to cancellation could be used until September 1, 1984 or final cancellation, whichever is later.
Post - Harvest Quarantine Fumigation	Subject to September 28, 1983 Notice of Intent to Cancel. However, cancellation not scheduled to be effective until September 1, 1984.
Minor Uses Termite Control Beehive keepers and Honeycombs Vault Fumigation Japanese Bettle Control	Subject to September 28, 1983 Notice of Intent to Cancel. Registrants could avoid cancellation by amending their labelling to reduce risk to acceptable level.

THE COMPLIANCE MONITORING STRATEGY FOR

CANCELLED LINDANE PRODUCTS

APR 25 1985

OFFICE OF COMPLIANCE MONITORING

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

U. S. ENVIRONMENTAL PROTECTION AGENCY

COMPLIANCE MONITORING STRATEGY FOR LINDANE

COMPLIANCE MONITORING STRATEGY
FOR LINDANE

APR 25 1985

OVERVIEW

Three Major Highlights Based on One Notice of Intent to Cancel and Two Subsequent Amended Notices of Intent to Cancel

° Notice of Intent to Cancel - For continued registration, Lindane products are required to bear a restricted use (RU) statement if the label allows for use on commercial ornamentals, avocados, pecans, spray* uses on livestock, forests, or Christmas trees; structural treatments, or use in dog shampoos and dog dusts. Other labeling statements are required for both RU and non-RU products.

° First Amended Notice - EPA Reg. No. 2781-3 is permitted continued registration as a dog dip to control pests in addition to mites provided labels bear certain precautionary language.

° Second Amended Notice - EPA Reg. No's. 495-6, -7, -8 are permitted continued registration as indoor smoke fumigation devices until May 31, 1986 provided labels bear certain precautionary modifications. The first two products are for indoor use. The third product will bear directions only for outdoor use; the indoor use has been deleted from the labeling.

The gamma isomer of hexachlorocyclohexane, commonly called Lindane, is an insecticide used for food crops, ornament3ls, forests, seed treatments, structures (indoors and outdoors), and animals. Based on oncogenicity concerns associated with potential exposure, the Agency issued a Notice of Intent to Cancel the use of Lindane for dog dips to control pests other than mites and for indoor smoke fumigation devices (except greenhouse use). The Agency also denied applications for registrations for Lindane products for the remaining uses unless registrants and applicants modified the terms and conditions of registration to comply with the requirements of the Notice of Intent to Cancel. The most notable condition was the restricted use classification for commercial ornamentals, avocados, pecans, spray* uses on livestock, forestry, Christmas trees, structural treatments, dog shampoos, and dog dusts. The proper restricted use pesticide statement does not appear in the Notice of Intent to Cancel but does appear in 40 CFR 162.10(j).

* The October 19, 1983 FR Notice incorrectly implied that all uses of Lindane on livestock were restricted. Only the spray uses were restricted (based on a discussion with George LaRocca, PM 15 on October 11, 1984).

Other labeling modifications were required both for restricted uses and other uses which were not classified as restricted. EPA announced its Intent to Cancel Pesticide Products Containing Lindane and Denial of Applications for Registrations of Pesticide Products Containing Lindane for these uses on September 30, 1983 (published in the Federal Register [FR] on October 19, 1983 [48 FR 48512]).

However, EPA amended the Notice of Intent to Cancel, as the result of a hearing request, to allow continued registration of one Lindane dog dip product (EPA Reg. No. 2781-3) to control other pests in addition to mites provided certain modifications were reflected on the labeling and accepted by OPP. This amendment was published in the FR on June 27, 1984 (49 FR 26282).

Additionally, a second hearing request resulted in EPA amending the Notice of Intent to Cancel to allow continued registration of three smoke fumigation devices (EPA Reg. No.'s 495-6, -7, and -8) until May 31, 1986 provided certain modifications are reflected on the labeling and accepted by OPP. This amendment was published in the FR on February 8, 1985 (50 FR 5424).

REQUIREMENTS/ACTION

Federal Registration Requirements under FIFRA §3 and §24(c)

° Persons (as defined by FIFRA §2(s)) may not distribute, sell, offer for sale, hold for sale, ship, deliver for shipment or receive and (having so received) deliver or offer to deliver to any person cancelled Lindane products other than existing stocks as defined by a letter to the registrants (October 28, 1983).

° Cancellation of products not conforming with the provisions of the October 19, 1983 FR Notice of Intent to Cancel became effective 30 days after the date registrants received that notice, except for products for which a hearing was requested.

° Persons were permitted to continue distribution of existing stocks of cancelled Lindane products until October 1, 1984, except as provided in 50 FR 5424, February 8, 1985.

° For EPA Reg. No.'s 495-6, -7, -8 for indoor homeowner uses and similar new registrations only, persons may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment or receive and (having so received) deliver or offer to deliver to any person these products including existing stocks until May 31, 1986 provided the registrant complies with 50 FR 5424, February 8, 1985.

NOTE: Existing stocks are defined to mean the quantity of Lindane products in the United States at the time of cancellation.

° For EPA Reg. No.'s 495-6, -7, -8 for indoor use only, registrants may distribute existing stocks of products not conforming with 50 FR 5424, February 8, 1985 until April 15, 1985.

FIFRA §5 Experimental Use Products

° Experimental Use Permits (EUPs) are issued to accumulate information necessary to register a pesticide under FIFRA §3. No EUPs are currently in effect to gather information for uses subject to the provisions of the October 19, 1983 FR and subsequent amendments.

FIFRA §18 Exemptions

° Exemptions issued under FIFRA §18 for any Federal or State agency are not subject to the provisions of the Notice of Intent to Cancel and subsequent amendments.

Intrastate Registrations

° Persons were required to submit applications for registration of Lindane products within 30 days after receipt of the October 19, 1983 Notice of Intent to Cancel. Only products conforming to the requirements of the Notice of Intent to Cancel were federally registered. This effectively cancelled any products not in conformance with this FR notice.

° Persons may not distribute, sell, offer for sale, hold for sale, ship, deliver for shipment or receive and (having so received) deliver or offer to deliver to any person cancelled Lindane products other than existing stocks as defined by the letter to the registrants (October 28, 1983).

° Cancellation of products not conforming to the provisions of the October 19, 1983 FR became effective 30 days after the date registrants received the Notice of Intent to Cancel.

° Persons were permitted to continue distribution of existing stocks of cancelled Lindane products with unrevised labeling until October 1, 1984.

Distributors (NOT INCLUDING REGISTRANTS)

° Persons may continue to distribute existing stocks of cancelled Lindane products until supplies are exhausted except as listed below.

° For EPA Reg. No.'s 495-6, -7, and -8 for indoor use only, persons may continue to distribute existing stocks of containers with either labeling revised in accordance with 50 FR 5424 (February 8, 1985) or non-revised labeling until November 30, 1986. This also applies for similar new registrations of indoor homeowner smoke fumigation devices.

Users:

° End Users are permitted to continue use of existing stocks of cancelled Lindane products until supplies are exhausted.

REGULATED INDUSTRY

° Number of Registrants with products cancelled - 170

° Number of Producer Establishments - 60 producing in FY83

° Number of Cancelled Products

317 Federally registered products
66 Intrastate registered products (16 of which were indicated as cancelled on printout but in fact were only denied registration)

° Major Producers:

Celamerck GMBH and Co. KG
Chevron Chemical Co. - Ortho Division
Chipman, Inc.
Southwest Petro Chemicals (Omaha) Division of Witco
Hopkins Chemical Co.

OUTREACH

To assure compliance with the provisions of the cancellation, OCM plans to issue Stop Sale, Use or Removal Orders (SSUROs) to all registrants who had products cancelled. For those registrants who have existing stocks with non-revised labeling in addition to stocks with accepted modified labeling (generally restricted use) for the same product, federal/state inspectors will issue SSUROs during site visits for stocks in violation of the labeling requirements. Under the authority of 40 CFR 169.2 persons are required to retain records of Lindane produced and shipped for a period of two years after creation of the record. SSUROs at the distributor level for indoor smoke fumigation devices (except greenhouses) will be issued after November 30, 1986.

NEUTRAL ADMINISTRATIVE INSPECTION SCHEME

For any cancelled Lindane registrations, State/EPA inspectors will inspect all establishments which produced Lindane after 1983. EPA will request the States to stop-sale any indoor smoke fumigation devices (except greenhouse use) subject to the provisions of 50 FR 5424, February 8, 1985, (EPA Reg. No's. 495-6, -7, -8 and similar new registrations) after November 30, 1986 which are found during random marketplace inspections.

PROGRAM MANAGEMENT & ALLOCATION OF RESPONSIBILITY

Office of Pesticide Programs (OPP)

OPP's Registration Division (RD) will:

o Provide OCM with list of Lindane products by registration number, and name and address of registrant.

Office of Compliance Monitoring (OCM)

OCM will be responsible for the following:

° Developing a list of establishments for cancelled Lindane products which submitted annual production reports for the last two years.

° Providing a list of establishments, product registration numbers and names and addresses for cancelled Lindane products to the Regions for distribution to the States.

° Issuing SSUROs to establishments for any cancelled Lindane indoor smoke fumigation devices (except greenhouses) after November 30, 1986.

Regions

The EPA Regions will be responsible for the following:

° Negotiating with States participating in the FIFRA Cooperative Enforcement Agreement Program to conduct inspections at producing establishments and distributors for compliance with the provisions of the cancellation and any SSUROs issued.

° Conducting inspections in States without Cooperative Agreements.

° Distributing a list developed by RD and OCM to participating States or field inspection offices in Colorado and Nebraska.

° Conducting import inspections (where appropriate).

States

Participating States will be responsible for developing the following:

° Conducting inspections for compliance with the provisions of the Lindane cancellation and any SSURO issued within the State as part of the FIFRA Cooperative Enforcement Agreement.

° Taking enforcement actions for violations of the Notice of Intent to Cancel and subsequent amendments or referring violations to EPA.

° Conducting import inspections (where appropriate).

ENFORCEMENT

VIOLATIONS

It shall be unlawful for:

Registrants

° §12(a)(2)(F) - to make available for use, or to use any pesticide classified for restricted use for some or all purposes other than in accordance with §3(d) of FIFRA and any regulations thereunder

° §12(a)(2)(I) - to violate any order issued under §13 of FIFRA (SSURO)

° §12(a)(2)(K) - to violate any cancellation of a pesticide registration

Distributors, Dealers & Others

° §12(a)(2)(F) - to make available for use, or to use any pesticide classified for restricted use for some or all purposes other than in accordance with §3(d) of FIFRA and any regulations thereunder

° §12(a)(2)(I) - to violate any order issued under §13 of FIFRA (SSURO)

° §12(a)(2)(K) - to violate any cancellation of a pesticide registration

Users

° §12(a)(2)(G) - to use any pesticide in a manner inconsistent with its labeling

° §12(a)(2)(I) - to violate any order issued under FIFRA §13 (SSURO)

° §12(a)(2)(K) - to violate any cancellation of a pesticide registration

RESPONSE TO VIOLATIONS

States

States are responsible for taking the enforcement actions for any misuse cases. States will refer violations of the cancellation order or SSURO to EPA unless the State has the authority to enforce these provisions in delegated programs. State action is based on the statutes specific to the State.

Federal

In those situations where EPA conducts the inspection or a State refers a case to EPA for enforcement action, the FIFRA Civil Penalty Policies will be used to determine the level of action.

Civil Administrative Enforcement Actions

Civil Penalties

The FIFRA penalty policies can be found in the FIFRA Compliance/Enforcement Guidance Manual. Relevant portions of the penalty policy are given below:

§12(a)(2)(F) - to make available for use, or to use any pesticide classified for restricted use for some or all purposes other than in accordance with §3(d) of FIFRA and any regulations thereunder.

	Size of Business Category				
	1	2	3	4	5
Penalty Amount	500	1250	2750	4250	5000

§12(a)(2)(G) - Use or Disposal of a pesticide in a manner inconsistent with its labeling.

	Size of Business Category				
	1	2	3	4	5
Adverse Effects Highly Probable	500	1250	2750	4250	5000
Adverse Effects Unknown	280	700	1540	2380	2800
Adverse Effects Not Probable	120	300	660	1020	1200

§12(a)(2)(I) - to violate any order issued under §13 of FIFRA (SSURO).

	Size of Business Category				
	1	2	3	4	5
Violation of a SSURO	5000	5000	5000	5000	5000
Failure to provide Names & Addresses of recipients of products believed in violation of SSURO	500	1250	2750	4250	5000

§12(a)(2)(K) - to violate any cancellation of registration of a pesticide.

	Size of Business Category				
	1	2	3	4	5
Knowledge of the Cancellation	500	1250	2750	4250	5000
No Knowledge of the Cancellation	100	250	550	850	1000

Stop-Sale, Use or Removal Orders

Inspectors will issue Stop-Sale, Use or Removal Orders (SSUROs) for cancelled Lindane products encountered at producer establishments. Also, SSUROs will be issued for indoor smoke fumigation devices except greenhouses (subject to 50 FR 5424) found during random marketplace inspections after November 30, 1986.

Criminal Actions

In situations where the person knowingly violates FIFRA requirements, EPA may refer such cases to the Department of Justice for criminal prosecution. FIFRA §14(b) provides for criminal penalties of up to $25,000 or $1,000 and/or imprisonment of up to 1 year or 30 days depending on the status of the violator, i.e., registrant, commercial applicator, or other person.

ENFORCEMENT STRATEGY FOR LINDANE PESTICIDE PRODUCTS

	CANCELLED USES	FR CITATION FOR CANCELLATION	CANCELLATION EFFECTIVE	DISTRIBUTION OF EXISTING STOCKS PERMITTED UNTIL
REGISTRANTS (Federal §§3 & 24(c))	all not specifically mentioned below	48 FR 48512 October 19, 1983	30 days after receipt of FR Notice	10-1-84
(Federal §5) experimental use permits	n/a	none	not affected, no current EUPs	no current existing stocks
(Federal §18)	n/a	none	exempt	exempt
Only for EPA Reg. No.'s 495-6,-7,-8 & similar new registrations	indoor use of smoke fumigation devices	48 FR 48512 October 19, 1983 AND 50 FR 5424 Feb. 8, 1985	30 days after receipt of 50 FR 5424* or May 31, 1986**	4-15-85* 5-31-86**
REGISTRANTS (Intrastate)	all	48 FR 48512 October 19, 1983	30 days after receipt of 48 FR 48512	10-1-84***
DISTRIBUTORS**** Federal & Intrastate	all not specifically mentioned below	48 FR 48512 October 19, 1983	30 days after registrants received FR Notice	supplies are exhausted
Only for EPA Reg. No.'s 495-6,-7,-8 & similar new registrations	indoor smoke fumigation devices	48 FR 48512 October 19, 1983 AND 50 FR 5424 Feb. 8, 1985	30 days after receipt of 50 FR 5424* or May 31, 1986**	11-30-86* and **

* Existing stocks of labeling not in conformance with 50 FR 5424, Feb. 8, 1985
** Existing stocks of labeling in conformance with provisions of 50 FR 5424, Feb. 8, 1985
*** Existing stocks of labeling not in conformance with 48 FR 48512 Oct. 19, 1983
**** Retail level and otherwise but not including registrants

ENFORCEMENT STRATEGY FOR LINDANE PESTICIDE PRODUCTS

	USES	FR CITATION FOR CANCELLATION	CANCELLATION EFFECTIVE	DISTRIBUTION OF EXISTING STOCKS PERMITTED UNTIL
USERS Federal & Intrastate	all not specifically mentioned below	48 FR 48512 October 19, 1983	30 days after registrants received 48 FR 48512	supplies are exhausted
Only for EPA Reg. No.'s 495-6,-7,-8 & similar new registrations	indoor use of smoke fumigation devices	48 FR 48512 October 19, 1983 AND 50 FR 5424 Feb. 8, 1985	30 days after receipt of 48 FR 48512* or May 31, 1986**	supplies are exhausted

* Existing stocks of labeling not in conformance with the provisions of 50 FR 5424, Feb. 8, 1985

** Existing stocks of those products conforming to provisions of 50 FR 5424, Feb. 8, 1985

[OPP-30000/10Q; PH-FRL 2776-5]

Lindane; Amendment of Notice of Intent To Cancel Pesticide Products Containing Lindane

AGENCY: Environmental Protection Agency (EPA).

ACTION: Amendment of Notice of Intent to Cancel.

SUMMARY: A Notice of Intent to Cancel Pesticide Products Containing Lindane was issued on September 30, 1983. This Notice amends that Notice of Intent to Cancel to change the effective date for the cancellation of the remaining registrations of lindane smoke fumigation devices for indoor use, provided certain additional protective measures are instituted within 30 days of the publication of this Amended Notice. The Environmental Protection Agency has determined that maintenance of the registrations until May 31, 1986, under the conditions specified will not cause unreasonable adverse effects on the environment.

EFFECTIVE DATE: February 8, 1985.

FOR FURTHER INFORMATION CONTACT: Judith W. Wheeler, Pesticides and Toxic Substances Division, Office of General Counsel (LE-132P), 401 M St., SW., Washington, D.C. 20460 (202-382-7510).

The docket of the administrative hearing (FIFRA Docket No. 524, *et al.*) is avaliable for public inspection in the Office of the Hearing Clerk, Room 3708A, 401 M St., SW., Washington, D.C. from 7:30 a.m. to 4 p.m., Monday through Friday, except legal holidays. An administrative file containing public comments and publicly released Agency documents relating to this action is available for public inspection from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays, in Rm. 711, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Regulatory Background

On September 30, 1983, EPA issued a Notice of Intent to Cancel Pesticide Products Containing Lindane which was published in the Federal Register of October 19, 1983 (48 FR 48512). This Notice, in relevant part, states the Administrator's intent to cancel the registrations of lindane smoke fumigation devices for indoor use. The decision to cancel registrations for lindane smoke fumigation devices for indoor use was a result of a careful evaluation of the risks to public health and benefits of this use.

Section 6(b) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides that a Notice of Intent to Cancel does not become a final order of cancellation if a person adversely affected by the Notice properly requests an adjudicatory hearing to contest the cancellation. A registrant, Continental Chemiste Corporation, did request a hearing on the cancellation of the registrations it holds for lindane smoke fumigation devices for indoor use. As a result of discussions between EPA and the remaining registrant of the smoke fumigation devices, Continental Chemiste Corporation, it was agreed that Continental Chemiste Corporation would withdraw its request for a hearing in FIFRA Docket No. 524, *et al.* following amendment of the notice of cancellation to provide that cancellation of registrations of its lindane smoke fumigation devices for indoor use will be effective May 31, 1986.

Continental Chemiste Corporation manufactures two lindane smoke fumigation devices for indoor use, Smo-Cloud and Moth-Cloud, and one, Bug-Tab, for indoor and outdoor use. Smo-Cloud is for general indoor use and Moth-Cloud is for use in closets. Only the indoor uses were cancelled by the September 30, 1983 Notice of Intent to Cancel.

B. Amendment to the Notice

This amendment to the September 30, 1983 Notice of Intent to Cancel changes the effective date for the cancellation of the remaining registrations of lindane smoke fumigation devices for indoor use to May 31, 1988, provided an appropriate application to amend registrations to impose certain additional protective measures is received by EPA within 30 days of the publication of this Amended Notice. In order for the registrations of lindane smoke fumigation devices for indoor use to continue until May 31, 1986 under this Notice, the registrant, Continental Chemiste Corporation, must amend its labels to reflect the terms and conditions which are detailed below. They are intended to provide additional protection to persons exposed to lindane smoke fumigation devices for indoor use to reduce the risk of cancer from exposure to the products during the interim period until cancellation becomes effective on May 31, 1986. The Agency has determined such registration will not have unreasonable adverse effects on the environment. Detailed below are specific requirements for registration of lindane smoke fumigation devices for indoor use until May 31, 1986, and the bases for the determination that such sale and use until May 31, 1986, will not have unreasonable adverse effects on the environment. Any other person who seeks to register lindane smoke fumigation devices for indoor use mu do so under the terms and conditions required herein, and any such registrations will also be subject to th May 31, 1986 cancellation date. Any such registration could be granted on if the applicant also complies with all other requirements for registration.

II. Bases for Determinations for Amendment to Cancellation Notice

The September 30, 1983 Notice of Intent to Cancel Pesticide Products Containing Lindane identified the risk associated with the indoor smoke fumigation device use of lindane. Bas on the cancellation of registrations of lindane smoke fumigation devices for indoor use effective May 31, 1986 and the label modifications and other term identified in Unit III of this Amended Notice, the Agency has determined th providing a period of time for the pha out of sales for these devices is consistent with the purpose of the Ac and will not have unreasonable adve effects on the environment.

The current registrations for indoor use permit significant exposure to humans and unacceptably high levels cancer risk. Therefore, for Smo-Cloud which has by far the largest volume sales of the three smoke fumigation devices, the revised labeling will limi use to two times per year. In order to further reduce exposure, the period of time for vacating the premises after lighting Smo-Cloud has been increase to 5 hours to allow for settling out of t particles. An aeration period of 2 hou after reentry has been specified to all for removal of remaining particles in air. To further reduce exposure the la modifications call for washing of horizontal surfaces, where most of th particulate settles, and require that impermeable gloves be worn during washing to limit dermal exposure to person doing the washing. For Moth-Cloud, use will also be limited to two times per year and periods for vacati and aeration are specified. Bug-Tab w no longer be available for indoor use, but will continue to be available for outdoor use.

Implementation of these measures will reduce substantially exposure fr the indoor use of lindane smoke fumigation devices and will reduce th risk to an acceptable level during the phaseout period. Based on a compari of the benefits of continued use of th smoke fumigation devices to these reduced risks, the Agency has determined that the continued

registration of these products during the phaseout period will not have unreasonable adverse effects on the environment.

III. Terms and Conditions for Continued Registration

This Unit of the Amended Notice establishes the terms and conditions governing registration of certain lindane smoke fumigation devices.

In order to allow for the continued registration of Smo-Cloud (Registration No. 495–6), Moth-Cloud (Registration No. 495–6) until May 31, 1986, and Bug-Tab (Registration No. 495–7), the registrant must request amendment to each registration incorporating all of the following terms and conditions, including all of the required labeling modifications.

1. Lindane smoke fumigation devices for indoor use only:

a. For Smo-Cloud and similar products, the label shall state: "Do not use more than two times per year on the same premises."

b. For Smo-Cloud and similar products, the label shall state: "Do not enter rooms for five hours after lighting. Air out rooms for two hours after reentering. After aeration, horizontal surfaces shall be washed. Impermeable gloves shall be worn during washing."

c. For Moth-Cloud and similar products, the label shall state: "Do not use more than two times per year on the same premises." It shall also state: "Closet door shall remain closed for one hour after lighting. Air out closet for one hour after opening door. All clothes in closet must be aired out before wearing."

d. The labels must be revised to meet current standards as specified in 40 CFR 162.10 and all other current standards as specified in 40 CFR 162.10 and all other current requirements applicable to these products. Labels must describe proper handling and disposal, symptoms of poisoning, practical treatment in the event of poisoning, and other warning statements approrpriate to the product's toxicity category.

e. The labels, must state: "Not to be sold after November 30, 1986."

2. Lindane smoke fumigation devices registered for indoor and outdoor use:

a. Lindane smoke fumigation devices registered for indoor and outdoor uses will no longer be registered for indoor use effective March 11, 1985.

b. Bug-Tab and similar products will continue to be registered for outdoor use only when accompanied by labeling which reflects the following limitation: The label must state: "Not for indoor use."

3. After April 15, 1985, lindane smoke fumigation devices for indoor use may not be distributed, offered for sale, held for sale, sold, shipped, or delivered for shipment by any registrant unless the labeling for the product complies with the amended terms of the registration.

4. After May 31, 1986, stocks of lindane smoke fumigation devices for indoor use in the possession of the registrant with lablels which comply with the amended terms of registration may not be distributed, offered for sale, held for sale, sold, shipped, or delivered for shipment.

5. Any existing stocks of products within the possession of the registrant after May 31, 1986, and within the possession of distributors other than the registrant, including retailers, after November 30, 1986, must be disposed of in the manner required by the Resource Conservation and Recovery Act. It is the responsibility of the registrant to notify distributors of this requirement by certified mail and maintain records of such notification until 5 years after such notification is accomplished. Existing stocks are defined in this Amended Notice as lindane smoke fumigation devices for indoor use which were registered products when marketed and which are present within the territorial United States.

6. The use of existing stocks by end-users is allowed to continue until the supply is exhausted.

7. Lindane smoke fumigation devices for indoor use whose registration becomes cancelled pursuant to the September 30, 1983 Notice of Intent to Cancel as amended by this Notice may not be distributed, shipped, delivered for shipment, received for delivery, sold, offered for sale, held for sale, or offered for delivery by or to any person or used or disposed of by any person in any State in any manner which would violate FIFRA section 12 of the product were still registered. For purposes of this paragraph, and FIFRA section 12(a)(1)(B) and (C), the term "statement required in connection with [the product's] registration" shall mean the statement on file with the Administrator in connection with the product's registration on the effective date of cancellation of the product.

IV. Procedural Matters

This Notice announces the amendment of the September 30, 1983 Notice of Intent to Cancel Pesticide Products Containing Lindane. This action is taken pursuant to the authority granted by section 6(b) of FIFRA and by the Agency's procedural regulations (40 CFR 164.21(b)). This amendment is effective immediately and relates only to the registrations of Continental Chemiste Corporation, Registration Nos. 495–6, 495–7, and 495–8, since those are the only registrations which were not cancelled by operation of law under the terms of the September 30, 1983 Notice of Intent to Cancel.

This Notice of Amendment creates no new opportunity to request a hearing pursuant to section 6 of FIFRA. Section 6(b) provides adversely affected persons the right to request a hearing to challenge a notice of intent to cancel a registration of a pesticide product within 30 days. The Notice of Intent to Cancel the use of lindane was issued on September 30, 1983. This Notice of Amendment merely modifies the terms of the September 30 Notice to change the effective date of cancellation of lindane smoke fumigation devices for indoor use to May 31, 1986 and to allow for the phaseout of stocks of lindane smoke fumigation devices for indoor use in accordance with the terms and conditions contained herein. Therefore this Notice of Amendment is not a notice of intent to cancel nor can any person be adversely affected by this Notice under the terms of section 6 of FIFRA. Continental Chemiste Corporation may comply with the agreement upon which this Notice is premised by filing with the Hearing Clerk (A–110), Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460, a withdrawal of its request for a hearing in the FIFRA Docket No. 524, *et al.* The company may continue its registrations of Smo-Cloud and Moth-Cloud until May 31, 1986 and its registration of Bug-Tab by submitting a copy of the amended labeling which conforms to the requirements of this Notice by March 11, 1985 to:

By mail: George LaRocca, Product Manager (PM–15), Registration Division (TS–767C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460.

In person, bring material to: Rm. 204, Crystall Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, (703–557–2400).

Although Continental Chemiste Corporation, petitioner in the lindane cancellation hearing (FIFRA Docket No. 524, *et al.*), is permitted as a matter of right to amend its objections to the September 30, 1983 Notice to reflect the terms of this Notice of Amendment under 40 CFR 164.22(c), the Administrator expects that the company will, instead, abide by its commitment to withdraw its challenges to the cancellation altogether. Any

amendments to objections which are filed must be received by the Hearing Clerk (A-110), Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460 within 30 days of the date of publication of this Notice.

Dated: February 4, 1985.

John A. Moore,

Assistant Administrator for Pesticides and Toxic Substances.

[FR Doc. 85-3333 Filed 2-7-85; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL EMERGENCY MANAGEMENT AGENCY

[Docket No. FEMA-REP-2-NY-1]

The New York State and Local Emergency Preparedness Site-Specific for the Nine-Mile Point/James A. Fitzpatrick Nuclear Power Generating Stations

ACTION: Certification of FEMA findings and determination.

In accordance with the Federal Emergency Management Agency (FEMA) rule 44 CFR Part 350, the State of New York submitted its plans relating to the Nine-Mile Point/James A. Fitzpatrick Nuclear Power Generating Stations to the Director of FEMA Region II on July 15, 1981, for FEMA review and approval. On September 28, 1984, the Regional Director forwarded his evaluation to the Associate Director for State and Local Programs and Support in accordance with section 350.11 of the FEMA rule. Included in this evaluation is a review of the State and local plans around the Nine-Mile Point/James A. Fitzpatrick facilities; an evaluation of the joint exercise conducted on September 15, 1981, August 11, 1982, and September 28, 1983, in accordance with section 350.9 of the FEMA rule; and a public meeting held on November 4, 1981, to discuss the site-specific aspects of the State and local plans around the Nine-Mile Point/James A. Fitzpatrick Nuclear Power Generating Stations in accordance with section 350.10 of the FEMA rule.

Based on the evaluation by the Regional Director and the review by the FEMA Headquarters staff, I find and determine that the State and local plans and preparedness for the Nine-Mile Point/James A. Fitzpatrick Nuclear Power Generating Stations are adequate to protect the health and safety of the public living in the vicinity of the plant. These offsite plans and preparedness are assessed as adequate in that they provide reasonable assurance that appropriate protective actions can be taken offsite in the event of a radiological emergency and are capable of being implemented. The adequacy of the public alert and notification system also has been verified as meeting the standards set forth in Appendix 3 of the Nuclear Regulatory Commission (NRC)/FEMA criteria of NUREG-0654/FEMA-REP-1, Revision 1, and in the Standard Guide for the Evaluation of Alert and Notification Systems for Nuclear Power Plants (FEMA-43).

FEMA will continue to review the status of offsite plans and preparedness associated with the Nine-Mile Point/James A. Fitzpatrick Nuclear Power Generating Stations in accordance with § 350.13 of the FEMA rule.

For further details with respect to this action, refer to Docket File FEMA-REP-2-NY-1 maintained by the Regional Director, FEMA Region II, 26 Federal Plaza, Room 1349, New York, New York 10278.

Dated: February 1, 1985.

For the Federal Emergency Management Agency.

Samuel W. Speck,

Associate Director, State and Local Programs and Support.

[FR Doc. 85-3174 Filed 2-7-85; 8:45 am]

BILLING CODE 6718-01-M

FEDERAL MARITIME COMMISSION

Intent to Terminate Approval of Agreement

Agreement No.: 206-009878.

Title: The Associated Latin American Freight Conferences.

Parties:

Atlantic & Gulf/West Coast of South America Conference
East Coast/Colombia Conference
United States Atlantic & Gulf/Ecuador Conference
United States Atlantic & Gulf/Jamaica and Hispaniola Steamship Freight Association
United States Atlantic & Gulf/Southeastern Caribbean Conference
United States Atlantic & Gulf/Venezuela Conference
United States Florida/Ecuador Freight Association
West Coast of South America Northbound Conference

Synopsis: By letter dated December 28, 1984, the Commission was advised by the Associated Latin American Freight Conferences that all member conferences had submitted their resignations, effective December 31, 1984. The Commission, therefore, gives notice of its intent to terminate its prior approval of Agreement No. 206-009878.

By Order of the Federal Maritime Commission.

Dated: February 5, 1985.

Bruce A. Dombrowski,

Assistant Secretary.

[FR Doc. 85-3207 Filed 2-7-85; 8:45 am]

BILLING CODE 6730-01-M

[Docket No. 85-2; Agreement No. 203-010633]

Order of Investigation and Hearing; Flota Mercante Grancolombiana, S.A. et al.; Correction

In the Order of Investigation and Hearing served in this proceeding on January 18, 1985 (50 FR 3406 appearing January 24, 1985—FR Doc. 85-1828), all references to "Agreement No. 207-010633," including the title of the proceeding, should have read "Agreement No. 203-010633." Additionally, the reference in the first line of the text of the Order in the Federal Register reprint to "Agreement No. 2078-010633" should have read "Agreement No. 203-010633."

Bruce A. Dombrowski,

Assistant Secretary.

[FR Doc. 85-3258 Filed 2-7-85; 8:45 am]

BILLING CODE 6730-01-M

FEDERAL RESERVE SYSTEM

BankEast Corp.; Application To Engage de Novo in Permissible Nonbanking Activities

The company listed in this notice has filed an application under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo*, either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased

[OPP 30000/10F; OPTS-FRL 2612-1]

Lindane; Amendment of Notice of Intent to Cancel Pesticide Products Containing Lindane

AGENCY: Environmental Protection Agency (EPA).

ACTION: Amendment of Notice of Intent to Cancel.

SUMMARY: A Notice of Intent to Cancel Pesticide Products Containing Lindane was issued on September 30, 1983. This Notice amends that Notice of Intent to Cancel to permit continued registration of lindane dip to control fleas, ticks, lice, sarcoptic mange, and scabies on dogs provided certain additional protective measures are instituted. The Agency has determined that continued registration with these additional protective measures will not cause unreasonable adverse effects on the environment.

DATE: June 27, 1984.

FOR FURTHER INFORMATION CONTACT: Judith W. Wheeler, Pesticides and Toxic Substances Division, Office of General Counsel (LE-132P), Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460 (202-382-7510).

The docket of the administrative hearing (FIFRA Docket No. 524, *et al.*) is available for public inspection in the Office of the Hearing Clerk, Room 3708A, 401 M St., SW., Washington, D.C.

from 7:30 a.m. to 4:00 p.m., Monday through Friday, except legal holidays. An administrative file containing public comments and publicly released Agency documents relating to this action is available for public inspection from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays, in Rm. 711, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Regulatory Background

On September 30, 1983 EPA issued a Notice of Intent to Cancel Pesticide Products Containing Lindane which was published in the Federal Register on October 19, 1983 (48 FR 48512). This Notice, in relevant part, proposed cancellation of the registrations of lindane products for use as dog dips for the treatment of pests other than mites. The decision to cancel registrations for the use of dog dips for the treatment of pests other than mites was a result of a careful evalation of the risks to public health and benefits of this use.

Section 6(b) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides that a Notice of Intent to Cancel does not become a final order of cancellation if a person adversely affected by the Notice properly requests an adjudicatory hearing to contest the cancellation. A registrant, Happy Jack, Inc., did request a hearing as to the dog dip use of its product, Happy Jack Kennel Dip. All other registrations for lindane dog dip products for treatment of pests other than mites were cancelled by operation of law at the end of 30 days after receipt or publication of the September 30, 1983 Notice, whichever came later, under the terms of that Notice.

B. Amendment of Notice

This amendment to the September 30, 1983 Notice of Intent to Cancel modifies EPA's determination that the remaining registration of lindane dog dip for treatment of pests other than mites was to be cancelled at the end of 30 days from receipt or publication of the September 30, 1983 Notice, whichever came later. Under the terms of the September 30 Notice as amended by this Notice, the terms and conditions of use of the registration of this product may be amended in accordance with this Notice and, if so amended, the registration may continue in effect. In order to remain in effect under the terms of the amended Notice, this registration must be amended to require certain addtional restrictions on the continued use of this product. These additional restrictions, which are detailed below, are intended to provide additional protection to persons applying lindane dog dip to reduce further the risk of cancer from exposure to the product. Taking into account the benefits of continued registration of lindane dip for use to control fleas, ticks, lice, sarcoptic mange, and scabies on dogs as well as the risks of adverse effects, primarily through applicator exposure, the Agency has determined that continued registration under these terms and conditions will not cause unreasonable adverse effects on the environment. Detailed below are specific requirements for modification of the terms and conditions for the remaining registration and the bases for the determination that such registration will not cause unreasonable adverse effects.

II. Requirement for Modification of Registration Terms and Conditions

In order to avoid cancellation under the terms of the September 30, 1983 Notice of Intent to Cancel, the remaining registration for lindane dip for use to control fleas, ticks, lice, sarcoptic mange, and scabies on dogs must be modified in the following manner, and the labeling of any pesticide product sold under such registration must reflect these modifications:

1. The following statement shall be on the label beneath the "MIX AS DIRECTED" statement under "CAUTION" AN INDIVIDUAL APPLICATOR MUST NOT APPLY THIS PRODUCT MORE THAN TWELVE TIMES PER YEAR.

2. The following statement shall be located on the front panel of the label beneath the product name and in the same size type as the signal word: FOR KENNEL, COMMERCIAL, FARM AND SPORT DOG USES ONLY.

3. Under "DIRECTIONS FOR USE" on the label, the last two sentences shall state:

An individual applicator must not use this product more than twelve times per year. Each treatment of three dogs or fewer should be considered one use.

4. Applicators must wear the following protective clothing during the treament process: elbow-length, waterproof gloves; a waterproof apron; and unlined, waterproof boots.

5. The label shall state that "improper dilution could cause serious injury to your dog."

6. The label shall state that children under the age of thirteen should not be allowed to handle or apply this product.

7. The label shall be revised in accordance with the provisions of the Notice of Intent to Cancel dated September 30, 1983, regarding disposal of dips.

8. The label shall be modified to meet current standards as specified in 40 CFR 162.10. Labels must describe proper handling and disposal, symptoms of poisoning, practical treatment in the event of poisoning, and other warning statements appropriate to the product's toxicity category.

III. Bases for Determinations for Amendment to Cancellation Notice

The September 30, 1983 Notice of Intent to Cancel Pesticide Products Containing Lindane identified the risks associated with the dog dip use of lindane. The estimated cancer risks upon which the regulatory actions in the September 30, 1983 Notice were based were approximately four excess cancers per one million exposed persons. Since the publication of that Notice, the Agency has obtained new information on use patterns for the dog dip use. When this new information was assessed in light of the modifications in conditions and terms of registration identified in Unit II of this Amended Notice of Intent to Cancel, the Agency determined that the use of lindane dip to control fleas, ticks, lice, sarcoptic mange, and scabies in dogs will not result in unreasonable adverse effects on the environment.

The exposure calculations which provided the basis for the regulatory actions contained in the original Notice of Intent to Cancel were based on an assumption of 26 exposures per year. Since the cancellation notice, the Agency has learned that use of this product by kennels and veterinarians is more limited than the Agency previously believed. By modifying the label to limit the number of treatments by one applicator to twelve per year, the exposure of any one individual is reduced substantially from that assumed in the previous assessment. This modification satisfies Agency concerns about the potential of excessive exposure to teenagers working for kennels or veterinarians. Moreover, since the actual treatment time of one dog is under one minute, it is reasonable to allow the treatment of three dogs or fewer to constitute one use.

The requirement for protective clothing (elbow-length, waterproof gloves; waterproof apron; and unlined, waterproof boots) substantially reduces risks from dermal exposure. These garments can be readily obtained at minimal cost.

Implementation of these measures will reduce substantially applicator exposure from the dog dip use and, thus,

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will reduce the risk to applicators to an acceptable level. Based on a comparison of the benefits of continued use of lindane dips to control fleas, ticks, lice, sarcoptic mange, and scabies on dogs to these reduced risks, the Agency has determined that the benefits of continued registration as modified herein outweigh the risks of use.

IV. Procedural Matters

This Notice announces the amendment of the September 30, 1983 Notice of Intent to Cancel Pesticide Products Containing Lindane. This action is taken pursuant to the authority granted by section 6(b) of FIFRA and by the Agency's procedural regulations (40 CFR 164.21(b)). This amendment is effective immediately, and affects only the registration of Happy Jack Kennel Dip, Registration No. 2781-3, for which a hearing was requested. Registrations for this use of lindane for which there have been no requests for a hearing have been cancelled by operation of law.

This Notice of Amendment creates no new opportunity to request a hearing pursuant to section 6 of FIFRA. Section 6(b) provides adversely affected persons the right to request a hearing to challenge a notice of intent to cancel a registration of a pesticide product within 30 days. The Notice of Intent to Cancel the use of lindane was issued on September 30, 1983. This Notice of Amendment merely modifies the terms of the September 30 Notice to allow the continued registration for the remaining lindane dip registration for use to control fleas, ticks, lice, sarcoptic mange, and scabies on dogs in accordance with the terms and conditions contained herein. Therefore, this Notice of Amendment is not a notice of intent to cancel nor can any person be adversely affected by this Notice under the terms of section 6 of FIFRA.

Registrants subject to a final cancellation order, as well as other persons, may apply for a new registration in accordance with the terms of the amended notice of intent to cancel and the requirements of the FIFRA and applicable implementing procedures. The registrant of the lindane dog dip product which is not already subject to a final cancellation order may comply with the amended notice of intent to cancel by amending the registration to make the necessary corrections. An application for an amended registration, together with a copy of the amended labeling must be submitted by July 27, 1984 to: By mail: George LaRocca, Product Manager (PM-15), Registration Division (TS-767C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460.

In person, bring material to: Room 204, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA (703-557-2400).

Happy Jack, Inc., petitioner in the lindane cancellation hearing (FIFRA Docket No. 524, *et al.*), is permitted as a matter of right to amend its objections to the September 30, 1983 Notice to reflect the terms of this Notice of Amendment. 40 CFR 164.22(c). Any amendments to objections should be filed within 30 days of the date of publication of this Notice with the Hearing Clerk (A-110), Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460.

Dated: June 11, 1984

John A. Moore,

Assistant Administrator for Pesticides and Toxic Substances.

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resolution of the issues in the former as time would have to be granted for discovery and hearing procedures to take place in the latter. The proceedings in Docket No. RP81-130, *et al.*, would virtually come to a halt.

Transwestern argues that failure to consolidate will result in unnecessary duplication in the development of the required records of the proceedings. The Commission believes that the opposite result would occur. To halt the proceedings in Docket Nos. RP81-130, *et al.*, in the last steps of hearing and to hold it is abeyance until the other is heard will create far more duplication and delay.

Finally, the public interest favors the denial of consolidation as well as the request for a stay. Given the advanced stage of the proceedings in Docket No. RP81-130, the failure of Transwestern to demostrate irreparable harm, and the possibility of harm due to a halt of those proceedings, we do not believe that the public interest would be served in consolidating the proceedings in Docket No. RP81-130, *et al.*, with that of a section 5(a) inquiry or staying the former until the record in developed in the latter.

For the above reasons, Transwestern's alternative request that the record of the proceedings in Docket No. RP81-130, *et al.*, be held open for consideration with the section 5(a) case must also be denied.

The Commission orders:

(A) Docket Nos. RP83-113, RP83-135 and RP83-136 are consolidated for purposes of hearing and decision.

(B) Pursuant to the Natural Gas Act, particularly Section 5 thereof, a hearing in Docket Nos. RP83-113, RP83-135 and RP83-136 is established to determine if the minimum purchase/minimum take provisions which PITCO, POPCO, and PGT have with their natural gas purchasers are unjust, unreasonable, unduly discriminatory or preferential.

(C) A Presiding Administrative Law Judge to be designated by the Chief Administrative Law Judge for that purpose (18 CFR 375.304), shall convene a prehearing conference to be held within 45 days after the date of this order in a hearing or conference room of the Federal Energy Regulatory Commission, 825 North Capitol Street, NW., Washington, D.C. 20426 to establish such further procedural dates as may be necessary, and to rule upon all motions (except motions to consolidate, sever or dismiss), as provided for in the Rules of Practice and Procedure.

(D) The request for consolidation of the proceedings in Docket No. RP81-130 with that of Docket No. RP83-100 by Transwestern Pipeline Company is denied.

(E) The request for a stay of the proceedings in Docket No. RP81-130, *et al., by Transwestern Pipeline Company is denied.*

(F) The request that the record in the proceedings of Docket No. RP81-130, *et al.*, be held open pending conclusion of the Section 5 proceeding is denied.

(G) Docket No. RP83-106 is hereby terminated.

By the Commission. Commissioner Sousa concurred in part and dissented in part.

Kenneth F. Plumb,

Secretary.

Appendix A

Southwest Gas Corporation
Pacific Gas Transmission Company
Pacific Gas and Electric Company
Northwest Central Pipeline Corporation
Public Utilities Commission of the State of California
Southern California Gas Company
Pacific Lighting Gas Supply Company
Southern Union Gas Company
Gas Company of New Mexico
El Paso Natural Gas Company
Arizona Public Service Company
San Diego Gas & Electric Company
Southern Union Gas Company
Southern California Edison Company
Gas Service Company
Governor George Deukmejian
Pacific Interstate Transmission Company
Pacific Offshore Pipeline Company

Appendix B

Gas Company of New Mexico
Southern Union Gas Company
Public Utilities Commission of the State of California
Pacific Gas Transmission Company
Samson Resources Company
Southern California Gas Company
Pacific Lighting Gas Supply Company
Arizona Public Service Company
Attorney General John K. Van de Kamp
Independent Petroleum Association of New Mexico
Hassell Energy Company
Ward Petroleum Corporation
Oklahoma Independent Petroleum Association
Railroad Commission of Texas
Phillips Petroleum Company
Raulo Petroleum Corporation
Oklahoma Corporation Commission
Southern California Edison Company
Southwest Gas Corporation
Pacific Interstate Transmission Company
Pacific Offshore Pipeline Company

Appendix C

Southern California Gas Company
Pacific Lighting Gas Supply Company
Gas Service Company
Governor George Deukmejian
Pacific Interstate Transmission Company
Pacific Offshore Pipeline Company
Public Utilities Commission of the State of California
Pacific Gas Transmission Company
Attorney General John K. Van de Kamp
Pacific Offshore Pipeline Company

Appendix D

Southern Union Gas Company
Gas Company of New Mexico
El Paso Natural Gas Company
Arizona Public Service Company
Samson Resources Company
Independent Petroleum Association of New Mexico
Hassell Energy Company
Ward Petroleum Corporation
Oklahoma Independent petroleum Association
Railroad Commission of Texas

[FR Doc. 83-28448 Filed 10-18-83; 8:45 am]
BILLING CODE 6717-01-M

ENVIRONMENTAL PROTECTION AGENCY

[OPP-30000/10E; PH-FRI 2453-1]

Intent To Cancel Pesticide Products Containing Lindane; Denial of Applications for Registration of Pesticide Products Containing Lindane; Determination Concluding the Rebuttable Presumption Against Registration; Availability of Position Document

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of intent to cancel; notice of denial of applications for registration; notice of determination; notice of availability of position document.

SUMMARY: Lindane-containing products are registered as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* On February 17, 1977, EPA initiated an RPAR process to consider whether the registrations for lindane products should be cancelled or modified. This notice concludes that RPAR process and announces the Administrator's intent to cancel the registrations of lindane for two uses, to continue the registration of all other uses subject to certain label requirements and use practice prohibitions, and to deny applications for registration of lindane products not in accordance with the terms of this Notice.

DATE: Requests by a registrant or applicant for registration for a hearing must be received on or before November 18, 1983 or within 30 days from receipt by mail of this Notice, whichever occurs later. Requests for a hearing by any other adversely affected party must be received on or before November 18, 1983.

ADDRESSES: Requests for a hearing must be submitted to: Hearing Clerk (A-1

[redacted]onmental Protection Agency, 401 M [redacted]W., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: By mail Jeff Kempter, Registration Division (TS-767C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Room 711, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, (703-557-7451).

Copies of the Decision Document are available upon request.

The administrative record containing public comments and publicly released Agency documents is available for public inspection from 8:00 am to 4:00 pm, Monday through Friday, except legal holidays in: Room 711E, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Regulatory Framework

Before a pesticide product may be sold, held for sale, or distributed in either intrastate or interstate commerce, the product must be registered in compliance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), [redacted]RA sections 3(a) and 12(a)(1). A [redacted]ide registration is a license allowing a pesticide product to be sold and distributed for a specified use or uses in accordance with label instructions and precautions and other terms and conditions of registration. A pesticide product will be registered only if it performs its intended pesticidal function without causing "unreasonable adverse effects on the environment," FIFRA section 3(c)(5), that is, without causing "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of [the] pesticide." FIFRA section 2(bb). Thus, to support an application for initial registration and to maintain an existing registration, the benefits of each of its uses must exceed the risks of that use when the product is used in accordance with commonly recognized practice and in compliance with the terms and conditions of registration. The burden of proving that a pesticide product satisfies the standard for registration is on the proponents of initial or continued registration.

Under FIFRA section 6, the Administrator of the Environmental Protection Agency (EPA, Agency) may c[redacted]l the registration of a pesticide [redacted]t or modify the terms and conditions of its registration whenever it is determined that the pesticide product causes unreasonable adverse effects on the enviroment. The Agency created the Rebuttable Presumption Against Registration (RPAR) process to facilitate the identification of pesticide products (or uses thereof) which may not satisfy the statutory standard for registration, and to provide an informal procedure through which to gather and evaluate information about the risks and benefits of these products and uses. The regulations governing the RPAR process are set forth at 40 CFR 162.11.

A rebuttable presumption arises if a pesticide meets or exceeds any of the risk criteria set out in the regulations. The Agency announces an RPAR by issuing a notice of determination in the Federal Register and by issuing a Position Document (PD 1), detailing the Agency's position and concerns. Registrants and other interested persons are invited to review the data upon which the presumption is based and to submit data and information to rebut the presumption of risk by showing that the Agency's initial determination of risk was in error, or by showing that use of the pesticide is not likely to result in any significant exposure to human beings or the environment. In addition to submitting evidence to rebut the risk presumption, respondents may submit evidence concerning the economic, social and environmental benefits of the use of the pesticide.

The RPAR process is concluded with a notice of determination in which the Agency states and explains its decision as to whether the presumption of risk has been rebutted. If all presumptions of risk are successfully rebutted, the RPAR is concluded and no regulatory action is commenced. If the Agency determines that any presumption of risk is not rebutted, the notice of determination contains an evaluation of the information available to the Agency concerning the social, economic, and environmental costs and benefits of continued use of the pesticide for each use pattern. In determining whether each use of such a pesticide poses risks which are greater than the benefits, the Agency considers possible changes to the terms and conditions of registration which can reduce risk and the impacts of such modifications on the benfits of the use. The Agency's determination is typically developed through a two-step process; the Position Document 2/3 (PD 2/3) contains the Agency's preliminary determinations and solicits comments and further information. The PD 2/3 is submitted to the Secretary of Agriculture (USDA) and to the FIFRA Scientific Advisory Panel (SAP) for the statutorily required reviews of a proposed notice of intent to cancel registration of a pesticide. FIFRA sections 6(b) and 25(d).

The Position Document 4 (PD 4) presents the final determination of the Agency. The final notice of determination may include a notice of intent to cancel the registrations of currently registered pesticide products and to deny applications for the registration of new products. It may also set out conditions which, if fulfilled by the registrant, would be adequate to bring the registration into compliance with the statutory requirements and thus avoid cancellation or denial of registration. The final notice may also require that the registration of the pesticide be reclassified from general to restricted use pursuant to FIFRA section 3(d)(2). In the event of a notice of intent to cancel, deny or reclassify the registration or application for registration of a pesticide product, any person adversely affected by the action may request an administrative hearing to challenge the action pursuant to FIFRA sections 6 (b) and (d).

B. Factual Background

On February 17, 1977, the Environmental Protection Agency issued in the Federal Register (42 FR 9816) a Notice of Rebuttable Presumption Against Registration (RPAR) and Continued Registration of Pesticide Products Containing Lindane, 42 FR 9816. The Agency took this action because risk criteria had been met or exceeded in three areas: (1) Acute toxicity to aquatic organisms [40 CFR 162.11(a)(3)(i)(B)(3)], (2) oncogenic effects in test animals [40 CFR 162.11(a)(3)(ii)(A)] and (3) chronic and/or delayed toxicity causing reproductive or fetotoxic effects in test animals [40 CFR 162.11(a)(3)(ii)(B)]. In addition to these criteria, the RPAR Notice listed four other possible adverse effects of lindane for which insufficient evidence existed to initiate a rebuttable presumption. The Agency requested registrants and other interested parties to submit data on the following effects: (1) Mutagenicity, (2) blood dyscrasias, (3) acute hazards to humans and domestic animals, and (4) population reduction in non-target avian species. Information was solicited also on the issue of the possible isomerization of lindane (gamma—BHC) to the alpha and beta isomers of BHC which have been shown to be oncogenic in rodents published in the Federal Register of July 21, 1978 (43 FR 31432).

As a result of the 1977 RPAR Notice, the Agency received numerous comments from interested parties regarding the risks and benefits which

result from the pesticidal uses of lindane. The Agency reviewed all comments and additional data received in response to the RPAR Notice, and issued a notice which was published in the Federal Register of July 3, 1980. (45 FR 45362) a "Preliminary Notice of Determination" for lindane. The detailed rationale for the Agency's proposed determination was contained in the lindane Position Document 2/3 (PD 2/3). The human pharmaceutical use of lindane for treatment of lice and scabies is not affected by this RPAR determination since it has been under the jurisdiction of the U.S Food and Drug Administration since 1979. 44 FR 63749.) At that time, the Agency determined that the benefits from the use of lindane were outweighted by the risks of oncogenicity and reproductive and fetotoxic effects. In addition, the Agency was also concerned (although RPAR criteria were not exceeded) about acute central nervous system effects and about childhood sensitivity to the toxic effects of lindane. Existing data did not support presumptions that lindane caused acute hazards to aquatic wildlife, that lindane was mutagenic, that lindane was linked to blood dyscrasia or that lindane was isomerized to more toxic compounds by microbial or eukaryotic organisms of any kind.

As required by FIFRA, the Agency submitted its findings to the Scientific Advisory Panel (SAP), to the U.S. Department of Agriculture (USDA) and to interested parties for review and comment. The SAP held public meetings concerning the lindane proposed determination on July 24, August 13, and August 14, 1980 and heard presentations by the Agency registrants and other interested members of the public. Both the SAP and USDA submitted comments on the lindane PD 2/3 to EPA. Their comments are presented with the Agency's responses in Unit IV of this Notice. After receiving numerous comments from these respective groups, the Agency reconsidered the extent to which risks were offset by social, economic, or environmental benefits and whether regulatory action might reduce risks without affecting the benefits of lindane's use.

A draft PD 4 dated February 23, 1983 was sent to several governmental, industry and environmental groups as well as members of the former SAP for comments because of the substantial changes being proposed from the regulatory position taken in the PD 2/3. (Congressional authorization of the Scientific Advisory Panel terminated as of September 30, 1981. See FIFRA section 25(d)). Comments received on that draft PD 4 were carefully considered by the Agency in the development of the Agency's final regulatory decision.

C. Content of This Notice

The Agency is initiating the following regulatory actions in this Notice.

(1) Cancel indoor use of lindane smoke fumigation devices.

(2) Cancel use of lindane dog dips for control of all pests except mites.

(3) Classify for restricted use the lindane uses for commercial ornamentals, avocados, pecans, livestock, Christmas trees, forestry, structural treatments, and dog shampoos and dusts, as well as require specified label amendments and protective clothing for applicators for these uses.

(4) Require specific label modifications, as appropriate, for all other lindane uses in order to reduce risks.

(5) Require mutagenicity data to be submitted.

The detailed rationale for the Agency's determinations is set forth in Position Document 4 (PD 4).

Unit II of this Notice provides a summary of the risk and benefits of the pesticidal uses of lindane. Unit III presents the Agency's regulatory decision. Unit IV sets out the comments on the PD 2/3 submitted to the Agency by the Secretary of Agriculture and members of the former Scientific Advisory Panel and the Agency's responses to those comments. Unit V of this Notice sets out the procedures by which a registrant or other person adversely affected by this Notice may request a hearing to challenge the actions proposed in this Notice. Unit V also sets out the procedures which registrants should follow in seeking amendments of their registration to conform to the requirements of this Notice in order to continue their registrations for those uses of lindane retained under this Notice.

II. Summary of Risks and Benefits of the Pesticidal Use of Lindane

The Agency, in reaching the decisions set out in this Notice, has considered information on the health risks, evironmental effects and the economic and social benefits associated with the pesticidal uses of linedane. Information was submitted by the United States Department of Agriculture, and the Scientific Advisory Panel, the Centre International d'Etudes de lindane, the California Department of Food and Agriculture, the Food and Drug Administration, the Natural Resources Defense Council, the National Audubon Society, and numerous other interested parties. The Agency's detailed assessments of risks and benefits and its regulatory conclusions are set forth in the lindane Position Document 4. This document is hereby adopted by the Agency as its statement of reasons for the determinations and actions announced in this Notice and as its analysis of the impacts of the proposed regulatory actions on human and environmental health as well as on the agricultural and industrial economy. For the reasons summarized below, and described in detail in PD 4, the determinations of the Agency on lindane are as follows.

A. Determinations of Risk

The Agency has made the following conclusions regarding the potential of lindane to cause oncogenicity, fetotoxicity and adverse reproductive effects, acute hazards to man and domestic animals, acute toxicity to wildlife, mutagenicity, and regarding the susceptibility of children to lindane and the association of lindane with blood dyscrasias.

1. *Oncogenicity.* After an exhaustive study of available data, the Agency believes that lindane should be considered to have the potential for inducing carcinogenic effects in humans. There is positive evidence that lindane causes liver tumors in mice based on two lifetime feeding studies. Two subchronic studies provide supportive evidence on oncogenicity consistent with that found in the lifetime studies. In addition, a metabolite of lindane, 2,4,6-trichlorophenol, has been shown to cause carcinogenic effects in rats and mice. There is no evidence that lindane is carcinogenic to rats.

2. *Fetotoxicity and reproductive effects.* The Agency's concern that lindane might cause adverse reproductive effects, as distinguished from fetal effects, has been successfully rebutted. Adverse fetal effects do occur but only at or above doses that also cause general toxic effects in the mother.

The presumption that lindane might cause reproductive or fetotoxic effects was originally based on three studies. In the preliminary determination (PD 2/3), EPA concluded that, due to a number of serious flaws in certain feeding studies, data were inadequate to assess the reproductive effects of lindane. One study was still considered to provide unrebutted evidence of fetotoxicity. However, a number of technical inadequacies in the study precluded its use to calculate a maternal or fetotoxic no observable effect level (NOEL). The

study was used in a qualitative sense by the Agency when it set the maternal NOEL at 5 mg/kg/day.

Subsequent to the presentation of the PD 2/3 to the SAP and after thorough reevaluation of the eight studies submitted in rebuttal to the Agency's PD 1 and PD 2/3 positions, the Agency has concluded that lindane does not cause reproductive effects, but that it does cause adverse fetal effects in test animals. The fetal effects occur only at or above doses that also cause general toxic effects in the mother. From a regulatory standpoint, the Agency has concluded that by protecting mothers from acute toxic effects, it will also simultaneously be protecting fetuses from possible adverse effects.

3. *Acute and subacute hazards to humans and domestic animals.* The Agency based its original concern regarding the acute effects of lindane on numerous studies in humans and animals which show that lindane causes symptoms of acute and subacute toxicity typical of central nervous system (CNS) effects. In PD 2/3, the Agency determined a NOEL of 2.5 mg/kg/day based on two studies. Subsequent to PD 2/3, commenters listed a number of serious deficiencies which they believed precluded the use of one of the studies (Hayes) to establish a NOEL. The Agency has reevaluated the studies and concluded that they can not be used to establish a NOEL. Although the Hayes study is not used to calculate a NOEL, it does support the Agency's original conclusion in PD 2/3 that humans and animals with similar exposure to lindane are likely to exhibit similar signs of toxicity.

The Agency has determined that the no effect level for general toxicity, found in the reproductive studies, is 5 mg/kg/day. Clinical evidence from the pharmaceutical uses of lindane suggests that exposures even higher than 5 mg/kg/day do not usually result in acute neurotoxic symptoms.

4. *Sensitivity of children to lindane.* Some commenters disputed the Agency's concern in PD 2/3 that children are more sensitive to the toxic effects of lindane than adults. Since there were serious differences in the interpretations of data, EPA reconsidered the issue of childhood sensitivity.

Children have a higher ratio of body surface area to body weight than do adults. Equivalent doses (per surface area) of lindane, applied to adults and children, produce a greater mg/kg/body weight dose to children. In addition, children lack mature hepatic conjugating enzymes for detoxification and excretion. Finally, a child's skin has greater permeability than an adult's. Thus, theoretically, toxicity could be enhanced. The pertinent studies all have serious deficiencies which preclude their use to make definitive statements regarding a unique childhood sensitivity to lindane. The Agency also reviewed the clinical reports, many of which involved children. Due to a vast array of diagnostic and observational variations and conditions, these reports did not allow for quantification of risk to children. The available data do, however, support the Agency's concern that children are more susceptible to the toxic effects of pesticides in general.

5. *Blood dyscrasias.* In the preliminary determination (PD 2/3) the Agency indicated that there were insufficient data to establish a cause and effect relationship between exposure to lindane and blood dyscrasias. The Agency also indicated that two epidemiological studies, which were in progress at that time, were intended to provide information regarding that relationship. Since that time the Agency has received a final report from one study in Iowa and the first draft of a second study being conducted in Hawaii. The results of the first study and preliminary data from the second study show that there is no statistically significant association between chronic exposure to lindane and the incidence of blood dyscrasias (including aplastic anemia).

6. *Acute toxicity to wildlife.* The Agency's original presumption of acute toxicity to aquatic wildlife was withdrawn in the preliminary determination. This was due to the fact that there were no lindane products registered for direct aquatic use. Since lindane is highly toxic to aquatic wildlife, the Agency is chiefly concerned about avoiding misuse or application practices that could result in drift or runoff. Therefore, even though the original presumption was withdrawn, the Agency will require label prohibitions against application practices which could result in drift or runoff. Such practices might include improper disposal of excess dip solution or aerial applications.

7. *Possible reductions in populations of non-target avian species.* There are no new data available to the Agency to support a presumption of population reduction of non-target avian species. The Agency maintains its position that there is currently no reason to believe lindane is causing reductions in populations of non-target avian species.

8. *Possible isomerization.* Since other isomers of BHC (alpha and beta) are carcinogenic, the Agency was concerned that lindane might isomerize to a more harmful form. EPA has concluded that the isomerization of lindane has not been established.

9. *General toxicity.* In the Notice of RPAR (PD 1) and the preliminary determination (PD 2/3), the general toxic effects of lindane were determined not to meet the RPAR criteria. Therefore, and Agency did not perform a complete review of lindane's general toxic effects. A three-month, subchronic oral feeding study in rats recently submitted to the Agency indicates a NOEL of 0.3 mg/kg/day with kidney damage at the next highest dose. In order to evaluate this study properly, it will be necessary for the Agency to review thoroughly the chronic and sub-chronic data base, which was not done as part of this RPAR. The Agency has decided not to delay the implementation of the regulatory measures contained in this Notice. However, the Agency will give high priority to the development of a Registration Standard for lindane which will include a complete review of lindane's general toxic effects.

10. *Mutagenicity.* In the Notice of RPAR (PD 1) and the preliminary determinations (PD 2/3), lindane was determined not to meet the RPAR criterion for mutagenicity. However, available mutagenicity studies on lindane were reviewed because of their bearing on the carcinogenicity issue. The review showed limited evidence for lindane's mutagenicity. Because of the lack of certain tests, a conclusive evaluation of lindane's mutagenicity was not possible. Consequently, further tests will be required to provide a more complete data base.

B. Exposure Analysis

The exposure estimates used in the PD 4, in many instances, have been changed from those used in the PD 2/3. These changes were based on three general factors: (1) Better data, including better surrogate data and new exposure information submitted after publication of the preliminary determination; (2) use of commonly accepted use practices rather than worst-case use practices because better data were available to replace theoretical assumptions used in the PD 2/3; and (3) acknowledgment of those uses in which protective clothing is routinely worn. This latter factor helped the Agency determine that protective clothing requirements will not require changes in use practices and assured the Agency that imposing protective clothing requirements for other uses will be effective in reducing risks.

1. *Applicator exposure.* Applicator exposure estimates (excluding dietary)

were calculated for the major uses of lindane: avocados, pecans, commerical ornamentals, forestry, homeowner ornamentals, foliar an stump/slash applications to Christmas trees, structural applications, dip applications (livestock, lumber, pet dips and shampoos), enclosed area sprays (moth sprays, uninhabited buildings and storage bins), dust applications (seed treatments and pet dusts), cucurbits, pineapples, and several household products. The details of these calculations are contained in Appendix III of PD 4.

2. *Dietary exposure.* The Agency's PD 2/3 estimate of dietary exposure was taken from the Food and Drug Administration's market (Total Diet Composites) survey for the years 1972 to 1975. Comments were received which indicate that more recent data should be used. The Agency agrees that the more recent data should be used and, therefore, has estimated dietary exposure from FDA data for the years 1976–1980. In addition, a second estimate has been made using the entire FDA data base of 1964–1980. For the period 1976–1980 the dietary exposure estimate is 0.003 ug/kg bw/day. The estimate for the entire data base (1964–1980) is 0.016 ug/kg/day. Details of the dietary assessment are contained in PD 4 (Table 5).

C. Determinations of Benefits

The Agency's determination of benefits was completed in June, 1978 and was expressed in terms of 1975–1976 dollar values. Although the benefits analysis was not updated in the PD 4 (except for a few cases), the Agency has concluded that the economic estimates are understated. The nominal dollar measure of impacts is larger due to inflation and to the conservative methods of assessment in PD 2/3.

The Agency received 141 comments in response to the PD 2/3. The vast majority addressed the high benefits of using lindane and the lack of alternatives for these uses.

1. *High Benefit Uses*

High benefit uses of lindane are defined by the Agency as those uses for which cancellation would result in significant impacts and for which there are no alternatives. High benefit uses are summarized as follows:

a. *Woody ornamentals, including Christmas trees.* The Agency estimates that cancellation of the use of lindane on woody ornamentals would have a $20.6 million economic impact due to borer damage. Lindane is the only pesticide registered to control all borers in all woody ornamentals. For Christmas trees and increased cost of $0.20–$1.70 per acre would result form the substitution of the alternative, osydimetomethyl, for lindane. There are no alternatives for use against certain beetles.

b. *Forestry.* Small, privately owned, southern forest areas would be the hardest hit economically by a cancellation of lindane for forest use since forest mangaers rely heavily on chemical control and cannot gemerally afford labor-intensive cultural management practices. There are no alternatives for control of various bark beetles.

c. *Seed treatment.* Major regional impacts for spring-planted small grains at the user level from wireworm infestation would result from cancellation. If significant production losses were to occur, there could be major small grain market level impacts. For lentils and dry peas, there are no alteratives to lindane seed treatment. The benefits of lindane seed treatment on small grains, lentils, and dry peas cannot be accurately quantified due to a lack of data. The Agency's position is that the estimated benefit for corn seed treatment is $690,000.

d. *Structures.* Lindane contains effective properties for the control of power post beetles. The alternatives are significantly more expensive and inconvenient.

e. *Avocados.* Lindane is used on up to 90 percent of the Florida avocado crop on an annual basis to control mirids. There are no registered alternatives for control of this pest. The unavailability of lindane was estimated to result in producer losses of $8.7 million due to downgrading and fruit loss. The impacts of cancellation would be moderate in most growing regions, but severe in Florida.

f. *Historic preservation.* There are no alternatives for the control of powder post beetles.

g. *Hardwood logs and lumber.* The Agency calculated the approximate no-alternative impact of the cancellation of lindane to be $247 million in 1980 dollars. Figures are not available on the potential impact of the recent registration of endosulfan as a control for hardwood lumber destroying beetles. Endosulfan will cost approximately $0.15 more per 1000 board feet on average, resulting in an average total U.S. cost impact of approximately $500,000 annually. There is a question of supply availability for endosulfan.

h. *Dog dips.* Lindane use in dog dips for treatment of mites is a high benefit use for which is no alternative. All other uses of lindane dog dips are low benefit uses.

2. *Moderate Benefit Uses*

Moderate benefit uses are those uses for which either alternatives are not available, but the impact of cancellation is minor, or alternatives are less effective or more expensive. Moderate benefit uses of lindane are as follows:

a. *Foral and foliage ornamentals.* There are no alternatives for certain uses, but cancellation would not cause severe impacts.

b. *Livestock dips.* There are several efficacious alternatives to lindane for control of livestock pests, with the exception of mites The economic impact of cancellation was estimated to be $1,603,400 annually, small relative to livestock industry revenues.

c. *Pineapples.* Lindane is used to treat about 9,700 acres or 72 percent of the total planted per year with pineapples in Hawaii. It is used in conjunction with soil fumigants to control symphylids. Total reliance on soil fumigants would result in an annual crop loss of 0.8 percent (5,150 tons) valued at $.515 million. Total economic impacts over the four-year production cycle in Hawaii were estimated at $1.018 million. For Puerto Rico, about 1,300 acres are planted annually and about 2,600 pounds of lindane are used annually. A total annual reduction in returns would amount to approximately $.375 million if lindane is unavailable for pineapple use in Puerto Rico.

3. *Low Benefit Uses*

Low benefit uses are those for which alternatives exist or cancellation of lindane would result in only minor impacts. Low benefit uses of lindane are:

a. *Cucurbits.* The impact of lindane cancellation for cucurbit growers was estimated to be $176,000 annually from increased costs due to adopting available alternative chemicals. No yield loss is expected.

b. *Pecans.* Lindane is used on pecans to control pecan phylloxera. The use of alternative pesticides was expected to result in grower level impacts of up to $1.5 million annually due to a combination of control costs and crop losses.

c. *Household products (including indoor smoke fumigation devices).* Effective, competitively priced alternatives to lindane products are available.

d. *Dog dips.* For treatment of pests other than mites, dog dips are a low benefit use since numerous alternatives are available in the same price range.

III. Initiation of Regulatory Action

A. Cancellation Actions

Based upon the determinations summarized above and discussed in detail in Position Documents 1, 2, 3, and 4, the Agency has determined that the risks resulting from the indoor use of smoke fumigation devices and from use of dog dips to control pests other than mites are greater than the social, economic, and environmental benefits from such uses. Therefore, the Agency is cancelling these uses, effective at the end of the 30 day period described in the statute.

Cancellation of the indoor smoke fumigation devices is based on the facts that the estimated lifetime cancer risk is about 10^{-4} for two applications per year, that the products are available to the general public, that there is no way of effectively limiting the number of applications or providing for suitable aeration after application, that there are numerous alternatives for the same spectrum of pests, and that there will not be a detectable economic impact to the user if these formulations are cancelled.

The Agency will limit the use of dog dips only to control mites and will cancel dog dips to control any other pest. This action is based on a determination that the benefits for uses other than treatment of mites were low because of the availability of alternatives and that risks were high when weighed against the benefits. The cancer risk is $4.2 \times 10^{-10^{-6}}$. Because of the potentially large cohort at risk, the Agency has determined that habitual treatment for pests other than mites would result in unacceptable cancer risks to the general public.

B. Actions Modifying Terms and Conditions of Registration

The Agency also has determined that the risks of all other registered uses of lindane are greater than the social, economic, and evironmental benefits of such uses, unless the terms and conditions of registration are modified. Briefly, these modifications involve (depending on the use) restriction of use to certified applicators, additional label precautions and use of protective clothing and equipment. The following use-by-use summary includes, for those uses which are not being cancelled, the modifications in terms and conditions that are necessary to maintain registrations or that must be met to obtain new registrations. Registrations will be cancelled and applications for registration will be denied unless registrants or applicants modify their labels in accordance with the terms and conditions set forth in this Notice.

1. *Commercial Ornamentals, Avocados, Pecans, Livestock, Forestry, Christmas Trees, Structural Treatment, Dog Shampoos, and Dog Dusts*

The Agency is requiring that all lindane products registered for the following uses be classified for restricted use: commercial ornamentals, avocados, pecans, livestock, forestry, Christmas trees, structural treatments, dog shampoos, and dog dusts. The labels must contain the following language:

Restricted Use Pesticide

For application only by or under the direct supervision of a certified applicator.

For all the above uses of lindane subject to the restricted use classification (except dog shampoos as noted below) the Agency is requiring that the labels be modified to contain the following language:

Applicators must wear the following protective clothing during the application process: a light-weight protective suit or coveralls; water-resistant hat; unlined, waterproof gloves; and unlined, lightweight boots. Mixers and loaders must also wear goggles or a face shield, waterproof gloves and a waterproof apron.

a. *Additional requirements for dog dust use.* In addition to the above requirements, labels for lindane products registered for dog dust use must contain the following label warning:

This product should be applied in a well-ventilated area.

b. *Additional requirements for structural treatment.* In addition to the above requirements, labels for lindane products registered for structural treatment use must contain the following label language:

Applicators working in enclosed areas, such as crawl spaces, must wear a respirator approved by OSHA (29 CFR 1910.134).

c. *Protective clothing requirements for dog shampoos.* Applicators of lindane dog shampoos must wear the following protective clothing during the application process: waterproof, elbow-length gloves; a water-proof apron; and unlined, waterproof boots.

2. *Homeowner Ornamentals*

For the use of lindane for homeowner ornamentals, the Agency is requiring that the labels be modified to contain the following language:

Applicators must wear the following protective clothing during the application process: long-sleeved shirt, long pants, waterproof gloves, full foot covering, and a head covering.

3. *Hardwood Logs and Lumber*

For the use of lindane for treatment of hardwood logs and lumber, the Agency is requiring that the labels be modified to contain the following language:

Applicators must wear the following protective clothing during the application process: lightweight protective suit or coveralls: unlined, waterproof gloves; and unlined, lightweight boots.

4. *Dog Dips*

For the use of lindane for dog dips, the Agency is requiring that the labels be modified to contain the following language:

Use of this product is permitted *only* for treatment of mites. The use of this product for treatment of other pests is prohibited. Applicators must wear the following protective clothing during the treatment process: elbow-length, waterproof gloves; a waterproof apron; and unlined, waterproof boots. Improper dilution of this product could cause serious injury to your pet. Children should not be allowed to handle or apply this product.

5. *Moth Sprays*

For the use of lindane for moth sprays, the Agency is requiring that the labels be modified to contain the following language:

Applicators must wear MSHA/OSHA-approved cartridge respirators when applying this product.

6. *Seed Treatment*

For the use of lindane for seed treatment applications, the Agency is requiring that the labels be modified to contain the following language:

Applicators who apply this product manually or without the use of a closed-system treatment procedure must wear the following protective clothing during the application process: long-sleeved shirt; long pants; gloves; and a disposable, paper dust mask which covers at least one-third of the face.

The labels must also carry the warning: This product should be applied in a well-ventilated area.

The Agency is not imposing a protective clothing requirement for automated or closed-system treatment procedures.

7. Other Household Uses (Flea Collars, Shelf Paper and Household Sprays

For the use of lindane in other household products (flea collars, shelf paper and household sprays), the Agency is requiring that the labels be modified to contain the following language:

Do not allow children to handle or apply this product.

Children and pets should not be allowed in treated areas until sprayed surfaces are dry.

8. *Label Modifications Applicable to All Lindane Products Subject to This Notice*

In addition to the label modifications specified above, the Agency is requiring that the labels for all lindane products be modified to meet current standards as specified in 40 CFR 162.10. Labels must describe proper handling and disposal, symptoms of poisoning, practical treatment in the event of poisoning, and other warning statements appropriate for the product's toxicity category.

Labels for applicable uses must contain the statement:

Aerial application of lindane is prohibited.

Finally, any lindane products registered for residential use (dog dips, household products) that contain more than 6.5 percent active ingredient must comply with EPA's child-resistant packaging regulations set forth in 40 CFR 162.10. See also Federal Register of March 31, 1981 (46 FR 15104).

9. *Applications for Registrations for Direct Application to Aquatic Environments*

All applications for registrations for direct application to aquatic environments will be denied.

10. *Disposal of Dips*

The following shall apply to all dip uses, except those intended for household use:

Used dip solutions must be disposed of in accordance with the Resource Conservation and Recovery Act (RCRA). If the applicator generates more than 1000 kg of used dip solution per month or more than 1000 kg used dip solution in combination with other hazardous waste, the material must be treated as a hazardous waste subject to subpart C of RCRA. Any user who wishes to treat, store or dispose of hazardous waste must obtain a permit to serve as a hazardous waste facility pursuant to RCRA.

C. Testing Requirements

The Agency has determined that there is an outstanding question as to whether lindane is a mutagen and that further mutagenicity testing is required. An informal agreement regarding mutagenicity testing has been reached between the Agency and the Centre International d'Etudes du Lindane (CIEL). The Agency will issue a notice pursuant to FIFRA section 3(c)(2)(B) to all registrants of lindane indicating that additional mutagenicity data are required. The Agency anticipates that the voluntary agreement with CIEL will satisfy the provisions of section 3(c)(2)(B) regarding joint data development. The tests which are being required include: (1) *in vitro* gene mutation testing in mammalian cells, (2) *in vivo* oral and parenteral assay for sister chromatid exchange, and (3) *in vitro* test in mammalian cells under anaerobic conditions. The requirement for these data will be independent of the Agency's RPAR determination as set forth in this Notice to modify the terms of registration.

IV. Comments of Scientific Advisory Panel and Secretary of Agriculture

A. comments of the scientific advisory panel

Pursuant to section 25(d) of FIFRA, notices of intent issued under section 6(b) are to be submitted to an advisory panel "for comment as to the impact [of the proposed action] on health and the environment."

The Agency transmitted the Position Document 2/3 to the Scientific Advisory Panel (SAP) in June, 1980, for review. On October 6, 1980, SAP responded to the Agency. The SAP's comments are reproduced below in their entirety.

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel

Review of Preliminary Notice of Determination Concluding the Rebuttable Presumption Against Registration (RPAR) of Pesticide Products Containing Lindane

The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Scientific Advisory Panel has completed review of plans by the Environmental Protection Agency (EPA) for initiation of regulatory action on pesticide products containing lindane under the provisions of section 6(b)(1) of FIFRA as amended. The review was completed in open meetings held in Arlington, Virginia, during the period July 24, 1980, and August 13–14, 1980. Maximum public participation was encouraged for the review. Public notices of the meetings were published in the Federal Register on July 3, 1980, and July 25, 1980. In addition, telephone calls and special mailings were sent to the general public who had previously expressed an interest in activities of the Panel. Written and oral statements were received from the technical staff of the Environmental Protection Agency, and from representatives of the Centre International d'Etudes de Lindane, the National Pest Control Association, the National Association of Wheat Growers, the Paper Products, Inc., North Dakota Crops Council, Oregon Wheat Growers League, Washington Wheat Commission, Rachel Carson Council, Inc., Idaho Wheat Commission, Athena Products Corporation, University of Idaho, and the North Dakota State Wheat Commission.

In consideration of all matters brought out during the meeting and careful review of all documents presented by the Agency and other parties, the Panel unanimously submits the following report:

Lindane, the gamma-isomer of hexachlorocy-clohexane, appears to be the least hazardous of the widely used organochlorine insecticides. Available data suggest than lindane is at worst a weak animal carcinogen, may have a low degree of fetotoxicity, may disrupt repoductive processes, and can produce central nervous system excitability after oral and dermal *ingestion*. The Panel agrees with EPA that lindane is substantially more toxic to young than adults in both humans and domestic animals and that chronic exposure can sometimes result in disastrous blood dyscrasias. However, for certain uses in insect pest control, e.g., scabies, bark beetles and powder post beetles, and seed treatment for wireworms, lindane has no available substitutes and these and certain very limited applications in agriculture and protection of ornamentals are both essential and well suited to Integrated Pest Management procedures. Furthermore, the total amounts of lindane used for these uses, e.g., <one million pounds annually, represent an minimal hazard to the environment. Therefore, the Panel has the following comments and recommendations:

1. Household used of lindane in treated shelf paper and floor waxes provide an unwarranted risk to the householder and should be cancelled immediately.

2. Pet uses for unrestricted use as flea collars, dog dusts, and dog shampoos should be cancelled immediately. Veterinary medical preparations of lindane for use in mange and scabies and for flea, louse and tick control should be available as collars, powders, sprays, shampoos, and dips under restricted classifications for use by licensed veterinarians only with label cautions and requirement for protective clothes, as proposed by EPA.

3. Ornamental applications for unrestricted use by the homeowner should be cancelled immediately. Ornamental uses restricted to commercial operators should be continued with full warning label cautions about the hazards of cancer, fetotoxicity, an central nervous system effects and a caution that women of child-bearing age and children must avoid exposure. Full protective clothing must be worn.

4. Lindane registrations for powder post beetle control should be continued under restricted classification for use by registered Pest Control Operators with full warning label cautions and full protective clothing proposed by EPA.

5. Livestock applications should be placed under restricted classification for use by certified applicators only with full warning label cautions and mandatory protective clothing as proposed by EPA.

6. Uses on pineapples should be retained with warning label cautions proposed by EPA.

7. Uses on cucurbits should be continued under restricted classification with full warning label and mandatory protective clothing proposed by EPA.

8. Uses on avocadoes should be conti[illegible] under restrictive classification with full

[redacted] label and mandatory protective [redacted] proposed by EPA.

[redacted]es on pecans should be continued under restricted classification with full warning label and mandatory protective clothing proposed by EPA.

10. Uses on Christmas trees should be continued under restricted classification with full warning label and mandatory protective clothing proposed by EPA.

11. Uses in forestry for bark beetle control should be continued under restricted classification for application by certified operators with full warning labels and mandatory protective clothing as proposed by EPA.

12. Applications to hardwood logs and lumber should be continued under restricted classification with full warning labels and mandatory protective clothing as proposed by EPA. Special caution should be given to improving work place practices and disposal of treated sawdust and shavings.

13. Seed treatment uses of lindane should be continued under restricted classification by certified applicators with full warning labels and mandatory protective clothing proposed by EPA. Testimony presented to the Panel suggests that 90% of lindane seed treatments are made with closed mechanical systems that essentially eliminate operator exposure. EPA should sponsor an educational program to make use of such closed mechanical seed treatment systems universal.

14. The suspicion that lindane interferes w[redacted] reproductive processes (hormones) i[redacted]es that a 3-generation reproductive s[redacted] should be performed on an appropriate laboratory animal.

For the chairman:

Certified as an accurate Report of Findings:

H. Wade Fowler, Jr., Ph.D.,

Executive Secretary, FIFRA Scientific Advisory Panel.

Date: October 6, 1980.

B. Response to Comments of the SAP

The SAP made some general comments regarding the risks and benefits of lindane and included a list of specific recommendations for each use. In response to the general comments, the Agency's final position on the risks and benefits of lindane is basically consistent but differs in details with the SAP's position.

The SAP asserted that lindane is a weak oncogen, that it may have a low degree of fetotoxicity, that it may disrupt reproductive processes, and that it can produce central nervous system excitability. The Agency finds that there is positive evidence that lindane causes liver tumors in mice. Although the biological data base is inconclusive, the Agency has used the linearized multistage model for estimating possible risks to humans. In light of carcinogenic [redacted]s of lindane in mice and the [redacted]nogenicity of a lindane metabolite in rats and mice, the Agency believes that lindane should be considered to have the potential for inducing carcinogenic effects in humans. However, as discussed in Unit II, the estimated risk levels have not been found to be unreasonable in most cases as long as certain use precautions and/or restrictions are observed.

Regarding reproductive and fetotoxic effects, the Agency has concluded that the presumption of reproduction effects has been rebutted because effects observed in certain studies could not be linked to treatment with lindane.

A NOEL has been established for fetotoxicity and maternal toxicity. The margins of safety for all uses are large enough not to prompt the Agency to cancel any uses because of fetotoxic effects.

Concerning central nervous system excitability and the possible effects of lindane, the Agency has concluded these effects still do not meet the RPAR criteria.

As discussed in Unit II, based on comments received, the Agency has reevaluated the benefits of lindane and found them to be greater than was thought at the time the PD 2/3 was developed. However, the Agency does not concur with SAP's assertion that "the total amounts of lindane for these user, e.g., more than one million pounds annually, represent a minimal hazard to the environment." the Agency believes that most of the uses of lindane present an unreasonable risk unless their use is made safer through use restrictions and lable modifications.

The SAP presented 14 specific recommendations, 13 of which recommended regulatory actions which should be adopted for specific uses. For many of the uses, the Agency's final position is the same as the SAP's. These uses and actions include: cancellation of household fumigation devices; cancellation of dog dips for pests other than mites; restriction of use on livestock, avodacos, pecans, Christmas trees, and forestry to certified applicators only; and requirement of label warnings for pineapples. On the other uses for which SAP either recommended cancellation or restricted use classification, the Agency has concluded that less stringent measures are adequate to prevent unreasonable adverse effects. Specifically, the Agency believes that shelf paper should not be cancelled; that pet uses should not be cancelled, but that dog shampoos and dusts should be restricted to veterinarians, while dog dips for control only of mites should continue to be available with label warnings and restrictions; that homeowner ornamental applications, use on cucurbits, applications to hardwood logs and seed treatments need not be classified for restricted use but that protective clothing and other label precautions are required. (All registrations for lindane floor wax have been withdrawn).

SAP's final recommendation was that a three-generation reproductive study should be performed. The Agency points out that such a study is now available, has been reviewed and shows no reproductive effects.

C. Comments of the United States Department of Agriculture

As required by FIFRA section 6(b), the comments of USDA on the Position Document 2/3 are presented below in their entirety.

November 17, 1980.

Hon. Douglas M. Costle,

Administrator, U.S. Environmental Protection Agency, Washington, DC 20460.

Dear Mr. Costle: This is in response to the U.S. Environmental Protection Agency's Notice of Determination concluding the Rebuttable Presumption Against Registration of Pesticide Products Containing lindane.

We interacted with EPA in developing the biological, economic, and exposure information according to the current Memorandum of Understanding between our two agencies. Thus, we are pleased to be able to review and comment on this Notice and the accompanying position document.

The opening sentence on Page III-1 is incorrectly cited. The full title of the June 1978 report is "Preliminary Benefit Analysis of lindane prepared jointly by USDA and EPA." The basic biological and economic information contained in the June 1978 and the October 1979 report is the same. Both of these reports were compiled by the joint USDA/States/EPA lindane assessment team. Because of the opening statement on page III-1, our state cooperators have voiced concern that their joint efforts may not be utilized by EPA.

There are areas of agreement as well as issues of concern to us and to the cooperating States. Our comments on these specific items are contained in the enclosure which is an integral part of this response.

The additional time you granted for our review of this document was very beneficial and is appreciated. We are hopeful EPA will give favorable consideration to these suggestions.

Sincerely,

Bob Bergland,

Secretary, U.S. Department of Agriculture.

Enclosure—Secretary of Agriculture's Response Lindane Notice of Determination, PD 2/3

1. We believe that every effort should be made to maintain pest control strategies without causing unacceptable risks to users and the public. We concur with EPA's selection of regulatory options regarding the continued registered uses of lindane on livestock, pineapples, pet washes, and

commercial ornamentals with certain lable modifications, including "Restricted Use."

2. We concur in EPA's proposed regulatory options of cancellation where the risks appear to exceed the benefits. These include

—Household use associated with shelf paper, waxes, sprays and smokes (fumigation devices), and the minor use associated with industrial moth sprays;

—Pet applications including collars, shampoos and dusts;

—Insect sprays—uninhabited buildings, and

—Empty storage bins—fog sprays. All of these uses involve continuous exposure for which there are adequate substitutes.

3. The precautionary statement, "Do not use lindane products on pregnant or young animals," may be desirable for veterinarians treating household pets. However, it may be impractical or impossible, in many cases, to make pregnancy determinations when livestock herds are being treated. We suggest that this statement be modified to be advisory rather than a label prohibition.

4. We share the EPA's concern for applicator exposure but would like clarification of the exposure calculations used since this was not explained in PD 2/3. Also, we recommend consistency in the selection of available protective clothing. The following label modifications on the use of protective clothing might be considered:

—Long sleeved shirts and pants.

—Impervious gloves (rubber or neoprene) and boots.

—Wide brimmed hats or roof type covers over spraying equipment when overhead spraying on agricultural and/or forestry sites.

—Approved respirators when handling dust formulations and when spraying in confined spaces.

—Impervious (rubber or neoprene) aprons in those areas where normal treatment practices could anticipate splashing of the treatment solutions and where aprons do not constitute a hazard around equipment.

5. *Livestock.*—As pointed out in the USDA/State/EPA benefit report, lindane is often used in combination with other pesticides, primarily toxaphene, to control pests on livestock. One of the more popular combinations is lindane (2%) and toxaphene (44%). This combination results in immediate control by lindane coupled with the longer residual activity provided by toxaphene. In developing the final regulatory action for lindane, the regulatory actions taken on toxaphene must also be considered.

We believe that if the lindane registrations for livestock are retained, but the registered uses of toxaphene are cancelled, the livestock industry would be unable to control certain pest problems.

6. *Hardwood Logs and Lumber.*—The decision to phase out this use over a 2 year period in the absence of effective registered alternatives seems inappropriate considering the extent of anticipated hazard. A July 28, 1980 letter from Southern Forest Experiment Station at Gulfport, Mississippi, to the Documents Control Office of the Chemical Information Division of EPA indicated the limited but critical amounts of lindane used in protecting wood from beetle attacks. As the assessment report notes, there are no chemical or nonchemical alternatives available for the registered uses of lindane on hardwood logs and lumber. Chlorpyrifos is not registered for use on felled hardwood logs and lumber and there are no assurances that it will be effective and that such registrations will be obtained. It is questionable as to whether 2 years is sufficient time for registrants to develop and have reviewed by EPA the volume of data needed for a new registration of this type. We therefore suggest that EPA give further consideration to the adoption of Option 2 (continued registration) with the appropriate label modifications to reduce exposure.

7. *Seed Treatment.*—We are concerned about the impact of the proposed cancellation of lindane as a seed treatment. The absence of an effective seed protectant results in insect injury to the seed with the resulting loss of plant stand, plant vigor, yield losses, and increased susceptibility to disease organisms. Some of these losses may necessitate the time and expense of replanting which results in yield losses due to the shortened growing season. EPA indicated that lindane seed treatments are applied as insurance treatments. Because of the pests involved, this is the only procedure that is practical and applies equally to the alternatives. Most crops are planted when soil temperatures are low. Lindane is effective and stable at these lower soil temperatures while the alternatives generally are not. There are no seed treatment alternatives for small grains, dry peas and beans, lentils, sorghum, sunflowers, sugar beets, and vegetables. In actual practice, the small grain producer that uses lindane seldom treats his own seed, but purchases it already treated. Lindane is registered and effective for the control of seed corn beetles, seed corn maggots, and wireworms. The possible alternatives to lindane on corn are diazinon and chlorpyrifos. Diazinon is not registered as a seed treatment for wireworms, and chlorpyrifos is only registered as a seed treatment for control of seed corn maggot. Therefore, without lindane, wireworm problems can be expected to increase to the extent that significant crop losses will occur. The alternatives can only be applied as a planter box treatment to corn.

Lindane, however, can be applied similarly, as a slurry treatment seed dealer or elevator, and in advance of planting by automatic seed treaters that meter the proper amount of material directly to seeds during the planting process.

These latter two options, which are essentially closed systems, should be considered as a means of reducing potential exposure, in lieu of cancellation.

8. *Avocados.*—We support the delayed "final decision" on this use until the Unviersity of Florida has had an opportunity to finalize its data on the avocado/mirid project. We believe that since this is truly a minor use, with no effective alternative controls available to producers, every consideration should be given to regulatory options to retain this registration.

9. *Ornamentals.*—As previously stated, we agree with the continued registration of lindane on ornamentals (including greenhouse and nursery plants) by commercial applicators.

Because continuous exposure is not involved and there are no satisfactory substitutes, we further recommend that registrations for lindane be retained for homeowner use on ornamentals with appropriate label modifications to reduce possible exposure. This use is only on an "as needed" basis and usually requires no more than one application every year or every few years. As pointed out in the PD 2/3, lindane is the only material registered for the control of all major borer species on woody ornamentals.

10. *Cucurbits.*—Lindane is registered for the control of a wide range of insects on cantaloupes, cucumbers, pumpkins, squash, and watermelons. This is not true for any of the alternative insecticides identified in PD 2/3. The USDA/State/EPA benefits report indicates that significant increased treatment costs can be expected from the cancellation of lindane for these uses. Most of the alternative insecticides may be more hazardous to the applicators, beneficial insects, and pollinators, and require more frequent applications. Therefore, we suggest the selection of Option 2 providing for the continued registered use on curcurbits.

11. *Minor Uses.*—There are minor use registrations not specifically addressed in either the USDA/State/EPA benefits report or in PD 2/3 that are important to regional or local areas and Puerto Rico. Of importance in the continental United States are preplant treatments labeled for the control of soil insects attacking celery, cucumbers, kale, lettuce, melons, pumpkins, spinach, and tomatoes. Of particular interest outside the continental U.S. are the control of the West Indian sugar cane root borer weevil and white grubs on sugar cane, symphylans and grubs in pineapples, cutworms and white grubs on vegetables, foliage applications for the control of scales, white flies and other foliage insects of mangos, lace bugs on ornamentals, registrations be retained with appropriate label modifications.

12. *Christmas Trees.*—The principal insects of concern on Christmas trees are the white pine weevil, the pales weevil, and the pine root weevil. The white pine weevil attacks new terminal growth, and this is the only area that requires treatment. Therefore, insecticidal applications can usually be made with compressed air, handgun, or backpack equipment which deliver coarse droplets. The only registered alternative for this use, oxydemeton-methyl (Metasystox-R), costs up to two times that of lindane. This insecticide is more toxic than lindane, especially from a dermal exposure aspect. The pales weevil and pine root collar weevil are attracted to recently cut pine stumps where they begin their life cycle in the roots of cut stumps. The most appropriate control for these insects is to make insecticidal applications to the cut stumps and adjacent soil. These treatments are normally applied with commercially available boom type sprayers, all of which deliver coarse sprays. In the case of the pales weevil, control must be obtained to prevent reinfestation for the remaining standing trees. Foliar sprays are seldom used for the control of this weevil if cut stumps are treated.

[illegible]ltural or non-chemical control's [illegible]g basal pruning, duff removal, stump or slash removal, or two year land fallow have been advocated but are not economically feasible and also increase the possibility of soil erosion. Losses to pines when only nonchemical controls are utilized have been calculated to range from $644 to $1,020 per acre. The lower figure considers only equipment and labor costs, the higher figure also includes yield losses (Scotch pines, Michigan).

In Pennsylvania, lindane is an essential part of their Christmas tree integrated pest management program. Due to the nature of the pests involved and the effectiveness of lindane for their control, we suggest that Option 2 be selected. Regulatory options, such as protective clothing and equipment modifications, should be considered as alternatives to cancellation.

13. *Pecans.*—The presently available chemical alternatives for pecan phylloxera control, identified in PD 2/3, include oil or malathion. These chemicals are not as effective as lindane and for six of the major pecan producing States, the use of these products as replacements for lindane would increase control costs by $631,000. For Georgia alone, control costs were estimated to increase $286,000. In these same six States, yield losses were estimated at $742,000. We also question the advisability of substituting endosulfan for this use because of its greater relative toxicity. Lindane is applied once per year so exposure is minimal. Further, there are [illegible] nonchemical control alternatives. Until other effective environmentally acceptable control measures are assured for those States having this problem pest, the availability of lindane is essential and should be retained.

14. *Forestry.*—Although lindane is not widely used in forestry, there are a number of locations where its use is critical to continued timber production. PD 2/3 is in error when it states that "a variety of chemical alternatives are presently registered" for forestry uses. For the mountain pine beetle, *Dendroctonus ponderosae* Hopkins, a major forest insect pest in many western areas, only three pesticides are registered: lindane, ethylene dibromide (EDB), and cacodylic acid. Both EDB and cacodylic acid are currently under Rebuttable Presumption Against Registration (RPAR) review and it appears likely that the forestry uses of EDB will be cancelled. Problems associated with the critical timing and method of application of cacodylic acid makes use of that chemical almost nonexistent. Further, the use of trap trees is not possible in very many situations, primarily because of the need to treat so many trees within a very limited amount of time. Ips spp. and the spruce beetle, *Dendroctonus rufipennis* (Kirby), are two other important bark beetles in the West for which lindane and EDB are the only chemicals reasonably useful for direct control. We do not believe chlorpyrifos, dicrotophos, and endosulfan can be considered alternatives to lindane. Forest S[illegible] research indicates that chlorpyrifos is in[illegible]ve against the mountain pine beetle. Dicrotophos and chlorpyrifos do not control the spectrum of insects that are controlled with lindane and are more expensive. Dicrotophos and endosulfan are acutely toxic and present a real hazard to applicators far greater than lindane. In addition, endosulfan is limited to use on logs. Along the Colorado Front Range and in South Dakota, areas where private landowners treat bark beetle infested trees with lindane. This is not a typical forestry application but the chemical is used in a forest environment and cannot be considered an ornamental use. Although the Forest Service does not have data on the amount of lindane being applied this way, based on the number of citizen inquiries received, we are sure that a substantial amount of lindane is being used. Lindane is the only chemical available to homeowners for the treatment of bark beetles, because the formulators of the EDB-registered products only sell to State or Federal agencies.

To reduce losses from bark beetles on an area-wide basis, a combination of methods is used. Various tools are necessary for satisfactory production of forest products at economical prices. Where insect infested timber is accessible and economically valuable, salvage logging is used to reduce the insect population and, at the same time, recover some value. Silvicultural practices are utilized to provide long term protection from bark beetle epidemics. High value trees in recreation areas and around homes are sprayed to prevent attack. Nonchemical and silvicultural controls are useful, but not applicable to all areas and situations. Direct control using lindane or EDB is used on infested trees where the other methods are not practical due to terrain, timber value, or other factors. If lindane is cancelled, one important tool of this integrated approach is lost. However, we agree that one of the major impacts of cancellation will be to the small private landowners in the South. Salvage logging of beetle infested and uninfested green timber trees is the only effective suppression technique that can be used during severe infestations. The cut-and-leave without chemical treatment alternative is the one most widely used when salvage is not practical. This method is only effective during the hot summer months when the beetles are most active. Heat is needed to drive the beetles out of the infested logs before they have fully developed, thus stopping the spread of the infestation. However, the best time to control the beetles is when they are in the trees during the colder winter months. This is when the cut-and-spray (Dudare) treatment must be used.

One of the questions of concern about this product is the possible adverse effect on human health when used inside the home. The Wood Preservative Assessment Team has recommended that PCP not be used in the home, and some labels already carry this statement. Because the hazards of PCP preclude its use inside dwellings, it cannot be considered an alternative to lindane. Lindane is effective for the control of the wood boring insect complexes, dry wood termites, and there are no other safe effective alternative control measures. We suggest the adoption of Option 2 (continued registration). Label modifications are suggested in lieu of cancellation.

D. Response to Comments of the USDA

The Agency's final regulatory position is similar to that recommended by the Secretary of Agriculture. While USDA concurred with the proposal to cancel household uses, pet applications, insect sprays in uninhabited buildings and empty storage bins, the Agency has concluded that only the indoor fumigation devices and dog dips for treatment of pests other than mites must be cancelled. The Agency and USDA are in agreement that most other uses should be retained with label modifications and, in some cases, classification for restricted use by certified applicators. In response to USDA's request for clarification of the exposure calculations, such calculations have been included in the appendix to the PD 4. USDA has suggested that consistency be established for the protective clothing requirements. Accordingly, these requirements have been standardized so that the same types of protective clothing are required for most uses.

V. Procedural Matters

This Notice announces the Administrator's intent to cancel the registration of products containing lindane for the indoor smoke fumigation use, to cancel dog dips for treatment of pests other than mites, and to cancel registrations and deny applications for registrations for lindane products for the remaining uses unless the registrants and applicants modify the terms and conditions of registration to comply with the requirements of this Notice. As provided in FIFRA sections 6(b) and 3(c)(6), the cancellations and denials proposed in this Notice shall become final and effective at the end of 30 days from receipt by the registrant or applicant, or publication of this Notice whichever occurs later, unless within that time either (i) the registrant or applicant makes the necessary corrections, if possible, or (ii) a request for a hearing is made by a person adversely affected by the Notice. The 30 day time period in which to request a hearing is applicable to all the regulatory actions proposed in this Notice. This unit of the Notice explains how registrants may seek to make any necessary corrections to modify the terms and conditions of registration and how registrants and other adversely affected parties may request a hearing on the actions set forth in this Notice.

A. Procedures for Amending the Terms and Conditions of Registration

To make the changes required to avoid cancellation, registrants, within 30

ays of receipt of this Notice, must mit amended label(s) and pplication(s) for amended gistrations(s) making the necessary rrections. Five copies of the amended abeling and an application for amended gistration(s) must be submitted to:

George LaRocca, Product Manager 15, egistration Division (TS-767c), Office of esticide Programs, Environmental Protection gency, 401 M Street, SW., Washington, D.C. 460. Office location and telephone number oom 204, Crystal Mall No. 2, 1921 Jefferson vis Highway, Arlington, VA. (703) 557-400.

Registrants should not submit label mendments at this time to bring labels nto conformance with the general tandards of 40 CFR 162.10. The Agency ill review amended labels for the ecessary corrections to prevent ancellation, and then will notify egistrants on a case-by-case basis if rther amendments are necessary to omply with 40 CFR 162.10.

. Procedure for Requesting a Hearing

Registrants and applicants for egistration adversely affected by the ctions described above may request a earing on such actions within 30 days f receipt of this Notice, or within 30 ays of publication of this Notice in the ederal Register, whichever occurs later. ny other person adversely affected by he actions described above, or any nterested person with the concurrence f an applicant whose application for egistration has been denied, may equest a hearing within 30 days of ublication of this Notice in the Federal egister.

All registrants, applicants, and other dversely affected parties who request a earing must file the request in ccordance with the procedures stablished by FIFRA and the Agency's ules of Practice Governing Hearings 40 CFR Part 164). These procedures equire among other things that (1) all equests must identify the specific egistration(s) by registration number(s) nd the specific use(s) for which a earing is requested, (2) all requests nust be accompained by objections that re specific for each use of the identified esticide product for which a hearing is equested, and (3) all requests must be eceived by the Hearing Clerk within the pplicable 30 day period. Failure to omply with these requirements will esult in denial of the request for a earing.

Request for a hearing must be ubmitted to:

Hearing Clerk (A-110), Environmental rotection Agency, 401 M Street, SW., Vashington, D.C. 20460.

C. Consequence of Filing or Failing to File a Hearing Request

1. *Consequence of filing a timely and effective hearing request.* If a hearing on any action initiated by this Notice is requested in a timely and effective manner, the hearing will be governed by the Agency's Rules of Practice Governing Hearings under FIFRA section 6 (40 CFR Part 164). The hearing will be limited to those uses and registrations (or applications) for which a hearing has been requested. In the event of a hearing, each cancellation and denial action subject to the hearing will not become effective except pursuant to an order of the Administrator at the conclusion of the hearing.

2. *Consequences of failure to file in a timely and effective manner.* If a hearing concerning the cancellation or denial of registration of a specific use of a specific pesticide product containing lindane has not been requested by the end of the applicable 30 day period, registration of that lindane product will be cancelled, or the application for registration denied, unless the registrant or applicant amends the terms and conditions of his registration as described in this Notice.

A registrant may contest the cancellation of his registration for some uses of a product, while modifying the terms and conditions of the registration of the same product to bring it into compliance with the requirements of this Notice. In order to do so, he must (1) make a timely request for a hearing challenging the cancellation of the product for the uses which he wishes to contest, and (2) make a timely application for amendment to modify the terms and conditions of the registration for uses permitted under this Notice which he wishes to retain.

D. Intrastate Products

The Agency is aware of a number of pesticide products containing lindane which are not federally registered and which are being marketed under the authority of 40 CFR 162.17. All persons producing or distributing such products must submit an application for federal registration, including all required supporting data as prescribed by the provisions of section 3 of FIFRA and of 40 CFR Part 162 within 30 days of receipt of this Notice or publication in the Federal Register whichever is later. The Agency further notifies all such applicants that only products which conform with the requirements of this Notice will be registered. Any person who wishes to register a product which would not conform with the requirements of this Notice is informed that the Notice is a denial of his application, and if he wishes to contest the denial, he must request a hearing within the applicable 30 day period provided by this Notice.

The 30 day period in which to request a hearing applies to all regulatory actions proposed in this Notice, including all denials of registration, all cancellations, and all registrations which must be amended to implement changes in the terms and conditions of use in order to avoid cancellation.

Dated: September 30, 1983.

Don R. Clay,

Acting Assistant Administrator for Pesticides and Toxic Substances.

[FR Doc. 83-28134 Filed 10-18-83; 8:45 am]

BILLING CODE 6560-50-M

[OPP-30000/7E; PH-FRL 2451-2]

Intent to Cancel Registrations of Pesticide Products Containing Strychnine; Denial of Applications for Registration of Pesticide Products Containing Strychnine; Determination Concluding the Rebuttable Presumption Against Registration; Availability of Position Document

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of determination; notice of availability of position document.

SUMMARY: Strychnine is registered as a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act. In December of 1976, EPA initiated an RPAR process to consider whether strychnine pesticide registrations should be cancelled, modified, or continued unchanged. This Notice concludes that RPAR process and announces the Administrator's intent to cancel registrations and deny applications for certain uses of strychnine, to continue the registration of other uses of strychnine only if the label is modified, and to require efficacy data to determine lowest toxic dosage for ground squirrels.

DATE: Requests by a registrant or applicant for a hearing must be received on or before November 18, 1983 or (for registrants) within 30 days from receipt by mail of this Notice whichever occurs later.

ADDRESSES: Requests for a hearing must be submitted to: Hearing Clerk (A-110), Environmental Protection Agency, 401 M St. SW., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT:

By mail: Bruce Kapner, Registration Division (TS-767C), Office of Pesticide Programs, Environmental Protection

JUL 10 1986

MEMORANDUM

SUBJECT: Lindane Notice of Intent to Cancel
vs. Registration Standard

FROM: A. E. Conroy II, Director
Office of Compliance Monitoring (EN-342)

TO: William A. Spratlin, Director
Air and Toxics Division
Region VII

This responds to Leo Alderman's June 20, 1986 memorandum regarding the Lindane Notice of Intent to Cancel (NOIC) versus the Lindane Registration Standard (RS).

Mr. Alderman requested answers to two questions in the memorandum. First, what is the violation for Lindane products found in the marketplace after December 30, 1986 without the labeling changes required by the RS? Second, what FIFRA authority can be cited to support enforcement actions against noncompliance with the RS?

As background, before answering the questions, the RS states that all Lindane products released for shipment after June 30, 1986 must bear EPA accepted labeling in accordance with the RS. Also, all Lindane products in channels of trade as of December 30, 1986 must bear these accepted labels. The NOIC did not impose relabeling dates for products found in channels of trade. Existing stocks of products cancelled by the NOIC and subsequently found in channels of trade are not subject to the RS. This is because the RS imposed requirements for continued registration and new registrations, and products cancelled by the NOIC do not fall into either category. However, products which complied with the NOIC labeling requirements and are still registered must now comply with the RS labeling requirements.

There is a twofold answer to your questions. If a registrant complies with the RS, submits the revised label to EPA, and Registration Division accepts the Lindane product label, then any of the products with that registration number found in the marketplace with labeling not in accordance with the RS after December 30, 1986, will be in violation of FIFRA §12(a)(1)(E) for misbranding. However, if the registrant does not comply with the RS by submitting labeling revised in accordance with the RS, then the product may be cancelled.

If you have any questions concerning this memorandum, please call Richard Green of my staff at (FTS) 382-5567.

cc:

Ken Shiroishi (EN-342)
John J. Neylan III "
Dexter Goldman "
Phyllis Flaherty "
John Martin "
Ralph Turpin "
Mike Wood "

John Mackenzie
Western Regional Compliance Director

A. Charles Lincoln
Eastern Regional Compliance Director

Louis F. Gitto, Director
Air Management Division, Region I

Barbara Metzger, Director
Environmental Services Division, Region II

Stephen R. Wassersug, Director
Hazardous Waste Management Division, Region III

Winston A. Smith, Director
Air, Pesticides and Toxics Management Division, Region IV

William H. Sanders III, Director
Environmental Services Division, Region V

William B. Hathaway, Director
Air, Pesticides, and Toxics Division, Region VI

Irwin L. Dickstein, Director
Air and Toxics Division, Region VIII

Harry Seraydarian, Director
Toxics and Waste Management Division, Region IX

Gary O'Neal, Director
Air and Toxics Division, Region X

cc: Regional Pesticides and Toxic Substances Branch Chiefs

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

28 OCT 1976

OFFICE OF ENFORCEMENT

TO: Enforcement Division Directors
Pesticide Branch Chiefs

FROM: A. E. Conroy II, Director
Pesticides and Toxic Substances
Enforcement Divison

A E Conroy II

RE: Conclusion of the Mercury Cancellation Proceeding

On August 19, 1976, the Administrator concluded the four year old mercurial pesticide product cancellation case by approving a settlement in In re Chapman Chemical Company, et al. between the registrants, and EPA. The purpose of this memorandum is to briefly review background events, to explain the terms and conditions of the settlement order, and to provide you with a revised mercury cancellation enforcement strategy.

I. BACKGROUND

The mercury hearings were initiated on March 22, 1972, when EPA Administrator Ruckelshaus issued PR Notice 72-5 announcing the Agency's intent to cancel the registrations of all mercurial pesticide products, and the immediate suspension of all alkyl mercury compound registrations and of all nonalkyl products registered for use on rice seed, in laundries, and in marine antifouling paint. In March of 1972, there were twenty registrants with thirty-seven alkyl mercury products registered, and four hundred eighty-four registered non-alkyl mercury products held by one hundred sixty-five registrants. None of the registrants of the suspended mercury pesticides opposed the Administrator's order and the products were therefore suspended and finally cancelled. Twenty-three registrants sought administrative review of the notice of intent to cancel; these registrants contested the cancellation of mercury as a bactericide/fungicide for use on turf, in paints and coatings, as a seed treatment, in dry formulations, in fabrics, on wood, and as a treatment for the control of the Dutch elm disease.

The formal adjudicatory hearings were held between October 1974 and September 1975. On December 12, 1975, Administrative Law Judge Bernard D. Levinson issued an initial decision, concluding that the following pesticides containing mercury should be cancelled because they create an unreasonable adverse effect on the environment:

(1) all uses in paints and coatings, except as an in-can preservative in water-based paints and coatings and as a fungicide in water-based paints and coatings used for exterior applications;

(2) all uses as a fungicide on golf courses, except as used on greens, tees, and aprons for the control of fungi of the snow mold complex;

(3) all uses for seed treatment;

(4) as a treatment for control of the Dutch elm disease; and

(5) all uses for any material that could be used in wearing apparel and other uses for textiles and fabrics, except as a fungicide in the treatment of textiles and fabrics for out-of-door use.

On February 17, 1976, the Administrator issued his decision and order in the consolidated mercury hearings (In re Chapman Chemical Company et al., FIFRA Docket No. 246, et al.). The Administrator found that the benefits from the continued use of mercurial pesticides for use as bactericides or fungicides "(1) in paints and coatings, (2) on turf, including golf course greens and all other areas of golf courses, (3) for seed treatment, and (4) for any other use not specifically identified and permitted" by the decision did not sufficiently outweigh the risks to man and the environment and were, therefore, cancelled. The decision and order cancelled the registrations for all remaining mercurial products, except for use

(1) as fungicides in the treatment of textiles and fabrics intended for continuous outdoor use;

(2) to control brown mold on freshly sawn lumber; and

(3) as a treatment for the control of Dutch elm disease.

As to the existing stocks issue, the Administrator provided that the sale and use of cancelled mercury products which were formulated on or before February 17, 1976, were permitted.

Several mercury registrants sought review in the United States Federal Court of the Administrator's cancellation of the seed treatment and the turf fungicide uses of their products. On March 2, 1976, the Administrator ordered that the effectiveness of the February 17th Cancellation Order be temporarily stayed pending judicial review in several United States Courts of Appeals. This order applied to all existing mercurial registrations and the stay was to continue through

June 30, 1976, or the conclusion of judicial review proceedings, which ever occurred first. An important feature of the March 2nd Order was that it prohibited the parties to the cancellation proceeding from increasing production of subject products or from stockpiling.

On March 29, 1976, the Administrator granted registrants' petition for reconsideration of his decision and order to cancel the registrations of mercurial pesticides for use in water-based paints and coatings.

The Administrator modified the February 17 cancellation order on May 27, 1976, to reinstate the registrations for certain mercurial water-based paints and coatings; and, he extended the stay of the effective date of the cancellation until November 30, 1976 (or until the conclusion of judicial review; if earlier).

On August 19, 1976, the Administrator approved a settlement in In re Chapman Chemical Company, et al. between respondent-EPA and registrant-appellants Parsons Chemical Works, Inc.; Troy Chemical Corporation; Gustafson, Inc.; Mallinckrodt, Inc.; W. A. Cleary Corporation; and O. M. Scott & Sons Company concerning certain contested uses awaiting review in the Eighth Circuit, U. S. Court of Appeals, as the result of an appeal filed following the February 17 cancellation order. In brief, the settlement will terminate the mercury case contingent upon the completion of necessary regulatory activities by the Registration Division, Office of Pesticide Programs, according to the following terms:

(1) Registrations for mercurial seed disinfectants and for mercurial turf fungicides for use against summer turf diseases will be finally cancelled on or before August 31, 1978. Production of these products in the interim is limited to prevent stockpiling; total permitted production will not exceed the equivalent of two years of production, as determined by production data for recent years. These uses involve 20,000-25,000 pounds of production of technical mercury annually.

(2) The cancellation of registrations for mercurial fungicides for use against winter turf diseases (10,000-15,000 pounds production of technical mercury annually) is vacated. Use of these products within 25 feet of water bodies where fish are taken for human consumption is prohibited. The products may be applied only by or "under the direct supervision of" golf course superintendents. The registrants will request that these products be classified as restricted use pesticides.

(3) Mercury products produced before the effective date of final cancellation (August 31, 1978 or the date on which maximum allowed quantity is reached) will be termed "existing stocks," the sale, distribution, and use of which will be permitted.

The Administrator has concluded that the terms and conditions of settlement agreed to by the parties to the cancellation proceeding satisfy appplicable statutory standards under FIFRA and that the settlement is in the public interest. See attached "Chapman Chemical Company, et al., Consolidated Mercury Cancellation Hearing, Settlement and Orde. (41 Fed. Reg. 36068, August 26, 1976) [hereinafter, Settlement and Order]."

Until such time as RD/OPP notifies the registrants of cancelled mercurial pesticide registrations of the status of these products under FIFRA §3, PTSED cannot be confident in the accuracy of any list of continued mercury registrations that this office might construct. At this juncture, it appears that all uses of mercury were cancelled on August 31, 1976, except as follows:

(a) for seed treatment (cancellation stayed by August 19 Settlement and Order),

(b) for control of summer turf disease (cancellation stayed by August 19 Settlement and Order),

(c) in the treatment of textiles and fabrics intended for continuous outdoor use,

(d) as a treatment for control of the Dutch Elm disease,

(e) as an in-can preservative in water-based paints and coatings,

(f) as a fungicide in water-based paints and coatings used for exterior application,

(g) as a fungicide for use against winter turf diseases, and

(h) to control brown mold on freshly sawn lumber.

II. ENFORCEMENT STRATEGY.

A. ENFORCEMENT OF THE STAY ORDER -- STATUS.

In my memorandum to you of May 14, 1976, entitled "Consolidated Mercury Hearing--March 2 Stay of the February 17 Cancellation Order," I outlined the Agency's enforcement strategy concerning the manufacture of mercurial pesticides during the pendency of the stay of the cancellation's effectiveness. The order staying the final cancellation could have been dissolved if the Administrator found that a party to the proceeding was increasing production and/or stockpiling mercurials during the pendency of the stay. Affected regions (II, III, IV, and V) were requested to initiate section 8 books and records inspections at all producer establishments, twenty in all, to determine the level of compliance with the Administrator's order. Your cooperation in ensuring that the terms

of the Administrator's orders--particularly, the "average monthly amount" restriction--were complied with by affected registrants is appreciated. The further need to monitor and to advise the Administrator as to the level of compliance by the registrants with the conditions of the stay order has been mooted by the issuance of his most recent order announcing the conclusion of the mercury proceedings.

B. TERMS OF THE "SETTLEMENT AND ORDER."

1. Registration Status of Mercury Products. The Administrator's August 31, 1976, Settlement and Order provides the following:

(a) the cancellation order provision cancelling the registrations of the following mercurial seed treatment products is stayed until August 31, 1978, or until the registrant has produced the maximum allowed quantity of the product under the conditions of the particular settlement agreement, whichever occurs first:

(i) Parsons Chemical Works (1969-MI-01) --

1969-57 PARSONS SLURRY CONCENTRATE "60"
1969-58 PARSONS LIQUID SEED SAVER
1969-91 PARSONS SEED SAVER DUST

(ii) Gustafson, Inc. (2079-NJ-01; 36209-NJ-01) --

7501-2 MIST-O-MATIC LIQUID SEED DISINFECTANT
7501-5 MIST-O-MATIC DRILL BOX TREATMENT

(iii) Troy Chemical Corporation (5383-NJ-01) --

605-37 GALLOTOX LIQUID SEED DISINFECTANT

(b) the cancellation order provision cancelling the registrations of the following mercurial fungicide products for use against summer turf diseases is stayed until August 31, 1978, or until the registrant has produced the maximum allowed quantity of the product under conditions of the particular settlement agreement, whichever occurs first 1/:

1/ As part of the settlement agreement, O. M. Scott, and W. A. Cleary have agreed to apply to the Registration Division, Office of Pesticides Programs on or before September 1, 1976, to amend the registrations of subject products to establish separate August dates for (i) products for use against summer turf diseases and (ii) products for use against winter turf diseases. You will be notified and supplied with the necessary information as soon as PTSED is apprised of the completion of this action by RD/OPP.

(i) O. M. Scott & Sons Company (538-OH-01) --

538-27	PRO-TURF BROAD SPECTRUM FUNGICIDE
538-36	PRO-TURF FERTILIZER PLUS FUNGICIDE
538-56	CALIFORNIA FERTILIZER PLUS FUNGICIDE

(ii) W. A. Cleary Corporation (1001-NJ-01) --

1001-4	PMAS CRABGRASS KILLER AND FUNGICIDE

(c) the cancellation order provision cancelling the registrations of the following Mallinckrodt, Inc. (372-PA-01; 372-NJ-01) mercurial fungicide products for use against winter turf diseases 2/ is vacated in accordance with the terms of the settlement agreement and production, sale, and distribution may resume unimpeded 3/:

372-5	CALO-CLOR
372-33	CALO-GRAN

(d) the order of March 2, 1976, staying the cancellation order of February 17, 1976, is dissolved effective August 31, 1976.

2. Enforcement Responsibilities Under Settlement and Order. Pursuant to the terms of the settlement agreements, registrant-appellants must fu certain substantive requirements to be afforded a stay of the effective da. of the cancellation of the seed treatment and summer turf disease product registrations. The conditions impacting on the Office of Enforcement include:

(a) During the pendency of the stay, the registrants must limit production of the subject mercurials for use against summer turf disease to the amount determined by multiplying the average monthly production rate during the base period (in most cases, April 1, 1972 to September 1, 1976) times the number of months the cancellation is stayed (24). If this total production figure is reached prior to August 31, 1978, the subject product's registration become immediately

2/ "Winter turf diseases" consist of Fusarium nivale (pink snow mold, ink patch, or fusarium patch), Typhula incarnc, Typhula ishikariensis, and sclerotinia borealis.

3/ As part of the settlement agreement, Mallinckrodt has agreed to mend the subject products' labeling to include the caution "Do not apply ithin twenty-five (25) feet of any body of water where fish are taken for man consumption" and the ... product may be used "... ly by or under the direct supervision of golf course superintendents." ese label additions will also be made to the O. M. Scott and W. A. Cleary bo( ) for use against winter turf diseases (see footnote 1/, supra).

cancelled, and the registrants must notify the Director of the Pesticides and Toxic Substances Division of such fact immediately.

(b) On or before September 1, 1976, the registrants were to provide PTSED with (a) production figures by product for the base period, (b) the total existing inventories of subject products as of September 1, 1976, and (c) a list of their customers likely to purchase the subject products. As of now, these data have not been fully submitted. PTSED is corresponding with the subject registrants, noting their delinquency and the necessity for delivery of the required information.

(c) Beginning on September 30, 1976, the registrants must submit quarterly production reports on subject registered products to PTSED (plus other reports and/or additional information necessary to effecutate the intended purpose of the agreement). As of now, these data are also incomplete.

C. ENFORCEMENT ACTIVITIES.

The Agency's enforcement strategy concerning mercurial pesticide products will have two general areas of emphasis: (1) the monitoring of the production limitation provisions of the settlement agreements for compliance by all affected registrants, and (2) the exercise of standard enforcement actions against persons who are discovered violating the terms of the mercury cancellation order.

1. Monitoring. The monitoring of settlement agreement compliance will be the joint enterprise of regional personnel with pesticide enforcement responsibilities and the Pesticide and Toxic Substances Enforcement Division. Initially, PTSED will review data submitted by the mercury registrants subject to the Settlement and Order, and will independently calculate and corroborate the figures submitted by subject companies as the "maximum allowed quantity" for each product to the final August 31, 1978 cancellation deadline. The official figures will be transmitted to the regions who will then be able to determine whether and when inspection of mercury producing establishments is warranted under the particular circumstances of each case. Deviations from the Administrator's Settlement and Order will be dealt with as appropriate.

2. Enforcement actions. As soon as PTSED is provided with an official list of those mercury products cancelled and those mercury registrations surviving the cancellation proceedings, you will be so advised. Additionally, as soon as there is a change in the registration status of those products whose effective dates of cancellation have been stayed by the Settlement and Order, regions will be notified. Violations of the cancellation order will be handled as routine enforcement matters. As the Administrator has provided for the use of existing stocks of products subject to the August 19 order, there will be no recall program initiated.

III. INQUIRIES.

Inquires concerning any facet of the mercury cancellation proceedings and the Agency's enforcement strategy should be referred to the appropriate regional coordinator.

O.M. Scott & Sons Company
ATTN: Gary N. Clark
Marysville, OH 43040

Gentlemen:

Subject: PROTURF BROOD SPECTRUM FUNGICIDE
(For Use on Winter Turf Diseases)
EPA Reg. No. 538-27
Letter of November 12, 1976

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable, and a stamped copy is enclosed for your records.

John H. Lee
Product Manager (22)
Fungicide Herbicide Branch
Registration Division

Enclosure

WH-567:FHB:JHLee:nlo:acs:638-6767:11/29/76

SCOTTS
THE LAWN PEOPLE

O M Scott & Sons
A Subsidiary of ITT
Marysville, Ohio 43040
(513) 642-6015

November 12, 1976

EPA Registration Division (WH-567)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460

Attn: Mr. John Lee, PM-22

Subject: ProTurf Broad Spectrum Fungicide
EPA Reg. No. 538-27
Resubmission

Gentlemen:

Enclosed are five copies of finished labeling for subject product including the following revisions:

1) "EPA Est. 538-OH-1" has been added to the front panel below the ingredient statement.

2) "EPA Reg. No. 538-27-AA" has been changed to "EPA Reg. No. 538-27".

If you have any questions concerning this matter, please give me a call at 513/644-0011, extension 2104.

Respectfully yours,

Gary N. Clark
Federal Regulatory Specialist

ca
enc.

[illegible]

fungicide

NET WEIGHT 26 LBS (11.8 Kg)

Scotts

ProTurf

broad spectrum fungicide

FOR USE ON
WINTER TURF DISEASES

FOR PROFESSIONAL USE ONLY

CAUTION: KEEP OUT OF REACH OF CHILDREN

Harmful if swallowed. Avoid prolonged contact with skin or getting into eyes. In case of ingestion, severe skin or eye irritation, get medical attention promptly. After using, wash all exposed skin areas thoroughly. Clear water may be used as eye wash. Keep away from feed and foodstuff. Do not apply within twenty five (25) feet of any water body where fish are taken for human consumption.

Toxic to fish and wildlife. Keep out of any body of water.

Active ingredients: Phenylmercuric acetate	0.69%
Thiram (Tetramethylthiuram disulfide)	4.65%
Inert ingredients	94.65%
Total	100.00%

[illegible]

US Pat No 3,093,059 — EPA Reg No 538-27 — Product of USA

ProTurf Division, O.M. Scott & Sons — Marysville, Ohio 43040

ACCEPTED
DEC 1 1976
...[illegible] Insecticide,
...[illegible] Rodenticide Act,
[illegible]
No. 538-27

ProTurf

broad spectrum fungicide

DIRECTIONS FOR USE

This product shall be used only by or under the direct supervision of golf course superintendents.

for use on winter turf diseases

Prevents or arrests fungus activity causing pink snowmold (Fusarium nivale) and gray snowmold (Typhula spp)

SUGGESTED SPREADER SETTINGS

to provide proper distribution calibrate spreader before application.

26 LBS (11.8 Kg) TREATS 11,000 SQ FT (¼ ACRE/1022 SQ M) AT NORMAL RATE
26 LBS (11.8 Kg) TREATS 5,500 SQ FT (1/8 ACRE/511 SQ M) AT DOUBLE RATE

SPREADER	GROUND SPEED	COVERAGE	SPREADER SETTING NORMAL RATE	SPREADER SETTING DOUBLE RATE
Scotts (Drop Type)	3 mph	overlap wheels	7	9½
Gandy 8 ft A Series Model	4.5 mph	overlap wheels	26	36
42 in Model	2.5 mph	overlap wheels	37	46

FOR USE ON GREENS, TEES, AND APRONS

Use before disease appears or when symptoms are first noticed. Repeat as necessary. To arrest severe infection use double rate.

Foliage may be either moist or dry when making application. On golf greens, rinse surface lightly after application to avoid pickup on shoes, golf balls or maintenance equipment.

ProTurf Division, O M Scott & Sons Marysville, Ohio 43040

NET WEIGHT 44 LBS. (20.4 Kg)

O.M. Scott & Sons Company
ATTN: Gary M. Clark
Marysville, OH 43040

Gentlemen:

Subject: PROTURF CALIFORNIA FERTILIZER plus FUNGICIDE
(For Use on Winter Turf Diseases)
EPA Reg. No. 538-55
Letter of Nov. 12, 1976

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable, and a stamped copy is enclosed for your records.

John H. Lee
Product Manager (22)
Fungicide Herbicide Branch
Registration Division

Enclosure

WH-567:FHB:JHLee:nlo:acs:639-6767:11/29/76

SCOTTS
THE LAWN PEOPLE

O M Scott & Sons
A Subsidiary of ITT
Marysville, Ohio 43040
(513) 642-6015

November 12, 1976

EPA Registration Division (WH-567)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460

Attn: Mr. John Lee, PM-22

Subject: ProTurf California Fertilizer Plus Fungicide
EPA Reg. No. 538-56
Resubmission

Gentlemen:

Enclosed are five copies of finished labeling for subject product including the following revisions:

1) "EPA Est. 538-OH-1" has been added to the front panel below the ingredient statement.

2) "EPA Reg. No. 538-56-AA" has been changed to "EPA Reg. No. 538-56".

If you have any questions concerning this matter, please give me a call at 513/644-0011, extension 2104.

Respectfully yours,

Gary N. Clark
Federal Regulatory Specialist

ca
enc.

NET WEIGHT 45 LBS. (20.4 Kg)

Scotts

ProTurf

22-5-5

California fertilizer plus fungicide

FOR USE ON WINTER TURF DISEASES

California fertilizer plus fungicide

California fertilizer plus fungicide

8C03

CAUTION: KEEP OUT OF REACH OF CHILDREN

Do not apply within twenty-five (25) feet of any water body where fish are taken for human consumption.

Total 100.00%

California fertilizer plus fungicide 22-5-5 guaranteed analysis

22%

5%

5%

Product of USA

Marysville, Ohio 43040

8C03

8C03

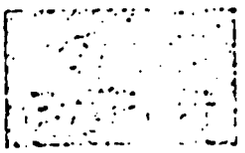
ACCEPTED

DEC 1 1976

Insecticide,

Act,

538-56



22-5-3

DIRECTIONS FOR USE

This product shall be used only by or under the direct supervision of golf course superintendents.

for use on winter turf diseases

Fertilizes turfgrasses. Controls fungus activity causing pink snowmold (Fusarium nivale) and gray snowmold (Typhula spp)

SUGGESTED SPREADER SETTINGS

to provide proper distribution calibrate spreader before application.

45 LBS (20.4 Kg) TREATS 11,000 SQ FT (¼ ACRE/1022 SQ M) AT NORMAL RATE
45 LBS (20.4 Kg) TREATS 5,500 SQ FT (1/8 ACRE/511 SQ M) AT DOUBLE RATE

SPREADER	GROUND OR PTO SPEED	WIDTH OF COVERAGE	SPREADER SETTING NORMAL RATE	SPREADER SETTING DOUBLE RATE
Scotts (Drop Type)	3 mph	overlap wheels	6½	8½
Scotts Rotary	3 mph	8 feet	1	N
Lely-WTR & WFR Models	4.5 mph	16 feet	5 III	6½ III
Lely-HR (PTO Model)	450 rpm @ 4.5 mph	16 feet	5 III	6½ III
Gandy 8 ft A Series Model	4.5 mph	overlap wheels	20	27

FOR USE ON GREENS, TEES, AND APRONS

Apply to moist or dry grass.

To control snowmold -- apply DOUBLE RATE in fall, late winter and early spring.

ProTurf Division, O M Scott & Sons, Marysville, Ohio 43040

NET WEIGHT 45 LBS. (20.4 Kg)

California fertilizer plus fungicide

Scotts

ProTurf

22-5-5

California fertilizer plus fungicide

FOR USE ON SUMMER TURF DISEASES

California fertilizer plus fungicide

CAUTION KEEP OUT OF REACH OF CHILDREN

Total

Product of USA

8503

ACCEPTED

1976

Under the Federal Insecticide, Fungicide and Rodenticide Act, for the pesticide

EPA Reg. No. 538-150

8503

8503

22-5-5

California fertilizer plus fungicide

DIRECTIONS FOR USE

for use on summer turf diseases

Fertilizes turfgrasses. Controls fungus activity causing brownpatch, leafspot, dollarspot, red thread and copperspot. Also controls moss.

SUGGESTED SPREADER SETTINGS

To provide proper distribution calibrate spreader before application.

45 LBS (20.4 Kg) TREATS 11,000 SQ FT (¼ ACRE/1022 SQ M) AT NORMAL RATE
45 LBS (20.4 Kg) TREATS 5,500 SQ FT (1/8 ACRE/511 SQ M) AT DOUBLE RATE

SPREADER	GROUND OR PTO SPEED	WIDTH OF COVERAGE	SPREADER SETTING NORMAL RATE	SPREADER SETTING DOUBLE RATE
Scotts (Drop Type)	3 mph	overlap wheels	6½	8½
Scotts Rotary	3 mph	8 feet	1	N
Lely-WTR & WFR Models	4.5 mph	16 feet	5 III	6½ III
Lely-HR (PTO Model)	450 rpm @ 4.5 mph	16 feet	5 III	6½ III
Gandy 8 ft A Series Model	4.5 mph	overlap wheels	20	27

Apply to moist or dry grass. On dichondra apply to dry leaves and then sprinkle lightly to wash off particles.

<u>On putting greens</u> -- may be used every month at NORMAL RATE during growing season for prevention or control. Interim protection can be achieved with ProTurf Broad Spectrum Fungicide. Rinse surface lightly after application to avoid pickup on shoes, golf balls or maintenance equipment.

<u>For all other areas</u> -- use before fungus damage appears or when symptoms are first noticed. May be repeated every other month at NORMAL RATE. If disease is severe or more frequent treatment is indicated apply at DOUBLE RATE.

<u>To control moss</u> – apply anytime at NORMAL RATE to moist foliage. Follow up at two week intervals with ProTurf Broad Spectrum Fungicide as needed.

[illegible] broad spectrum fungicide

NET WEIGHT 26 LBS (11.8 Kg)

Scotts

ProTurf

broad spectrum fungicide

FOR USE ON
SUMMER TURF DISEASES

FOR PROFESSIONAL USE ONLY

CAUTION KEEP OUT OF REACH OF CHILDREN

Harmful if swallowed. Avoid prolonged contact with skin or getting into eyes. In case of ingestion, severe skin or eye irritation, get medical attention promptly. After using, wash all exposed skin areas thoroughly. Clear water may be used as eye wash. Keep away from feed and foodstuff.

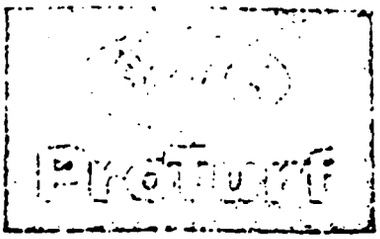
Toxic to fish and wildlife. Keep out of any body of water.

Active ingredients: Phenylmercuric acetate	0.69%
Tetramethylthiuram disulfide [illegible]	4.65%
Inert ingredients	94.66%
Total	100.00%

US [illegible] EPA Reg. No. 538-149 [illegible]

Marysville, Ohio [illegible]

ACCEPTED
OCT 1 1976
Under the Federal Insecticide, [illegible]cide, and Rodenticide Act, [illegible] registered under
EPA Reg. No. 538-149



broad spectrum fungicide

DIRECTIONS FOR USE

for use on summer turf diseases

Prevents or arrests fungus activity causing disease such as brownpatch, leaf-spot, dollarspot, red thread and copperspot. Also controls moss.

SUGGESTED SPREADER SETTINGS

to provide proper distribution calibrate spreader before application.

26 LBS (11.8 Kg) TREATS 11,000 SQ FT (¼ ACRE/1022 SQ M) AT NORMAL RATE
26 LBS (11.8 Kg) TREATS 5,500 SQ FT (1/8 ACRE/511 SQ M) AT DOUBLE RATE

SPREADER	GROUND SPEED	COVERAGE	SPREADER SETTING NORMAL RATE	SPREADER SETTING DOUBLE RATE
Scotts (Drop Type)	3 mph	overlap wheels	7	9½
Gandy 8 ft A Series Model	4.5 mph	overlap wheels	26	36
42 In Model	2.5 mph	overlap wheels	37	46

FOR USE ON TURFGRASSES OR DICHONDRA

Use before disease appears or when symptoms are first noticed. Repeat as necessary. To arrest severe infection use double rate.

Foliage may be either moist or dry when making application (except moss control requires application to moist foliage only). On golf greens, rinse surface lightly after application to avoid pickup on shoes, golf balls or maintenance equipment.

ProTurf Division, O M Scott & Sons Marysville, Ohio 43040

O.M. Scott & Sons Company
ATTN: Gary N. Clark
Marysville, OH 43040

Gentlemen:

Subject: PROTURF FERTILIZER plus FUNGICIDE
(For Use on Winter Turf Diseases)
EPA Reg. No. 538-36
Letter of November 12, 1976

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended is acceptable, and a stamped copy is enclosed for your records.

John H. Lee
Product Manager (22)
Fungicide Herbicide Branch
Registration Division

Enclosure

WH-567:FHB:JHLee:nlo:acs:638-6767:11/29/76

SCOTTS
THE LAWN PEOPLE

O M Scott & Sons
A Subsidiary of ITT
Marysville, Ohio 43040
(513) 642-6015

November 12, 1976

EPA Registration Division (WH-567)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D. C. 20460

Attn: Mr. John Lee, PM-22

Subject: ProTurf Fertilizer Plus Fungicide
EPA Reg. No. 538-36
Resubmission

Gentlemen:

Enclosed are five copies of finished labeling for subject product including the following revision:

"EPA Reg. No. 538-36-AA" has been changed to "EPA Reg. No. 538-36".

If you have any questions concerning this matter, please give me a call at 513/644-0011, extension 2104.

Respectfully yours,

Gary N. Clark
Federal Regulatory Specialist

ca
enc.

Scotts

ProTurf

24-5-3

fertilizer *plus* fungicide

FOR USE ON WINTER TURF DISEASES

FOR PROFESSIONAL USE ONLY

NET WEIGHT 46½ LBS (21.1 Kg)

CAUTION: KEEP OUT OF REACH OF CHILDREN

Harmful if swallowed. Avoid contact with skin or getting into eyes. In case of ingestion, severe skin or eye irritation, get medical attention promptly. After using, wash all exposed skin areas thoroughly. Clear water may be used as eye wash. Keep away from feed and foodstuffs.

Do not apply within twenty-five (25) feet of any water body where fish are taken for human consumption.

Toxic to fish and wildlife. Keep out of any body of water.

Active ingredients: Phenylmercuric acetate	0.60%
Thiram (Tetramethylthiuram disulfide)	5.60%
Inert ingredients	93.60%
EPA Reg No 538-36 EPA Est 538-OH-1	Total 100.00%

Net Weight 46½ lbs ProTurf Fertilizer Plus Fungicide 24-5-3 Guaranteed analysis*

Total nitrogen (N)	24%
1.1% ammoniacal nitrogen from ammoniated phosphate	
14.9% [illegible]	
8.0% [illegible]	
Available phosphoric acid (P_2O_5) from ammoniated phosphate	5%
Soluble potash (K_2O) from [illegible]	3%
Potential acidity equivalent to [illegible] lbs calcium carbonate per ton	

US Process Pat Nos 3,231,363; 3,705,794 Other Pat Pend Product of USA

ProTurf Division, O. M. Scott & Sons Marysville, Ohio 43040

*In Mich. can and Canada read "minimum guaranteed analysis"

ACCEPTED

DEC 1 1976

[illegible] Federal Insecticide, Fungicide, and Rodenticide Act, [illegible] registered [illegible] No. 538-36

ProTurf

24-8-3

Fertilizer plus fungicide

DIRECTIONS FOR USE

This product shall be used only by or under the direct supervision of golf course superintendents.

for use on winter turf diseases

Fertilizes turfgrasses. Controls fungus activity causing pink snowmold (Fusarium nivale) and gray snowmold (Typhula spp.)

SUGGESTED SPREADER SETTINGS

to provide proper distribution calibrate spreader before application.

46½ LBS (21.1 Kg) TREATS 22,000 SQ FT (½ ACRE/2044 SQ M) AT NORMAL RATE
46½ LBS (21.1 Kg) TREATS 11,000 SQ FT (¼ ACRE/1022 SQ M) AT DOUBLE RATE
46½ LBS (21.1 Kg) TREATS 44,000 SQ FT (1 ACRE/4088 SQ M) AT HALF RATE

SPREADER	GROUND OR PTO SPEED	WIDTH OF COVERAGE	SPREADER SETTING NORMAL RATE	DOUBLE RATE	HALF RATE
Scotts (Drop Type)	3 mph	overlap wheels	4½	6	3½
Scotts Rotary	3 mph	6 feet	D	G	B
Lely-WTR & WHR Models	4.5 mph	16 feet	2½ turns	3½ turns	1½ turns
Lely-HR (PTO Model)	450 rpm @4.5 mph	16 feet	2½ turns	3½ turns	1½ turns
Gandy B H A Series	4.5 mph	overlap wheels	13½	17½	10½
Model 42" model	2.5 mph	overlap wheels	24	30	19

FOR USE ON GREENS, TEES, AND APRONS

Apply to moist or dry grass.

To control snowmold—apply DOUBLE RATE in fall (before first snow), late winter and early spring.

ProTurf Division, O M Scott & Sons, Marysville, Ohio 43040

Scotts

ProTurf

24-5-3

fertilizer *plus* fungicide

FOR USE ON SUMMER TURF DISEASES

FOR PROFESSIONAL USE ONLY

NET WEIGHT 46½ LBS (21.1 Kg)

CAUTION: KEEP OUT OF REACH OF CHILDREN

Harmful if swallowed. Avoid contact with skin or getting into eyes. In case of ingestion, severe skin or eye irritation, get medical attention promptly. After using, wash [illegible] skin areas thoroughly. Clear water may be used as [illegible]. Keep away from feed and foodstuffs.

Toxic to fish and wildlife. Keep out of any body of water.

Active ingredients: Phenylmercuric acetate [illegible]	0.33%
Thiram (Tetramethylthiuram disulfide)	5.67%
Inert ingredients	94.00%
EPA Reg No 538-[illegible] EPA Est 538-OH-1	Total 100.00%

Net Weight 46½ lbs ProTurf Fertilizer Plus Fungicide 24-5-3 guaranteed analysis*

Total nitrogen (N)	24%
1.1% ammoniacal nitrogen from ammonium phosphate	
14.9% soluble nitrogen from urea and methylene ureas	
8.0% [illegible] nitrogen from methylene ureas	
Available phosphoric acid (P_2O_5) from ammonium phosphate	5%
Soluble potash (K_2O) from [illegible]	3%
Potential [illegible] equivalent [illegible] calcium carbonate per ton	

US [illegible] 3,705,794 Other Pat. Pend. Product of USA

ProTurf Division, O M Scott & Sons Marysville, Ohio 43040

*In Michigan and Canada reads "minimum guaranteed analysis"

ACCEPTED

[illegible] 1975

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for [illegible] registered under EPA Reg. No. 538-148

24-5-5

fertilizer plus fungicide

DIRECTIONS FOR USE

for use on summer turf diseases

Fertilizes turfgrasses. Controls fungus activity causing brownpatch, leafspot, dollarspot, red thread and copperspot. Also controls moss.

SUGGESTED SPREADER SETTINGS

To provide proper distribution calibrate spreader before application.

46½ LBS (21.1 Kg) TREATS 22,000 SQ FT (½ ACRE/2044 SQ M) AT NORMAL RATE
46½ LBS (21.1 Kg) TREATS 11,000 SQ FT (¼ ACRE/1022 SQ M) AT DOUBLE RATE
46½ LBS (21.1 Kg) TREATS 44,000 SQ FT (1 ACRE/4088 SQ M) AT HALF RATE

SPREADER	GROUND OR PTO SPEED	WIDTH OF COVERAGE	SPREADER SETTINGS NORMAL RATE	DOUBLE RATE	HALF RATE
Scotts (Drop Type)	3 mph	overlap wheels	4½	6	3½
Scotts Rotary	3 mph	8 feet	D	G	B
Lely-H,TR & WFR Models	4.5 mph	16 feet	2½	3½	1½
Lely-HR (PTO Model)	450 rpm @4.5 mph	15 feet	2½	3½	1½
Gandy 3 h 4 Series Model 42 - model	4.5 mph 2.5 mph	overlap wheels overlap wheels	13½ 24	17½ 30	10½ 19

Apply to moist or dry grass.

Putting greens—may be used every two weeks at NORMAL RATE during growing season for prevention or control. Interim protection can be achieved with ProTurf Broad Spectrum Fungicide. Syringe surface lightly after application to avoid pickup on shoes, golf balls or maintenance equipment.

All other areas—use before fungus damage appears or when symptoms are first noticed. May be repeated every month at NORMAL RATE. If disease is severe or more feeding is desired apply at DOUBLE RATE.

To control moss—apply anytime at NORMAL RATE to moist foliage. Follow up at two week intervals as needed.

ProTurf Division, O M Scott & Sons, Marysville, Ohio 43040

OCT 10 1968

Parson Chemical Works
Post Office Box 146
Grand Ledge, Michigan 48837

Attention: Mr. A. R. Fox

PARSONS SEED SAVER SHRUB CONCENTRATE "60"
USDA Reg. No. 1969-57
Your letter of September 3, 1968

Submit two copies of the finished label when printing is completed.

Harold G. Alford

Harold G. Alford

Enclosure-stamped label
PR FORM 9-253
AMS:PR:ZSW:cls
10-10-68

PARSONS

SEED SAVER

SLURRY CONCENTRATE

"60"

WHEAT OATS

This Will Dye Seed Grain Red

A MERCURIAL FUNGICIDE

DANGER — KEEP OUT OF REACH OF CHILDREN

See directions panel for additional warnings

POISON

See antidote statement and other required warning statements on the direction panel

ACTIVE INGREDIENTS: PHENYL MERCURIC AMMONIUM ACETATE	13.50%
INERT INGREDIENTS:	86.50%
CONTAINS: METALLIC MERCURY	7.0%

**DIRECTIONS FOR USE

Seed should be cleaned and well cured before treating. Liq SLURRY CONCENTRATE "60" must be diluted with water l lowing table shows proper dilution for use of SEED SAVER "6 Treater:

SEED	SEED SAVER "60" Gallon	WATER Gallon	SLURRY BUCKET	SE GA
WHEAT	One (1)	20	23 cc.	15
OATS	One (1)	12	23 cc.	20

Additional dye may be added if desired

Use only recommended dosage. Effective control may not be amounts are used.

WARNING

ANTIDOTE — If swallowed, give milk or white of egg beaten tablespoonful of salt in a glass of warm wate repeat until Repeat milk or white of egg beaten with w Call a physic

Warning — May Produce Delayed Chemical Burns. Do not b This product should be considered poisonous and handled wit quate ventilation for the operator. If spilled on skin, immediate with soap and water. May be fatal if swallowed. Do not get clothing. If it does get into eyes, flush with water for at least medical attention. This product contains a strong concentration of dle with care because it will dye hands or articles that come into c is hard to wash off. Suggest wearing gloves and old clothing.

Store in a cool place. Keep container closed. Keep liquid away spark-producing equipment, or heated surfaces. Do not reus Destroy it by perforating or crushing. Bury or discard in a sa

NOTICE TO PURCHASER — Parsons Chemical Works Inc. m warranty, expressed or implied, concerning the use of this pro dicated on the label. Buyer assumes all risk of use and/or hand when such use and/or handling is contrary to label instructions.

DIRECTIONS FOR USE

...ed and well cured before treating. LIQUID SEED SAVER ...ATE "60" must be diluted with water before use. The fol... per dilution for use of SEED SAVER "60" in a Slurry Seed

...D "60" ...on	WATER Gallon	SLURRY BUCKET	SEED CATE	RATE PER BUSHEL
(1)	20	23 cc.	15	¼ fl. oz.
(1)	12	23 cc.	20	¼ fl. oz.

...added if desired.
...dosage. Effective control may not be obtained if lower

WARNING

...owed, give milk or white of egg beaten with water, then a ... a glass of warm water, and repeat until vomit fluid is clear. ...f egg beaten with water. Call a physician immediately.

...e Delayed Chemical Burns. Do not breathe spray mist. ... considered poisonous and handled with care. Allow ade... operator. If spilled on skin, immediately wash thoroughly ...day be fatal if swallowed. Do not get in eyes, on skin or ... into eyes, flush with water for at least 15 minutes and get ...oduct contains a strong concentration of dye, therefore h... will dye hands or articles that come into contact with it an... ...rgest wearing gloves and old clothing.

...Keep container closed. Keep liquid away from open flame, ...ent, or heated surfaces. Do not reuse empty container. ...g or crushing. Bury or discard in a safe place.

...ER -- Parsons Chemical Works Inc. and Seller mak... implied, concerning the use of this product other than ...yer assumes all risk of use and/or handling of this material ...ndling is contrary to label instructions.

GENERAL INFORMATION

WILL NOT FREEZE ABOVE 10 DEGREES BELOW ZERO

Contents treats 512 bushels per gallon of concentrate according to type of seed treated.

PARSONS SEED SAVER SLURRY CONCENTRATE "60" is recommended for the control of diseases caused by organisms carried on the seed and in the soil, such as: seedborne stinking smut or bunt of wheat, oat smut and seed borne oat blight.

For best results, treated grain should be stored in sacks or in a covered pile for at least 24 hours. Treated grain may then be planted.

NOTICE: Head smut of sorghums, brown loose smut of barley, and loose smut of wheat can not be controlled by any known chemical seed treatment.

PARSONS SEED SAVER SLURRY CONCENTRATE "60" when properly diluted will dye seed red.

**For treating seed grain use PARSONS SEED SAVER SLURRY CONCENTRATE "60" according to table on "directions for use." It is important that slurry machine run a few minutes after dilution has been made. Shortest tripping pin by hand, allowing two cups to empty into machine before letting grain drop into treater. After flow of grain has been shut off (or batch run through), let machine operate a few seconds to empty remaining grain from treater into bag, then turn motor off. Always use fresh, clean water when making proper dilution.

LABEL TREATED SEEDS

Treated seeds should be plainly labeled or tagged as follows:

"DISINFECTED SEED — POISONOUS TO ANIMAL AND MAN.
DO NOT USE FOR FOOD, FEED OR OIL."

USDA REG. NO. 1960-57

1 GALLON

PARSONS CHEMICAL WORKS, Inc.
Laboratories - Grand Ledge, Michigan

ACCEPTED
OCT 10 1968
UNDER THE FEDERAL INSECTICIDE FUNGICIDE AND RODENTICIDE ACT FOR ECONOMIC POISON REGISTRATION NO. 1960-57

Parsons Chemical Works
Attention: Mr. A. R. Fox
Post Office Box 146
Grand Ledge, Michigan 48837

Gentlemen:

Subject: PARSONS SEED SAVER BRAND LIQUID READY MIX
USDA Reg. No. 1969-SC
Your letter of September 4, 1968

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act is acceptable, and a stamped copy is enclosed for your records.

It is assumed that the word "Poison" will be printed in red.

Sincerely yours,

Harold G. Alford

Harold G. Alford
Assistant Director
for Registration

Enclosure
Stamped Label
A-4
ARS:PR:HSH:ibf/9-25-68

DIRECTIONS FOR USE

...d and well cured before treating. Not to be diluted with ... table shows proper amounts:

...e	Adaptors or Conversion Kits	Panogen*	Slurry Machines
...bu. ...6⅔ ...ad. ...bu.	¾ fl. oz. per bu.	¾ fl. oz. per bu.	½ fl. oz. per bu. 23 cc. cup to 10.5 pounds use 1 pt. per gal. water Seed Gate 16
[illegible] ...ad.	¾ fl. oz. per bu.	¾ fl. oz. per bu.	½ fl. oz. per bu. 23 cc. cup to 8.6 pounds use 1½ pt. per gal. water Seed Gate 20
[illegible] ...ad.	¾ fl. oz. per bu.	¾ fl. oz. per bu.	½ fl. oz. per bu. 23 cc. cup to 10 pounds use 1½ pt. per gal. water Seed Gate 18
...bu. ...ad.	1½ fl. oz. per bu.	1½ fl. oz. per bu.	1½ fl. oz. per bu. 23 cc. cup to 9 pounds use 3 pt. per gal. water Seed Gate 10

...p size and pan load.

WARNING

...e milk or white of egg beaten with water, then a tablespoonful of salt in a ... til vomit fluid is clear. Repeat milk or white of egg beaten with water. ... on skin. Wash immediately with soap and warm water. If in eyes. Flush ... and get medical attention.

...d Chemical burns. Do not breathe spray mist. Do not get in eyes, on skin ... after handling.

...container closed. Do not get in eyes, on skin or clothing. Wash thoroughly. ... sparks, open flame, or heated surfaces. This product contains a ... the hands with care because it will dye hands or articles that come into ... with it. Suggest wearing gloves and old clothing.

...sons Chemical Works, Inc. or Seller make no warranty, expressed or implied, ... other than indicated on the label. Buyer assumes all risk of use and/or ... use and/or handling is contrary to label instructions.

GENERAL INFORMATION

WILL NOT FREEZE ABOVE 10 DEGREES BELOW ZERO

One Gallon Will Treat 170 Bushels of Seed Grain According to Type of Seed Treated

PARSONS LIQUID SEED SAVER is recommended for the control of diseases caused by organisms carried on the seed and in the soil, such as: seed-borne stinking smut or bunt of wheat, oat smut and seed-borne oat blight.

For best results, treated grain should be stored in sacks or in a covered pile for at least 24 hours. Treated grain may then be planted.

NOTICE: Head smut of sorghums, brown loose smut of barley, and loose smut of wheat can not be controlled by any known chemical seed treatment.

PARSONS LIQUID SEED SAVER will dye seed red and complies with the "Seed Laws" regarding the detection of treated seed grains.

**For treating seed grain use PARSONS LIQUID SEED SAVER according to table on "directions for use." It is important that machine run a few minutes before treating. See that machine is clean and in good operating condition before treating. Do not let solution stand in treater for extended periods of time.

CAUTION

This product should be considered poisonous and handled with care. Allow adequate ventilation for the operator. If spilled on skin, wash thoroughly with soap and water. May be fatal if swallowed. Do not reuse empty container. Destroy it by perforating or crushing. Bury or discard in a safe place.

LABEL TREATED SEEDS

Treated seeds should be plainly labeled or tagged as follows:

"DISINFECTED SEED — POISONOUS TO ANIMAL AND MAN. DO NOT USE FOR FOOD, FEED OR OIL."

USDA REG. NO. 1969-58

1 GALLON

PARSONS CHEMICAL WORKS, Inc.

Laboratories - Grand Ledge, Michigan

Parsons

LIQUID SEED SAVER

[illegible]

BARLEY WHEAT
FLAX OATS

A MERCURIAL FUNGICIDE

WARNING — KEEP OUT OF REACH OF CHILDREN
See direction panel for additional warnings

POISON

See antidote statement and other required warning statements on the direction panel

ACTIVE INGREDIENTS: Phenyl Mercuric Ammonium Acetate 3.50%
INERT INGREDIENTS 96.50%
CONTAINS Metallic Mercury 2.0%

ACCEPTED
SEP 25 1968
UNDER THE FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT FOR ECONOMIC POISON REGISTERED UNDER NO. [illegible] SUBJECT TO ATTACHED COMMENTS

DIRECTIONS [illegible]

Seed should be cleaned and well cured before [illegible] anything else. The following table shows proper amount [illegible]

SEED	Mist O-Matic	Adaptors or Conversion Kits	Pa[illegible]
WHEAT	½ fl. oz. per bu. 2½ cc. cup to 6⅔ pounds pan load. 9 dumps per bu.	¾ fl. oz. per bu.	¾ f[illegible] per [illegible]
OATS	½ fl. oz. per bu. 2½ cc. cup to 3½ pounds pan load. 9 dumps per bu.	¾ fl. oz. per bu.	¾ f[illegible] per [illegible]
BARLEY	½ fl. oz. per bu. 2½ cc. cup to 6½ pounds pan load. 9 dumps per bu.	¾ fl. oz. per bu.	¾ f[illegible] per [illegible]
FLAX	1½ fl. oz. per bu. 6 cc. cup to 6⅔ pounds pan load. 9 dumps per bu.	1½ fl. oz. per bu.	1½ f[illegible] per [illegible]

*See machine manual for cup size and panload.

WARNING

ANTIDOTES — If swallowed, Give milk or white of egg beaten with glass of warm water, and repeat until vomit fluid is clear. [illegible] Call a Physician immediately! If on skin, Wash immediately with water for at least 15 minutes, and get medical attention.

Warning: May Produce [illegible] Chemical Burn. Do not [illegible] or on clothing. Wash thoroughly after handling.

Store in a cool place. Keep container closed. [illegible] Keep liquid away from open flame, [illegible] equipment, or strong concentration of dye, therefore handle with care because it [illegible] contact with it and it is hard to wash off. [illegible]

NOTICE TO PURCHASER — Parsons Chemical Works, Inc., [illegible] concerning the use of the product other than [illegible] handling of this material when such use and or handling [illegible]

AUG APR 1972

Parsons Chemical Works
Attn: A. R. Fox
P.O. Box 146
Grand Ledge, Michigan 48837

Gentlemen:

Subject: PARSONS SEED SAVER DUST-DRILL BOX SEED TREATMENT
File Symbol 1969-RR
Your letter of May 18, 1970

Please refer to the enclosed PR Notice 72-5.

Since the subject product contains mercury, and is subject to cancellation we cannot process your submission.

Sincerely,

T. E. Adamczyk
Chief,
Fungicide-Herbicide Branch

Enclosure
PR Not. 72-5
EPA:PR:RH:je 4-14-72

AGRICULTURAL RESEARCH SERVICE
PESTICIDES REGULATION DIVISION
WASHINGTON, D. C. 20250

APPLICATION FOR NEW REGISTRATION OF ECONOMIC POISONS

(Under the Federal Insecticide, Fungicide, and Rodenticide Act)

SUBMIT — READ INSTRUCTIONS ON REVERSE

1. DATE OF APPLICATION: April 7, 1970

2. NAME OF ECONOMIC POISON *(Must be same product name on label-do not list active ingredients)*

Seed Saver Dust
Drill Box Treatment

3. TYPE OF PESTICIDE

INSECTICIDE [X] FUNGICIDE [ ] HERBICIDE [ ] RODENTICIDE [ ] GERMICIDE-DISINFECTANT [ ]
OTHER *(Specify)*

4. NAME & MAILING ADDRESS OF FIRM TO WHOM REGISTRATION IS TO BE ISSUED *(Include Zip Code)*

PARSONS CHEMICAL WORKS, INC.
P. O. Box 146
Grand Ledge, Michigan 48837

5. IS THE REGISTRANT SHOWN IN ITEM 4 THE MANUFACTURER?
YES [X] NO [ ]
(If "No", see instruction 5 on reverse)

6. TYPE OF FORMULATION
DUST [X] WETTABLE POWDER [ ] PRESSURIZED PRODUCT [ ] GRANULAR [ ] EMULSIFIABLE LIQUID [ ] BAIT [ ]
OTHER *(Specify)*

7. TYPE OF CONTAINER
METAL XXXX GLASS [ ] PLASTIC [ ] PAPER [ ] (circled)
OTHER *(Specify)*

8. NET CONTENTS OR CONTAINER SIZES: 2-lb. and 6-lb.

9. MANNER IN WHICH LABEL IS AFFIXED TO PRODUCT
LITHOGRAPHED [ ] PAPER, GLUED [X] STENCILED [ ]
OTHER *(Specify)*

10. PLACE WHERE DIRECTIONS FOR USE APPEAR
ON LABEL [X] IN PRINTED MATTER ACCOMPANYING PRODUCT [ ]

11. DATA SUBMITTED WITH THIS APPLICATION *(Identify and submit in triplicate)*
EFFICACY DATA [ ] TOXICOLOGY DATA [ ] RESIDUE DATA [ ] PETITION FOR TOLERANCE [ ]
OTHER *(Specify)*:

12. ANY ADDITIONAL PERTINENT INFORMATION *(Do not enter confidential formula here-see item 13, below)*

13. THE FOLLOWING MUST BE SUBMITTED WITH APPLICATION
- Five (5) copies of proposed labeling, including all printed or graphic matter which may accompany the sale of this product. Copies must be clearly legible and identical.
- Five (5) copies of the complete formula, showing the precise name and percentage of each active and each inert ingredient. *(This information is treated confidentially.)*

14. SIGNATURE OF AUTHORIZED FIRM REPRESENTATIVE
[signature] 4/7/70
Technical Dept.

15. DATE SIGNED: 4-7-70

17. RECEIVED BY USDA - PESTICIDES REGULATION DIVISION, WASHINGTON, D. C.
IN ANY CORRESPONDENCE ON THIS PRODUCT, REFER TO THIS FILE SYMBOL NO.:

PR FORM 9-109
MAY 1969

EXISTING STOCK OF PR FORM 9-149 (JULY 1968) WILL BE USED UNTIL EXHAUSTED

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

JAN 6 1977

OFFICE OF ENFORCEMENT

TO: Enforcement Division Directors
Pesticides Branch Chiefs

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

A. E. Conroy II/AT

RE: Enforcement of Mercury Settlement

In a memorandum of October 28, 1976, entitled "Conclusion of the Mercury Cancellation Proceeding" (attached), I outlined the background and conclusion of In Re Chapman Chemical Company, et al., including, at pp 5-7, the terms of the settlement and order and the Agency's projected enforcement thereof. Review of the compliance with the order by the six registrants affected indicates that there exist degrees of compliance activities, varying from none to complete.

On December 24, 1976, five registrants (not including Mallinckrodt) were advised by registered letter (copies attached) of the Agency's record of their compliance, of those activities required to be completed, of a general deadline of January 14, 1977, for initial compliance, and of EPA's intention to immediately enforce against non-compliance.

As a follow-up to these letters, you are requested to make plans to inspect, between January 19 and 21, 1977 those manufacturing facilities in your region where section 7 records indicate subject products are produced for the purpose of placing stop sales against those products whose registrations are no longer valid in that information was not submitted as required by the "Settlement and Order". Attached is a list of affected products, labels, producing establishments and addresses. On the afternoon of January 18, 1977, your Regional Coordinator will contact you to indicate which producers and products have attained an acceptable level of compliance and which ones have not.

You may use the revised stop sale form provided at p. 13 in the new section 13 (10-76) of the Case Proceedings Manual. In the paragraph specifiying the violation, it is suggested you insert the following:

> . . . there is reason to believe that (product name) is in violation of section 12(a)(2)(K) of the Act in that the registration of said product was continued subject to the terms of the "Settlement and Order" signed August 19, 1976, in Re Chapman Chemical Company, et al., and said registration is no longer valid in that [base period production reports, calculation of total allowable production, customer lists, existing inventories, and quarterly production reports] were not submitted as required by the Settlement.

This is the first of several so-called "phased cancellations" which the Agency is handling. It is of great importance that we enforce compliance firmly and swiftly in this intial order to build an awareness of and appreciation for the Agency's intentions to enforce similar cases in the future. Should you have questions, please contact the appropriate Regional Coordinator.

TO: Enforcement Division Directors
Pesticides Branch Chiefs

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

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Already has memo

Region V Pesticide Products and
Company Addresses Involved In
The Mercury Settlement

1. O. M. Scott & Sons Company

a. Corresponding Address:

Mr. John P. Kennedy, General Counsel
O. M. Scott & Sons
Marysville, Ohio 43040

b. Establishment Address & Est. #:

O. M. Scott & Sons Company
Marysville, Ohio
Est. #538-OH-01

c. Product involved:

1) Pro-Turf Broad Spectrum Fungicide; EPA Reg. No. 538-27

2) Pro-Turf Fertilizer Plus Fungicide; EPA Reg. No. 538-36

3) Pro-Turf California Fertilizer Plus Fungicide; EPA Reg. No. 538-56

Note: O. M. Scott is currently in compliance with settlement agreement and enforcement actions are not anticipated during January 77.

2. Parsons Chemical Works, Inc.

a. Corresponding Address:

Mr. C. R. Parsons, President
Parsons Chemical Works, Inc.
P.O. Box 146
Grand Ledge, Michigan 48837

b. Establishment Address & Est. #:

Parsons Chemical Works, Inc.
Grand Ledge, Michigan
Est. # 1969-MI01

c. Products Involved:

1) Parsons Slurry Concentrate "60"; EPA Reg. No. 196957

2) Parsons Liquid Seed Saver; EPA Reg. No. 1969-58

3) Parsons Seed Saver Dust; EPA Reg. No. 1969-91

Note: Parsons Seed Saver Dust was included in the settlement agreement, but a search of EPA records has revealed that it was never registered. It carries the file symbol No. 1969-RR.

ENVIRONMENTAL PROTECTION AGENCY

DEC 27 1976

Mr. John P. Kennedy, General Counsel
O. M. Scott & Sons
Marysville, Ohio 43040

Dear Mr. Kennedy:

Thank you for your timely submission of the quarterly report for the period of July 1, 1976 through September 30, 1976.

We are attaching for your convenience, a schedule showing when the next quarterly reports are due in this office. The reports should be sent by certified mail and addressed as follows:

A. E. Conroy II, Director
Pesticides and Toxic Substances
Enforcement Division (EN-342)
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

The data you submit will be treated as confidential, unless you advise otherwise.

We appreciate the promptness with which you have responded to the requirements of the Settlement Order and hope that you will continue to meet the conditions and requirements imposed upon you, However, we should emphasize that failure to submit the reports in a timely manner will result in the initiation of stop sale and seizure actions as well as the immediate cancellation of registrations for the products involved in the Settlement Order.

Sincerely yours,

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

SURNAME ▶	Conroy						
DATE ▶							

OFFICIAL FILE COPY

ENVIRONMENTAL PROTECTION AGENCY

O. M. Scott & Sons

SCHEDULE FOR SUBMISSION OF REPORTS.

Period	Due To PTSED
Oct. 1 - Dec. 31, 1976	Jan. 15, 1977
Jan. 1 - Mar. 31, 1977	Apr. 15, 1977
April. 1 - June 30, 1977	July 18, 1977
Jul. 1 - Sept. 30, 1977	Oct. 17, 1977
Oct. 1 - Dec. 31, 1977	Jan. 17, 1978
Jan. 1 - Mar. 31, 1978	Apr. 17, 1978
Apr. 1 - June 30, 1978	July 18, 1978
July. 1 - Aug. 31, 1978	Sept. 18, 1978

12/23/76

OFFICIAL FILE COPY

DEC 27 1976

Mr. C. R. Parsons, President
Parsons Chemical Works, Inc.
P. O. Box 146
Grand Ledge, Michigan 48837

Dear Mr. Parsons:

This letter is to acknowledge receipt of your September 10, 1976, communication containing the signed settlement agreement and order pursuant to the Administrator's Order and Settlement of August 19, 1976, (41 FR 36068), in In re Chapman Chemical Company, et al., the mercury pesticide cancellation case.

As you are well aware, the settlement to which you agreed specified, in part, that Parsons Chemical Works, Inc. would provide the Director of the Pesticides and Toxic Substances Enforcement Division (PTSED) with (a) certain production records on your mercurial products, Parsons Slurry Concentrate "60" (EPA Reg. No. 1969-57), Parsons Liquid Seed Saver (EPA Reg. No. 1969-58), and Parsons Seed Saver Dust (EPA Reg. No. 1969-91), (b) a computation of the total maximum amounts of production of these products that are allowed under the terms of the settlement agreement, (c) a list of immediate customers, and (d) an inventory of the quantities of these products on hand. PATSED has not yet received this information. In addition, your first quarterly report, due on September 30, 1976, has not yet arrived. We would also remind you that the next quarterly Report covering the period through December 31, 1976, is also due to be submitted.

The above information and the quarterly reports for September and December must be submitted by January 14, 1977. The two week period between December 31st and January 14th should allow ample time to complete the production reports for the December quarter and still provide sufficient time for mailing the information. If there is no production during reporting periods, then zero production figures should be reported.

The information should be sent by certified mail and addressed as follows:

A. E. Conroy II, Director
Pesticides and Toxic Substances
Enforcement Division (EN-342)
U. S. Environmental Protection Agency
401 M Street, S.W.
Washington, D. C. 20460

You may rest assured that the data you submit will be treated as confidential, unless you advise otherwise.

Attached for your convenience is a schedule showing when the various reports are due. There will be no further reminders from this Agency. The conditions and requirements imposed upon you by the August 19, 1976, Settlement and Order are self-executing. Your strict compliance with these terms is not only anticipated, but required. Failure to submit the required reports in a timely manner will result in the initiation of stop sale and seizure action on all products affected by this Order and the immediate cancellation of the registrations for these products.

We are also attaching a copy of the Settlement Order entitled "Proposed Terms of Settlement of Certain Portion of FIFRA Docket Nos. 246 et al.: Mercury Pesticide Cancellation Case", signed by you on September 10, 1976. We suggest you review the document.

Sincerely yours,

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

cc: Colburn T. Cherney

PARSONS CHEMICAL WORKS, INC.

SCHEDULE FOR SUBMISSION OF REPORTS.

PERIOD	DUE TO PATSED
Amount formulated each month during period between April 1, 1972 and July 31, 1976. Computation of total maximum amount of production. Inventory of quantity of product on hand as of Sept. 1, 1976. List of immediate customers	Jan. 14, 1977
July 1 - Sept. 30, 1976	Jan. 14, 1977
Oct. 1 - Dec. 31, 1976	Jan. 14, 1977
Jan. 1 - Mar. 31, 1977	Apr. 15, 1977
Apr. 1 - Jun. 30, 1977	Jul. 18, 1977
Jul. 1 - Sept. 30, 1977	Oct. 17, 1977
Oct. 1 - Dec. 31, 1977	Jan. 17, 1978
Jan. 1 - Mar. 31, 1978	Apr. 17, 1978
Apr. 1 - Jun. 30, 1978	Jul. 18, 1978
Jul. 1 - Aug. 31, 1978	Sept. 18, 1978

Fell Central Chemical Mercury

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

SEP 12 1990

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Compliance Strategy for the Conditional Registration and Voluntary Cancellation of Certain Mercury Biocides

FROM: John J. Neylan III, Director
Policy and Grants Division
Office of Compliance Monitoring

TO: Addressees

On June 25, 1990 the Director of the Special Review and Reregistration Division, Office of Pesticide Programs, signed a FEDERAL REGISTER Notice entitled: "Pesticide Products Containing Phenylmercury and Other Mercury Compounds; Receipt of Requests for Voluntary Cancellation and Amendments to Delete Uses." As a result of negotiations between EPA and registrants of products containing these uses, the registrants have applied to amend registrations for certain mercury products to delete labeling for use in interior paints, and have requested voluntary cancellation for other mercury products used in paints and coatings. Finally, the National Paint and Coatings Association (NPCA) agreed to instruct members to voluntarily relabel existing stocks of mercury-containing interior/exterior and exterior paints and to either reformulate or relabel existing stocks of interior paints containing high levels (i.e., >200 ppm) of mercury.

Attached are the Final Compliance Monitoring Strategy, a summary of the Strategy, a copy of the Cancellation Order, a copy of correspondence regarding the NPCA agreement to instruct members about the voluntary paint labeling program, and a list of producer/registrant establishments that will be used to target inspections. Targeting information for user/formulator establishments will be distributed to each Region under a separate cover. Please transmit a copy of the Strategy and other attachments to the States. Please note that because of the nature of this action, this Compliance Strategy is immediately effective. If you have any questions or comments regarding the Strategy, contact Steve Howie (E-mail EPA 7201, FTS 475-7786) of my staff.

Thank you for your cooperation.

Attachments

ADDRESSEES

Douglas D. Campt	(TS-766C)
Edwin F. Tinsworth	(TS-767C)
Anne Lindsay	(TS-767C)
Mike Walker	(LE-134A)
Mark Greenwood	(LE-132A)
Connie Musgrove	(EN-342)
John J. Neylan III	"
David Dull	"
Mike Wood	"
Phyllis Flaherty	"
Jerry Stubbs	"
Maureen Lydon	"
Ken Kanagalingam	"
Bob Zisa	"
Sherry Sterling	"
Jan Bearden	"

Jake Mackenzie
Western Regional Compliance Director

I	Louis F. Gitto, Director Air, Pest. & Toxics Mangt. Div.	Marvin Rosenstein, Chief Pesticides & Toxic Substances Br
II	Barbara Metzger, Director Environmental Services Division	Ernest Regna, Chief Pesticides & Toxic Substances Br
III	Thomas J. Maslany, Director Air, Toxics, & Radiation Mangt. Div	Larry Miller, Chief Toxic & Pesticides Branch
IV	Winston A. Smith, Director Air, Pest. & Toxics Mangt. Div	Richard D. Stonebraker, Chief Pesticides & Toxic Substances Br
V	William H. Sanders III, Director Environmental Services Division	Phyllis Reed, Chief Pesticides & Toxic Substances Br
VI	Robert Hannesschlager, Acting Dir. Air, Pesticides & Toxic Division	Robert Murphy, Chief Pesticides & Toxic Substances Br
VII	William A. Spratlin, Director Air and Toxics Division	Leo Alderman, Chief Pesticides & Toxic Substances Br
	913-551-7020	
VIII	Irwin L. Dickstein, Director Air and Toxics Division	C. Alvin Yorke, Chief Toxic Substances Branch
IX	David P. Howekamp, Director Air Management Division	Davis Bernstein, Chief Pesticides & Toxics Branch
X	Gary O'Neal, Director Air and Toxics Division	Kenneth Feigner, Chief Pesticides & Toxic Substances Br

cc:	Artie Williams	(H-7508C)
	John Tice	(TS-769C)
	Jan Andersen	(H-7508C)
	Beth Edwards	(H-7508C)
	Tim Backstrom	(LE-132P)
	OCM Staff	

MERCURY BIOCIDE CONDITIONAL REGISTRATION AND VOLUNTARY CANCELLATION COMPLIANCE MONITORING STRATEGY SUMMARY SHEET

INSPECTION DATE	INSPECTION SITE	INSPECTION PURPOSE/ CONDITIONS TO BE MONITORED
by 10/23/90	Producer Establishment	Relabeling must have been done of existing stocks of ALL Hg biocides sold or distributed on or after 7/23/90;
		Proof must be available that stickers were delivered to customers by 7/23/90.
by 2/20/91	User/Formulator Establishment (Paint companies)	Restickering of ALL stocks of Hg biocide must have been done by 8/20/90.
		Use of ALL Hg biocide must be in accordance with the label: all use on or after 8/20/90 must be in accordance with revised labeling.
		Paint produced on or after 8/20/90 must be labeled in accordance with biocide label instructions.
		Existing stocks of all paint products produced prior to 8/20/90 should be labeled in accordance with NPCA agreement.
between 6/28/91 and 8/28/91	Producer Establishment	No shipment of cancelled products after 6/27/91.
between 6/28/91 and 8/28/91	User/Formulator Establishments (Paint companies)	No use of cancelled products after 6/27/91

Conditionally registered products: Cosan PMA-100; Thor PMA-100; Vikon PMA-30 and Merkyl MAP.
Cancelled products: Intercide 60 (Akzo); Cosan PMO-30; Cosan PMA-30; Troysan PMDS-10; Troysan CMP Acetate; Troysan PMA-30; Thor PMA-100; Huls PMA-18; Huls PMA-60; Super-Ad-It Fungicide (Huls).

COMPLIANCE STRATEGY FOR THE CONDITIONAL REGISTRATION AND VOLUNTARY CANCELLATION OF CERTAIN MERCURY BIOCIDES

OVERVIEW

Certain mercury biocides are registered as pesticides for use in paints as antimicrobial agents. In addition, mercury biocides are registered for numerous miscellaneous uses, including textiles, adhesives, joint compounds, and other products. As such, these pesticides are used at the manufacturing level and the final treated products are exempt from regulation under FIFRA, provided that a registered pesticide was used and no pesticidal claims are made for the treated product. However, mercury biocides have been implicated in a recent human poisoning incident that apparently involved mercury-containing paint applied to the interior of a residence. EPA has conducted a risk/benefit analysis considering the exposure of painters as well as persons living and working in buildings painted with mercury-containing paints. EPA determined that there was an unreasonable risk to both painters and residents. In response, EPA worked with mercury biocide registrants to eliminate registered uses of such pesticides for formulating indoor paints and coatings, and to reduce risks involved in remaining registered uses.

As a result of negotiations between EPA and registrants of products containing these uses, the registrants have applied to amend registrations for certain mercury products to delete labeling for use in interior paints, and have requested voluntary cancellation for other mercury products used in paints and coatings. On June 25, 1990 the Director of the Special Review and Reregistration Division, Office of Pesticide Programs, signed a FEDERAL REGISTER Notice entitled: "Pesticide Products Containing Phenylmercury and Other Mercury Compounds; Receipt of Requests for Voluntary Cancellation and Amendments to Delete Uses." This Notice was published on June 29, 1990 (Attachment 1).

The cancellation order and amendments to delete uses were effective July 2, 1990. Effective July 23, 1990, it is illegal for registrants to sell or distribute any existing stocks that do not meet labeling provisions. By July 23, 1990, stickers and instructions for restickering of all existing stocks must be delivered to all persons holding existing stocks subject to restickering. The language to be added to stickers and new labeling prohibit the use of mercury biocides in formulating interior paints and coatings, include precautionary statements on exterior paints formulated using mercury biocides, and specify the rate of application for the remaining uses. The instructions accompanying the labeling will state that each container of mercury biocide subject to this action must be relabeled by August 20, 1990. All paint manufactured or formulated with mercury biocides after August 20, 1990, must comply with the revised label.

Finally, to provide additional protection for users of paints, EPA negotiated a voluntary stickering program with the National Paint and Coatings Association (NPCA). Pursuant to this arrangement, NPCA agreed to instruct members by direct mailings to label existing stocks of mercury-containing interior/exterior and exterior paints "for

exterior use only", and to either reformulate or relabel "for exterior use only" existing stocks of interior paints with high levels (i.e., >200 ppm) of mercury. Labels are also to include warning and use statements. The language to be used in the voluntary labeling is identical to that required in the mandatory labeling that applies to stocks produced after August 20, 1990, as described in the terms of the conditional registration and the Cancellation Order, above. Members of NPCA were instructed to comply with the voluntary program by August 20, 1990. A copy of the letters used for the direct mailing, including the initial mailing, the EPA response to that mailing, and a followup mailing from NPCA as a result of the EPA response, are attached to this Strategy (Attachment 2).

Compliance with the terms of the Conditional Registration Agreement and the Cancellation Order will be monitored through inspection of registrant/producer facilities and user/formulator facilities. The voluntary existing paint stocks stickering program will be monitored concomitantly with inspections of use facilities. States may wish to monitor paint retailers to determine whether paint products that are being sold are relabeled according to the terms of both the cancellation order and the voluntary labeling agreement.

REGULATED COMMUNITY

The registrants (who are generally also the producers and distributors), and the users of mercury biocides (i.e., paint companies), and the users of paints containing mercury biocides, are affected by the Conditional Registration and the Cancellation Order, although responsibility for meeting the terms of the Agreement and Cancellation is primarily on the registrants. There are six companies with mercury biocides registered for use in paints. A list of these can be found in the Appendix.

REQUIREMENTS OF CONDITIONAL REGISTRATION

Two companies (Cosan and Troy), have applied to conditionally amend the registrations of two PMA pesticides:

Cosan PMA-100; EPA Reg. No. 8489-5
Troysan PMA-100; EPA Reg. No. 5383-8

The applications are granted effective July 2, 1990. The revised labeling will: (1) Prohibit use in formulating interior paints and coatings; (2) Limit use to those exterior paints and coatings that are labeled against interior use; and (3) Specify maximum use rates. The registrants have also agreed as a condition of registration to develop and submit certain data.

One company (Vikon), has applied to conditionally amend the registrations of two pesticides presently labeled for use in outdoor fabrics and paint by deleting all paint uses:

MERKYL MAP; EPA Reg. No. 6390-20
VIKON PMA-30; EPA Reg. No. 6390-21

The applications are granted effective July 2, 1990.

Stocks of Products With Amended Stickering/Labeling

Effective July 23, 1990, the registrants may not distribute or sell existing stocks of mercury biocides that have not been relabeled, and, as a condition of registration, they must deliver sufficient stickers to their customers to relabel all existing stocks in the customers' inventories. Registrants must have proof that delivered stickers were delivered with required instructions. The instructions, which are considered to accompany the product, state the manner in which the sticker must be affixed to each container, and that stickers must be in place on all user stocks by August 20, 1990.

CONDITIONS OF CANCELLATION

Five registrants have agreed to voluntarily cancel a total of ten pesticide products, effective July 2, 1990. The registrants and the cancelled products are listed below.

Akzo Chemicals, Inc.: Intercide 60 (EPA # 34688-24).

Cosan Corp.: Cosan PMO-30 (EPA # 8489-1); and Cosan PMA-30 (EPA # 8489-2).

Hüls America, Inc.: Super Ad-It Fungicide (EPA # 1100-37); PMA-18 (EPA # 1100-56); and PMA-60 (EPA # 1100-80).

Thor Chemicals Inc.: Thor PMA-100 (EPA # 53034-1);

Troy Chemical Corp.: Troysan PMA-30 (EPA # 5383-4); Troysan CMP Acetate (EPA # 5383-10); Troysan PMDS-10 (EPA # 5383-62);

The existing stocks of the cancelled products may be sold and used until June 27, 1991, provided they are relabeled. The revised labeling will: (1) Prohibit use in formulating interior paints and coatings; (2) Limit use to those exterior paints and coatings that are labeled against interior use; (3) Specify maximum use rates; and (4) Provide that sale, distribution, and use will be unlawful after June 27, 1991.

Effective July 23, 1990, the registrants may not distribute or sell existing stocks of cancelled products that have not been relabeled. They must also deliver sufficient stickers to their customers to relabel all existing stocks in the customers' inventories. Registrants must have proof that the stickers were delivered with required instructions. The cancellation order requires that by August 20, 1990, no person who uses existing stocks of cancelled products may use the product unless the approved sticker has been affixed to the product.

Noncompliance with the cancellation order or its terms is a violation of FIFRA sections 12(a)(1)(A) and/or 12(a)(2)(K).

CONDITIONS OF VOLUNTARY PAINT LABELING AGREEMENT

The National Paint and Coatings Association (NPCA) agreed to instruct members to sticker all existing stocks of mercury-containing interior/exterior and exterior paints "for exterior use only", and to either reformulate or relabel "for exterior use only" existing stocks of interior paints with high levels (i.e., >200 ppm) of mercury. Labels are also to include advisement that the product contains mercury biocides, and warning and use statements; label statements to be used under the NPCA program are identical to the paint label statements that must be used under the conditional registrations and cancellation order affecting certain mercury biocides. Members of NPCA have been instructed to comply with the voluntary program by August 20, 1990.

This agreement is entirely voluntary and noncompliance does not carry direct penalties under FIFRA. However, since alternative actions would be necessary to protect public health if this agreement is not adhered to, it is necessary that EPA be aware of the degree of compliance.

COMPLIANCE MONITORING

Compliance with the terms of the Conditional Registration Agreement and the Cancellation Order will be monitored through inspection of registrant/producer facilities (Attachment 3) and user/formulator facilities. Since there are only eight registrant/producer facilities, each of these facilities will be inspected. These inspections will be conducted after July 23, 1990, and will be completed by October 23, 1990.

User/formulator facilities will be selected for inspection from the list of facilities that are known to have received mercury biocides and produced interior paints or coatings, or products other than paint that may be used indoors. Selection of facilities will be made at the regional level and will be based on number of facilities meeting appropriate criteria, resources, and tips and complaints. OCM will develop a targeting scheme based on available information and transmit it to the Regions. These

inspections will be conducted after August 20, 1990, and will be completed by February 20, 1991.

Additionally, after June 27, 1991, registrant/producer and user/formulator establishments will be inspected to assure that no cancelled products are sold or used on or after June 27, 1991.

Inspections at user/formulator facilities will include determination of compliance with voluntary existing stocks labeling. All existing stocks of paint products which contain mercury biocides and were produced before August 20, 1990, should be labeled pursuant to this agreement, with the exception of interior paints demonstrated to have low levels (i.e., $\leq$200 ppm) of mercury.

Regional/State Activities

Inspections will be conducted by States and EPA (in non-grant states) to monitor compliance with the Conditional Registration Agreement, the Cancellation Order, and the voluntary paint-relabeling agreement. This will be accomplished through registrant/producer establishment and user/formulator establishment inspections. Enforcement actions regarding the Cancellation Order will be taken, as appropriate, by the States and Regions, with reports of such actions and/or potential violations made to EPA headquarters. States and Regions will also report to EPA headquarters all violations or potential violations of the conditions of registration of mercury biocide products. Reports of non-violative findings, i.e., non-compliance with the voluntary agreement, will be made to EPA headquarters.

Registrant/Producer Level

By October 23, 1990, the Regions/States will schedule and conduct inspections of all of the registrant's producer establishments to obtain assurance that the labeling and user-notification requirements of the Agreement and Cancellation Order have been followed. In particular, these inspections will assure that : (1) all products that have been sold or distributed after July 22, 1990, have the correct amended labels or stickers; and (2) all stickers have been sent, with required instructions, to all customers holding existing stocks by July 23, 1990. All stocks not properly labeled are subject to Stop Sale, Use, Removal Orders (SSUROs). Additionally, registrant/producer establishments will be inspected to assure compliance with requirements under FIFRA section 17(a) relating to labeling and foreign purchaser notification of pesticides produced for export. Regions/States will either perform such inspections concomitantly with inspections prescribed by this Strategy or report such establishments as uninspected for compliance with FIFRA section 17(a) to allow for subsequent targeting for inspection.

After June 27, 1991, inspections will be conducted at those registrant/producer facilities that produced products subject to cancellation to determine that no existing stocks of cancelled products are being sold after this date. All such stocks are subject to Stop Sale, Use, Removal Orders (SSUROs).

User/Formulator Level

Interior-paint producing establishments that have been identified as having received shipments of mercury biocides within the last year shall be targeted for inspection to determine compliance with conditions of labeling.

By February 20, 1991 inspections at selected user/formulator establishments will assure that: (1) all current stocks, including products maintained in stock after August 20, 1990, have been restickered; (2) all use of stocks is according to their label instructions. In particular, the inspector should assure that no mercury-containing products have been used for interior paint production on or after August 20, 1990, that labels of all exterior paint products produced on or after August 20, 1990, contain the appropriate precautionary language, and that users do not exceed labeled use rates when formulating exterior paints.

In addition, these inspections will include examination of existing stocks of any mercury-containing paint produced prior to August 20, 1990. Inspectors should examine these stocks to first determine how they are labeled (exterior use only; interior/exterior use; or interior use only.) For any paints labeled for interior use, including interior/exterior paints, it should be determined whether the paint contains greater than 200 ppm mercury. All stocks of such exterior paints and interior paints with greater than 200 ppms should be examined for labeling in accordance with the NPCA voluntary relabeling agreement. Determination of mercury levels of existing stocks of paint produced prior to August 20, 1990, and conformance with voluntary relabeling, is to provide information regarding the need for additional regulation. Inspectors are advised that they may rely on statements by paint formulators concerning the mercury content of paints produced prior to August 20, 1990, and that no additional investigatory measures are required.

After June 27, 1991, inspections will be conducted at selected user/formulator facilities to determine that no existing stocks of cancelled products are in use after this date. All such stocks are subject to Stop Sale, Use, Removal Orders (SSUROs).

ALLOCATION OF RESPONSIBILITIES

Office of Pesticide Programs

Will develop and provide OCM with a list of all products affected by the Conditional Registration Agreement and the Cancellation Order.

Will develop and provide OCM with a list of user/formulator establishments that use mercury biocides in paint production.

Office of Compliance Monitoring

Will develop and transmit the Compliance Monitoring Strategy to the Regions.

Will transmit to the Regions a targeting scheme for user/formulator establishments.

Will transmit to OPP any information regarding violation of the conditions of registration.

Regions

Will provide copies of the Compliance Monitoring Strategy to States.

Will distribute a list of products and producing establishments to the States.

Will transmit to the States a list of the user/formulator establishments.

Will conduct inspections in States without Cooperative Enforcement Agreements as specified in this Strategy.

Will take enforcement action as appropriate.

Will report to the Director of the Compliance Division, OCM detailing State inspection activities per their reports.

Will report information to States which indicates possible noncompliance with the requirements of the Agreement, including information on tips and complaints received.

Will report to the Director of the Compliance Division, OCM regarding violations of the conditions of registrations, cancellations, or voluntary labeling agreements immediately upon receiving such information.

States

Will conduct inspections as specified in this Strategy.

Will make reports to the Regions detailing the number and dates of inspections related to this Strategy.

Will take enforcement action as appropriate provided they have the authority.

Will report to the Regions on potential violations of the mercury biocide conditional registration agreement, including enforcement actions for violations of the Cancellation Order. Reports will be submitted within two weeks of knowledge of violation or enforcement action.

Will investigate tips and complaints as received. If States receive information which indicates possible noncompliance with the Agreement, they should investigate to ensure compliance.

ATTACHMENT 1
CANCELLATION ORDER

almond hulls at 15.0 ppm, almond nutmeat at .04 ppm, peaches at 1.0 ppm, nectarines at 1.0 ppm, meat and meat byproducts of cattle at 0.05 ppm, cattle kidney at 0.05 ppm, cattle liver at 0.20 ppm, and milk at 0.05 ppm.

These temporary tolerances have been extended to permit the continued marketing of the raw agricultural commodities named above when treated in accordance with the provisions of experimental use permit 45639-EUP-33, which is being extended under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended (Pub. L. 95-396, 92 Stat. 819; 7 U.S.C. 136).

The scientific data reported and other relevant material were evaluated, and it was determined that the extension of these temporary tolerances will protect the public health. Therefore, the temporary tolerances have been extended on the condition that the pesticide be used in accordance with the experimental use permit and with the following provisions:

1. The total amount of the active ingredient to be used must not exceed the quantity authorized by the experimental use permit.

2. Nor-Am Chemical Co. must immediately notify the EPA of any findings from the experimental use that have a bearing on safety. The company must also keep records of production, distribution, and performance and on request make the records available to any authorized officer or employee of the EPA or the Food and Drug Administration.

These tolerances expire April 2, 1991. Residues not in excess of these amounts remaining in or on the raw agricultural commodities after this expiration date will not be considered actionable if the pesticide is legally applied during the term of, and in accordance with, the provisions of the experimental use permit and temporary tolerances. These tolerances may be revoked if the experimental use permit is revoked or if any experience with or scientific data on this pesticide indicate that such revocation is necessary to protect the public health.

The Office of Management and Budget has exempted this notice from the requirements of section 3 of Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

Authority: 21 U.S.C. 346a(j).

Dated: June 18, 1990.

Anne E. Lindsay,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 90-15200 Filed 6-28-90; 8:45 am]

BILLING CODE 6560-50-D

[OPP-66141; FRL-3773-6]

Pesticide Products Containing Phenylmercury and Other Mercury Compounds; Receipt of Requests for Voluntary Cancellation and Amendments To Delete Uses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Pesticide cancellations and amendments.

SUMMARY: In response to concerns by EPA regarding the risks associated with use of mercury products in interior paints and coatings, the registrants have applied to amend the registrations for certain mercury products to delete labeling for use in interior paints and coatings and have requested voluntary cancellation of the registrations for certain other mercury products labeled for use in paints and coatings. All stocks of affected products, including stocks in the hands of end-users, must be stickered by August 20, 1990, with language prohibiting use in interior paints and coatings. Existing stocks of cancelled products which have been properly stickered may be sold and used until June 27, 1991.

DATES: The cancellation order and amendments to delete uses incorporated in this notice will become effective July 2, 1990. Use of cancelled and amended mercury products in interior paints and coatings will be unlawful effective on August 20, 1990. Existing stocks of cancelled products which have been properly stickered may be sold and used until June 27, 1991.

FOR FURTHER INFORMATION CONTACT: Beth Edwards, Special Review Branch, Special Review and Reregistration Division (H7508C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: 3rd Floor, 2805 Jefferson Davis Highway, Arlington, VA (703) 308-8010.

SUPPLEMENTARY INFORMATION:

I. EPA Conclusions Concerning Use of Mercury in Interior Paints and Coatings

Following receipt of reports concerning a 4-year old child who developed acrodynia (a rare form of mercury poisoning) after his home was painted with paint containing mercury and a followup investigation by the Centers for Disease Control and the State of Michigan of mercury levels in other homes painted with similar paint, EPA initiated a comprehensive review of the risks and benefits associated with the use of mercurial compounds in paints and coatings. After evaluating the available evidence concerning exposure to mercury resulting from use in paints and coatings, toxicity of mercury and mercury compounds, and availability of alternative biocides, EPA concluded that the continued use of mercurial compounds in the manufacture of interior paints and coatings would present an unreasonable risk of adverse health effects. EPA also concluded that the available data were insufficient to enable full evaluation of the risks and benefits associated with use of mercurial compounds in exterior paints and coatings, and that the registrants should develop and submit additional data concerning this use.

After completing its review, EPA initiated discussions with the registrants of mercury products labeled for use in paints and coatings to determine whether the necessary changes in the legal status of such products could be achieved by voluntary action. The registrants then agreed to submit the amendments to delete uses and the requests for voluntary cancellation described in this notice. This notice is being published to advise the public of the changes in sale, distribution, and use to be implemented for the affected products, and to meet the legal requirements established by FIFRA section 6(f)(1), 7 U.S.C. 136d(f)(1).

II. Conditional Amendments to Delete Uses

Cosan Chemical Corporation and Troy Chemical Corporation have applied to conditionally amend pursuant to FIFRA section 3(c)(7)(a) their registrations for certain pesticide products containing phenylmercuric acetate (PMA) which are presently labeled for use in formulation of paints and coatings. The names and EPA registration numbers for these products are as follows:

Cosan PMA-100 EPA Registration No. 8469-6

Troysan PMA-100 EPA Registration No. [illegible]

5383-4

(Example)

EPA intends to grant the applications to amend the registrations for these products on July 2, 1990. The revised labeling required by the amended registrations for these products will: (1) Prohibit use of these products in manufacture or formulation of any paint or coating intended or labeled for interior use, (2) limit use of these products to only those exterior paints and coatings which are labeled with a specific warning against interior use, and (3) specify maximum application rates for use of these products in exterior paints and coatings. The registrants have also agreed as a condition of registration to develop and submit additional data pertaining to the risks and benefits associated with continued use of PMA products in exterior paints and coatings.

For each of the products concerning which Cosan Chemical Corporation or Troy Chemical Corporation has submitted an application for conditional amendment, the registrant will be required to affix a sticker incorporating the new label requirements to all stocks of the product distributed or sold by the registrant on or after July 23, 1990. For each product, the registrant will also be required by July 23, 1990, to deliver stickers to all end-users who are holding inventory of the product. Each end-user will be required to affix the stickers on or before August 20, 1990, to all stocks of the product remaining in its inventory. After August 20, 1990, use of any stocks of these products in a manner inconsistent with the amended labeling will be unlawful.

Vikon Chemical Company has also applied to conditionally amend pursuant to FIFRA section 3(c)(7)(a) its registrations for MERKYL MAP, EPA Registration No. 6390-20 and VIKON PMA-30, EPA Registration No. 6390-21, products which are presently labeled for use in manufacture of outdoor fabrics and in paint, to delete all label instructions and claims pertaining to use of these products in paint. EPA intends to grant the applications to amend the registrations for these products on July 2, 1990. Vikon will be required to affix revised labeling to all stocks of these products which are distributed or sold by Vikon on or after July 23, 1990. Vikon will also be required to deliver revised labels to each of its customers holding stocks of these products by July 23, 1990.

III. Requests For Voluntary Cancellation

Akzo Chemicals, Inc., Cosan Chemical Corporation, Huls America, Inc., Thor Chemicals, Inc., and Troy Chemical Corporation have each submitted requests pursuant to FIFRA section 6(f)(1) for voluntary cancellation of the registrations for particular pesticide products which contain phenylmercuric acetate (PMA), di(phenylmercuric) dodecenyl succinate (PMDS), phenylmercuric oleate (PMO), or 3-(chloromethoxy)propylmercuric acetate (CMPA), and which are labeled for use in formulation of paints and coatings. The registrants, product names, and EPA registration numbers for these products are as follows:

Registrant	Product	EPA Registration No.
Akzo Chemicals, Inc.	Intercide 60	34688-24
Cosan Corporation.	Cosan PMO-30.	8469-1
Cosan Corporation.	Cosan PMA-30.	8469-2
Huls America, Inc.	Super Ad-It Fungicide.	1100-37
Huls America, Inc.	PMA-16	1100-56
Huls America, Inc.	PMA-60	1100-69
Thor Chemicals, Inc.	Thor PMA-100.	53094-1
Troy Chemical Corporation.	Troysan PMA-30.	5383-4
Troy Chemical Corporation.	Troysan CMP Acetate.	5383-10
Troy Chemical Corporation.	Troysan PMDS-16.	5383-62

EPA intends to grant the requests for voluntary cancellation of the registrations for the above products on July 2, 1990.

IV. Existing Stocks

EPA has decided that it will permit continued sale and use of existing stocks of voluntarily cancelled products containing PMA, PMDS, PMO, and CMPA, for manufacture and formulation of exterior paints and coatings until June 27, 1991, subject to specific mandatory terms and conditions. FIFRA section 6(a)(1), 7 U.S.C. section 136d(a)(1), provides that EPA may permit continued sale and use of existing stocks of cancelled products for specific uses and subject to specific conditions, if EPA determines "that such sale or use is not inconsistent with the purposes of this Act and will not have unreasonable adverse effects on the environment." The terms and conditions which will govern sale and use of existing stocks of cancelled mercury products are essentially identical to the amended terms and conditions which will apply to the specific mercury products that will remain registered for use in exterior paints and coatings. Thus, the analysis of risks and benefits upon which the Agency's decision to permit continued registration is based also provides the basis for the substantive determination required by FIFRA section 6(f)(1).

Each registrant of a voluntarily cancelled mercury product has submitted the text for a sticker which includes provisions that: (1) Prohibit use of the product in manufacture or formulation of any paint or coating intended or labeled for interior use, (2) limit use of the product to only those exterior paints and coatings which are labeled with a specific warning against interior use, (3) specify maximum application rates for use of the product in exterior paints and coatings, and (4) provide that sale, distribution, and use of the product will be unlawful after June 27, 1991. Except for the expiration date for use of existing stocks, these are the same provisions included in the revised labeling for PMA paint and coating products with amended registrations.

The cancellation order will require each registrant or other person to affix a sticker incorporating the new label requirements to all stocks of the product distributed or sold by on or after July 23, 1990. The cancellation order also will require each registrant of a cancelled product to deliver stickers by July 23, 1990, to all end-users who are holding inventory of the product, and will provide that stocks of each cancelled product remaining in the inventory of end-users may not be lawfully used after August 20, 1990, unless the end-user has affixed the new sticker to the product and all use of the product is in full conformity with the instructions on the sticker.

V. Cancellation Order

Effective on July 2, 1990, the registrations for the following pesticide products are cancelled pursuant to section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. section 136d(f)(1):

Registrant	Product	EPA Registration No.
Akzo Chemicals, Inc.	Intercide 60	34688-24
Cosan Corporation.	Cosan PMO-30.	8469-1
Cosan Corporation.	Cosan PMA-30.	8469-2

Registrant	Product	EPA Registration No.
Huls America, Inc.	Super A&R Fungicide.	1160-57
Huls America, Inc.	PMA-10	1160-58
Huls America, Inc.	PMA-50	1160-60
Troy Chemicals, Inc.	Troy PMA-100	5905-4-1
Troy Chemical Corporation.	Troysan PMA-20.	5905-4
Troy Chemical Corporation.	Troysan CMP Acetate.	5905-10
Troy Chemical Corporation.	Troysan PMDS-10.	5905-62

Effective on July 2, 1990, it shall be unlawful under FIFRA section 12(a)(1)(A) and/or FIFRA section 12(a)(2)(K), 7 U.S.C. sections 136j(a)(1)(A), 136j(a)(2)(K), for any person to distribute or sell, or to use for any pesticidal purpose, any of these cancelled products except in full compliance with all of the provisions concerning existing stocks set forth below.

The Agency has determined that existing stocks of each pesticide product cancelled by this order may be sold, distributed, and used until June 27, 1991, subject to all of the following mandatory terms and conditions. For each cancelled product, the registrant has submitted as part of its request for voluntary cancellation under FIFRA section 6(f)(1) the text for a sticker which includes label provisions: (1) Prohibiting use of the product in manufacture or formulation of any paint or coating intended or labeled for interior use, (2) limiting use of the product in exterior paints and coatings to only those products which are labeled with a warning against interior use, (3) specifying maximum application rates for use in exterior paints and coatings, and (4) providing that sale, distribution, and use of the product will be unlawful after June 27, 1991. Effective on July 23, 1990, no person shall distribute or sell in any State any quantity of a pesticide product cancelled by this order unless the approved sticker for that product has been affixed to each container of the product. Effective on August 20, 1990, no person shall use in any State any quantity of a pesticide product cancelled by this order unless the approved sticker for that product has been affixed to each container of the product and such use is in full conformity with all of the instructions on the sticker. For each cancelled product, the registrant shall by July 23, 1990, deliver to, and verify receipt by, each customer or other end-user holding inventory of the product: (1) Quantities of the approved sticker for that product which are sufficient to affix the sticker to each container of the product in the customer's or end-user's inventory, and (2) a letter advising the customer or end-user of the effective dates for the revised labeling on the stickers and instructing the customer or end-user to affix the sticker to each container of the product on or before August 20, 1990.

Dated: June 25, 1990.

Edwin F. Tinsworth,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 90-15089 Filed 6-28-90; 8:45 am]

BILLING CODE 6560-50-D

[OPTS-51750; FRL 3779-2]

Toxic and Hazardous Substances; Certain Chemicals Premanufacture Notices

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5(a)(1) of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture or import a new chemical substance to submit a premanufacture notice (PMN) to EPA at least 90 days before manufacture or import commences. Statutory requirements for section 5(a)(1) premanufacture notices are discussed in the final rule published in the Federal Register of May 13, 1983 (48 FR 21722). This notice announces receipt of 162 such PMNs and provides a summary of each.

DATES: Close of Review Periods:

P 90-1118, 90-1119, 90-1173, 90-1176, 90-1177, 90-1178, 90-1181, 90-1183, 90-1184, 90-1185, 90-1186, 90-1191, 90-1192, 90-1193, 90-1194, 90-1195, 90-1196, 90-1197, 90-1198, 90-1199, 90-1200, 90-1201, 90-1202, 90-1203, 90-1204, 90-1205, 90-1206, 90-1207, 90-1208, 90-1209, 90-1210, 90-1211, 90-1212, 90-1213, 90-1214, 90-1215, 90-1216, 90-1217, 90-1218, 90-1219, 90-1220, 90-1221, 90-1222, 90-1223, 90-1224, 90-1225, 90-1226, 90-1227, 90-1228, 90-1229, 90-1230, 90-1231, 90-1232, 90-1233, 90-1234, 90-1235, 90-1236, 90-1237, 90-1238, 90-1239, 90-1240, 90-1241, 90-1242, 90-1243, 90-1244, 90-1245, 90-1246, 90-1247, 90-1248, 90-1249, 90-1250, 90-1251, 90-1252, 90-1253, 90-1254, 90-1255, 90-1256, 90-1257, 90-1258, 90-1259, 90-1260, 90-1261, 90-1262, 90-1263, 90-1264, 90-1265, 90-1266, 90-1267, 90-1268, 90-1269, 90-1270, 90-1271, June 21, 1990.

P 90-1272, 90-1273, 90-1274, 90-1275, 90-1276, 90-1277, June 22, 1990.

P 90-1278, July 22, 1990.

P 90-1279, 90-1280, June 22, 1990.

P 90-1281, June 23, 1990.

P 90-1282, 90-1283, 90-1284, 90-1285, June 25, 1990.

P 90-1286, 90-1287, 90-1288, 90-1289, 90-1290, June 28, 1990.

P 90-1291, 90-1292, 90-1294, 90-1295, 90-1296, 90-1297, 90-1298, 90-1299, 90-1300, 90-1301, 90-1302, 90-1303, 90-1304, 90-1305, 90-1306, 90-1307, 90-1308, July 29, 1990.

P 90-1309, 90-1310, 90-1311, 90-1312, July 30, 1990.

P 90-1313, 90-1314, 90-1315, 90-1316, 90-1317, July 31, 1990.

P 90-1318, 90-1319, 90-1320, 90-1321, 90-1322, 90-1323, 90-1324, August 1, 1990.

P 90-1325, August 4, 1990.

P 90-1326, 90-1327, 90-1329, 90-1330, 90-1331, 90-1332, 90-1333, 90-1334, 90-1335, 90-1336, 90-1337, August 5, 1990.

P 90-1338, 90-1339, 90-1340, 90-1341, 90-1342, 90-1343, August 6, 1990.

Written comments by:

P 90-1118, 90-1119, 90-1173, 90-1176, 90-1177, 90-1178, 90-1181, 90-1183, 90-1184, 90-1185, 90-1186, 90-1191, 90-1192, 90-1193, 90-1194, 90-1195, 90-1196, 90-1197, 90-1198, 90-1199, 90-1200, 90-1201, 90-1202, 90-1203, 90-1204, 90-1205, 90-1206, 90-1207, 90-1208, 90-1209, 90-1210, 90-1211, 90-1212, 90-1213, 90-1214, 90-1215, 90-1216, 90-1217, 90-1218, 90-1219, 90-1220, 90-1221, 90-1222, 90-1223, 90-1224, 90-1225, 90-1226, 90-1227, 90-1228, 90-1229, 90-1230, 90-1231, 90-1232, 90-1233, 90-1234, 90-1235, 90-1236, 90-1237, 90-1238, 90-1239, 90-1240, 90-1241, 90-1242, 90-1243, 90-1244, 90-1245, 90-1246, 90-1247, 90-1248, 90-1249, 90-1250, 90-1251, 90-1252, 90-1253, 90-1254, 90-1255, 90-1256, 90-1257, 90-1258, 90-1259, 90-1260, 90-1261, 90-1262, 90-1263, 90-1264, 90-1265, 90-1266, 90-1267, 90-1268, 90-1269, 90-1270, 90-1271, July 21, 1990.

P 90-1272, 90-1273, 90-1274, 90-1275, 90-1276, 90-1277, July 22, 1990.

P 90-1278, August 27, 1990.

P 90-1279, 90-1280, July 22, 1990.

P 90-1281, July 23, 1990.

P 90-1282, 90-1283, 90-1284, 90-1285, July 25, 1990.

P 90-1286, 90-1287, 90-1288, 90-1289, 90-1290, July 28, 1990.

P 90-1291, 90-1292, 90-1294, 90-1295, 90-1296, 90-1297, 90-1298, 90-1299, 90-1300, 90-1301, 90-1302, 90-1303, 90-1304, 90-1305, 90-1306, 90-1307, 90-1308, July 29, 1990.

P 90-1309, 90-1310, 90-1311, 90-1312, July 30, 1990.

P 90-1313, 90-1314, 90-1315, 90-1316, 90-1317, July 31, 1990.

P 90-1318, 90-1319, 90-1320, 90-1321, 90-1322, 90-1323, 90-1324, August 1, 1990.

P 90-1325, August 4, 1990.

P 90-1326, 90-1327, 90-1329, 90-1330, 90-1331, 90-1332, 90-1333, 90-1334, 90-1335, 90-1336, 90-1337, August 5, 1990.

P 90-1338, 90-1339, 90-1340, 90-1341, 90-1342, 90-1343, August 6, 1990.

Written comments by:

P 90-1118, 90-1119, 90-1173, 90-1176, 90-1177, 90-1178, 90-1181, 90-1183, 90-1184, 90-1185, 90-1186, 90-1191, 90-1192, 90-1193, 90-1194, 90-1195, 90-1196, 90-1197, 90-1198, 90-1199, 90-1200, 90-1201, 90-1202, 90-1203, 90-1204, 90-1205, 90-1206, 90-1207, 90-1208, 90-1209, 90-1210, 90-1211, 90-1212, 90-1213, 90-1214, 90-1215, 90-1216, 90-1217, 90-1218, 90-1219, 90-1220, 90-1221, 90-1222, 90-1223, 90-1224, 90-1225, 90-1226, 90-1227, 90-1228, 90-1229, 90-1230, 90-1231, 90-1232, 90-1233, 90-1234, 90-1235, 90-1236, 90-1237, 90-1238, 90-1239, 90-1240, 90-1241, 90-1242, 90-1243, 90-1244, 90-1245, 90-1246, 90-1247, 90-1248, 90-1249, 90-1250, 90-1251, 90-1252, 90-1253, 90-1254, 90-1255, 90-1256, 90-1257, 90-1258, 90-1259, 90-1260, 90-1261, 90-1262, 90-1263, 90-1264, 90-1265, 90-1266, 90-1267, 90-1268, 90-1269, 90-1270, 90-1271, June 21, 1990.

P 90-1272, 90-1273, 90-1274, 90-1275, 90-1276, 90-1277, June 22, 1990.

P 90-1278, July 22, 1990.

P 90-1279, 90-1280, June 22, 1990.

P 90-1281, June 23, 1990.

P 90-1282, 90-1283, 90-1284, 90-1285, June 25, 1990.

P 90-1286, 90-1287, 90-1288, 90-1289, 90-1290, June 28, 1990.

P 90-1291, 90-1292, 90-1294, 90-1295, 90-1296, 90-1297, 90-1298, 90-1299, 90-1300, 90-1301, 90-1302, 90-1303, 90-1304, 90-1305, 90-1306, 90-1307, 90-1308, June 29, 1990.

P 90-1309, 90-1310, 90-1311, 90-1312, June 30, 1990.

P 90-1313, 90-1314, 90-1315, 90-1316, 90-1317, July 1, 1990.

ATTACHMENT 2
VOLUNTARY RELABELING LETTER

FOR

IMMEDIATE ATTENTION

July 5, 1990

TO: NPCA MEMBERSHIP

FROM: Stephen R. Sides, Director
Health, Safety & Environmental Affairs
and
Marilyn E. Ludwig, Director
Communications

RE: MERCURY BIOCIDES: STATUS REPORT AND FOLLOW-UP ACTIONS

On June 29, 1990, the U.S. Environmental Protection Agency, in concert with the Centers for Disease Control, held a press conference to advise consumers of the alleged hazards of mercurial biocides in paint. The focus of the press conference was a voluntary agreement between the EPA and the biocide manufacturers which, in effect, eliminates the use of mercurial biocides in interior paints, and specifies labeling language for mercury-containing exterior paints. (Although we were aware of negotiations between the biocide producers and the EPA, NPCA was not a party to this agreement.)

Shortly before the press conference, EPA and CDC had indicated that they intended to advise consumers not to use any paints containing mercury. Such a statement would have been tantamount to a market-driven ban and recall.

Last-minute discussions between NPCA and EPA established certain important facts, which resulted in EPA spokespersons being willing to state publicly that consumers can buy and use existing stocks of interior paints, formulated with mercury at under 200 parts per million, without unreasonable risk. (The great majority of paints formulated properly for interior use should fall below the 200 ppm/mercury threshold.)

NPCA offered to work with our members to label stocks of products now in the marketplace, containing more than 200 ppm mercury. Events that will affect paint product reformulation and labeling are summarized below.

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1. Effective August 20, 1990, no interior paint product may be manufactured using mercurial biocides.

2. Also effective August 20, 1990, exterior paint products manufactured with mercurial biocides must have a revised label statement (Attachment A to this memo).

3. Existing stocks of interior or exterior paint containing more than 200 ppm mercury may not be sold or distributed without the previously referenced label statement (Attachment A). Manufacturers should move as quickly as possible to relabel these products, but in no instance should these products be sold without the new label statement after August 20, 1990. (Existing stocks, for purposes of this memo, include all products manufactured since June 1, 1990 and subsequently distributed.)

For your further information, during the press conference on June 29, NPCA learned of the EPA's intention to set up a "hotline" for consumers through the National Pesticide Telecommunications Network. Consumers wanting information on the presence or absence of mercurial biocides may now call a toll-free number (1-800-858-7378), where operators will provide information collected as part of EPA's survey completed March 30, 1990.

However, NPCA is concerned about the quality and accuracy of the information being provided. EPA has compiled two lists: one of paint companies that reported using mercury during the two years prior to filling out the EPA questionnaire, and the second, of companies that reported no use of mercury during that period.

First, the lists do not address the subject of which product lines do or do not currently contain mercury; they merely include company names. In addition, since the EPA questionnaire requested information dating back two years, some companies are included in the USE MERCURY list, although they may have discontinued its use some time ago.

NPCA is requesting that the EPA immediately instruct its hotline operators to read a qualifying statement to this effect to consumers, and to suggest that the consumer contact the paint company for more detailed and definitive information.

Meanwhile, company spokespersons should be aware that the EPA's press conference, and its reporting by the media, have probably created more confusion than enlightenment among the public. The spokesperson should be prepared to answer all consumer and media questions concerning the presence or absence of mercury in company product lines. They should be prepared to deal with questions concerning the anticipated retail shelf-life of company products, and to be specific about the presence or absence of mercurial biocides, and the concentration of them, in individual product lines and batch-numbers.

They should also be aware of the Association's statements concerning mercurial biocides, formulated at the appropriate levels, in both interior and exterior products.

The enclosed fact sheet (Attachment B) may be useful in responding to questions. In brief: NPCA does not believe that there is scientific evidence to indicate that mercurial biocides in paints properly formulated and properly applied in accordance with existing label instructions, pose a problem -- but to alleviate public concern, it and its members have voluntarily taken all appropriate steps to deal with the situation.

ATTACHMENT A

LABEL STATEMENT FOR EXTERIOR PRODUCTS

FOR EXTERIOR USE ONLY

This product contains a phenyl mercury compound as a biocide for in-can preservation or mildew control. This product is intended solely for exterior use in well-ventilated areas. Use of this product inside, or to treat any materials used inside any building or structure, may be hazardous to your health or the health of those occupying the building. Some children may be particularly sensitive to mercury. Keep this product out of the reach of children.

Note: EPA has no requirement for type size or label placement at this time. It is advisable to oversee the placement of the label on each container of product within your care, custody, or control. You may elect to provide the required labels to retailers for placement on your products as they are removed from previously shipped cartons. In an effort to avoid opening cartons at independent or non-company owned or controlled distribution facilities, you may wish to affix an envelope with sufficient labels for the number of containers in the carton along with clear instructions for affixing at the point of sale. Whatever method of labeling is used by your company, please keep detailed records of your efforts to locate your products in commerce and provide or affix the required labels.

ATTACHMENT B

FACT SHEET

1. Small amounts of mercurial compounds are added to some interior latex paints to preserve the paint in the can to keep it from spoiling.

   At higher concentrations, mercurial biocides are sometimes used in exterior latex paints to protect the paint, or the surface to which it is applied, from mildew.

2. There is no basis in available scientific studies to conclude that paints, properly formulated with mercurial biocides in accordance with U.S. government regulations, pose an unreasonable risk.

3. In the case of a Michigan child who became ill after being exposed to interior paint that contained a mercury biocide, investigations by the Centers for Disease Control contend that the paint to which the child was exposed had a substantially greater amount of mercury biocide than that allowed under current regulations.

4. The Michigan case is the only one reported in over twenty years where juvenile mercury poisoning has been linked to exposure to paint containing a mercury biocide.

   For some sensitive children who may react to many materials, exposure to mercury in any form or in any amount may cause an allergic-like response.

5. Shipments of mercury biocide for the manufacture of interior latex paints will stop as of July 20, 1990, and manufacturers have agreed to stop using mercury biocide in formulating interior latex paints as of August 20, 1990.

6. Also on August 20, 1990, manufacturers have agreed to denote the presence of mercury and to put health and precautionary warning labels on exterior paint formulated with mercury biocide.

7. Of the over 500-million gallons of house paint produced annually in the United States, the NPCA estimates only one to three million gallons of interior latex paint with mercury biocide content over the EPA acceptable limit of 200 parts per million are currently in the distribution pipeline.

8. The National Paint and Coatings Association is a voluntary non-profit association which has as its members about 550 companies that manufacture consumer paint products and industrial coatings and approximately 200 companies that supply raw materials to the coating industry. Total dollar volume for the industry's products is over 12 billion dollars per year.

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

JUL 13 1990

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Mr. J. Andrew Doyle
Executive Director
National Paint and Coatings Association
1500 Rhode Island Avenue, N.W.
Washington, D.C. 20005

Dear Mr. Doyle:

Thank you for your July 5, 1990 letter outlining the steps which the National Paint and Coatings Association proposes to take to reduce the potential exposure to mercury associated with continued sale and use of existing stocks of paints and coatings containing mercury.

There are several points in your letter which need to be discussed further.

Your letter indicates that the stickering program for existing stocks would extend only to products manufactured since June 1, 1990. This specific date was never discussed with me, and I have very serious concerns about it. Our understanding of the June 28, 1990 agreement was that NPCA would request that individual paint and coating companies sticker (or otherwise relabel) all stocks of paints containing mercury compounds including those manufactured between June 29 and August 20, and those currently in warehouses and channels of trade and which: (1) are intended or labeled for exterior use, (2) are intended or labeled for both interior and exterior use, or (3) contain more than 200 ppm mercury and are intended or labeled only for interior use. In those instances where a paint product contains more than 200 ppm and the paint is formulated in a manner which makes it inappropriate for exterior use, you agreed to request that the paint product be reformulated or properly disposed. No stickers were to be placed on interior paints containing less than 200 ppm mercury. You agreed that the sticker to be placed on these products would contain the same label statement which will be required on all new production of exterior paints containing mercury effective on August 20, 1990. I have appended the text of this statement as Enclosure A. The Agency interpreted your agreement to extend to all stocks of all paints and coatings formulated with the following mercurial active ingredients: phenylmercuric acetate (PMA), di(phenylmercuric)

dodecenyl succinate (PMDS), phenylmercuric oleate (PMO), and 3-(chloromethoxy)propylmercuric acetate (CMPA).

The Agency realizes that this program is voluntary and that NPCA cannot legally compel individual companies to comply with the agreed sticker program for paints with higher mercury levels. However, the Agency expects that you will make conscientious efforts to implement this program and to persuade individual companies to comply. We expect you to determine the degree of compliance by member companies and to share your findings with the Agency. The Agency may also monitor compliance with the stickering program at all levels from the paint manufacturer to the retail point of sale.

In reliance on your commitment to work with the paint industry to redirect paint with a higher mercury content away from use on interior surfaces, I agreed to make appropriate revisions in the text of the Agency's press statements to reflect that commitment. If the Agency determines that the magnitude or timing of compliance with the NPCA program is unsatisfactory, I will consider further measures, including but not limited to, revisions in the Agency's recommendations to consumers, identification of particular companies which are not in compliance with the NPCA program, or appropriate regulatory action.

I realize that in some respects this has been a frustrating experience, both for your staff and for mine. In retrospect, it would have been better for both EPA and the NPCA if we had reached an agreement on satisfactory measures to address the problem of existing stocks at an earlier time. I hope that you will understand that the changes in the tone of the Agency's message during the final weeks were attributable in significant part to our perception that the paint industry was unwilling or unable to do enough to address the existing stocks problem. However, I believe that the agreement which was finally reached, if properly implemented, should substantially mitigate the risks associated with the continued sale and use of indoor paints containing mercury.

You also had a few comments concerning the information provided by EPA in the two lists of paint companies who do/don't use mercury. It is apparent by your letter that your are not aware that there is a third list which lists for each company that uses mercury the specific <u>product lines</u> which contain mercury. Further, there is an accompanying instruction sheet for these three lists which explains that if a company is listed as using mercury, it does not necessarily mean that all of their products contain mercury and, therefore, the third list of specific products <u>must</u> be checked. EPA personnel and those

answering our 800 number have not left the impression that if a company has used mercury in one product line, it must, therefore, have used it in all product lines.

I am aware that several companies have recently reported to EPA that they have discontinued the use of mercury in all of their products. Specifically, The Glidden Co. has stated that it has not used mercury since September 1989 and that it is planning to withdraw all of its remaining mercury-containing paint from store shelves and channels of trade. EPA commends this type of voluntary action and is issuing a Press Advisory announcing Glidden's decision.

I think it would be useful at this time for you to meet with my staff to duscuss the NPCA program. We will contact you to schedule the meeting.

Sincerely yours,

Linda J. Fisher
Assistant Administrator

Enclosure

ENCLOSURE A

FOR EXTERIOR USE ONLY

This product contains a phenyl mercury compound as a biocide for in-can preservation or mildew control. This product is intended solely for exterior use in well-ventilated areas. Use of this product inside or to treat any materials used inside any building or structure may be hazardous to your health and the health of those occupying the building. Some children may be particularly sensitive to mercury. Keep this product out of reach of children.

National Paint & Coatings Association

July 31, 1990

TO: NPCA MEMBERSHIP

FROM: Stephen R. Sides, Director
Health, Safety and Environmental Affairs

RE: MERCURY BIOCIDES REMINDER

NPCA recently met with representatives of the U.S. Environmental Protection Agency (EPA) to discuss the paint industry's voluntary efforts to relabel existing stocks of paint containing more than 200 ppm of mercury. This voluntary labeling program was communicated to NPCA members in a July 5, 1990 memorandum.

To address EPA's concerns regarding the progress of the voluntary program, NPCA is issuing this reminder notice to clarify recommended industry action for relabeling. The EPA's future regulatory activities with respect to mercury will be based on the paint industry's response to this voluntary program.

A reasonable voluntary effort to relabel existing stocks should include the following actions:

* Label <u>all</u> stock containing more than 200 ppm mercury that is still within your care, custody and control (see enclosed label). This would include such products present in the manufacturing facility, company owned warehouses and distribution centers, or in company owned or operated retail outlets.

  NOTE: NPCA previously recommended (6/25/90) that <u>all</u> exterior products containing <u>any</u> level of mercury be clearly labeled for exterior use.

* Where feasible, locate and relabel affected products manufactured since June 1, 1990 <u>and subsequently distributed or sold</u>.

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NOTE: Where company records indicate that turnover has depleted the affected product in commerce, either in total or at specific outlets, no further action is warranted. Similarly, it may not be feasible to locate products in secondary distribution.

* Begin relabeling of existing stocks as soon as possible, but in all circumstances complete by August 20, 1990.

While the relabeling program is voluntary, EPA will enforce mandatory restrictions on mercury biocide use scheduled to go into effect on August 20, 1990. EPA inspections will be initiated at manufacturing facilities where mercury biocides are in use, at which time questions pertaining to the voluntary relabeling of existing stocks may be raised.

LABEL STATEMENT FOR PRODUCTS CONTAINING GREATER THAN 200 PPM MERCURY

"For Exterior Use Only

This product contains a phenyl mercury compound as a biocide for in-can preservation or mildew control. This product is intended solely for exterior use in well-ventilated areas. Use of this product inside, or to treat any materials used inside any building or structure, may be hazardous to your health or the health of those occupying the building. Some children may be particularly sensitive to mercury. Keep this product out of the reach of children."

ATTACHMENT 3
REGISTRANTS AND PRODUCING ESTABLISHMENTS

PMA AND PMA-RELATED PRODUCT REGISTRANTS
U.S. CORPORATE AND PRODUCER ESTABLISHMENT ADDRESSES

1. Troy Chemical Corporation, Inc.
One Avenue L
Newark, NJ 07105
(Co. No. 5383)

U.S. establishments that produced Troy products:

Troy Chemical Company
One Avenue L
Newark, NJ 07105

2. Cosan Chemical Company
400 14th St.
Carlstadt, NJ 07072
(Co. No. 8489)

U.S. establishments that produced Cosan products:

Cosan Chemical Company
400 14th St.
Carlstadt, NJ 07072

Bartlo Packaging Inc.
61 Willett St.
Passaic, NJ 07055

3. Hüls America, Inc.
P.O.Box 365
Turner Place
Piscataway, NJ 08855-0365
(Co. No. 1100)

U.S. establishments that produced Hüls products:

Hüls America, Inc.
830 Magnolia Ave.
Elizabeth, NJ 07201

Bartlo Packaging Inc.
61 Willett St.
Passaic, NJ 07055

4. Thor Chemicals, Inc.
Brook House
37th North Ave.
Norwalk, CT 06851
(Co. No. 53034)

U.S. establishments that produced Thor products:

Thor Chemicals, Inc.
120 Gracey Ave.
Meridan, CT 06450

5. Akzo Chemicals, Inc.
300 S. Riverside Plaza
Chicago, IL 60606
(Co. No. 34688)

U.S. establishments that produced Akzo products:

Bartlo Packaging Inc.
61 Willett St.
Passaic, NJ 07055

Akzo Chemicals, Inc.
500 Jersey Ave.
New Brunswick, NJ 08903

6. Van Waters and Rogers, Inc.
Subsidiary of Univar
2256 Junction Ave.
San Jose, CA 95131
(Co. No. 550)

U.S. establishments that produced Van Waters and Rogers products:

Van Waters and Rogers, Inc.
Subsidiary of Univar
2256 Junction Ave.
San Jose, CA 95131

7. Vikon Chemicals Company, Inc.
514 E. Parker St.
Graham, NC 27253
(Co. No. 6390)

U.S. establishments that produced Vikon products:

Vikon Chemicals Company, Inc.
241 W. River St.
Box 1520
Graham, NC 27215

Mercury
Central Chemical
Co

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

DEC 20 1991

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Compliance Strategy Addendum for the Cancellation of Phenylmercuric Acetate Pesticides.

FROM: John J. Neylan III, Director
Policy and Grants Division
Office of Compliance Monitoring

TO: Addressees

Attached is a copy of the Compliance Strategy Addendum for the cancellations of September 13, 1990, and July 1, 1991. The Addendum includes copies of the FEDERAL REGISTER notices of September 12, 1990, and July 10, 1991. Also attached is a summary sheet addendum, which addresses the inspectional needs resulting from the attached Cancellation Orders.

On July 1, 1991, the Acting Director of the Special Review and Reregistration Division, Office of Pesticide Programs, signed two Cancellation Orders which cancelled the last two remaining pesticide registrations for phenylmercuric acetate (PMA) for use in formulating paints and coatings. These Orders, which were effective on the date signed, were published in the FEDERAL REGISTER on July 10, 1991 (56 FR 31403 and 31404) under the title "Phenylmercuric Acetate: Cancellation Order." Under the terms of the cancellations, existing stocks of one of the cancelled products cannot be sold or distributed after June 27, 1991, while existing stocks of the other pesticide may be distributed and sold until September 30, 1991.

The details of these cancellations and the existing stocks provisions are included in the strategy addendum. The addendum, which is to be used in conjunction with the September 12, 1990, strategy titled "Compliance Strategy for the Conditional Registration and Voluntary Cancellation of Certain Mercury Biocides," also addresses the cancellation of two non-coating PMA pesticides which were cancelled in a separate FEDERAL REGISTER notice signed on September 4, 1990, and published on September 12, 1990, (55 FR 37541) titled "Pesticide Products Containing Phenylmercuric Acetate; Receipt of Requests for Voluntary Cancelation." Those cancellations were effective September 13,

1990, and contained provisions allowing the sale of existing stocks until June 27, 1991.

If you have any questions or comments regarding this Addendum, please contact Steve Howie of my staff at (703) 308-8290.

Attachments

ADDRESSEES

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	Daniel Barolo	(H7508W)
	Anne E. Lindsay	(H7505C)
	Stephen L. Johnson	(H7506C)
	Mike Walker	(LE-134A)
	Mark Greenwood	(LE-132A)
	Michael Stahl	(EN-342)
	Connie Musgrove	"
	John J. Neylan III	"
	Mike Wood	"
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	Phyllis Flaherty	"
	Frances Liem	"
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	Maureen Lydon	"
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Jake Mackenzie
Western Regional Compliance Director

I	Linda M. Murphy, Director Air, Pest. & Toxics Mangt. Div.	Marvin Rosenstein, Chief Pesticides & Toxic Substances Br
II	Barbara Metzger, Director Environmental Services Division	Ernest Regna, Chief Pesticides & Toxic Substances Br
III	Thomas J. Maslany, Director Air, Tox. & Radiation Mangt. Div	James Burke, Chief Toxics & Pesticides Branch
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VI	Stanley Meiburg, Director Air, Pesticides & Toxic Division	Robert Murphy, Chief Pesticides & Toxic Substances Br
VII	William A. Spratlin, Director Air and Toxics Division	Leo Alderman, Chief Pesticides & Toxic Substances Br
VIII	Irwin Dickstein, Director Air and Toxics Division	C. Alvin Yorke, Chief Toxic Substances Branch
IX	David P. Howekamp, Director Air Management Division	Davis Bernstein, Chief Pesticides & Toxics Branch
X	Gary O'Neal, Director Air and Toxics Division	Kenneth Feigner, Chief Pesticides & Toxic Substances Br

cc:	Artie Williams	(H-7508C)
	Kathy Taylor	(H7506C)
	OCM Staff	

MERCURY BIOCIDE CONDITIONAL REGISTRATION
AND VOLUNTARY CANCELLATION
COMPLIANCE MONITORING STRATEGY SUMMARY SHEET
ADDENDUM

INSPECTION DATE	INSPECTION SITE	INSPECTION PURPOSE/ CONDITIONS TO BE MONITORED
By March 31, 1992	Cosan Chemical, Bartlo Chemical	JTA-20 and JTA-10 may not be sold after June 27, 1991. Stocks of Cosan PMA-100 may not be sold after September 30, 1991. No stocks of Cosan PMA-100 produced after July 1, 1991 may be sold.
By March 31, 1992	Troy Chemical	Troysan PMA-100 may not be sold or distributed after June 27, 1991.

Cancelled mercury products:

Pesticides canceled 6/29/90: Intercide 60 (Akzo); Cosan PMO-30; Cosan PMA-30; Troysan PMDS-10; Troysan CMP Acetate; Troysan PMA-30; Thor PMA-100; Hüls PMA-18; Hüls PMA-60; Super-Ad-It Fungicide (Hüls).

Pesticides canceled 9/12/90: JTA-20 and JTA-10 (Cosan).

Pesticides canceled 7/1/91: PMA-100 (Cosan); PMA-100 (Troy).

COMPLIANCE STRATEGY FOR THE CONDITIONAL REGISTRATION AND VOLUNTARY CANCELLATION OF CERTAIN MERCURY BIOCIDES

ADDENDUM

OVERVIEW

This amends the Compliance Monitoring Strategy issued September 12, 1990, for cancellations and amendments of pesticide products containing phenylmercury and other mercury compounds. The actions that the above Strategy addressed were published in the Federal Register (55 FR 26754) on June 29, 1990.

The reason for this addendum is to update the strategy to accommodate additional voluntary cancellations of the remaining miscellaneous and exterior paint formulating uses of mercury pesticides. This addendum should be used in conjunction with the September 1990 Strategy to target final inspections to ensure that the terms of all of the cancellations have been complied with.

Since the June 29, 1990, cancellation of mercury pesticides for use in indoor paints and coatings, four additional products have been canceled. These include two pesticides which were registered for use in formulating miscellaneous non-paint/coating products, and two pesticides which were registered for use in formulating exterior-only paints and coatings.

The two miscellaneous non-paint pesticide products (Cosan JTA-20, EPA Reg. No. 8489-3, and Cosan JTA-10, EPA Reg. No. 8489-10) were registered by the Cosan Chemical Corporation (Cosan). The Cancellation Order for these products was published in the Federal Register on September 12, 1990, (55 FR 37541, Attachment A) and was effective September 13, 1990. The Cancellation prohibited sale and distribution of stocks after September 17, 1990, unless such stocks had been relabeled with certain instructional language. Properly labeled stocks were allowed to be distributed and sold until June 27, 1991. The cancellation also required relabeling of existing stocks of products in the hands of end-users (formulators) with instructional language by October 17, 1990.

One of the exterior-paint-use products (Cosan PMA-100, EPA Reg. No. 8489-5) was also registered by Cosan while the other (Troysan PMA-100, EPA Reg. No. 5383-4) was registered by the Troy Chemical Company. The Cancellation Orders for these registrations were signed and became effective on July 1, 1991. The Orders were published in the Federal Register on July 10, 1991 (56 FR 31403 and 56 FR 31404 for Troy and Cosan, respectively, Attachment B).

As stated in the June 29, 1990 notice, conditional amendments to registrations had been granted to the two companies, Cosan and Troy, effective July 2, 1990 for the two exterior paint/coating products canceled in the July 1, 1991, Orders. These amendments

were conditional to the registrants: (1) changing the labeling of the pesticides to prohibit use in formulating indoor paints, limit use to exterior paints that are labeled against interior uses, and specify maximum use rates; and (2) developing and submitting certain data. Subsequently, the two registrants Cosan and Troy determined to request voluntarily cancellation of their products rather than comply with the data submission requirements of the registration amendments.

Troy voluntarily ceased production of Troysan PMA-100 on February 28, 1991. Through the agreement reached between Troy and the Agency, only stocks of Troysan PMA-100 packaged and labeled on or before February 28, 1991, were allowed to be distributed or sold until June 27, 1991, under the existing stocks provision of this cancellation. No sale or distribution of any existing stocks of Troysan PMA-100 were permitted to occur after June 27, 1991. Use of existing stocks of Troysan PMA-100 delivered on or before June 27, 1991, for formulating exterior paints and coatings is permitted. Such uses will end after existing stocks have been consumed.

Cosan negotiated an existing stocks provision to accommodate its greater inventory of unformulated pesticidal active ingredient. Under the Cosan existing stocks provisions of the cancellation order, stocks of Cosan PMA-100 which are packaged and labeled by July 1, 1991 were allowed to be sold and distributed until September 30, 1991. No stocks of Cosan PMA-100 were permitted to be sold or distributed after September 30, 1991. Use of existing stocks of Cosan PMA-100 delivered on or before September 30, 1991, for formulating exterior paints and coatings is permitted. Such uses will end after existing stocks have been consumed.

REGULATED COMMUNITY

The Cancellation Orders affect the registrants (who are generally also the producers and distributors), and the users of mercury biocides (i.e., paint companies and other formulators). Responsibility for meeting the terms of the Cancellation is on the two registrants, Cosan and Troy.

SUMMARY OF CANCELLATION ORDERS

Cosan JTA-20 and JTA-10

All stocks of Cosan JTA-20 and Cosan JTA-10 distributed or sold after September 17, 1990, were required to have a sticker affixed with the following label provisions (see attachment A): (1) limiting use to building product adhesives, drywall compounds, and acoustical plasters and prohibiting use in interior paints and coatings; (2) reducing the maximum application rate to 120 ppm in the formulated product; (3) limiting use to those products allowed in (1) above which are labeled with a specific precautionary statement; and (4) stating that distribution and sale after June 27, 1991, would be unlawful. The registrant was required to deliver by September 17, 1990, sufficient stickers to customers/end users to resticker their stocks and to instruct the users to resticker all stocks by October 15, 1990.

Cosan PMA-100

The existing stocks of the Cosan products packaged and labeled before July 1, 1991 were allowed to be sold and distributed until September 30, 1991. After September 30, 1991, Cosan was not permitted to distribute or sell any existing stocks of canceled products. However, products packaged and labeled on or before July 1, 1991, and delivered by September 30, 1991, may continue to be used for manufacturing of exterior paints and coatings after September 30, 1991.

Troysan PMA-100

The existing stocks of the canceled Troysan PMA-100 packaged and labeled before February 28, 1991 were allowed to be sold and distributed until June 27, 1991. After June 27, 1991, Troy was not permitted to distribute or sell any existing stocks of canceled products. Continued use of Troysan PMA-100 products for manufacturing of exterior paints and coatings after June 27, 1991, is permitted.

COMPLIANCE MONITORING

All inspections to determine compliance with this strategy are to be conducted at producing establishments. The purpose of inspections will be to determine that sale and distribution of the existing stocks has been in compliance with the provisions of the Cancellation Orders for each canceled product. As was stated in Attachment 3 of the

1990 compliance strategy for the cancellation of mercury-containing biocides, the following establishments have been identified as producing Cosan and Troy products:

Troy products:

Troy Chemical Company
One Avenue L
Newark, NJ 07105

Cosan products:

Cosan Chemical Company
400 14th Street
Carlstadt, NJ 07072

Bartlo Packaging Inc.
61 Willett Street
Passaic, NJ 07055

By March 31, 1992 the Cosan and Troy producer establishments are to be inspected to determine that there has been no distribution and sale of stocks after the dates specified in the existing stocks provisions of the cancellation orders. Distribution of stocks of Cosan JTA-20, Cosan JTA-10, and Troysan PMA-100 after June 27, 1991, or of stocks of Cosan PMA-100 after September 30, 1991 is illegal.

Reports of inspectional findings shall be made by April 30, 1992 to Maureen Lydon, Chief, Compliance Branch, Office of Compliance Monitoring.

ALLOCATION OF RESPONSIBILITY

Refer to the allocation of responsibility section of the original cancellation strategy.

ATTACHMENT A

CANCELLATION ORDER OF SEPTEMBER 4, 1990
55 FR 37541, SEPTEMBER 12, 1990

[OPP-66142; FRL-3800-2]

Pesticide Products Containing Phenylmercuric Acetate; Receipt of Requests for Voluntary Cancellation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of pesticide cancellations.

SUMMARY: Based on the risks associated with indoor use of paints containing mercury, EPA recently announced a series of pesticide cancellations and amendments which have eliminated all use of mercury biocides in interior paints. EPA has also expressed concerns regarding the potential risks associated with use of mercury compounds in other interior products such as joint compounds, adhesives, and plasters. The only remaining registrant of mercury biocides labeled for these miscellaneous interior uses has requested voluntary cancellation of the registrations for these products. All stocks of affected mercury biocides, including stocks in the hands of end-users, must be stickered by October 15, 1990, with language reducing the maximum use rate and requiring a specific precautionary statement on products manufactured from the biocides. Existing stocks of cancelled mercury products which have been properly stickered may be sold and used until June 27, 1991.

DATES: The cancellation order incorporated in this notice will become effective September 13, 1990. Existing stocks of products cancelled pursuant to this notice must be stickered with new label language by October 15, 1990. Existing stocks of such cancelled products which have been properly stickered may be sold and used until June 27, 1991.

FOR FURTHER INFORMATION CONTACT: Beth Edwards, Special Review Branch, Special Review and Reregistration Division (H7508C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: 3rd Floor, 2805 Jefferson Davis Highway Arlington, VA. (703) 308-8010.

SUPPLEMENTARY INFORMATION:

I. EPA Conclusions Concerning Use of Mercury in Interior Products

Following receipt of reports concerning a 4-year old child who developed acrodynia (a rare form of mercury poisoning) after his home was painted with paint containing mercury and a followup investigation by the Centers for Disease Control and the State of Michigan of mercury levels in other homes painted with similar paint, EPA initiated a comprehensive review of the risks and benefits associated with the use of mercurial compounds in paints and coatings. After evaluating the available evidence concerning exposure to mercury resulting from use in paints and coatings, toxicity of mercury and mercury compounds, and availability of alternative biocides, EPA concluded that the continued use of mercurial compounds in the manufacture of interior paints and coatings would present an unreasonable risk of adverse health effects. EPA also determined that continued use of mercury in the manufacture of other miscellaneous interior products such as joint compounds, adhesives, and plasters would present qualitatively similar risks which could only be quantified after development and submission of additional data.

As a result of discussions with the registrants of mercury products labeled for use in paints and coatings, the registrants agreed to rapidly eliminate use of mercury biocides in interior paints and coatings and to require that exterior paints and coatings containing mercury biocides be labeled with a warning against interior use. These changes were effectuated by conditional amendments to specific registrations and requests for voluntary cancellation of other registrations, as described in a prior notice published in the Federal Register of June 29, 1990 (55 FR 26754).

As part of the same discussions, EPA and Cosan Chemical Corporation ("Cosan"), the registrant of certain mercury products labeled exclusively for miscellaneous interior uses, discussed at some length the data which would be required to support continued registration of such products. Ultimately, Cosan decided to cease production of such products and to request voluntary cancellation of the registrations rather than committing to develop the required data. This notice is being published to advise the public of the changes in sale, distribution, and use to be implemented for the products to be cancelled, and to meet the legal requirements established by FIFRA section 6(f)(1), 7 U.S.C. section 136d(f)(1).

II. Requests for Voluntary Cancellation

Cosan has requested voluntary cancellation pursuant to FIFRA section 6(f)(1) of its registrations for JTA-20, EPA Registration No. 8469-3, and JTA-10, EPA Registration No. 8469-10, products containing phenylmercuric acetate which are presently labeled for use in the formulation of products such as joint compounds, textures, adhesives, and plasters. EPA intends to grant these requests for voluntary cancellation effective on September 13, 1990.

III. Existing Stocks

EPA has decided that it will permit continued sale and use of existing stocks of JTA-20 and JTA-10 until June 27, 1991, subject to specific mandatory terms and conditions. FIFRA section 6(a)(1), 7 U.S.C. section 136d(a)(1), provides that EPA may permit continued sale and use of existing stocks of cancelled products for specific uses and subject to specific conditions, if EPA determines "that such sale or use is not inconsistent with the purposes of this Act and will not have unreasonable adverse effects on the environment." The terms and conditions which will govern sale and use of remaining stocks of JTA-20 and JTA-10 are identical to the terms and conditions which EPA would have required during the pendency of data development if Cosan had committed to develop the data necessary to support continued registration of either of these products. Cosan has not produced JTA-10 for years and believes that no stocks of JTA-10 remain in the hands of end-users, but has elected to commit to the required terms and conditions for that product as a precaution in the event that some small quantity of the product remains.

Cosan has submitted to EPA the text for a sticker for each affected biocide which includes provisions that: (1) Expressly limit use to building products adhesives, drywall compounds, and acoustical plasters and prohibit use in any other interior paint or coating, (2) reduce the maximum permissible application rate to 120 ppm mercury in the ready-to-use product, (3) limit use to only those building products adhesives, drywall compounds, and acoustical plasters which are labeled with a specific precautionary statement, and (4) state that sale, distribution, and use of the mercury product will be unlawful after June 27, 1991.

The cancellation order requires the sticker incorporating the new label requirements to be affixed to all stocks of each product distributed or sold by

Cosan or any other person on or after September 17, 1990. The cancellation order also will require Cosan to deliver stickers by September 17, 1990, to all end-users who are holding inventory of each product, and will provide that stocks of each product remaining in the inventory of end-users may not be lawfully used after October 15, 1990, unless the end-user has affixed the new sticker to the product and all use of the product is in full conformity with the instructions on the sticker.

IV. Cancellation Order

Effective on September 13, 1990, the registrations for the following pesticide products are cancelled pursuant to section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. section 136d(f)(1):

Registrant	Product	EPA Registration No.
Cosan Corporation	Cosan JTA-20	8468-9
Cosan Corporation	Cosan JTA-10	8468-10

Effective on September 13, 1990, it shall be unlawful under FIFRA section 12(a)(1)(A) and/or FIFRA section 12(a)(2)(K), 7 U.S.C. sections 136j(a)(1)(A), 136j(a)(2)(K), for any person to distribute or sell, or to use for any pesticidal purpose, either of these cancelled products except in full compliance with all of the provisions concerning existing stocks set forth below.

The Agency has determined that existing stocks of each pesticide product cancelled by this order may be sold, distributed, and used until June 27, 1991, subject to all of the following mandatory terms and conditions. For each cancelled product, the registrant has submitted as part of its request for voluntary cancellation under FIFRA section 6(f)(1) the text for a sticker which includes label provisions: (1) Limiting use of the pesticide product to building products adhesives, drywall compounds, and acoustical plasters and prohibiting use of the pesticide product in any other interior paint or coating, (2) reducing the maximum permissible application rate for the pesticide product to 120 ppm mercury in the ready-to-use manufactured product, (3) limiting use of the pesticide product to only those building products adhesives, drywall compounds, and acoustical plasters which are labeled with a specific precautionary statement, and (4) stating that sale, distribution, and use of the pesticide product will be unlawful after June 27, 1991. Effective on September 17, 1990, no person shall distribute or sell in any State any quantity of a pesticide product cancelled by this order unless the approved sticker for that product has been affixed to each container of the product. Effective on October 15, 1990, no person shall use in any State any quantity of a pesticide product cancelled by this order unless the approved sticker for that product has been affixed to each container of the product and such use is in full conformity with all of the instructions on the sticker. For each cancelled product, the registrant shall by September 17, 1990, deliver to, and verify receipt by, each customer or other end-user holding inventory of the product: (1) Quantities of the approved sticker for that product which are sufficient to affix the sticker to each container of the product in the customer's or end-user's inventory, and (2) a letter advising the customer or end-user of the effective dates for the revised labeling on the stickers and instructing the customer or end-user to affix the sticker to each container of the product on or before October 15, 1990.

Dated: September 4, 1990.

Edwin F. Tinsworth,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 90-21381 Filed 9-11-90; 8:45 am]

BILLING CODE 6560-50-F

ATTACHMENT B

CANCELLATION ORDERS OF JULY 1, 1991
56 FR 31403 & 31404, JULY 10, 1991

number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

Authority: 21 U.S.C. 346a(j).

Dated: June 23, 1991.

Anne E. Lindsay,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 91-16122 Filed 7-9-91; 8:45 am]

BILLING CODE 6560-50-F

[PP 1G3927/T609; FRL 3926-6]

Fenoxaprop-ethyl; Establishment of Temporary Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has established a temporary tolerance for the combined residues of the herbicide fenoxaprop-ethyl and its metabolites in or on the raw agricultural commodity barley, grain at 0.05 part per million (ppm).

DATES: This temporary tolerance expires April 10, 1992.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne Miller, Product Manager (PM) 23, Registration Division (H7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 237, CM#2, 1921 Jefferson Davis Highway, Arlington, VA, (703)-557-1830.

SUPPLEMENTARY INFORMATION: Hoechst Celanese Corp, Route 202-205, P.O. Box 2500, Somerville, NJ 08876-1258, has requested in pesticide petition (PP) 1G3927, the establishment of a temporary tolerance for the combined residues of the herbicide fenoxaprop-ethyl [(±)-ethyl 2-[4-[(6-chloro-2-benzoxazolyl)oxy]phenoxy]propanoate)] and its metabolites [2-[4-[(6-chloro-2-benzoxazolyl)oxy]phenoxy]propanoic acid and 6-chloro-2,3-dihydrobenzoxazol-2-one], each expressed as fenoxaprop-ethyl, in or on the raw agricultural commodity barley, grain at 0.05 part per million (ppm). This temporary tolerance will permit the marketing of the above raw agricultural commodity when treated in accordance with the provisions of the experimental use permit 8340-EUP-13, which is being issued under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (Pub. L. 95-396, 92 Stat. 819; 7 U.S.C. 136).

The scientific data reported and other relevant material were evaluated, and it was determined that establishment of the temporary tolerance will protect the public health. Therefore, the temporary tolerance has been established on the condition that the pesticide be used in accordance with the experimental use permit and with the following provisions:

1. The total amount of the active ingredient to be used must not exceed the quantity authorized by the experimental use permit.

2. Hoechst Celanese Corp. must immediately notify the EPA of any findings from the experimental use that have a bearing on safety. The company must also keep records of production, distribution, and performance, and on request make the records available to any authorized officer or employee of the EPA or the Food and Drug Administration.

This tolerance expires April 10, 1992. Residues not in excess of this amount remaining in or on the raw agricultural commodity after this expiration date will not be considered actionable if the pesticide is legally applied during the term of, and in accordance with, the provisions of the experimental use permit and temporary tolerance. This tolerance may be revoked if the experimental use permit is revoked or if any experience with or scientific data on this pesticide indicate that such revocation is necessary to protect the public health.

The Office of Management and Budget has exempted this notice from the requirements of section 3 of Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

Authority: 21 U.S.C. 346a(j).

Dated: June 9, 1991.

Anne E. Lindsay,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 91-16121 Filed 7-9-91; 8:45 am]

BILLING CODE 6560-50-F

[OPP-66148A; FRL-3934-1]

Phenylmercuric Acetate; Cancellation Order

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of cancellation order.

SUMMARY: Pursuant to a request for voluntary cancellation submitted by the registrant Troy Chemical Corporation ("Troy"), EPA is cancelling the registration for the pesticide product Troysan PMA-100, EPA Registration No. 5383-4. Effective on July 1, 1991, EPA will not permit any further distribution or sale of this product. Manufacturers of exterior paints and coatings may continue to use all stocks of this product which were packaged and labeled with the registered labeling by Troy on or before February 28, 1991, and which were purchased by and delivered to the end-user on or before June 27, 1991.

DATES: This cancellation order will be effective on July 1, 1991. EPA will permit stocks of Troysan PMA-100 which were packaged and labeled with the registered labeling by Troy on or before February 28, 1991, and which were purchased by and delivered to the end-user on or before June 27, 1991, to be used in manufacture of exterior paints and coatings.

FOR FURTHER INFORMATION CONTACT: Beth Edwards, Special Review and Reregistration Division (H7508C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: 3rd Floor, 2800 Jefferson Davis Highway, Arlington, VA. (703) 308-8010.

SUPPLEMENTARY INFORMATION:

I. Background

In a letter dated November 26, 1990, Troy submitted a request for voluntary cancellation of Troysan PMA-100, EPA Registration No. 5383-4. In its initial request, Troy advised EPA that it was immediately ceasing all production of Troysan PMA-100 and requested that EPA permit sale, distribution, and use of existing stocks of Troysan PMA-100 until November 28, 1991. In subsequent discussions, EPA indicated to Troy that it would not be willing to permit sale and distribution of Troysan PMA-100 after June 27, 1991, or use of any stocks of Troysan PMA-100 purchased by the user after June 27, 1991. On February 28, 1991, Troy wrote an additional letter to EPA confirming its prior request for voluntary cancellation and accepting the existing stocks provisions specified by EPA. EPA published a notice of

voluntary cancellation for Troysan PMA-100 in the Federal Register of May 31, 1991 (56 FR 24809). Further information on the background and the basis for this action may be found in that notice.

II. Cancellation Order

Effective on July 1, 1991, the registration for Troysan PMA-100, EPA Registration No. 5383-4, is cancelled pursuant to section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. section 136d(f)(1). Effective on July 1, 1991, it shall be unlawful under FIFRA section 12(a)(1)(A) and/or FIFRA section 12(a)(2)(K), 7 U.S.C. sections 136j(a)(1)(A), 136j(a)(2)(K), for any person to distribute or sell Troysan PMA-100 in any State. Effective on July 1, 1991, it shall be unlawful under FIFRA section 12(a)(2)(K), 7 U.S.C. section 136j(a)(2)(K), for any person to use Troysan PMA-100 for any pesticidal purpose in any State, except as specifically provided below.

For purposes of this order, existing stocks are defined as stocks which were in the United States and packaged and labeled with the registered labeling on or before July 1, 1991, the effective date of cancellation. Existing stocks of Troysan PMA-100 which were packaged and labeled with the registered labeling by Troy Chemical Corporation on or before February 28, 1991, and which were purchased by and delivered to the end-user on or before June 27, 1991, may continue to be used in the manufacture of exterior paints and coatings, subject to the following mandatory terms and conditions. No existing stocks of Troysan PMA-100 may be used which do not bear the registered labeling: (1) Prohibiting use of the product in manufacture or formulation of any paint or coating intended or labeled for interior use, (2) limiting use of the product in exterior paints and coatings to only those products which are labeled with a warning against interior use, and (3) specifying maximum application rates for use in exterior paints and coatings. All use of existing stocks of Troysan PMA-100 must also be in full conformity with all label requirements.

Dated: July 1, 1991.

Stan A. Abramson,

Acting Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 91-16417 Filed 7-9-91; 8:45 am]

BILLING CODE 6560-50-F

[OPP-66149A; FRL-3934-2]

Phenylmercuric Acetate; Cancellation Order

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of cancellation order.

SUMMARY: Pursuant to a request for voluntary cancellation submitted by the registrant Cosan Chemical Corporation ("Cosan"), EPA is cancelling the registration for the pesticide product Cosan PMA-100, EPA Registration No. 8469-5. The cancellation of this product will be effective on July 1, 1991. EPA will permit sale and distribution of existing stocks of this product bearing the registered labeling until September 30, 1991. Manufacturers of exterior paints and coatings may continue to use all stocks of this product which were packaged and labeled with the registered labeling by Cosan on or before July 1, 1991, and which are purchased by and delivered to the end-user on or before September 30, 1991.

DATES: This cancellation order will be effective on July 1, 1991. EPA will permit stocks of Cosan PMA-100 bearing the registered labeling to be sold and distributed until September 30, 1991. EPA will also permit stocks of Cosan PMA-100 which were packaged and labeled with the registered labeling by Cosan on or before July 1, 1991, and which are purchased by and delivered to the end-user on or before September 30, 1991, to be used in manufacture of exterior paints and coatings.

FOR FURTHER INFORMATION CONTACT: Beth Edwards, Special Review and Reregistration Division (H7508C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: 3rd Floor, 2800 Jefferson Davis Highway, Arlington, VA, (703) 308-8010.

SUPPLEMENTARY INFORMATION:

I. Background

On April 1, 1991, EPA advised Cosan representatives that it intended to issue a notice of intent to cancel Cosan PMA-100, EPA Registration No. 8469-5, pursuant to FIFRA section 6(e), based on the failure of Cosan to satisfy certain conditions regarding development and submission of data included in the conditional registration for the product. At that time, EPA suggested that Cosan consider requesting voluntary cancellation of Cosan PMA-100. In subsequent discussions, EPA and Cosan discussed the options available to Cosan, the scope and potential outcomes of a cancellation hearing, and the provisions for sale, distribution, and use of existing stocks to be incorporated in a cancellation order. On May 10, 1991, Cosan submitted the request for voluntary cancellation which is the basis for this cancellation order. EPA published a notice of voluntary cancellation for Cosan PMA-100 in the Federal Register of May 31, 1991 (56 FR 24807). Further information on the background and the basis for this action may be found in that notice.

II. Cancellation Order

Effective on July 1, 1991, the registration for Cosan PMA-100, EPA Registration No. 8469-5, is cancelled pursuant to section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. section 136d(f)(1). Effective on July 1, 1991, it shall be unlawful under FIFRA section 12(a)(1)(A) and/or FIFRA section 12(a)(2)(K), 7 U.S.C. sections 136j(a)(1)(A), 136j(a)(2)(K), for any person to distribute or sell Cosan PMA-100 in any State, except as specifically provided below. Effective on July 1, 1991, it shall be unlawful under FIFRA section 12(a)(2)(K), 7 U.S.C. section 136j(a)(2)(K), for any person to use Cosan PMA-100 for any pesticidal purpose in any State, except as specifically provided below.

For purposes of this order, existing stocks are defined as stocks which were in the United States and packaged and labeled with the registered labeling on or before July 1, 1991, the effective date of cancellation. Existing stocks of Cosan PMA-100 may be sold and distributed until September 30, 1991, subject to the mandatory terms and conditions below. Existing stocks of Cosan PMA-100 which were packaged and labeled with the registered labeling by Cosan Chemical Corporation on or before July 1, 1991, and which are purchased by and delivered to the end-user on or before September 30, 1991, may continue to be used in the manufacture of exterior paints and coatings, subject to the following mandatory terms and conditions. No existing stocks of Cosan PMA-100 may be sold, distributed, or used which do not bear the registered labeling: (1) Prohibiting use of the product in manufacture or formulation of any paint or coating intended or labeled for interior use, (2) limiting use of the product in exterior paints and coatings to only those products which are labeled with a warning against interior use, and (3) specifying maximum application rates for use in exterior paints and coatings. All use of existing stocks of Cosan PMA-100 must also be

in full conformity with all label requirements.

Dated: July 1, 1991.

Allan S. Abramson,

Acting Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 91-16418 Filed 7-9-91; 8:45 am]

BILLING CODE 6560-50-F

[FRL-3973-3]

Proposed De Minimis Settlement Under 122(g), Colorado Avenue Subsite, Hastings Ground Water Contamination Site

AGENCY: Environmental Protection Agency.

ACTION: Notice of proposed de minimis settlement under 122(g), Colorado Avenue Subsite.

SUMMARY: The United States Environmental Protection Agency is proposing to enter into a de minimis administrative settlement to resolve claims under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), 42 U.S.C. 9622(g). This settlement is intended to resolve the liabilities of two parties for the response costs incurred and to be incurred at the Colorado Avenue Subsite of the Hastings Groundwater Contamination Site, Hastings, Nebraska.

DATES: Written comments must be provided on or before August 4, 1991.

ADDRESSES: Comments should be addressed to the Regional Administrator, United States Environmental Protection Agency, Region VII, 726 Minnesota Avenue, Kansas City, Kansas 66101 and should refer to: In the Matter of the Colorado Avenue Subsite of the Hastings Groundwater Contamination Site, Hastings, Nebraska, EPA Docket No. VII-90-F-0025.

FOR FURTHER INFORMATION CONTACT: Audrey Asher, United States Environmental Protection Agency, Office of Regional Counsel, Region VII, 726 Minnesota Avenue, Kansas City, Kansas 66101, (913) 551-7255.

SUPPLEMENTARY INFORMATION: The proposed settlers are the Burlington Northern Railroad (BNRR), Morton Zuber and Zuber Company (collectively Zuber), parties who own property that is part of the Colorado Avenue Subsite of the Hastings Gound Water Contamination Site. Trichloroethylene (TCE), 1,1,1-trichloroethane (TCA) and tetrachloroethene (PCE) have been detected in the soil and ground water at the Colorado Avenue Subsite and downgradient from the subsite. Contamination was first discovered on the BNRR property in 1986 and on the Zuber property in 1988 when soil sampling was undertaken. BNRR and Zuber had acquired their properties at the Colorado Avenue subsite in 1871 and 1984, respectively; in both cases, ownership preceded discovery of contamination.

EPA's investigation of the source of the Colorado Avenue Subsite contamination revealed that neither the BNRR nor Zuber has generated, stored, treated, or disposed of the contaminants found at the Colorado Avenue subsite. EPA's investigation also revealed that TCE and TCA were stored and disposed at property adjacent to and upgradient from the Zuber and BNRR property. This property, located at 106 S. Colorado Avenue, has been a manufacturing facility for several decades.

EPA has selected soil vapor extraction (SVE) as the technology to remediate the contaminated soils at the Colorado Avenue Subsite. Location of the SVE system will be on an area owned by BNRR and Zuber. Access is needed onto the BNRR and Zuber properties for installation of equipment, storage of equipment and operation of equipment.

This proposed settlement will provide access to EPA, the state of Nebraska, and parties designated by EPA as its representative solely for the purpose of access, for thirty years or until EPA determines that all response actions are completed, whichever is first. This proposed settlement also requires Zuber to clear the area in preparation for access to drill deep wells and to trench to make connections. Additionally, this proposed settlement requires BNRR and Zuber, upon transfer of title or arrangement for lease, to enter into a written agreement with the subsequent owner or lessee that requires such party to provide access to EPA to the same extent as set forth in the de minimis agreement. Access that may be needed as part of subsequent ground water remediation is also covered in this proposed settlement.

The proposed settlement involves no financial terms; the proposed settling parties are being asked solely to grant access. The proposed de minimis settlement provides that EPA will covenant not to sue the de minimis parties for response costs or for injunctive relief pursuant to sections 106 and 107 of CERCLA and section 7003 of Resource Conservation and Recovery Act (RCRA), 42 U.S.C. 6973. The proposed settlement contains a reopener if any information becomes known to EPA that indicates any of the proposed settlers (1) conducted or permitted the generation, transportation, storage, treatment, or disposal of any hazardous substance at the subsite; (2) contributed to a release or threat of release of a hazardous substance at the subsite through any act or omission; (3) or that the proposed settling parties otherwise no longer meet the section 122(g)(1)(B) de minimis criteria.

Martha Steincamp,

Acting Regional Administrator.

[FR Doc. 91-16419 Filed 7-9-91; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA-909-DR]

Alaska; Amendment to a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Alaska (FEMA-909-DR), dated May 30, 1991, and related determinations.

DATES: June 28, 1991.

FOR FURTHER INFORMATION CONTACT: Neva K. Elliott, Disaster Assistance Programs, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-3614.

NOTICE: The notice of a major disaster for the State of Alaska, dated May 30, 1991, is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of May 30, 1991:

The communities of Alakanuk, Emmonak, Galena, and Shageluk for Public Assistance.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

Grant C. Peterson,

Associate Director, State and Local Programs and Support, Federal Emergency Management Agency.

[FR Doc. 91-16999 Filed 7-9-91; 8:45 am]

BILLING CODE 6718-02-M

[FEMA-909-DR]

Alaska; Amendment to a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency.

ACTION: Notice.

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

MAR 7 1979

OFFICE OF ENFORCEMENT

SUBJECT: Enforcement of the Administrator's Emergency Orders Suspending 2,4,5-T and Silvex Registrations

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

TO: Enforcement Division Directors
Pesticide Branch Chiefs

On February 23, 1979, the Administrator signed Emergency Suspension Orders pursuant to FIFRA section 6(c)(3) immediately suspending the registrations of all pesticide products containing 2,4,5-T for forestry uses (including site preparation, conifer release, and brush and weed control), rights-of-way uses (including brush and weed control), and pasture uses */, and of all pesticide products containing Silvex for forestry uses (including site preparation, conifer release, and brush and weed control), rights-of-way uses (including brush and weed control), pasture uses, home and garden uses, commercial/ornamental turf uses (including recreational area uses), and aquatic weed control/ditch bank uses (use on rice not suspended), pending the final outcome of Agency cancellation proceedings which were also initiated by Order of the Administrator on February 28th. Copies of these Orders are being mailed under separate cover. The purpose of this memorandum is to set forth the Agency's enforcement strategy concerning products suspended by the February 28th Orders. It is the Agency's intention to ensure that the Administrator's Orders are strictly complied with by all affected persons, including manufacturers, formulators, registrants, wholesalers, retailers, distributors, government agencies, and users.

*/ Pasture is defined as land producing forage for animal consumption, harvested by grazing, which has annual or more frequent cultivation, seeding, fertilization, irrigation, pesticide application, and other similar practices applied to it. Fencerows enclosing pastures are included as part of the pasture.

I. SUSPENSION ORDER PROVISIONS

The February 28th Orders provide:

(1) As of February 28, 1979, all registrations of pesticide products containing 2,4,5-T and Silvex for the uses described above are suspended. For 2,4,5-T this means that in addition to the uses cancelled in 1970, all pasture land, right-of-way and forestry uses are now suspended. For Silvex this means that all aquatic (except for use on rice), home and garden, recreation area, as well as pasture land, right-of-way and forestry uses are now suspended. None of the products with any of the suspended uses may be sold or distributed in the United States. The Agency is officially notifying by certified mail all affected registrants of products any use of which has been suspended by the February 28th Orders (hereafter referred to as suspended products).

(2) As of February 28, 1979, all 2,4,5-T and Silvex products, regardless of how and when they were obtained, may only be used or applied for non-suspended uses, and only if the particular product in the user's possession is currently labeled for one of the allowable uses.

II. CATEGORIES OF 2,4,5-T AND SILVEX PRODUCTS

The following is a numerical breakdown of producers and registrants of the suspended products:

Producers

2,4,5-T:	43
Silvex:	58
TOTAL	101 */

Registrants

2,4,5-T:	80
Silvex:	87
TOTAL	167

*/ There is an overlap in the production of suspended 2,4,5-T and Silvex products. As a result, there is only a total of 81 individual producers of such products.

Distributor Registrants

2,4,5-T: 376

Silvex: 382

TOTAL 758

There are seven (7) 2,4,5-T registrants and fifteen (15) Silvex registrants not affected by the Administrator's Suspension Orders.

There are three categories of 2,4,5-T and Silvex products:

(A) Federally registered products, all uses of which have been suspended. An example of a product in this category would be a product registered for use only in forests. None of the products in this category may be sold, distributed or used in the United States during the duration of the Administrator's Suspension Orders.

(B) Federally registered products, some uses of which have been suspended. There is a category of registered products some of but not all of whose uses were suspended by the February 28th Orders. An example of a product in this category would be a product registered for use on range land as well as for forest use (the former being a permitted use, the latter being a suspended one). Until the completion of certain initial procedural steps resulting from the Notices of Cancellation as well as the Suspension Orders, which will help clarify the future status of products in this category, such products may not be sold or distributed for use in the United States. PTSED will be preparing further guidance on the status of these products after discussions with OGC and OPP. Products in this category may only be used or applied for non-suspended uses, and only if the particular product in the user's possession is currently labeled for an allowable use.

(C) Federally registered products, no uses of which have been suspended. There is a small number of federally registered 2,4,5-T and Silvex products none of whose uses were suspended by the February 28th Orders, and whose sale, distribution and use may continue. An example of a product in this category would be a product registered for use only on rice. Also included in this category are 2,4,5-T and Silvex technicals, which are registered for manufacturing use only.

You will be receiving shortly a list of suspended product registration numbers, product names, registrant names, and the names and addresses of establishments where 2,4,5-T and Silvex products with suspended uses have been produced. You will also receive a copy of the site/registration listing. In order to

determine whether a particular product fits into category A or B, you will only need to look up the product by its registration number and determine whether all or only some of its listed uses have been suspended.

In addition to the federally registered products discussed in paragraphs A through C above, all products being sold pursuant to State 24(c) registrations are subject to the requirements of the Administrator's February 28th Suspension Orders. A final list of these products is not yet available. As soon as this information is prepared, it will be forwarded to the regional offices. In the meantime, the regional offices should inform the States in their regions that State registrations for suspended uses of 2,4,5-T and Silvex issued pursuant to FIFRA section 24(c) have also been suspended by the Administrator's February 28th Orders, and that no further State 24(c) registrations may be issued for suspended uses of the affected products.

Intrastate registrations with assigned accession numbers are not included in the Administrator's February 28th Orders. A listing of these products and the States in which they are registered is being mailed under separate cover. The regional offices should contact the State agencies responsible for the original registrations to see that appropriate steps are taken by the States to limit the possible distribution, sale and use of these products consistent with the Administrator's Suspension Orders of February 28th.

III. ENFORCEMENT POLICY AND STRATEGY

A. POLICY

The Office of Enforcement intends to ensure that the Administrator's February 28th Orders are strictly complied with. The Agency's enforcement policy has a two-fold objective: 1) to prevent the distribution and sale of suspended 2,4,5-T and Silvex products; and 2) to prevent any use of these products for other than non-suspended uses.

The general policy of the Agency has been to request a national recall where product registrations have been suspended in order to prevent an imminent hazard to man or the environment. However, because of the emergency nature of the Administrator's actions and the fact that such a recall approach would not have the effect of immediately halting sales, distribution, and use, the Office of Enforcement is issuing Stop Sale, Use and Removal Orders as quickly as possible to all registrants, distributor registrants and producers of 2,4,5-T and Silvex products subject to the Administrator's Orders, as well as to all identifiable large scale users of these products. In addition, the Agency is taking special steps to notify interest groups who represent producers, sellers and user/applicators of the suspended products of the Administrator's Orders and the resulting legal obligations.

B. STRATEGY

The initial Stop Sale, Use, or Removal Orders directed at 2,4,5-T and Silvex registrants, producers, distributor registrants, identifiable large scale users and federal government agencies */ have been prepared and sent by certified mail by PTSED. A copy of the Stop Sale Order forms and cover letter being used are being mailed under separate cover. Each region will be sent a copy of each Stop Sale Order issued to any person within their region. A regional contact has been named at the bottom of each Stop Sale Order. This contact person should be able to assist the recipients of the Stop Sale, Use, or Removal Orders with any questions that might arise. In addition, the cover letter accompanying the Stop Sale Orders requests that certain information be provided to the regional contact person specified on the Stop Sale Order. Note that certain information from producers of the suspended products is mandatory in accordance with section 7(c)(2) of FIFRA. The information requested is intended to assist the Agency in tracking shipments of the suspended products through the channels of trade. Additional information is requested of all recipients of the Stop Sale Orders to assist EPA in monitoring compliance. The regional offices who will be receiving information from Stop Sale recipients should maintain the information about stocks on hand and report monthly and cumulative totals to PTSED by the 10th of each month.

The regional offices, working closely with States, are to conduct books and records inspections at establishments of registrants or producers who fail to comply with the Agency's request for information about suspended products. Such inspections will be necessary in order to obtain updated information about quantities of production and locations of recent shipments.

The regional offices and States should visit the headquarters offices or major distribution points of food, drug, hardware, lumber, garden supply, variety stores, etc., to inform them of the Suspension Orders and obtain assurances that they will take immediate action to instruct their outlets to remove the suspended products from sale. In addition, the regional offices and the States will undertake special marketplace inspections at a representative sampling of these and other retail outlets in order to monitor compliance with the Administrator's Orders. The dealers and retailers who are visited are to be advised of the Administrator's February 28th Orders and asked to voluntarily remove suspended products from their shelves(if they have not already done so). Persons who refuse or for some other reason fail to comply voluntarily with an inspector's request to remove the suspended products from his available stocks should be issued a Stop Sale, Use, or Removal Order. Further decisions about future efforts aimed at the retail level will depend on the degree of voluntary compliance occurring at that level. PTSED should be kept advised as to the extent of voluntary compliance as well as any problems concerning the retail sale of suspended products.

*/ Twelve federal agencies have been sent Stop Sale, Use, or Removal Orders. A list is being mailed under separate cover.

Since the time for annual spraying with some of the suspended products is imminent, regional offices and the States should take immediate steps to inform users and applicators of the Administrator's February 28th Orders. Although the regional offices and cooperating State personnel should first seek voluntary compliance, they should not hesitate to issue Stop Sale, Use, or Removal Orders to persons who are holding quantities of the suspended products for application. Such orders may be issued to applicators who are in the process of making an application with a suspended product. An inspection of the applicator's business establishment is not required for the issuance of such an order. A copy of the Stop Sale, Use, or Removal Order form applicable to users (as opposed to producers or registrants) is being mailed under separate cover for your information and/or use.

Once final action has been concluded on requests for an expedited hearing pursuant to the provisions of section 6(c), and the status of 2,4,5-T and Silvex products pending the outcome of the future cancellation proceedings has been settled, the Agency will review the need for a possible request for a voluntary recall of the suspended products by the registrants and producers. Until that time the Stop Sale, Use or Removal Orders will remain in effect, subject to suggestions from the affected parties about possible disposition of the current stocks of suspended products.

C. SUMMARY OF PROPOSED ENFORCEMENT RESPONSIBILITIES

1. Headquarter's Responsibility

a. Issue Stop Sale, Use, or Removal Orders via certified mail to all registrants, distributor registrants and producers of all suspended 2,4,5-T and Silvex products.

b. Issue Stop Sale, Use, or Removal Orders to Federal agencies involved with the use or application of the suspended products.

c. Issue Stop Sale, Use, or Removal Orders to identifiable large scale users of the suspended products after conferring with the regional office.

d. Supply regional offices with copies of the following:

1) The Administrator's Suspension and Cancellation Orders.

2) Copies of the Stop Sale, Use, or Removal Order forms and accompanying cover letter.

3) Stop Sale, Use, or Removal Orders mailed by EPA Hdqrs.

2. Regional office Responsibility

a. Notify States of the Administrator's Suspension Orders and Agency enforcement strategy, and develop cooperative approach to implementation of the enforcement strategy.

b. Compile information supplied by producers concerning 1978-79 distribution, as well as additional information requested from all Stop Sale, Use, or Removal Order recipients. Report data to PTSED on monthly basis.

c. Conduct books and records inspections at those major producer establishments, who do not supply the requested information, to update information about quantities of production and locations of shipments.

d. Review information obtained from producers (per b. and c. above) to identify recipients of shipments of the suspended products in order to target distributor and marketplace inspections.

e. Contact headquarters offices or major distribution points of food, drug, hardware, lumber, garden supplies, variety stores etc. to inform them of the Suspension Orders and to solicit their cooperation in informing their customers of the Suspension Orders.

f. Conduct marketplace inspections in order to locate possible improper retail sale or distribution of suspended products.

g. Undertake special efforts to inform State pesticide user associations, applicators and other users about the Suspension Orders and their legal requirements.

h. Issue SSUROs when appropriate.

i. Undertake appropriate enforcement action against any persons violating the terms of the Administrator's Suspension Orders or SSUROs.

j. Regional contact person, with assistance from EPA Headquarters, should be prepared to answer questions about the Agency's actions and to assist persons directly affected (e.g. producers, registrants, sellers, users, applicators, etc.) with compliance.

3. State Responsibility

States, especially those with Cooperative Enforcement Agreements, are expected to cooperate fully with the enforcement efforts outlined in this memorandum. Specifically, they will be asked to assist in items c, d, e, f, g, h, and i above.

IV. ENFORCEMENT ACTIONS

Enforcement actions will be taken in accordance with normal procedures and at levels consistent with those set forth in the Case Proceedings Manual against any person found in violation of the 2,4,5-T and Silvex Suspension Orders or Agency SSUROs. Note: Section 26 of the amended FIFRA, which grants to the States the primary enforcement responsibility for pesticide use violations, does not extend to situations involving the use of a suspended product in violation of Sections 12(a)(2)(J) or 12(a)(2)(I).

V. DISPOSAL OF 2,4,5-T AND SILVEX PRODUCTS

Until the conclusion of Agency cancellation proceedings involving 2,4,5-T and Silvex registrations, persons requesting information about the possible disposal of quantities of the suspended products should be advised to place the material in storage in accordance with label directions.

VI. INDEMNITIES

PTSED has been advised by the Office of General Counsel that consideration of requests for indemnification under section 15 of FIFRA by persons possessing quantities of the suspended products will not take place until the conclusion of Agency cancellation proceedings for the suspended products.

VII. INQUIRIES

Any questions about this memorandum and the 2,4,5-T or Silvex Suspension Orders should be directed to the appropriate regional coordinator.

VIII. SENT UNDER SEPARATE COVER

(1) Administrator's Suspension Orders, Feb. 28, 1979.

(2) Administrator's Notices of Cancellation, Feb. 28, 1979.

(3) PTSED Stop Sale Order forms and cover letter.

(4) List of Intrastate 2,4,5-T and Silvex Products.

(5) Copies of Headquarters Issued Stop Sale, Use, or Removal Orders.

(6) List of federal agencies sent Stop Sale Order.

(7) List of federally registered 2,4,5-T and Silvex products suspended by the Administrator's Feb. 28, 1979 Orders.

(8) Site/registration listing.

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

APR 05 1979

OFFICE OF ENFORCEMENT

SUBJECT: Further Guidance Concerning Enforcement of the Administrator's Emergency Orders Suspending 2,4,5-T and Silvex Registrations

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

A E Conroy II

TO: Enforcement Division Directors
Pesticide Branch Chiefs

In a memorandum dated March 7, 1979, I explained the Agency's enforcement strategy concerning 2,4,5-T and Silvex products suspended by the Administrator on February 28th. In that memorandum I indicated that I would provide you with additional guidance concerning the status of [illegible]tally registered 2,4,5-T and Silvex products which have both suspended and non-suspended uses on their labels. In the meantime, such products could not be sold or distributed for use in the United States. However, affected products in the user's or applicator's possession could be used or applied for non-suspended uses, if the particular product in the user's possession was currently labeled for an allowable use.

In a letter dated March 22, 1979, the Agency advised registrants of 2,4,5-T and Silvex products with both suspended and non-suspended uses on their labels that they would be allowed to distribute and sell such products for use in the United States once they had prepared adequate interim labeling designed to inform the purchaser that certain of the uses on the label are allowable, but that others are suspended. I have attached a copy of the letter, which is self explanatory, and do not plan to summarize it in this memorandum.

As you will see, registrants of such products have been instructed to send copies of their interim labeling to the appropriate regional office along with information about what steps they have taken to comply with the letter. Since many of the products are distributed and sold throughout the United States, as each regional office receives copies of the interim labeling, they should forward copies to all the other EPA regional offices. A list of regional contacts who are responsible for matters relating to 2,4,5-T and Silvex products is attached to the March 22nd letter. Although the Agency is not requiring advance approval for each registrant's interim labeling, the regional office receiving the original of the interim labeling should briefly review each label as it is received to make certain that on its face it appears adequate to inform purchasers of the product that certain of its uses are no longer allowable. Any questions about specific interim labeling should be directed to Mr. A. J. Dellavecchia, Chief of PTSED's Policy and Guidance Branch, and his staff.

As you know, immediately following the release of the Administrator's February 28th Orders, PTSED issued over 1,000 Stop Sale, Use, or Removal Orders to all affected 2,4,5-T and Silvex registrants, producers and distributor registrants. As a result of the Agency's subsequent decision to allow certain of the registrants to prepare interim labeling so they can sell and distribute their products which have some non-suspended uses on their labels, it will be necessary to formally vacate or lift the Stop Sale Orders affecting those products which can be properly relabeled. In other words, registrants who have prepared interim labeling can only begin to sell and distribute their products as soon as the interim labeling is attached and after they have notified EPA of their actions. Other 2,4,5-T and Silvex products in their custody or control which were subject to the Stop Sale Order and/or which have not been properly relabeled still may not be moved in commerce without advance approval from the appropriate EPA regional office.

A question has been raised whether the Stop Sale, Use, or Removal Orders issued by PTSED should be amended, vacated, etc. by PTSED or by the appropriate regional office. Once the Stop Sale Order has been issued, it is the responsibility of the regional office listed on the Order to take whatever future action is appropriate in connection with that Order. For example, if a distributor registrant is able to arrange for the return of a particular product to the registrant or producer, it will be the regional office's responsibility to amend or vacate the Stop Sale Order to allow the pesticide to be returned.

A question has also been raised about the possible violation of the Administrator's Suspension Orders if a pesticide dealer attempts to return quantities of the suspended products to the distributor, producer or registrant. Although the Administrator's Orders state that "the sale, distribution, or other movement in commerce (emphasis added) and the use of all such pesticide products ... is prohibited", it is not the Agency's intention to prevent the return by a dealer of suspended products to a registrant, producer, or distributor. However, it is necessary for the Agency to know whether quantities of the suspended products are going to be moved in commerce, to whom, in what quantities and for what purposes. Therefore, if a dealer plans to return unsold quantities of suspended products to a producer or distributor he should first contact the appropriate EPA regional office in writing notifying them of his plans and wait for confirmation before actually shipping the material. If the same dealer is subject to a federal Stop Sale, Use, or Removal Order, it will be necessary for him to have the Order vacated or lifted before he ships the pesticide. Similarly, if the products under his control have been detained pursuant to a State order, it will be necessary for him to contact the appropriate State officials about his plans to return the pesticide(s).

Finally, based on an extensive computer listing provided by the Office of Pesticide Programs of possible users of suspended 2,4,5-T or Silvex products, PTSED is about to begin issuing approximately 24,000 Stop Sale, Use, or Removal Orders. These Orders will be sent directly to various persons who might be holding suspended products for use or planning to use such products including timber tract owners, aerial applicators, lawn service companies, electric power companies, pipeline operators, railroads, irrigation operators, etc. A complete listing of the persons receiving such Orders, broken down alphabetically, by State, will be sent to each regional office along with a copy of the cover letter and Stop Sale forms as soon as the Orders have been mailed.

Attachment

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

AUG 20 1979

OFFICE OF ENFORCEMENT

SUBJECT: Further Guidance on the Cancellation and Suspension of 2,4,5-T and Silvex

TO: Enforcement Division Directors
Pesticides Branch Chiefs

On July 9, 1979, the Assistant Administrator for Toxic Substances signed two notices of intent to hold hearings pursuant to FIFRA section 6(b)(2) to determine whether or not the uses of 2,4,5-T and silvex not subject to the Emergency Suspension Orders of February 28, 1979 should be cancelled (copies attached). This essentially means that all uses of 2,4,5-T and silvex will now be reviewed as part of the ongoing cancellation proceedings.

In preparing the two notices the Office of General Counsel concluded that the list of non-suspended uses of both 2,4,5-T and silvex products was broader than originally assumed. In my earlier guidance memoranda I expressed the Agency's view that only rice, rangeland, sugarcane and certain orchard uses of these products were not affected by the February 23, 1979 Suspension Orders. This same view was expressed in the Registration Division/Pesticides and Toxic Substances Enforcement Division March 22, 1979 letter to all 2,4,5-T and silvex registrants.

It is now the Agency's view that a number of uses of both 2,4,5-T and silvex that were previously considered to be suspended are not suspended and products with these additional uses on their labeling can be sold and used in the United States pending the outcome of the cancellation proceedings. According to the 6(b)(2) notice, in addition to use on rice and rangeland, non-crop uses of 2,4,5-T at the following sites are not suspended:

airports; fences, hedgerows (not otherwise included in suspended uses, e.g., rights-of-way, pasture); lumber yards; refineries; non-food crop areas; storage areas; wastelands (not otherwise included in suspended uses, e.g., forestry); vacant lots; tank farms; industrial sites and areas (not otherwise included in suspended uses, e.g., rights-of-way).

Similarly, according to the 6(b)(2) notice, in addition to use on rice, rangeland, sugarcane and orchards, non-crop uses of silvex at the following sites are not suspended: fencerows, hedgerows, fences (not otherwise included in the suspended uses, e.g. rights-of-way, pasture, home and garden); industrial sites or buildings (not otherwise included in suspended uses, e.g. rights-of-way, commercial/ornamental turf); storage areas; waste areas; vacant lots; and parking areas. Attached to this memorandum is a revised version (dated July 24, 1979) of the list of suspended and non-suspended uses for 2,4,5-T and silvex products. This list supersedes the version provided to you in connection with my guidance of April 5th and the March 22nd letter to affected registrants.

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

Attachment

2,4,5-T 1/	SILVEX
[2,4,5-trichlorophenoxy acetic acid, esters, amine salts]	[2-(2,4,5-trichlorophenoxy) propionic acid, esters, amine salts]
Firetrails and lanes	Farm buildings
Forest lands, management areas, plantations, and stumplands	Forestlands and management areas
Rights-of-way: highways, pipelines, powerlines, utilities, roadsides, roadways, etc.	Golf courses
Pasture	Home use, lawns, grass, ornamental turf, patios, sidewalks, driveways, farmyards
	Ditchbanks, drainage ditchbanks
	Ponds, pond margins, standing water
	Lake, lake margins
	Rights-of-way, all; roadsides, roadways, etc.
	Pasture
	Ditches - water
	Parks, athletic fields
	Marshlands, canals, aquatic sites

NON-SUSPENDED USES

2,4,5-T	SILVEX
Rice	Rice
Rangeland	Rangeland
Airports	Sugarcane
Fences, hedgerows (not otherwise included in suspended uses, e.g. rights-of-way, pasture)	Preharvest fruit drop of apples, prunes and pears
Lumberyards	Fence rows, hedgerows, fences (not otherwis included in suspended uses, e.g., rights-of-way, pasture, home and garden)
Refineries	Nonfood crop areas
Nonfood crops	Noncrop areas
Storage areas	Storage areas
Noncrop areas	Waste areas
Wastelands (not otherwise included in suspended uses, e.g., forestry)	Vacant lots, parking areas, etc.
Vacant lots	Industrial sites or buildings (not otherwise included in suspended uses, e.g., rights-of-way, commercial/ornamental turf)
Industrial sites and areas (not otherwise included in suspended uses, e.g., rights-of-way)	

1/ Certain uses of 2,4,5-T were suspended and cancelled in 1970. P. R. Notice 70-11, April 20, 1970, suspended the registrations for products containing 2,4,5-T and bearing directions for all uses in lakes, ponds and ditchbanks, and liquid formulations for use around the home, recreation areas, and similar sites. P. R. Notice 70-13, May 1, 1970, cancelled the registrations of 2,4,5-T products including all granular formulations for use around the home, recreation areas and similar sites, and all uses on food crops intended for human consumption, except for products whose labeling could be modified by deleting such claims.

1-1-82

TOXAPHENE CANCELLATION COMPLIANCE STRATEGY

Overview

On May 25, 1977 EPA issued a Notice of Rebuttable Presumption Against Registration and Continued Registration of Pesticide Products Containing Toxaphene. This RPAR notice was issued primarily on the basis of studies showing that toxaphene causes tumors in laboratory animals, acute toxicity of toxaphene to aquatic organisms, and the high likelihood that toxaphene causes reductions in the populations of nontarget animal species. Further examination of the data available to the Agency showed that toxaphene is extremely persistent, moves readily through the environment, contaminates habitats of vulnerable aquatic and avian species at levels sufficient to reduce their populations, and that humans are exposed to toxaphene through occupational contact and contamination of a range of food products, particularly fish.

On October 18, 1982 the Agency announced it's decision to cancel most uses of toxaphene. This action was taken pursuant to Section 6 of the Federal Insecticide, Fungicide and Rodenticide Act, as amended (FIFRA). On November 29, 1982, the Agency published in the Federal Register, 47 FR 53784 the notice cancelling most uses of toxaphene, the conditions for continued registration of toxaphene for certain uses, disposition of existing stocks and hearing rights of affected registrants. The cancellation is effective 30 days after notification by the Registration Division.

Requirements of the Rule

Allowable Uses

The order cancels all uses of toxaphene with the following exceptions:

1) Dipping of beef cattle and sheep to control scabies.

2) Use on cotton, corn or small grains to control armyworms, cutworms or grasshoppers. Use is restricted to 18 emergency exemptions only.

3) Use on pineapples to control mealybug and pineapple gummosis moth and use on bananas for weevil control in the Virgin Islands and Puerto Rico only.

4) Manufacturing use only for formulating to products listed above.

The order further restricts use to certified applicators, specifies protective clothing to be worn when mixing or applying the pesticide, and mandates improved directions for use, disposal, and to reduce exposure.

Used dip solutions must be disposed of in accordance with the Resource Conservation and Recovery Act (RCRA). If the owner generates more than 1000 kg of used dip solution per month or more than 1000 kg of used dip solution in combination with other hazardous waste, the material must be treated as a hazardous waste subject to subpart C of RCRA. Any user who wishes to manage the disposal of this material as a hazardous waste must obtain a permit to serve as a hazardous waste facility pursuant to RCRA. The label may exempt from these disposal requirements any farmer/rancher who uses the product solely to treat beef cattle or sheep which he and/or his immediate family owns as individuals.

Existing Stocks

Existing stocks are defined in the order a those stocks of cancelled toxaphene products existing within the territorial United States on or before November 29, 1982.

The rule allows the use of existing stocks of toxaphene in the following manner:

1) Existing stocks within the physical possession of registrants, (i.e., stocks stored in facilities owned or leased by the registrant or within the the registrants direct control):

   a) If the formulation is of a type that permits label conversion to one of the following uses, the relabeled product may be sold and used until December 31, 1986. Existing stock may be relabeled for:

      1) control of sicklepod in soybeans and peanuts only in States with this use as a current or future §24 (c) registration,
      2) use on insects in no-till corn,
      3) use on dry or southern peas, or
      4) §18 emergency use exemptions,

   b) If the formulation is of a type that does not permit label conversion, the product may be sold for one (1) year (until December 31, 1983) utilizing amended labeling.

c) Registrants wishing to qualify for the existing stocks provisions of the order must notify EPA, within 30 days of receipt of the notice, of their decision regarding disposition of existing stocks and provide EPA with an itemized inventory of their stocks. Failure by a registrant to notify EPA of their decision to attempt to qualify for the provisions for existing stocks will cancel the product and require the registrant to dispose of existing stocks of that product within 90 days of publication of the order. Cancelled existing stocks must be disposed of as required by the Resource Conservaton and Recovery Act (RCRA).

d) Any registrant wishing to sell or distribute any existing stocks in their possession must either relabel or apply supplemental labeling to the product as required by the Notice sent by Registration Division, OPP.

Existing stocks of registered technical products must be used in the formulation of products with registered uses prior to manufacturing any new toxaphene technical chemical.

Existing stocks of any type may not be sold, distributed or used after December 31, 1986.

2) Existing stocks outside the physical possession of registrants (i.e., products already in the channels of trade or in the possession of dealers and retailers).

a) Existing stocks already in the channels of trade or in the possession of dealers retailers may be sold, shipped or distributed for use in accordance with the labeling accompanying the product until December 31, 1983. These products may be used until December 31, 1986 utilizing existing labeling. Any existing stocks of this type unsold as of December 31, 1983 must be disposed of according to RCRA regulations.

3) Existing stocks in the hands of users.

a) Existing stocks already in the hands of users may be used according to existing labeling until December 31, 1986.

Hearing Rights

The order offers affected registrants the opportunity for a hearing pursuant to [illegible] FIFRA. Such a hearing will consider only whether [illegible] has instituted and pursued appropriate action to [illegible] within the time provided or whether the Administrator [illegible] regarding the disposition of existing stocks is inconsistent with the Act.

Any action concerning the registrant's products will be held in abeyance pending the outcome of the hearing.

Regulated Industry

Appendix A of this strategy lists those registrants affected by this order.

Enforcement

The Agency's efforts to achieve compliance with this order shall be directed towards assuring that cancelled products are disposed of properly and that proper labeling is affixed to those products introduced to or remaining in the marketplace.

Compliance Monitoring

Compliance monitoring of this order will be achieved first through inspections of affected producer establishments and secondarily, dealer inspections and marketplace surveillance.

Producer establishment inspections shall be conducted to determine if the registrant is complying with the order. Producer establishment inspections will be conducted in the following order of priority:

1) Inspection of registrants with cancelled products.

2) Inspection of registrants with non-convertible existing stocks, i.e. products which cannot be relabeled and must be sold within one year.

3) Inspection of registrants with existing stocks which can be relabeled to one of the allowable existing stocks uses.

4) Inspection of registrants with products which will remain registered.

It is likely that registrants may have products which fall into some or all of the categories listed above. The Agency is most concerned that cancelled products are disposed of properly. For products which may be sold after relabeling, the inspector should determine what types of toxaphene products are in the registrant's possession (i.e., products with registered uses, relabeled existing stocks or existing stocks that cannot be relabeled) and whether they are properly labeled. The inspector should also determine whether the manufacturing use product used in the formulation of registered products is a new chemical or previously manufactured. Registrants must use existing stocks of manufacturing use product to manufacture registered products until

such stocks are depleted. Registrants may not sell or distribute any toxaphene not labeled for a registered use or not labeled in accordance with the existing stocks provisions of this order.

Regions will provide the States with all pertinent materials regarding the order and work closely with the States to develop a compliance monitoring schedule.

After initial producer establishment inspections have been conducted, regions will coordinate marketplace inspections with the States to determine compliance with the existing stocks provisions of the order.

Dealer inspections and marketplace surveillance will be conducted to assure that products are properly labeled and sold. Existing stocks of toxaphene already on dealer's shelves may be sold without label modification until December 31, 1983, provided the registrant has notified EPA within 30 days of their decision to attempt to qualify for the existing stocks provisions of the order. Dealer inspections will become a major activity after December 31, 1983, the last date existing stocks which do not have allowable uses on the label may be sold.

Use inspections will become critical after the December 31, 1986 cut-off date for all uses of existing stocks. Use inspections may be conducted before then at the option of the Region and the State or if problems regarding the use of toxaphene are noted.

Administrative Considerations

Allocation of Resources

1) EPA Headquarters - EPA headquarters shall:

a) Provide Regions with a copy of the cancellation order, compliance strategy and a list of names and addresses of affected registrants.

b) Provide the Regions with a list of those registrants who intend to amend their regisration and remain registered, registrants who intend to relabel their existing stocks of toxaphene for permitted uses, and those who took no action and therefore face cancellation of their product.

c) Provide the Regions with the yearly inventory of existing stocks of toxaphene.

d) Provide additional support and guidance as the Regions may require.

2) Regions - The regions shall:

a) Provide the States with copies of the materials received from headquarters.

b) Coordinate inspectional activities related to this order with the States.

c) Provide support and guidance as the States may require.

3) States - The States shall:

a) Conduct producer establishment inspections of registrants affected by this order.

b) Conduct dealer inspections and marketplace surveillance to determine compliance with existing stock provisions of this order.

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

OCT 23 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Final Compliance Monitoring Strategy for the Wood Preservative Uses of Creosote, Pentachlorophenol, and Inorganic Arsenicals

FROM: A. E. Conroy II, Director
Office of Compliance Monitoring

TO: Addressees

Attached is the final Compliance Monitoring Strategy for the Wood Preservative Uses of Creosote, Pentachlorophenol, and Inorganic Arsenicals. On January 10, 1986, the Agency published the amended Notice of Intent to Cancel in the Federal Register. The Notice amended the July 13, 1984 Notice of Intent to Cancel and incorporated the terms of the settlement agreement which ended the hearings resulting from the July 13 notice.

Producer establishment inspections will be conducted within a year of the November 10, 1986 deadline for relabeling products and should have been negotiated with the States during the FY87 cooperative agreement negotiations. Use inspections will be integrated into the priority setting for each State.

We appreciate the comments made on the draft Strategy. If you have any questions with the Strategy, please contact David Stangel at FTS 382-7845.

The final Strategy has incorporated comments received on the draft document. A discussion of the comments follows:

Comment:

Three comments addressed the training program for pole framing, piling and railroad tie repair where creosote is used. The comments were that the program was not coordinated through the States, that the States will have to conduct inspections with no way of knowing whether an applicator has been trained, that the authority for conducting these inspections is unclear, and that there is no way of judging the adequacy of the training.

Response:

The January 10, 1986 amended Notice stated that, pursuant to the September 30, 1985 settlement agreement, the Agency would not require restricted use labeling for creosote products intended for pole framing, piling and railroad tie repair uses. The Agency instead required that persons using creosote products for these uses undergo special training and that this training be conducted by the wood preservative trade associations. The trade associations are developing a training program under extensive EPA oversight. At the insistence of EPA, a card will be issued at the completion of the training stating that the holder has successfully completed the training course. While EPA cannot require that the card be on the applicator's person at all times, we have indicated to the trade associations that if an inspector can assure that a person has been trained at the time of inspection, it would alleviate the need to contact the company to get this information. The labeling for these creosote products requires that all applicators complete the training program. Please note that the amended Notice does not allow for application under the direct supervision of a certified applicator. All applicators must be trained. Application by untrained applicators is a misuse. In a recent letter (attached to the strategy) the Agency has allowed applicators certified to use restricted wood preservatives to apply creosote for the unrestricted uses. The American Wood Preservers Institute (AWPI) is coordinating the development and dissemination of the training materials. If a Region is interested in attending a training session they should contact the AWPI at (703) 893-4005 to make arrangements to attend a session.

Comment:

One comment dealt with who is monitoring compliance with the Consumer Awareness Program (CAP).

Response:

The CAP is a voluntary program administered by the trade associations. A contractor, Techlaw, Inc., has been selected to conduct compliance audits at the registrant and dealer levels. The results of this audit will be submitted to EPA for review. If the rate of noncompliance is unacceptable, EPA has the option of requiring a mandatory CAP under TSCA. EPA has no jurisdiction over this program at the present time, other than approval of the industry audit program. All inspections will be conducted by Techlaw.

Comment:

Four comments addressed the Permissible Exposure Limitation (PEL) Program. The comments expressed concern that inspectors didn't have experience with air monitoring methodologies or equipment, that the Regions had not been provided with a list of arsenical wood treatment plants, and questioned the jurisdiction of State Lead Agencies and state OSHAs regarding inspections on the state level.

Response:

The Office of Compliance Monitoring is providing the Regions with a list of arsenical wood treatment plants (attached to the strategy). Inspections of plants participating in the PEL Program will primarily involve inspection of records. If an inspector observes employees of an arsenical wood treatment plant working without respirators, the inspector should see if the employer conducted air monitoring and has records of the results of the monitoring. Inspectors will not routinely take air samples. The amended Notice specifically avoids listing a particular air monitoring device, but rather, lists design criteria. Any device which meets these criteria would be acceptable. Inspections for compliance with the PEL Program are clearly the responsibility of EPA. The settlement agreement and the amended Notice provide the arsenical wood treatment plants the opportunity to forego the requirement for workers to wear respirators. This requirement is an EPA requirement, therefore State Lead Agencies must conduct inspections under EPA authority.

Comment:

Two comments suggested that the title "Allocation of Resources" be changed to "Allocation of Responsibilities" since this section is really talking about who will be doing what.

Response:

The title has been changed.

Comment:

One comment remarked on the tone of the Compliance Monitoring Section regarding state roles.

Response:

The responsibilities of all parties involved in the compliance monitoring of the Notice of Intent to Cancel are clear. All parties involved will perform certain functions. It is the responsibility of the Region to have negotiated the Federal priorities initially in accordance with the Performance Based Guidance Document. In addition, Regions were requested to forward the draft to States for comment.

Comment:

One comment questioned what was to be accomplished by the Region reviewing labels of existing stocks of cancelled products if that review is not in connection with a case.

Response:

The regional responsibility listed on page 8 of the draft was included because the Regions were asked to review revised labeling of existing stocks of products cancelled by the July 13, 1984 NOIC. Registrants of cancelled products were required to submit an inventory of existing stocks and have the Region review the labeling they intended to place on their existing stocks in order to vacate the Stop Sale, Use or Removal Order placed on their product. As part of the inspection program, Regions should be reviewing the labeling of cancelled products to determine if the current labeling is identical to the labeling they reviewed in accordance with the Notice. The language has been deleted with the understanding that the Regions will still be reviewing labels as part of the inspection program.

Comment:

One comment expressed concern that certification programs would not be in place by November 10, 1986, the date by which products must bear restricted use labeling.

Response:

This office has been assured that certification programs will be in place and applicators certified by November 10, 1986. States have either created a category for wood preservatives or fit wood preservation into an existing category. Many States are already training applicators.

COMPLIANCE STRATEGY FOR WOOD PRESERVATIVE PRODUCTS CONTAINING CREOSOTE, PENTACHLOROPHENOL, AND INORGANIC ARSENICALS

OVERVIEW

In October 1978, the Agency began the administrative review process for the wood preservative uses of creosote, pentachlorophenol and inorganic arsenicals.

On July 13, 1984, the Agency issued in the Federal Register (49 FR 28666) a Notice of Intent to Cancel for the wood preservatives hereafter called "the July 13, 1984 Notice". The Notice stated that if the terms and conditions of registration were not amended, wood preservative products containing creosote, pentachlorophenol, and the inorganic arsenicals would be cancelled within 30 days from the date of publication of the Federal Register Notice or from date of receipt of the Cancellation Notice, whichever occurred later.

Persons who requested a hearing with the Agency regarding the Notice were exempt from the requirements of the Notice until resolution of the issues. The Office of Compliance Monitoring issued a Stop Sale, Use or Removal Order (SSURO) to those registrants of products cancelled. A list of these is attached. In order to sell stocks subject to a SSURO, the registrant had to make appropriate labeling changes, report inventories of existing stocks, and request the Regional office to vacate the SSURO. Two subsequent Federal Register Notices postponed indefinitely the requirements to relabel those products for which the registrant had requested an amended registration under the terms of the July 13 Notice.

On September 30, 1985, EPA entered into a settlement agreement with many of the parties who requested a hearing pursuant to the July 13, 1984 Notice. The settlement agreement modified the terms of the July 13, 1984 Notice. As a result of the settlement agreement, on January 10, 1986, the Agency published an amended Notice of Intent to Cancel which incorporated the terms of the settlement agreement.

Compliance with the Notice will be monitored through State/EPA inspections to determine compliance with the labeling provisions of the January 10, 1986 amended Notice and the SSURO's issued to registrants of cancelled products. Monitoring will be accomplished primarily through use and producer establishment inspections.

REQUIREMENTS

The July 13, 1984 Notice established the requirements a registrant would have to meet to avoid cancellation. Registrants were afforded the opportunity to request a hearing or amend the labeling of a product. In addition to relabeling, registrants of pentachlorophenol products wishing to continue their registrations were required to amend their Confidential Statement of Formula to indicate that their products contained levels of hexachlorodibenzo-p-dioxin (HxCDD) at or below specified amounts. Failure to either amend labeling or request a hearing, resulted in immediate cancellation. Registrants of cancelled pesticides were required to relabel in accordance with the Notice, submit information on inventories of existing stocks to Regional offices and have the Regional office vacate the SSURO in order for existing stocks to be sold. See Unit IV A-D of the Notice for complete labeling requirements. All products in the control or possession of registrants were required to bear new labeling by November 1, 1984. Products in the channels of trade were required to be relabeled by February 1, 1985.

On October 31, 1984, the Environmental Protection Agency (EPA) published a Federal Register Notice (49 FR 43772) which postponed until further notice, the requirement to relabel products for those registrants who requested an amended registration under the terms of the July 13 Notice. The October 31 Notice still required that existing stocks in the control of persons other than the registrant be relabelled by February 1, 1985.

On January 30, 1985, EPA published a Federal Register Notice (50 FR 4269) which postponed until further notice, the requirement to relabel products other than those cancelled products in the control or possession of registrants. This applied to both registered and cancelled products in the channels of trade. Registrants with cancelled products were still required to relabel existing stocks in their control or possession in order to sell them.

On June 11, 1985, Judge Spencer T. Nissen ruled on a hearing request brought by the American Wood Preservers Institute and others (In re Chapman Chemical Co., et al., FIFRA Docket No. 529 et al.). A summary of the decision is found in Appendix 1.

On September 30, 1985, the American Wood Preservers Institute, et al., the National Forest Products Association, the Society of American Wood Preservers, Inc., et al., Chapman Chemical Company, et al., and the Environmental Protection Agency entered into a settlement agreement which resolved most of the issues arising from the July 13, 1984 Notice of Intent to Cancel.

On January 10, 1986, the Agency published an amended Notice of Intent to Cancel which incorporated the terms and conditions of the settlement agreement and made certain minor modifications to the July 13, 1984 Notice. Registrants were allowed thirty (30) days from the date of publication of the Notice or date of receipt, whichever is later, to renew their hearing requests or file requests for amended registration in accordance with the requirements of the amended Notice. Certain registrants of technical pentachlorophenol products were not party to the AWPI, et al. settlement agreement. Negotiations are continuing with these registrants. The primary remaining issues relate to the levels of contaminants in pentachlorophenol products. Except for issues relating to the level of contaminants in pentachlorophenol products, no signatories to the settlement agreement raised a challenge to the amended Notice. Three companies have filed a hearing request to challenge the Agency's position on contaminant levels in pentachlorophenol products. These companies are:

Vulcan Materials Company, the only registrant of technical pentachlorophenol currently producing in this country,

Reichold Chemical Company, which also holds registrations for technical pentachlorophenol, but is not currently producing the chemical, and

Idacon, Inc., a registrant of manufacturing-use and end-use pentachlorophenol products.

To date, no other registrants have renewed their hearing requests in response to the January 10, 1986 Notice. A summary of the Notice follows:

Summary of the January 10, 1986 Amended Notice

The three (3) major components of the Amended Notice are:

1) Labeling and Consumer Awareness Program (CAP)
2) Training
3) Permissible Exposure Limitation (PEL) Program - Arsenicals

1) Labeling and Consumer Awareness Program (CAP)

- Registrants are allowed thirty (30) days from the date of publication or date of receipt of the amended Notice to submit amended labeling.

- Labeling modifications include restricted use (with an exception for certain creosote products), protective clothing and equipment requirements, proper use and disposal information, arsenic ambient air level limitations, closed emptying and mixing requirements for certain formulations, a requirement for no visible arsenic surface deposits on the treated wood, a teratogenicity label warning for pentachlorophenol products, a restriction against applying pentachlorophenol to logs used in construction of log homes and certain limitations in the level of contaminants in pentachlorophenol products.

- All products must be relabeled by November 10, 1986.

- On November 10, 1986, only certified applicators or persons under their direct supervision may apply restricted wood preservatives.

- CAP is voluntary.

- Trade associations will administer the CAP, audit the program after one year and report on compliance. Audit to be submitted 30 days after completion. Within four (4) months from the date of settlement, the trade associations will consult with EPA on study protocol and selection of a contractor.

- If EPA notes widespread non-compliance with the voluntary program, EPA has the option of taking action under TSCA.

2) Applicator Training

- Creosote products for pole framing, piling applications, and railroad tie repair will not require a restricted use label. A training program administered by the trade associations will be instituted instead. Alternatively, applicators certified in the use of restricted

wood preservatives may also apply these creosote products per the attached letter dated July 17, 1986 to Burton R. Evans.

- By April 10, 1986, the parties will submit, for Agency approval, a training program for these applicators.

- The training program must be implemented and all applicators trained by November 10, 1986 (10 months after the date of publication of the amended Notice).

3) Permissible Exposure Limitation (PEL) Program

- Each arsenical wood treatment plant shall require employees to wear respirators if they are exposed to airborne inorganic arsenic in the absence of monitoring.

- An alternative is implementation of a PEL Program.

- Exposure over 10 ug/m^3 of airborne inorganic arsenic requires workers to wear respirators.

- When exposure is between 5 ug/m^3 - 10 ug/m^3, workers do not have to wear respirators but the employer must repeat monitoring every six (6) months until 2 consecutive measurements taken at least seven (7) days apart are below 5 ug/m^3.

- If monitoring reveals levels below 5 ug/m^3, monitoring may be discontinued.

- Existing plants electing to adopt a PEL Program must comply with the terms of the order and complete testing by July 10, 1986.

- New plants have 3 months from the date of initial operation to comply with the Notice.

- EPA may request random remonitoring of establishments.

- Employers must re-evaluate and remonitor if production changes in such a manner that they answer questions on the PEL Checklist in a positive manner.

- Employers must maintain records and responses to the PEL Checklist.

- The employer must submit certified monitoring records to OCM annually. This would include negative responses to the PEL Checklist.

Regulated Industry

The regulated industry consists of registrants, distributors, and users of wood preservative products containing creosote, pentachlorophenol and inorganic arsenicals.

COMPLIANCE MONITORING

Compliance monitoring will be accomplished through State/EPA inspections to determine compliance with the SSUROs issued to registrants of cancelled products and with the labeling provisions of the January 10, 1986 amended Notice. States have primary use enforcement responsibility in States with delegated programs. In non-grant States, Regional personnel will inspect and enforce the terms of the cancellation order and labeling provisions.

Effective compliance monitoring will depend on close coordination with OCM and OPP to maintain current lists of persons affected by the July 13, 1984 Notice and the January 10, 1986 amended Notice. All persons who were issued SSUROs will be inspected within the first year of issuance of this strategy if they have not been already.

The following types of inspections will be conducted by the States and EPA (in non-grant States) to monitor compliance with the requirements of the SSUROs, the July 13, 1984 Notice, and the January 10, 1986 amended Notice.

Use inspections and producer establishment inspections will be the primary compliance monitoring activities for this regulatory action. Marketplace, dealer recordkeeping, and import inspections are lower priority activities to be carried out as part of normal inspectional activities.

Use inspections will be conducted to verify that persons using products bearing restricted use labeling are certified applicators and adhere to label directions. These inspections will be directed primarily at large-scale pressure treating or dipping operations. Use inspections will be conducted to determine if persons using products intended for pole framing, piling applications and railroad tie repair have undergone

training as required, Plants using inorganic arsenic products to treat wood will be inspected to verify compliance with the requirement for employees to wear respirators or alternatively, participation in the PEL program. Misuse complaints and tips will be investigated as a high priority, if appropriate.

Producer establishment inspections will be conducted to verify that by November 10, 1986, all products, including all existing stocks, are relabeled in accordance with the January 10, 1986 amended Notice.

All producers of cancelled products (Attachment A) will be inspected the first year to assure compliance with the SSURO, verify that the products are not being produced, and verify that the products are in compliance with the requirements of Subunit IV of the January 10, 1986 amended Notice.

Recordkeeping inspections will be conducted to verify that dealers are maintaining records of sales of RUP's.

Import inspections will be conducted to determine if imported wood preservative products are in compliance with the January 10, 1986 Notice.

Marketplace inspections will be conducted to verify that products are in compliance with the terms of the January 10, 1986 Notice.

ALLOCATION OF RESPONSIBILITIES

Office of Pesticide Programs/Registration Division(OPP/RD)

° Will develop and maintain the list of registrants who have requested amendments to their registration and those registrations which have been cancelled.

° Will provide this information to OCM.

Office of Compliance Monitoring (OCM)

° Will act as liaison with other Agency offices and the Regions to collect information concerning the action.

° Will provide lists to the Regions on the status of products.

° Will review annual PEL records submissions and provide them to the Regions to be compared against previous submitters for inspection targetting.

Office of Training and Technical Support

° Will review any amendments to Certification and Training Plans.

Regions

° Will provide copies of strategy to States.

° Will negotiate with the States regarding Federal priorities during grant negotiations.

° Will conduct inspections in States without Cooperative Enforcement Agreements.

° Will distribute the list of registrants and registered products to the States.

° Will provide PEL information to States.

States

° Will conduct inspections and take enforcement action, as appropriate, provided they have the authority.

CERTIFICATION AND TRAINING

Registered products are required to bear restricted use labeling by November 10, 1986 under the terms of the amended Notice of January 10, 1986. Cancelled products were required to bear restricted use labeling in order to sell existing stocks under the terms of the July 13, 1984 Notice. These conditions of sale require users to be certified or under the direct supervision of a certified applicator.

In response to the diverse levels of State preparedness to train and certify persons, OPTS has formed a committee composed of the USDA (both HQ and State Cooperative Extension Service reps), Regional representatives, a State Lead Agency, and the Office of Training and Technical Support. The committee will consider the needs of both pressure treatment applications and brush-on applications and will (a) review existing mechanisms of State certification and training programs to determine what is available, (b) review existing training materials and determine whether it fulfills current needs, and (c) coordinate these efforts with the user associations.

APPENDIX 1

Summary of ALJ Spencer T. Nissen's Decision of June 11, 1985

1. The Consumer Awareness Program insofar as it requires labeling of pressure-treated wood, which is not a pesticide, is not authorized by FIFRA and may not be required as a condition of the registration of the pesticides at issue.

2. EPA's authority under FIFRA to specify required labeling on pesticides in order to prevent adverse effects on the environment is extremely broad and with a single exception (No. 5 below) labeling for nonpressure-treatment of wood with the preservatives at issue is within EPA's authority under the Act.

3. Labeling provisions prohibiting use of treated wood where the preservatives at issue may become a component of food or animal feed may be required by EPA under FIFRA, because they complement prohibitions in effect under the Food, Drug and Cosmetic Act.

4. Pesticide labeling requirements designed to prevent contamination of drinking water from pesticides or pesticide residues may be required under FIFRA, notwithstanding that primary jurisdiction to establish contaminant levels and standards for drinking water is conferred upon EPA by the Safe Drinking Water Act.

5. Because FIFRA §19(a) specifically limits EPA's authority over disposal to pesticides and pesticide containers, EPA may not through a labeling requirement in a FIFRA cancellation notice regulate the disposal of treated wood.

6. OSHA has deferred to EPA regulation of the workplace exposure to arsenic involving its application as a pesticide and EPA may, under FIFRA, require a Permissible Exposure Limit program for workers in arsenical wood treatment plants.

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Index

The documents in this index are referenced by the Compendium subject/volume abbreviation and the date of the document. However, FIFRA Compliance Program Policy Compendium documents are referenced by the subject/volume abbreviation and the document number. The abbreviations for the subject/volumes in this index are as follows:

- TG -- Technical Guidance (Volume 1);
- SRG -- State-Related Guidance (Volume 2);
- ES -- Enforcement Strategies (Volume 3);
- ERP -- Enforcement Response Policies (Volume 4); and
- FCPP -- FIFRA Compliance Program Policy Compendium (Volume 5)

Vegetable oil diluent, FCPP 12.5
Velsicol Chemical Corporation, ES 04-13-88
Vinyl Chloride, TG 02-00-90
Violation history, TG 10-17-80

Water purification devices, TG 08-30-75, TG 03-15-76, ES 10-00-80
Wood Preservatives, ES 10-23-86, TG 02-00-90
Worker protection program, SRG 06-13-89, SRG 07-31-89
Worker protection statements, TG 02-00-90
Written examinations, FCPP 4.1