EPA

Federal Insecticide, Fungicide, and Rodenticide Act

Compliance/Enforcement Guidance Manual

Policy Compendium

U.S. Environmental Protection Agency
Washington DC 20460

Issued by

Pesticides and Toxic Substances
Compliance Monitoring Staff

and

Office of Enforcement and Compliance Monitoring

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 5 1984

MEMORANDUM

SUBJECT: FIFRA and TSCA Compliance/Enforcement Guidance Manual Policy Compendiums

FROM: A. E. Conroy II, Director
Compliance Monitoring Staff
Office of Pesticides and Toxic Substances

Glenn Unterberger, Director
Office of Legal and Enforcement Policy
Office of Enforcement and Compliance Monitoring

TO: Addressees

As part of our effort to produce guidance manuals for personnel involved in case development activities for the United States Environmental Protection Agency, we are transmitting to you the Compendium of Operative Enforcement Policies for the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA). The Compendiums not only identify those FIFRA and TSCA compliance/enforcement guidances and policies that are currently in effect, but they also provide a mechanism for organizing such memoranda.

We intend to update the Compendiums periodically and we welcome comments on them or on policy issues that might be addressed in the future. Questions or comments on the contents of the Compendiums can be addressed to Ted Firetog (FTS 426-7503) or Barbara Paul (FTS 382-7826).

Addressees:

Regional Counsels
Associate Enforcement Counsel for Pesticides
and Toxic Substances
Director, Office of Criminal Investigations
Director, NEIC
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IV, VI, VII, VIII, and X
Director, Environmental Services Division - Region III
Director, Waste Management Division - Region V
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Attachments

cc: Assistant Administrator for Pesticides
and Toxic Substances
Assistant Administrator for Enforcement
and Compliance Monitoring
General Counsel
Senior Enforcement Counsel

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This Compendium contains the following FIFRA compliance/enforcement-related policies and guidances currently in effect.

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

Director of Compliance Monitoring Staff
Office of Pesticides and Toxic Substances (EN-342)
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

TITLE OF DOCUMENT	DATE OF DOCUMENT
Technical Guidance	
Institution of Pesticides Enforcement Policy Statements (PEPS) [40 Fed. Reg. 19,526]	5/5/75
"Water Purifiers"	8/30/75
"Guidance for Enforcement Actions Involving Water Purifier Products"	3/15/76
PEPS #3: Certain Enforcement Policies to be Followed During the Phased Implementation of FIFRA Section 3 [41 Fed. Reg. 13,984]	4/1/76
PEPS #4: Preventive Pest Control Treatments in the Absence of Target Pests [41 Fed. Reg. 28,005]	7/8/76
Pest Control Devices and Device Producers [41 Fed. Reg. 51,065]	11/19/76

"Enforcement Priorities in Structural Pest Control a) Establishment Inspections of Pest Control Firms b) Pesticides Use Inspections c) Prosecutorial Discretion in Pesticide Use Enforcement"	1/24/77
"Enforcement Policy Applicable to Bulk Shipments of Pesticides"	7/11/77
"Federal Pesticide Act of 1978"	8/22/78
Notice of Rescission of Pesticide Enforcement Policy Statements (PEPS) Nos. 1,2,5,6,7 [44 Fed. Reg. 33,151]	6/8/79
Enforcement Policy Regarding Failures to Report Information Under §6(a)(2) of FIFRA [44 Fed. Reg. 40,716]	7/12/79
Agency Interpretation of Requirement Imposed on Registrants by §6(a)(2) of FIFRA [43 Fed. Reg. 37,611]	8/23/78
Suspended and Cancelled Pesticides (Booklet)	10/79 (2nd Revision)
Pesticide Use and Production by Veterinarians; Statement of Policy on the Applicability of the Federal Insecticide, Fungicide, and Rodenticide Act to Veterinarians [44 Fed. Reg. 62,940]	11/1/79
"Enforcement Actions Concerning Nonhazardous Pesticides Devices"	12/19/79
"Federal Facilities Compliance"	1/16/80
Statement of Policy on the Labeling Requirements for Exported Pesticides, Devices, and Pesticide Active Ingredients and the Procedures for Exporting Unregistered Pesticides [45 Fed. Reg. 50,274]	7/28/80
"Request Procedures for Pesticide Samples and Followup on Pesticide Complaints"	7/30/80
"Enforcement Facts and Strategy; Compliance Monitoring Procedures; Water Purification Devices"	10/80

"Routine Use of SEC '10-K' Statements in TSCA and FIFRA Civil Penalty Actions" 10/17/80

"Regulation of Public Health Related Disinfectant Products" 12/17/80

Pesticide Registration, Reregistration, and Classification Procedure; Clarification of Policy Issues on Special Packaging [46 Fed. Reg. 51,104] 3/3/81

"Strategy for the Enforcement of the Child-Resistant Packaging Regulation Under FIFRA" 6/8/81

"General Compliance Strategy for Products Subject to the FIFRA Label Improvement Program" 4/21/83

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"Primary Use Enforcement Responsibility" 1/4/79

"Review of State Certification Plans Pursuant to FIFRA Section 26" 3/14/79

"Clarification of Primary Use Enforcement Responsibility Guidance" 3/4/80

"Appropriate Documents to be Presented by State Inspectors Conducting Pesticide Use Inspections in States Having Primacy" 12/18/80

Federal Insecticide, Fungicide, and Rodenticide Act, State Primary Enforcement Responsibilities [48 Fed. Reg. 404] 1/5/83

"Final FY84 Cooperative Agreement Program Guidance" 4/21/83

Cancellation-Suspension Enforcement Strategies

Aldrin Dieldrin

"Continuing State Registration of Products Containing Aldrin and Dieldrin for Which Uses Have Been Suspended" 1/10/75

Chlordane-Heptachlor

"Enforcement of Administrator's Decision and Order Suspending Most Uses of Heptachlor and Chlordane" 1/15/76

"Clarification of Heptachlor/Chlordane Suspension Order" 1/22/76

"Status Report on Heptachlor/Chlordane Suspension" 2/19/76

"Heptachlor/Chlordane Suspension Order Enforcement Strategy" 3/23/76

"Heptachlor/Chlordane Suspension Order Enforcement Strategy--CORN USE" 8/27/76

"Continued Enforcement of Suspension of Registration for Certain Products Containing Heptachlor and Chlordane" 11/23/76

Mercury

"Conclusion of Mercury Cancellation Proceeding" 10/28/76

"Enforcement of Mercury Settlement" 1/6/77

2,4,5-T and Silvex

"Enforcement of Administrator's Emergency Orders Suspending 2,4,5-T and Silvex Registrations" 3/7/79

"Further Guidance Concerning Enforcement of the Administrator's Emergency Orders Suspending 2,4,5-T and Silvex Registrations" 4/5/79

"Further Guidance on the Cancellation and Suspension of 2,4,5-T and Silvex" 8/20/79

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"General Compliance Strategy for Products Suspended Under §3(c)(2)(B) of FIFRA" 7/2/82

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FIFRA Compliance Program Policy Compendium

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Penalty Policies (These may be found in the Appendix 4 of FIFRA Compliance/Enforcement Guidance Manual.)

Guidelines for Assessing Civil Penalties Under Section 14(a) and Citation Charges for Violation of FIFRA

Memorandum (22 Apr 1975)--Interim Deviation from Civil Penalty Assessment Schedule

Memorandum (11 Jun 1981)--FIFRA Enforcement
Policy Interim Penalty Guidelines

Miscellaneous Sources (These sources are not contained in this Compendium but may be obtained from Headquarters.)

EPA Delegations of Authority Manual

EPA Manual of Pesticide Misuse Review
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Advisory Opinions

EPA Security Manual

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SFIREG Charter

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENFORCEMENT
OFFICE OF GENERAL ENFORCEMENT
PESTICIDES ENFORCEMENT DIVISION

INSTITUTION OF PESTICIDE ENFORCEMENT POLICY STATEMENTS

Reprinted from the Federal Register of May 5, 1975
(40 FR 19526)

Institution of Pesticide Enforcement Policy Statements

I. *1972 Amendments to the Federal Insecticide, Fungicide, and Rodenticide Act.* On October 21, 1972, the Federal Environmental Pesticide Control Act of 1972 (Pub. L. 92-516; 86 Stat. 973; 7 U.S.C. 136 et seq.) was signed by the President. This legislation amended the Federal Insecticide, Fungicide, and Rodenticide Act of 1947 (61 Stat. 163 (1947); amended at 78 Stat. 190 (1964); 7 U.S.C. 135 a-k; (hereinafter referred to as FIFRA)).

These amendments expanded the regulatory scope of pesticide control. They contained new substantive provisions regarding pesticide registration, and the registration of products sold only in intrastate commerce. They extended regulatory jurisdiction to provide a means to regulate the application or other use of pesticides. Since the enactment of the 1972 amendments, the Agency has issued regulations implementing many of the new substantive provisions of the Act.

The 1972 amendments also made additional enforcement tools available to the Agency. These include the authority to assess civil money penalties, to issue civil penalty warning citations, and to issue stop sale orders and stop use orders. Where necessary, the Agency has published rules of practice and other enforcement guidelines implementing the new enforcement powers authorized in FIFRA.

While pesticide enforcement activities have been conducted for some time by EPA and its predecessor agencies, the Agency feels that there is a need to inform the pesticide chemicals industry, the pest control industry, and the general public regarding the pesticide enforcement policies of the Agency, particularly those which have arisen out of the implementation of FIFRA as amended. Publication of these policy statements will increase the predictability of Agency enforcement actions, establish enforcement precedent and will focus analysis within the Agency upon those questions regarding pesticide application or other use which are of general importance. It is anticipated that the further dissemination of the Agency's enforcement policies will result in additional compliance with the law by all segments of the pest control industry and by the general public.

II. *Scope of Pesticide Enforcement Policy Statement (PEPS).* The Agency hereby announces the initiation of a series of Pesticide Enforcement Policy Statements (PEPS). These PEPS are designed to inform those engaged in the formulation, distribution, sale, application or other use of pesticides, as well as interested segments of the general public, of the policies adopted by the Agency in the exercise of its prosecutorial discretion in the enforcement of FIFRA as amended. PEPS will be issued periodically by, and at the discretion of, EPA's Office of Enforcement. The Agency distinguishes between statements which define the Agency's regulatory jurisdiction and statements which report the Agency's exercise of prosecutorial discretion. Where an Agency statement defines the scope of FIFRA jurisdiction, the Agency shall inform the public by means of regulations promulgated by the Administrator of EPA. Where an Agency statement reports the exercise of its prosecutorial discretion, the Agency shall inform the public by means of published notices. This series of Pesticide Enforcement Policy Statements represents an exercise of prosecutorial discretion. Accordingly, each PEPS will be published in the "Notices" section of the FEDERAL REGISTER under the signature of the Assistant Administrator for Enforcement. If the Administrator promulgates regulations which affect matters contained in a prior PEPS, the Office of Enforcement will revoke or amend such PEPS to conform to such subsequent regulations.

Enforcement policies announced in this series of PEPS will remain in effect until amended or modified by subsequent published PEPS or by subsequent regulations promulgated by the Administrator. On or before October 22, 1976, the Agency shall have re-registered all of the pesticides registered prior to the passage of the 1972 amendments as well as all pesticides sold only in intrastate commerce. It shall be a part of this re-registration process to incorporate on the approved label, where appropriate, the policies contained in these PEPS. As the contents of these PEPS are incorporated in the approved product label, such PEPS will be revoked or amended.

This series of enforcement policy statements is intended to address issues which are of national significance and which will not be expeditiously resolved through the section 3 registration process. It shall not lessen the ability of a State to further regulate the sale or use of a pesticide under section 24(c) of the Act (7 U.S.C. 136 v. (c)). No

PEPS will be issued to resolve a problem which clearly represents a "special local need" as provided in section 24(c) whether or not a state has implemented such a state registration program. The Office of Enforcement will not utilize the PEPS to preempt a State (authorized to do so by the Administrator) from registering a pesticide for a "special local need."

The series of PEPS will deal with all aspects of the pesticides enforcement program of the Agency. It is anticipated that the bulk of these policy statements will disseminate pesticide enforcement policy regarding (a) the registration of products sold only in intrastate commerce, (b) the implementation of enforcement remedies contained in the 1972 amendments, and (c) the regulation of the application and other use of pesticides.

This series of policy statements is intended to clarify and illuminate the Agency's policy regarding the enforcement of FIFRA. Accordingly, every effort will be made to provide clear and specific instructions to the reader as to the content and implementation of such policy. Where questions regarding the interpretation of Pesticide Enforcement Policy Statements arise, the Agency will adopt the rules of construction generally applied to statutory interpretation. The meaning of language used in a policy statement will reflect the definitions given to the words in everyday discourse or adopted by the Agency in the implementation of the Act. Passages will be interpreted to give effect to the passage so that no part of the PEPS will be inoperative, insignification, or void, and to insure consistency with the overall intent and objectives of the Agency in formulating and announcing the enforcement policy contained in the statement. Further, the Agency in interpreting these policy statements will apply an objective standard in giving those PEPS the meaning which would be assigned to them by an ordinarily prudent and reasonable man.

The Agency in enforcing these policy statements will apply a similar standard to determine that level of compliance and understanding normally associated with the actions of a prudent and reasonable man. The Agency recognizes the need to continue regulation of the pesticide industry and pesticide use, in particular, in a common sense manner. However, circumstances in which repeated and knowing abuse of this policy has occurred may require an appropriate enforcement response by the Agency. The Office of Enforcement tends to utilize the full range of enforcement tools in the regulation of these uses including minor Notices of Warning pursuant to section 9(c), civil penalty warning citations, civil penalty assessments, stop use orders, criminal prosecution and injunctive relief.

A. *Enforcement policy with regard to intrastate products.* Section 3(a) of FIFRA as amended established for the first time Federal jurisdiction over pesticides sold only in intrastate commerce. It is clear from the legislative history that this expansion of Federal jurisdiction was one of the most important aspects of the new legislation. The Senate Committee on Agriculture and Forestry noted in its first paragraph comparing the 1972 amendment with the prior legislation that:

> (FIFRA of 1947 does not) * * * regulate pesticides moving only in intrastate commerce. The amendments (to FIFRA) which is a registration and labeling law, would extend the regulation of pesticides to their manufacture and use, and Federal regulatory authorities would apply throughout the States, not just to the interstate commerce of pesticides [H. Rep. No. 92-511, 92d Cong. 1st Sess. 12 (1971)].

On January 9, 1973, the Administrator of EPA published in the FEDER REGISTER (39 FR 1142) a timetable f the implementation of the 1972 amendments. This document set forth the Agency's plan for implementing the amendments to the FIFRA, informed the public as to the date when specific provisions of the amendments became or would become effective, and indicated the general form and content that various regulations would take.

With regard to the implementation of the registration provision of the 1972 amendments, the Implementation Plan noted that (except with regard to cancelled or suspended products) that:

> (u)ntil such time as section 3 of (FIFRA as amended) is implemented, but no later than 2 years after its date of enactment, intrastate shipments will be allowed to the same extent as under prior law and will, until such time as section 3 is operable, be subject to regulation under State law (39 FR 1143).

The series of PEPS will disseminate the enforcement policy of the Agency as it pertains to the phased registration of intrastate products. The Agency has stated its view of the current enforceability against intrastate products of those statutory provisions of FIFRA which do not relate to the registrati requirements of FIFRA as amend and which became effective upon enact-

nent, or which have since been effectuated by regulations (39 FR 36973, 36975). During the implementation of the registration provisions of FIFRA as amended with respect to intrastate products, PEPS will be used to announce enforcement policy regarding questions involving the registration status of intrastate products or the applicability of particular sections of the Act to such products.

B. *Implementation of Enforcement Remedies.* The 1972 amendments contained new enforcement remedies not authorized in the prior legislation. Foremost among these are the provisions for administratively assessed civil money penalties, civil penalty warning citations, stop sale orders, and stop use orders. FIFRA as amended also expands the Agency's authority to petition a federal district court of competent jurisdiction to order the seizure for confiscation or condemnation of violative pesticide products (7 U.S.C. 136k(b)), or to specifically enforce and prevent and restrain violations of the Act (7 U.S.C. 136n(c)). These provisions represent important additions to the administrative powers of the Agency.

The provisions authorizing the use of these new remedies are deemed in the Implementation Plan to have become effective upon the enactment of the amendments. On July 31, 1974, EPA promulgated final rules of practice governing proceedings conducted in the assessment of civil penalties against persons alleged to be in violation of FIFRA (39 FR 276561). These rules of practice established procedures whereby persons alleged to have violated the Act may be given notice of the charges against him, and may receive an opportunity to request a public hearing regarding (1) the facts constituting the alleged violation, and (2) the appropriateness of the civil penalty which is proposed to be assessed. They established procedures for the conduct and final disposition of such actions. The Agency has also published Guidelines for the Assessment of Civil Penalties. These guidelines reveal the manner in which the Agency assigns specific dollar penalties against persons who violate specific statutory provisions (39 FR 27711).

Pesticide Enforcement Policy Statements will also be used to disseminate Agency policy regarding the triggering of specific enforcement remedies, the procedures which the Agency will follow in applying such remedies, and the application of enforcement remedies which existed under the prior legislation (such as criminal penalties or notices of warning) to substantive provisions contained in the 1972 amendments.

C. *Expansion of Regulatory Jurisdiction to Control Pesticide Use.*—1. *Background.* In recent years people have become increasingly sensitive to the risks certain pesticides have inflicted upon man and his environment. The President noted in his 1971 environmental message, that "the use and misuse of pesticides has become one of the major concerns of all who are interested in better environment." In outlining the need for additional regulatory authority over pesticide use, the President stated that:

> (t)he administrative processes contained in the (current) law are inordinately cumbersome and time consuming, and there is no authority to deal with the actual use of pesticides. The labels approved under the Act specify the uses to which pesticides may be put, but there is no way to insure that the label will be read or obeyed. The comprehensive strengthening of our pesticide control laws is needed (H.R. Rep. No. 92-511, 92d Cong. (1971)).

A primary emphasis of the 1972 amendments was to expand the regulatory jurisdiction of the Federal government to include the regulation of pesticide use. The House Committee on Agriculture

> * * * found the greatest need for revision of existing law to be in the areas of strengthening regulatory controls on the uses and users of pesticides * * * (and) strengthening enforcement procedures to protect against misuse of these biologically effective materials; * * *
>
> The Committee has worked on each of these problems. (FIFRA 1972) imposes new controls and sanctions on both the uses and the users of pesticides. Old FIFRA is changed from a labeling to a regulatory program. New tools for restricting the introduction and dissemination of pesticides into the environment are given to the EPA. (H.R. Rep. No. 92-511, 92d Cong. 4 (1971)).

In a later report on FIFRA, as amended, the Senate Committee on Agriculture and Forestry mentioned as the first item in its Short Summary that: "The new bill (would) prohibit the use of any pesticide in a manner inconsistent with its labeling" (S. Rep. No. 92-838, 92d Cong., 2d Sess. 1 (1972)). It is also unlawful under the new bill to "use any pesticide which is under an experimental use permit contrary to the provisions of such permit". It is likewise unlawful to "violate any order issued under section 13 (stop use order)." These provisions appear in

FIFRA sections 12(a)(2)(G), 12(a)(2)(H), and 12(a)(2)(I), respectively (7 U.S.C. 136 1(a)(2) (G), (H), and (I)). The Senate Committee on Agriculture and Forestry noted the fundamental nature of the expanded use regulation authorized by FIFRA 1972:

> Registration for specific uses under specified conditions, as well as directions for use, warnings and cautions, constitute the major means to control pesticide use under present law. But there is nothing in the present law requiring that those directions, warnings, and cautions be followed. The provisions of the bill requiring compliance with the labeling, providing for classifying pesticides for restricted use, in some cases requiring that they be applied by or under the supervision of a certified applicator, and in other cases requiring them to be subject to different regulatory restrictions are the key new authorities of the bill. (S. Rep. No. 92-838, 92d Cong., 2d Sess. 21 (1972)).

2. *Scope of Use Regulation.* The term "use" in this document and in subsequent PEPS is to be broadly interpreted and applied. The term "use" shall refer to any practice or act of handling or release of a pesticide, or exposure of man or the environment to a pesticide.

The term "use pattern" means the manner in which a pesticide is applied or otherwise used, particularly when considering such factors as (a) the target pest, (b) the crop or animals treated, (c) the application site, and (d) the application technique and rate.

The definition of the terms "use" and "use pattern" will be further clarified in the series of Pesticide Enforcement Policy Statements.

3. *Regulation of Pesticide Use: Meaning of section 12(a)(2)(G).* Considerable thought has been given to the meaning of the word "inconsistent" as it is used in FIFRA as amended. The reports of the committees which drafted the Act evidence repeated attempts by Congress to define the term and to anticipate the administrative construction which would be applied by the Agency. In the Supplemental Report of the Senate Committee on Agriculture and Forestry, Senator Allen noted:

> On the day that this bill is enacted it will become illegal to use any pesticide in a manner that is inconsistent with the labeling. The Committee on Agriculture and Forestry worked with the Environmental Protection Agency over a period of some weeks to see if there was not a better word than "inconsistent" but was unable to solve this problem (Supplement. Report to S. Rep. No. 92-838 51 (1972)).

In its deliberations on the 1971 version of what became the 1972 amendments, the House Committee on Agriculture "* * * recognize(d) the need to apply the standard of use 'inconsistent with respect to labeling in a common sense manner" (H.R. Rep. 92-511, 92d Cong. 1st Sess. 16 (1971)).

The Senate Committee on Agriculture and Forestry, while addressing the application of the term "use inconsistent with the label", noted that:

> This bill would regulate the use of a pesticide for the first time. * * * The Committee considered an amendment to the bill to assure that such use would not be prohibited, but concluded that this was a matter which would have to be left to the good sense of the Administrator, the manufacturers, and the users. It is the hope of the Committee that by proper administration of the labeling and the labels approved by him, the Administrator will be able to make it clear to users that such uses are not prohibited (S. Rep. No. 92-838, 92d Cong. 2d Sess. 16 (1972)).

Congress ultimately determined that the regulation of pesticide use presented problems of sufficient detail and sophistication that the precise substance of standards regulating pesticide use should be left to the informed discretion of the agency administering the legislation. This congressional deference to the discretion of the administrative agency is common in circumstances which involve determinations of a detailed and precise nature; Congress routinely delegates to administrative agencies the responsibility of making such regulatory determinations within the standard which Congress articulates and consistent with that broad public policy which formed the impetus for the legislation in the first place.

4. *Implementation of section 12(a)(2)(G).* The Agency's Implementation Plan for effectuating the 1972 amendments noted that section 12(a)(2)(G) of FIFRA became effective on the date of enactment. With regard to the enforcement of section 12(a)(2)(G), the Plan noted that:

> The Agency will entertain requests to issue pesticide use rulings on a case-by-case basis and furnish its interpretation of the Act. While such rulings will, after notice, be subject to revocation, they will assist the public in understanding the Agency's interpretation of the Act (39 FR 1142).

It is clear that discretion remains in the Agency to determine both whether a violation has occurred and whether an activity will subject a violator to enforcement liability. Mindful of the will of Congress in this matter and aware of its own public trust, the Agency has determined to treat these matters on a case-by-case basis, allowing the rule of reason to apply. It was

intent of the Administrator in instituting a case-by-case review of pesticide use cases to provide a mechanism for the development of a uniform national policy regarding the enforcement of section 12(a)(2)(G). This provision is the only provision of section 12 which was deemed to require specialized policy interpretation by the Agency.

In September 1974, the Office of Enforcement initiated the Pesticide Misuse Review Committee (PMRC) to review on a case-by-case basis all enforcement actions involving the misuse of a pesticide, and to address (by means of PMRC Advisory Opinions) general questions of pesticide use practice which require policy-level attention. The PMRC is comprised of personnel from the Agency's Office of Enforcement, Office of General Counsel and Office of Pesticide Programs.

The Agency has taken the position that any use of a pesticide in contravention of its label provision is, strictly speaking, a violation of the FIFRA and may subject the violator to civil or criminal sanctions. Notwithstanding this narrow construction of section 12(a)(2)(G), the Agency recognizes that the FIFRA, including section 12(a)(2)(G), must be administered in a manner which will achieve compliance with the statutory mandate without placing unreasonable or unworkable burdens upon producers and users of pesticides. The Senate Committee on Agriculture and Forestry expressed the hope that by the "proper administration of the labeling requirements," by "administrative interpretations of the law" and by the "labels approved by him," the Administrator will be able to make it clear to users which pesticide uses are and are not allowed. (Supplemental Report, S. Rep. No. 92-838 92d Cong. 2d Sess. 51, (1972)). In the course of its implementation of the 1972 amendments, and as a result of its experience with the PMRC, the Office of Enforcement has recognized the need to better inform the public regarding pesticide enforcement policy, and the remedies available to regulate pesticide formulation, distribution, use and application.

This narrow construction of section 12(a)(2)(G) will continue to be reflected in the Agency's pesticide enforcement policy except insofar as explicit and well-defined exceptions to this narrow construction are enumerated in the series of PEPS announced by this document. The Agency may, in the exercise of its prosecutorial discretion, announce in subsequent PEPS that specific pesticide applications or other uses which are not explicitly provided for on the approved product label may be performed without subjecting the applicator or user to prosecution.

III. *Solicitation of Public Comment.* The Pesticides Enforcement Policy Statements relate directly to internal Agency procedures and practice and constitute "interpretive rules" or "general statements of policy." As such, the Agency does not solicit public comment regarding matters published in this series of notices. However, interested persons may submit written comments regarding the policy set forth in this PEPS to the Pesticides Enforcement Division (EN-342), Office of Enforcement, Environmental Protection Agency, Washington, D.C. 20460. Three copies of the comments should be submitted to facilitate the work of the EPA and others interested in inspecting the document.

Dated: April 30, 1975.

ROBERT L. BAUM,
Acting Assistant Administrator for Enforcement.

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

OFFICE OF ENFORCEMENT

AUG 20 1975

To: Branch Chiefs
Enforcement Directors

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

Subject: "Water Purifiers"

I. Background:

In recent months the Agency has experienced a dramatic increase in activity relating to products which purport to purify water, to ensure clean water, to filter water, or to remove bacteria and other disease-causing microorganisms. While these "water purifiers" do not represent a new area of interest to the Agency, there being a history of enforcement actions relating to this class of products, the volume of recent activity is a departure. The detection of these products in greater numbers and their elevation to a level of greater Agency attention might be explained by broadened surveillance procedures adopted following passage of the 1972 FIFRA amendments and by the appearance on the market of these products in ostensibly greater volume as a result of current public interest in the safety of public drinking water.

Notwithstanding the Agency's willingness to register "water purifiers" which can be shown to be safe and effective, and the fact that some of these products have been registered, there may be a number of these products which qualify as pesticides by virtue of their claims and/or chemical construction that are being manufactured and sold without registration, and are thus in violation of the Act. Those "water purifying" products which qualify as devices are subject to the misbranding provisions of the amended FIFRA. Any violations relating to either of these categories of products should be dealt with in accordance with normal enforcement procedures which are reiterated in the section following:

II. Enforcement

1. Surveillance

Because of the acute public concern about drinking water safety following the release of results of EPA's National Drinking Water Survey of 80 cities, and the potential of that report to create increased business interest in the manufacture and distribution of "water purifying" products, special attention should be given to locating and examining these products for the purpose of determining whether they come under the jurisdiction of the Act, and if so, whether they are in compliance with all requirements.

2. Sampling

When a "water purifier" is discovered either at a distributor or in a producing establishment, it should be sampled (either physical or documentary) and the appropriate regional coordinator notified at headquarters. The regional office, the headquarters PED regional coordinator, and the Registration Division staff should jointly determine in each case: 1) whether the product qualifies as a pesticide or device, 2) if necessary, whether it is registered or properly branded, and 3) whether the sample complies with registration and/or other requirements.

3. Stop Sale

If the "water purifier" qualifies as a pesticide and it is not registered, or if it is a misbranded device, a stop sale should be issued against the producer or distributor establishment where the sample was obtained. If at the latter, the sample should be traced back to the producing establishment and a stop sale entered there as well. A stop sale order pursuant to the provisions of section 13(a) of the Act may be entered on the basis of nonregistration or misbranding against the product at any producer or distributor establishment.

4. Testing and Recall

Immediately upon determination of non-registration of any "water purifier" deemed subject to the jurisdiction of the Act as a pesticide, or upon finding any "water purifier" which qualifies as a device, the product sample should be forwarded for chemistry, efficacy, and safety testing. We have been advised by the Technical Services Division, OPP, that the facilities at either Beltsville, Maryland or the Mississippi Test Facility, Bay St. Louis, Mississippi, are preferable for this type of chemistry analysis.

The Beltsville laboratory can perform efficacy and safety testing. Coordination between the regional office and the appropriate laboratory supervisor is important. Dr. Ronald Davis, Beltsville laboratory, (301) 344-2187, should also be contacted prior to forwarding samples to Beltsville for efficacy and safety testing.

A finding that the product is ineffective or dangerous may result in the need to institute recall procedures by the manufacturer. Any consideration of recall should be made in strict accordance with the procedures of Section 12 of the Case Proceedings Manual and with the full knowledge of the headquarters PED regional coordinator.

5. Other Enforcement Action

Where a "water purifier" registration or misbranding violation has occurred, Agency officials may consider the usual range of enforcement sanctions including a notice of warning pursuant to Section 9(c)(3) of the Act, a Section 14(a)(1) civil complaint or a criminal referral under Section 14(b).

III. Interim Standards

The Registration Division, Office of Pesticide Programs has developed an "Interim Standard for Water Purifiers." This document, a copy of which has been sent to each Region, will aid Agency officials and the public in clarifying questions regarding the applicability of FIFRA to certain categories of these "water purifying" products and the standards which those qualifying as pesticides must meet for registration.

JUN 18 1975

This document sets forth interim standards which will be used in evaluating applications for registration of water purifiers under the Federal Insecticide, Fungicide and Rodenticide Act, as amended as administered by the Environmental Protection Agency.

INTERIM STANDARDS FOR WATER PURIFIERS

I. There are three Federal Laws which must be conformed with when the treatment of drinking water is under consideration. They are: (1) The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (Public Law 92-516); (2) The Safe Drinking Water Act (SDWA) (Public Law 92-516), and (3) The Food Additives Amendment of the Federal Food, Drug, and Cosmetic Act (Section 409). Both the FIFRA and the SDWA are administered by the Office of Water and Hazardous Materials and the Office of Enforcement of the Environmental Protection Agency (EPA). The Federal Food, Drug, and Cosmetic Act is administered by the Food and Drug Administration, Department of Health, Education and Welfare.

II. It has been held that products represented to purify, filter or ensure clean water, correct bad water or give pure drinking water or cooking water, constitute representations that they will remove bacteria and other disease-causing microorganisms. Thus, water purifiers sold under labeling with or without representations of efficacy against bacteria or other harmful microorganisms are identified as "pesticides" or "devices" as those terms are defined in the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. [Ref: Giant Food, Inc. VS. Federal Trade Commission, Docket 7773, 322 F 2d, 997 (1963).] Based upon this legal decision, any chemical or device represented by statement or implication to be a water "purifier", or to provide "pure", "potable", or "safe" drinking water is subject to provisions of the three

laws cited above. Also, any product, or device containing a substance which has no known value other than pesticidal, will automatically be considered a "pesticide", subject to regulation by the Environmental Protection Agency under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended.

Products or devices which are intended or represented solely to remove odors, chemicals, debris, coloration, or any substance other than those identified as "pests" in the FIFRA, as amended, and do not contain a pesticide are not subject to regulation under this law. They may, however, be subject to regulation under other Federal Laws. Products of this type cannot be represented by statement or implication as "water purifiers." They may be represented as water "clarifiers," "filters," "deodorizers," (or other terminology deemed by EPA not to be a pesticidal representation).

III. Based upon the Interim Primary Drinking Water Standards published by the Environmental Protection Agency (FR, Vol. 40, No. 51 - Part II, Friday, March 14, 1975), municipal drinking water must be potable from both a microbiological and chemical standpoint. The use of so-called water "purifiers" such as treated filters, or physical filters on municipally treated tap water for the purpose of rendering microbiologically potable water more "potable" is grossly misleading to the consumer. Such devices actually trap the few bacteria (at a contaminant level permitted in accordance with USPHS Standards for Drinking Water) that may be present in treated tap water, causing them to accumulate, grow, and concentrate. From a microbiological standpoint, these devices are actually potentially more

detrimental than beneficial to human health; and present a potential health hazard which would not exist if they were not used.

It is well recognized that potable municipal drinking water from the tap must have the chemical purity set forth in the Proposed Interim Standards for Primary Drinking Water as referred to earlier. Since implementation of portions of the Safe Drinking Water Act dealing with the removal of chemical contaminants and/or impurities (other than microorganisms) from municipal water supplies will not be immediate, the use of untreated coarse filters, clarifiers, or deodorizers may be desirable from the standpoint of improving the chemical quality of drinking water received from the tap. It must be emphasized that devices of this type are not subject to the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, but may be subject to regulation under other Federal Laws.

IV. There are instances where chemically and/or microbiologically impure raw water may be the only available source of supply; eg. (1) in certain rural areas where it may be routinely used, and (2) as an emergency source of supply for campers, hikers, hunters, tourists, etc. In such instances, the treatment of this raw water is essential to render it potable from both a microbiological and a chemical standpoint.

The use of pesticidal filters (or water-purifiers) on raw waters of the types described above must be demonstrated to be efficacious and safe according to the requirements outlined below. The only difference in the registration requirements for the treatment of raw water on a routine

basis in rural areas, and the temporary emergency use described above will be the necessity for an adequate monitoring system when the treatment involves raw water on a routine basis.

V. At the present time, numerous types of water filters incorporating silver as an antimicrobial agent are being marketed and advertised widely throughout the country. The following reference summarizes the status of this chemical when used as an antimicrobial additive. "The use of silver as a drinking water disinfectant has been much more popular in Europe than in the United States, and a voluminous literature is available on its application to water disinfection. A comprehensive review of the subject has been published in two papers by Zimmerman (1952), and in a recent paper by Woodward (1963). Additional information on its oligodynamic action, chemistry and types of products available can be found in Chapter 24. Generally, the literature on the effectiveness of silver in water disinfection is confusing and rather contradictory. This confusion is in part a reflection of the variations in test procedures and, in some cases, the result of failure to use a neutralizing agent in the reported tests. Inability to recognize or appreciate some of the unique properties of silver also has contributed to discrepancy.

The marked tendency of silver to adsorb onto surfaces can seriously interfere with bacteriologic tests of its effectiveness. This property of silver has been carefully studied by Chambers and Proctor (1960).

The low concentrations of silver used or suggested for use in water disinfection necessitate the use of a very sensitive and accurate analytical procedure for measuring silver concentrations. A number of procedures have been employed (Feigl, 1928; Chambers, Proctor and Kabler, 1962;

Uman, 1963; Lombardi, 1964), but a really satisfactory technique has not yet been developed." [Ref. Lawrence and Block, Disinfection, Sterilization and Preservation, 1963, Lea Febiger, Philadelphia, Pa.].

VI. Assuming that the water purifying devices (referred to in V. above) can be demonstrated to be both safe and efficacious, the only warranted claims for such products based on the chemical and microbiological tests herein described are essentially as follows:

1. This product (or device) has been thoroughly tested to insure that the silver concentration in the drinking water will never exceed the maximum level of 50 parts per billion allowed for potable water.
2. This product has been thoroughly tested to demonstrate that it meets the standards for providing microbiologically potable water under stringent conditions against Escherichia coli.

Claims differing in essence from the above far exceed those supportable by the requirements outlined herein and in the Public Health Service Drinking Water Standards (1962) which are currently being implemented, and such claims are, therefore, not permitted on labeling or in advertising of water purifiers unless additional evidence of effectiveness is submitted, evaluated, and found to fully substantiate such added claims of effectiveness.

VII. Requirements to support claims permitted in VI. (1) and (2), above, are as follows: Since there is currently no known "standard" raw water,

for the purposes of standardization and uniformity, dechlorinated, sterilized tap water will be used in the laboratory testing of treated filters (water purifiers). A chemical analysis of this test water must be submitted together with the results of testing. Additional evidence of performance and/or efficacy of these treated filters, using raw water may also be meaningful provided the raw water used in such tests is chemically defined.

The consumer cannot be expected to have the capability of performing a chemical analysis on the raw water he may be forced to use. Therefore, those water purifiers which require any limitations on the chemical content of raw water (eg., chlorides, sulfates, iron, turbidity, pH, hydrogen sulfide, etc.) to insure effectiveness which cannot be readily determined by sensory perception are impractical misleading, unwarranted, and unacceptable for registration.

A. Chemical Analysis for Silver Concentration in Treated Drinking water. (This test is designed for the sole purpose of determining the silver content of the effluent water after treatment).

1. Chemical analysis for silver must be performed by the Atomic Absorption Method on at least ten different complete units, each representing a different batch preparation of the silver-impregnated filtering medium.

2. Tap water must be used to challenge each unit.

3. The unit must be challenged intermittently (to include an 8 to 10 hour non-use or stagnation period) and the effluent sampled (and immediately analyzed) at frequently defined intervals (recorded as water volume) during the expected lifetime of the filters (as represented by the manufacturer) to determine any variations in concentrations of the silver present in the effluent. The flow rate utilized must be specified, and the total volume of water filtered to demonstrate the "lifetime" of the filter must be provided.
4. Parameters such as pH and temperature of the water before and after treatment must be provided.
5. The requirement for conducting a silver analysis immediately after sampling is <u>mandatory</u> because of the unique property of silver to quickly absorb into the surfaces of the collecting containers.
6. Unless disposable equipment is used in the chemical analyses for silver, as well as the bacteriological tests, all equipment to be re-used must be treated to remove adsorbed silver as follows. (See attached "Notes" for procedural suggestions.)

When the chemical analyses of the effluent water have demonstrated that the maximum allowable concentration of silver (50 ppb) released by the treated filter has not been exceeded during the life of the filter, the bacteriological assays outlined in (B) below should be undertaken.

B. Bacteriological Assays. (This test is designed for the sole purpose of determining the bacteriological efficacy of water purifiers). Escherichia coli has been selected as the test microorganism because it is the commonly recognized indicator organism prescribed in the United States Public Health Service Drinking Water Standards of 1962.

1. Bacteriological assays will be conducted on samples of the intermittent effluent collected at the beginning, middle, and end of the represented lifetime of the filter, on three separate units.
2. Dechlorinated, sterilized tap water seeded with Escherichia coli (ATCC 11229) at a concentration of 200,000 to 300,000 microorganisms per ml must be employed in the test. This inoculum level must be determined by actual plate count using Bacto-Tryptone Glucose Extract Agar as the plating medium, and the results submitted. This artifically "contaminated" water should be prepared from a 24-hour nutrient agar slant of the test organism and 100 ml of this inoculum reserved as a control.

3. The effluent must be sampled at the three prescribed intervals, after a holding period recommended by the manufacturer.
4. The flow rate, pH, temperature, and silver ion concentration of the water effluent must be determined at each test interval, and included in the results reported.
5. Bacteriological assays should be conducted on two one hundred ml samples at each interval. To the two samples and the control add 1.0 ml of a sterile neutralizing solution containing 5% sodium thioglycollate and 7.3% sodium thiosulfate (according to directions on the label with respect to the holding period).

Both the filtered neutralized (test) water and the neutralized, unfiltered, inoculum (control) must be tested by the Fermentation Tube Test (as outlined in the Standard Methods for the Examination of Water and Waste-water, American Public Health Association, Inc., 1740 Broadway, New York, New York 10019). Both the MPN ("most probable number"), and an actual dilution plating of the test and control waters must be conducted. In conducting these tests, lactose

broth should be used for the fermentation tube tests; and plate counts should be made using Difco Tryptone Glucose Extract Agar (TGE). Since pure cultures are to be used in these laboratory tests, no differentiating medium is necessary. If naturally contaminated raw water is tested, appropriate differential and confirmatory media must be employed.

It should be clearly understood that both the chemical and bacteriological tests outlined in A. and B. above may also be conducted by the Environmental Protection Agency Laboratories, but only after submission by an applicant of satisfactory test results. These results may require confirmation by EPA Laboratories before a final decision can be reached concerning registration.

NOTE: The standards outlined herein are tentative, as indicated by the title. Final standards which may or may not differ from these will ultimately supersede this document.

NOTES

Ag Sample Containers (Use and Cleaning)

I. Sample Collection (18 x 150 capped soft glass test tubes).

1) Collect approximately 15 ml of sample in the test tube.

2) As soon as possible add three drops of concentrated HNO_3 to the sample and cap.

3) Invert test tube 3 or 4 times to mix sample and conc. HNO_3.

4) Sample is now ready for AA analysis of Ag^+.

Note: Always collect at least two samples for analysis.

II. Cleaning procedure (only for test tubes which have been used with HNO_3 to inhibit Ag adsorption).

1) Soak 18 x 150 soft glass test tube in 3% NH_4OH for 30 min.

2) Using test tube wash rack wash in Hobart Laboratory Washer as described by washer manufacturer.

If the test tube has been used to collect a Ag sample without the use of HNO_3, use the following procedure prior to the NH_4OH soak.

1) Fill test tube with conc. HNO_3 and allow to soak 5 min.

2) Discard this HNO_3.

3) Repeat Step 1 two additional times.

4) Then go to NH_4OH soak as described previously.

Cleaning Procedure for flasks used in Ag-Bac-T Kill Tests (250 ml Erlenmeyer).

1) Add ~25 ml of conc. HNO_3 to flask.

2) Swirl manually or mechanically for five minutes. Make sure entire wetted surface is contacted by the HNO_3.

3) Discard this HNO_3.

4) Repeat Step 2 two additional times.

5) Soak flask in a 3% HNO_3 solution for 30 minutes.

6) Soak flask in a 3% NH_4OH solution for 30 minutes.

7) Wash in Hobart Laboratory Washer as described by manufacturer.

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

MAR 15 1976 OFFICE OF ENFORCEMENT

Subject: Guidance for Enforcement Actions Involving Water Purifier Products

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

To: Enforcement Division Directors
Pesticide Branch Chiefs

Background

On August 20, 1975, the Pesticides Enforcement Division issued guidance to all Enforcement Division Directors and Pesticide Branch Chiefs concerning water purifiers. Subsequently, at the direction of the Assistant Administrator for Enforcement, this policy was modified by telephone to provide for a hazard review prior to imposition of a stop sale. This policy, applying to both intra and interstate water purifiers, was formalized by memorandum of the Assistant Administrator on January 19, 1976. It is anticipated that PEPS #3, dealing with the phased implementation of section 3 of the Act, will be published shortly. This PEPS establishes a general procedure and policy for dealing with nonregistered intrastate products consistent with the water purifier policy as modified.

The following represents a compilation and summarization of policy and procedures as they have developed to date with respect to water purifier products. This guidance should suggest a pattern generally consistent with your present program activities and is intended to provide a clarification and collection of existing policy.

Policy:

In the exercise of its prosecutorial discretion, the Agency has determined to allow a narrow category of water purifier products which qualify as pesticides under the Act but which have never been registered federally or by the states to continue in commerce pending section 3 registration or denial of registration, provided all the following conditions are satisfied:

1) producer or distributor can show no knowledge of the applicability of the FIFRA registration requirements;

2) use pattern and formulation of the product in question are substantially similar to EPA registered products, provided no ingredients have been cancelled or suspended and no residues result which exceed stated standards for drinking water;

3) minimum labeling and packaging requirements as provided by 40 C.F.R. §162.17(f) are met;

4) application for federal product registration is made within 60 days after notice of the requirement and pursued in good faith; and

5) the product is produced in an establishment registered pursuant to the requirements of section 7 of the Act, or for which application is submitted within ten (10) days after notice of the requirement.

Procedure:

1) Sampling - When a water purifier is discovered either at a distributor or in a producing establishment, it should be sampled (either physical or documentary) and the appropriate regional coordinator at headquarters notified and supplied with the following information:

a. the name of the product;
b. the claims made for the product;
c. the ingredients of the product, if stated on the label or if obtained from other sources;
d. the use directions of the product (in summary);
e. the name and address of the producer;

f. information relevant to a determination that the producer or distributor had prior knowledge that the product was required to be registered, including: 1) contact with the regional office, including inspectional staff, concerning the product in question or a similar product; 2) contact with the Registration Division, including the filing of an application for registration; 3) contact with Pesticides Enforcement Division concerning establishment registration or other enforcement matters concerning the product at issue or a similar product; and
g. any other information that may be useful in reviewing the product.

The coordinator should also be informed as to whether or not a registration packet should be mailed to the firm by the Registration Division.

The inspector should inform the producer (directly when sampling at a producing establishment or by tracing back when sampling at a distributor) of the Agency's general policy with regard to these products and of his obligation to pursue registration under sections 3 and 7 of the Act. The inspector should provide the registrant with necessary information for him to proceed to apply for product and establishment registrations and should inform him of his obligation to pursue both registration activities in good faith upon receipt of further instructions. [This information should be supplied even though the section 3 knowledge determination may not yet have been made.]

2) Stop Sale Where a water purifier does not meet the terms specified by the Agency in the exercise of its prosecutorial discretion, detailed above, a stop sale should be imposed against the violative product. Where such products are initially located and stop saled in the chains of distribution, follow-up action should be taken to locate the producer of the product for imposition of a stop sale at that location also. Stop sales should also be issued to any additional distributors who, through routine surveillance activities, are found to be selling a product which has been stop saled at the producer.

3) Follow-up Should the producer of a stop-saled water purifier product be able to show, subsequent to the stop sale action, that he can meet the conditions for this interim stop sale exemption, or that he can modify labeling to avoid classification as a pesticide or device, the stop sale may be vacated. Conversely, if a product is initially determined to meet the conditions for the stop sale exemption but later found not to meet these conditions, a stop sale should then be issued.

In any case where the exemption is permitted, follow-ups should be made periodically to determine whether registration activities are being pursued in good faith. The first such follow-up should occur shortly after the initial visit. If it is determined that a producer has not pursued either section 3 or 7 registration in good faith, a stop sale should be imposed. Vacation can be considered if meaningful registration activity is resumed by the producer.

4) Other Enforcement Actions - All producers of unregistered water purifiers who had no prior knowledge of the requirement to obtain federal registration, and who filed an application for registration within 60 days after being informed of this requirement, or who cease the sale and distribution of water purifiers, shall be issued a section 9 (c)(3) letter of warning. All other producers shall, in addition to a stop sale action, be subject to the penalties provided under section 14 of the Act.

Conclusion:

Notwithstanding the prospect that issuance of stop sales in this area may be substantial, at least until producers take steps adequate to qualify for stop sale exemption, PED is of the view that the policies and procedures set forth here represent a viable and equitable accomodation of the needs of water purifier produers and distributors with the obligations of the Agency to regulate pesticides in a manner which insures the public safety.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENFORCEMENT
OFFICE OF GENERAL ENFORCEMENT
PESTICIDES ENFORCEMENT DIVISION

PESTICIDE ENFORCEMENT POLICY STATEMENT NO. 3

CERTAIN ENFORCEMENT POLICIES TO BE FOLLOWED DURING THE PHASED IMPLEMENTATION OF FIFRA SECTION 3

Reprinted from the Federal Register of April 1, 1976
(41 FR 13984)

federal register

THURSDAY, APRIL 1, 1976

NOTICES

PESTICIDE ENFORCEMENT POLICY STATEMENT NO. 3

Certain Enforcement Policies To Be Followed During the Phased Implementation of FIFRA Section

I. General Background

On May 5, 1975, the Environmental Protection Agency (EPA) published in the Federal Register a document entitled "Institution of Enforcement Policy Statements" (40 Fed. Reg. 19526). It was the Agency's purpose in instituting this series of Pesticide Enforcement Policy Statements (PEPS) to inform the general public and persons engaged in the formulation, distribution, sale, application, or other use of pesticides of the policies adopted by the Agency in the enforcement of the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended in 1972 and 1975 (P.L. 92-516, 86 Stat. 973; P.L. 94-140, 89 Stat. 751; 7 U.S.C. 136 et seq.; hereinafter referred to as FIFRA). PEPS are published by EPA's Office of Enforcement. Unless otherwise expressely provided, a PEPS indicates how the Agency will exercise its prosecutorial discretion, and does not interpret the law or otherwise define what is and what is not lawful conduct under FIFRA. A detailed explanation of the purpose and scope of the PEPS series was set forth in the May 5, 1975, Federal Register notice.

On July 3, 1975, the Agency promulgated regulations governing registration, reregistration and classification procedures pursuant to FIFRA section 3 (40

Fed. Reg. 28242). The section 3 regulations became effective on August 4, 1975.[4] The regulations prescribe procedures and policies governing the Federal pesticide registration program, and are designed to implement the significant changes to that program which were mandated by Congress in the 1972 amendments. The Agency has attempted to implement these significant changes in a common sense manner causing minimum disruption to pesticide manufacturers, distributors, and users, while at the same time accomplishing the changes required by Congress. Accordingly, the Agency has provided for a period of phased implementation of the new requirements. This PEPS addresses several important problems which have arisen during the phased implementation of the modifications to the Federal registration program, and indicates the policies which the Agency will follow in these areas during the implementation period. Specifically, this PEPS:

1. Resolves certain questions which have arisen concerning the authority of States under FIFRA to authorize the distribution, sale or other movement in commerce of pesticide products through actions taken under state law, including State registration of pesticide products. [Part II]

2. Identifies classes of pesticide products which were not Federally registered on August 4, 1975, and delineates the circumstances under which enforcement discretion will be exercised under section 12(a)(1)(A) of FIFRA to permit the continued movement in commerce of certain classes of these pesticide products pending final action regarding their registration under FIFRA. [Part III]

3. Delineates the circumstances under which enforcement discretion will be exercised under section 12(a)(2)(A) of FIFRA to permit a Federally registered pesticide product to be converted to a State registered product, other than by repackaging the Federally registered pesticide product. [Part IV].

As stated in the document announcing the inception of the PEPS series, the policies announced in a PEPS will remain in effect until amended or modified by subsequent PEPS or by subsequent regulations promulgated by the Administrator. Because the policies announced in Parts II and III of this PEPS pertain only during the phased implementation of the modifications to the federal registration program, the enforcement policies announced in Parts II and III of this PEPS will remain in effect only until the completion of the reregistration process, unless amended or modified in the manner described above prior to that date.

Finally, the Agency cautions that producers and distributors of pesticide products are subject to numerous requirements under other provisions of FIFRA and regulations promulgated thereunder, which are beyond the scope of this PEPS. These other requirements include, without limitation, the following:

1. recordkeeping requirements [FIFRA section 8; 40 CFR Part 169];

2. requirements that EPA inspectors be given access to establishments and records [FIFRA sections 8 and 9].

3. prohibitions against violations of stop sale, u.e. removal or seizure orders issued under FIFRA section 13 [FIFRA section 12(a)(2)(I)];

4. prohibitions against violations of any suspension or cancellation order issued under FIFRA section 6. [FIFRA sections 12(a)(2)(J) and 12(a)(2)(K)], (and)

5. prohibitions against falsification of records [FIFRA section 12(a)(2)(M)]

II. Authority of States To Register Pesticides Under FIFRA[5]

The 1972 amendments to FIFRA significantly broadened the Federal requirement for registration of pesticides by making it unlawful 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 (which is not registered pursuant to FIFRA) [FIFRA, sections 3(a)(1) and 12(a)(1)(A)] (emphasis added)

Previously, the Federal registration requirement had only applied to pesticides in *interstate* commerce. It is clear from the legislative history that extension of [Fed]eral pesticide regulation "* * * to [operati]ons entirely within a single State" [H. Rep. No. 92-838, 92d Cong., 2d Sess. 1 (1972)] was one of the most important aspects of the new legislation. The House Committee on Agriculture noted in its first paragraph comparing the 1972 amendment with the prior legislation, that:

> The amendments [to FIFRA] * * *, which is a registration and labeling law, would extend the regulation of pesticides to their manufacture and use, and Federal regulatory authorities would apply throughout the States, not just to the interstate commerce of pesticides [H. Rept. No. 92-511, 92d Cong., 1st Sess., 12 (1971)].

The Senate Committee on Commerce noted that, while prior to 1972 FIFRA did not "regulate pesticides moving solely in intrastate commerce," the 1972 amendments would require "that all pesticides moving in interstate or intrastate commerce be registered with EPA" [S. Rept. No. 92-970, 92d Cong., 2d Sess. 8 (1972)].

In addition to the extension of the Federal registration requirement to products sold and distributed exclusively in intrastate commerce, the 1972 amendments prohibit a State from permitting [the] sale or use prohibited pursuant to [FIF]RA, by actions taken under its own law. This prohibition is found in section 24(a) of FIFRA. The combined effect of the establishment of a Federal registration requirement, and the creation of the section 24(a) prohibition was to eliminate the authority of a State to register or otherwise authorize the movement [in] commerce of a pesticide product which was not already registered by EPA.[6] This extinguishment of State authority to authorize the movement in commerce of pesticide products which were not Federally registered did not, however, become effective immediately upon the enactment of the 1972 amendments to FIFRA. Rather, it became effective on August 4, 1975, the effective date of the regulations which the Agency promulgated to implement section 3 of the 1972 amendments.

In order to provide for an orderly transition to the new registration requirements, section 162.17 of the section 3 regulations established special provisions regarding intrastate pesticide products which had valid State registrations on August 4, 1975. Section 162.17 provided that registrants of such products could submit, within 60 days of the *effective date of the section 3 regulations*, a notice of application for Federal registration. Products with respect to which such a notice was filed within the time prescribed were allowed to remain in commerce pending final decision either approving or denying Federal registration subject to certain conditions discussed in more detail below. In addition, section 162.17(b) specifically permitted states to renew the State registration of a product which had a valid State registration on August 4, 1975, and with respect to which notice of application for Federal registration was filed on or before October 3, 1975.

Section 24(c) of FIFRA gives the Administrator authority to give back to States some of their authority which was extinguished on August 4, 1975. Section 24(c) authorizes the Administrator to certify a State to register pesticides for "special local needs", upon finding that the State is

> capable of exercising adequate controls to assure that [registrations issued by it] will be in accord with the purposes [of FIFRA].

Proposed regulations to implement section 24(c) were published in the Federal Register on September 3, 1975 (40 Fed. Reg. 40538). The Agency is currently in the process of evaluating comments which were received, and preparing final regulations. The preamble to the proposed regulations announced an interim section 24(c) certification program, which would be in effect during the time period necessary to promulgate final section 24(c) regulations and certify States pursuant to the final regulations. A number of States [illegible]

[4] The final section 3 regulations were published in the Federal Register on July 3, 1975 (40 Fed. Reg. 28242), and became effective on August 4, 1975, in the sense that after that date they governed Agency action regarding pesticide registration matters. However, pursuant to section 4(a) of the 1972 Amendments, enforcement action could not be taken for violations of requirements effectuated by the new regulations until 90 days after the date of publication, i.e., October 3, 1975.

[5] This part of PEPS No. 3 presents the Agency's legal interpretation of the effect of the 1972 amendments and the implementing regulations on the authority of States to register pesticide products, or otherwise authorize the movement of a pesticide product in commerce. As indicated above, PEPS generally describe how the Agency will exercise its prosecutorial discretion under FIFRA. Except in rare instances, a PEPS does not interpret the law or otherwise prescribe what is and what is not lawful conduct under FIFRA. As in this instance, any portion of a PEPS which interprets the law will be accompanied by an express indication that the portion is in fact interpretive. All interpretive portions of a PEPS have the [illegible] of the Agency [illegible]

[6] The section 3 regulations define "pesticide product" as "a pesticide offered for distribution and use, and include[ing] any labeled container and any supplemental labeling." [40 CFR 162.3(hh)] Accordingly, any change in the label or labeling of a Federally registered pesticide product creates a different pesticide product, which is not a Federally registered pesticide product. Section 24(a) therefore extinguished State authority to supplement Federal registrations by adding uses, because in so doing the States would be permitting the distribution of a pesticide product not registered pursuant to FIFRA, and thereby would be permitting the distribution of a pesticide product prohibited under FIFRA. Additionally, section 24(a) prohibits States from authorizing uses which are inconsistent with the Federally registered label, since by so doing the State would be authorizing a use prohibited under FIFRA.

Certification to issue special local needs registrations pursuant to section 24(c).

Finally, it is important to note that section 24(a) of FIFRA expressly authorizes State regulation of the sale or use of pesticides, *provided that such regulation does not permit any sale or use prohibited by FIFRA.* This authority clearly permits a State to register or otherwise regulate the distribution or use of pesticide products which have been registered pursuant to FIFRA.

In summary, after August 4, 1975 a State may register or otherwise authorize the intrastate sale, distribution or other movement in intrastate commerce of the following types of pesticide products:

1 A pesticide product which had a valid State registration on August 4, 1975, and with respect to which a notice of application for Federal registration was filed before October 3, 1975;

2 a pesticide product for a special local need, provided that the State has been certified pursuant to FIFRA section 24(c), to issue the type of special local need registration concerned; and

3 a pesticide product which has a valid EPA registration pursuant to FIFRA.

III. Enforcement Status of Non-Federally Registered Products During Phased Implementation of FIFRA Section 3.

A. General

Section 12(a)(1)(A) of FIFRA makes it unlawful 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 which is not registered [pursuant to FIFRA].

Persons who violate this provision are subject to enforcement liability under FIFRA. The Agency will review each alleged violation and will assign enforcement liability to any person (as defined by FIFRA) out of whose action or failure to act the violation arose. Upon a finding of enforcement liability the Agency may take the following types of enforcement actions under FIFRA: (1) Issuance of notices of warning under FIFRA section 9(c)(3) in the case of minor violations, (2) commencement of civil or criminal proceedings under FIFRA section 14, (3) issuance of stop-sale orders, stop-use orders, or removal orders under FIFRA section 13(a), or (4) commencement of proceedings in an appropriate Federal District Court (a) specifically to enforce the Act or to prevent and restrain violations of the Act [FIFRA section 16(c)], or (b) to seize or confiscate pesticides which violate specified provisions of the Act [FIFRA section 13(b)].

B. Categories of Non-Federally Registered Products, and Their Enforcement Status During Phased Implementation of FIFRA Section 3

1. Pesticide Products Manufactured Formulated for the First Time After August 4, 1975

Products in this category are those created for the first time after the effective date of the new section 3 regulations. The guiding concept behind the Agency's policy of phased implementation of the new registration requirements is to disrupt as little as possible the manufacture and distribution of products which were in commerce before the effective date of the new requirements, consistent with the Agency's discharge of its augmented responsibilities under FIFRA. This policy has no applicability to pesticide products manufactured for the first time after August 4, 1975. Accordingly, the Agency will take enforcement action against any person distributing, selling or otherwise moving in intrastate or interstate commerce any pesticide product manufactured for the first time after August 4, 1975.

2. Pesticide Products Manufactured or Formulated for the First Time Prior to August 4, 1975

a. Pesticide Products Distributed, Sold or Otherwise Moved in Interstate Commerce Before August 4, 1975.

Pesticides products in this category were subject to the Federal registration requirement before August 4, 1975. The changes in the requirement for Federal registration effected no change in the status of these products under FIFRA. Accordingly, the policy of phased implementation of the changes in the Federal registration requirement has no applicability with respect to products in this category, and the Agency will in most circumstances take enforcement action against any person distributing, selling or otherwise moving any such products in interstate or intrastate commerce.

b. Pesticide Products Distributed, Sold or Otherwise Moved Solely in Intrastate Commerce Before August 4, 1975 ("Intrastate Products")

(1) Intrastate Pesticide Products Which Had Valid State Registrations on August 4, 1975, Or Had Otherwise Received Permission To Be Distributed Or Otherwise Moved in Intrastate Commerce, Pursuant to Other Procedures Authorized by State Law.

Section 162.17(a) of the section 3 regulations authorized persons (including State and Federal agencies) who held valid State registrations for pesticide products on August 4, 1975, *to submit*, within 60 days (i.e., by October 4, 1975), notices of application for Federal registration. In practice, the Agency has extended this same opportunity to persons (including State or Federal agencies) who had on August 4, 1975 valid permission pursuant to other procedures authorized by State law (e.g. the California "use variance" procedure) to distribute, sell or otherwise move a pesticide product in intrastate commerce or to use a pesticide product within a State in a manner inconsistent with its approved labeling.

Pursuant to section 162.17, the timely filing of a notice of application with respect to a product in this category has important consequences on the status of the product during the implementation period. Specifically, section 162.17(a) allows the distribution or sale of the product in intrastate commerce pending a final decision on the Federal registration application, provided that the product satisfies certain minimum requirements in areas such as labeling and packaging. These minimum requirements are set out in section 162.17(f) of the section 3 regulations, and are restated below in this PEPS.*

As noted, section 162.17(a) only authorizes the distribution or other movement in intrastate commerce of qualifying state registered products, with respect to which notices of application for federal registration were filed by October 4, 1975. In the exercise of its prosecutorial discretion, the Agency will generally not take enforcement action under section 12(a)(1)(A) against persons shipping, distributing or moving in interstate commerce an intrastate product which otherwise satisfies the requirements of 40 CFR section 162.17, provided that the product is intended for distribution for use or sale for use only within the State where the product is registered.

Intrastate pesticide products with valid State registrations or other valid State authorizations on August 4, 1975, with respect to which notices of application for Federal registration were *not* timely filed cannot lawfully be distributed, sold or otherwise moved in interstate or intrastate commerce in view of the fact that special procedures were included in the section 3 regulations to provide for a smooth transition to the new requirements for products in this class, there is no basis for exercising enforcement discretion with respect to those products for which the special procedures were not followed. Accordingly, the Agency will institute enforcement proceedings against persons distributing, selling, or otherwise moving in intrastate or interstate commerce pesticide products which had valid State registrations or other valid State authorizations on August 4, 1975, but for which no timely notice of application for Federal registration was filed.

(2) Intrastate Pesticide Products Which Were Subject to State Requirements, But Which Did Not Have Valid State Registrations or Other Authorizations Required Under Applicable State Law on August 4, 1975

Intrastate pesticide products in this class were being distributed or otherwise moved in intrastate commerce illegally on August 4, 1975, under applicable State laws. Sound principles of comity between State and Federal governments alone militate against exercise of enforcement discretion with respect to such products. Therefore, enforcement action will be taken against any person distributing, selling or otherwise moving any such product in interstate or intrastate commerce.

(3) Intrastate Products Classified as Pesticides Under FIFRA, But Not Subject to State Registration Requirements.

Certain pesticide products which were distributed, sold or otherwise moved solely in intrastate commerce before August 4, 1975 are considered to be pesticides under FIFRA, but were not subject to registration or other authorization requirements under applicable State law. Depending upon the State concerned, such products may include certain disinfectants, sanitizers, pesticide-fertilizer blends and products containing antimicrobial agents intended for the purification of drinking water (sometimes referred to as "water purifiers").

On September 17, 1971, in a Federal Register notice entitled "Notice Concerning Federal Requirements for Registration-Intrastate Pesticides," 139 Fed. Reg. 33935, the Agency stated that

[s]hipment of such pesticides (products which are defined as pesticides under FIFRA, but which were not legally required to be registered under applicable state law) in the absence of final Federal registration will be in violation of FIFRA after the effective date of the regulations under section 3.

* As provided in the section 3 regulations, persons using a product in this category in a manner inconsistent with its labeling are subject to enforcement liability under FIFRA section 12(a)(2)(G). See 40 CFR 162.17(f).

This prohibition was included in the section 3 regulations, and is now codified at 40 CFR 162.17(c):

> Products currently being shipped, distributed, and sold solely within intrastate commerce and which are not legally required to be registered under State law must meet the registration requirement of the Act if the product is a pesticide * * *. 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 any such product until the product has been finally registered [pursuant to FIFRA].

However, under the policy announced in the September 17, 1974, Federal Register or otherwise authorized under 162.17 of the section 3 regulations, producers of products not required to be registered or otherwise authorized under applicable State law were not afforded the opportunity of filing notices of application for Federal registration, and continuing to distribute the product pending final action on their Federal registration applications. As indicated in section 162.17(c), it is now illegal to distribute, sell or otherwise move any such products in interstate or intrastate commerce, unless they are registered pursuant to FIFRA.

One of the fundamental assumptions underlying the decision not to make the notice of application procedure available to these products was that it was not possible to make informed judgments concerning whether these products as a class generally satisfied minimum standards in such areas as labeling, packaging and product formulation, because they had never been subject to any registration requirement. Another key assumption underlying the approach taken with respect to these products was that it would be possible to process applications for Federal registration of such products under the 1947 FIFRA prior to the effective date of the section 3 regulations. Thus, one of the primary purposes of the September 17, 1974 Federal Register notice was to alert producers of products in this class to obtain registrations under the 1947 FIFRA prior to the effective date of the section 3 regulations.

Many producers of products in this class are small businesses, and apparently in some instances notice of the requirement to obtain Federal registration before the effective date of the section 3 regulations was not received. Strict enforcement of section 12(a)(1)(A) with respect to products in this class would be seriously disruptive, if not fatal, to these small businesses. Moreover, the Agency believes that some products in this class meet minimum standards in such areas as labeling, packaging and formulation, and pose no greater hazard to man or the environment than other products which are being allowed to remain in commerce pending a full review of and final decision on applications for Federal registration. Accordingly, while the distribution, sale, or other movement in intrastate or interstate commerce of products in this class at this time is a violation of section 12(a)(1)(A), the Agency, in the exercise of its prosecutorial discretion, will not generally take enforcement action against persons moving such products in intrastate commerce, if the following conditions are satisfied:

(i) The producer or distributor had no knowledge of the requirement to obtain Federal registration for the product prior to the effective date of the section 3 regulations;

(ii) The use patterns and formulation of the product satisfy the requirements specified below;

(iii) The product satisfies the labeling, packaging and formulation requirements specified in 40 CFR 162.17(f), and restated below;

(iv) The producer or distributor satisfies the requirements specified below with respect to obtaining Federal Registration for the product; [and]

(v) The product is produced in an establishment registered pursuant to FIFRA section 7.

If the Agency determines that intrastate products in this class either do not satisfy these requirements or no longer satisfy these requirements, a stop sale order, as provided in section 13(a) of FIFRA, will be issued immediately. Pursuant to section 13(a), no further distribution or sale of the product may take place until such stop sale order has been vacated. The stop sale order may be vacated if information is provided which shows that the product or its labelling have been modified to bring it into full compliance with all the requirements specified above. In addition to the issuance of a stop sale order, persons distributing, selling or otherwise moving the product in commerce may be subjected to other enforcement remedies, as set forth in Part III A, above. Prosecutorial discretion will be exercised only until the product is accorded full Federal registration or a notice of denial of registration for the product is issued. If registration is denied, continued distribution, sale or other movement of the product in commerce will result in enforcement action under section 12(a)(1)(A) of FIFRA.

(i) *Knowledge of the Requirement to Obtain Federal Registration.* The Agency will determine whether the person distributing, selling or otherwise moving an unregistered intrastate product in this class in commerce had knowledge of the requirement for Federal registration prior to the effective date of the section 3 regulations on a case by case basis. In the case of manufacturers and formulators, a primary consideration in reaching this determination will be whether the person manufactures or formulates other products which have Federal registration and, in particular, whether the person had applied for Federal registration with respect to other products produced by him not subject to State regulation in the period before the effective date of the section 3 regulations. It is important to note, however, that in announcing this policy the Agency is not making lack of knowledge of the requirement for Federal registration an affirmative defense to a violation of section 12(a)(1)(A) in this or any other instance. Instead, the Agency is indicating that it will not initiate or pursue enforcement action against a person for a violation of FIFRA section 12(a)(1)(A), in cases where it is persuaded that the person did not have knowledge of this requirement, provided that the other conditions controlling the exercise of prosecutorial discretion in this instance are satisfied.

(ii) *Requirements Regarding Use Patterns and Formulation of the Product.* Products which fall in this class must be substantially similar to products with valid Federal registrations. A product will be deemed to be substantially similar to a product with a valid Federal registration if:

(1) The formulation* of the product is substantially similar to the formulation of a product with a valid Federal registration,

(2) The use pattern** of the product is substantially similar to the use pattern of a product with a valid Federal registration which has a substantially similar formulation.

The determination as to whether a product is substantially similar to products with valid Federal registrations will be made by the scientific and technical personnel in the Agency's Office of Pesticide Programs.

In addition, the product must not be a product with any of the following characteristics:

(1) Any product containing an active or inert ingredient not contained in any EPA-registered product;

(2) Any product which contains an active or inert ingredient which was included in a product whose registration has been suspended or cancelled by EPA because it contained that ingredient, or which has been the subject of an EPA notice of intent to suspend or cancel because of human health, environmental or other considerations with regard to such ingredients;

(3) Any product or use which is substantially similar to a product or use has been the subject of a notice of denial of registration published in the Federal Register pursuant to section 3(c)(6) of FIFRA; or

(4) Any product or use which can reasonably be expected to (a) result in residues on or in food or feed unless the use is supported by the necessary tolerances, exemptions, or other clearances under the Federal Food, Drug and Cosmetic Act [21 U.S.C. Section 301 et seq.], or (b) violate any applicable standard issued under the Safe Drinking Water Act [42 U.S.C. 1401 et seq.].

(iii) *Requirement to Obtain Federal Registration.* Persons distributing, selling, or otherwise moving in intrastate commerce an unregistered intrastate product in this class must initiate an application for Federal registration and pursue this application in good faith. In

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* In some instances, States have by regulation exempted products which are pesticides pursuant to FIFRA from State registration requirements. For example the regulations of the State of Washington provide that:

> Germicides, disinfectants, or sterilizers for use in hospitals, public swimming pools, on glassware in public establishments, for dental, or purely public health uses outside the field of agriculture and related activities are not subject to registration under the Washington Pesticide Act if the label and claims do not exceed those boundaries.

WAC 16-222 020(2), effective March 23, 1973.

In other instances, States have not exercised regulatory jurisdiction over certain types of products which are pesticides pursuant to FIFRA.

* As used in this PEIS, the term "formulation" has the same meaning as the term "pesticide formulation" in the section 3 regulations:

> The term 'pesticide formulation' means the substance or mixture of substances composed of all active and inert (if any) ingredients of a pesticide product. [40 CFR 162.3(cc)].

** As used in this PEIS, the term "use pattern" has the same meaning given it in the section 3 regulations:

> The term 'use pattern' means the manner in which a pesticide is applied, and includes the following parameters of pesticide application:
>
> (1) Target pest,
> (2) Crop or animals treated,
> (3) Application site, and
> (4) Application technique, rate and frequency. [40 CFR 162.3(gg)].

order to satisfy this requirement, the person must:

(1) File an application for Federal registration with the Registration Division, Office of Pesticide Programs, within 60 days after notice that the product is being distributed, sold or otherwise moved in commerce in violation of section 12(a)(1)(A); (and)

(2) Pursue the registration application in good faith according to procedures governing the Federal registration process.

The Agency cautions that it will review the status of applications for Federal registration for products in this class on a regular basis. Persons found not to be pursuing an application for Federal registration in good faith will be subject to appropriate enforcement action).

(iv) *Requirements Regarding Labeling and Packaging and Other Subjects.* In the implementation Plan which was published in the FEDERAL REGISTER shortly after enactment of the 1972 amendments to FIFRA, the Agency provided a list of the requirements imposed by the amendments on intrastate pesticide products in such areas as labeling and formulation. (38 Fed. Reg. 1142, January 7, 1973). These requirements became effective on October 21, 1972, the date of enactment of the amendments. These requirements were again listed in the preamble to the proposed section 3 regulations (39 Fed. Reg. 36973, 36976 (October 18, 1974)). In addition, the requirements were included in the section 3 regulations, as express limitations on the authorization extended to certain State registered products to remain in commerce pending Federal registration (40 CFR 162.17(d)). Unregistered intrastate products in the class under discussion are subject to these requirements. They are summarized here for convenience to pesticide manufacturers and distributors, and in order to assure the widest possible dissemination of this information.

(1) *Minimum Labeling Requirements.* The labeling of all intrastate pesticide products which are not Federally registered must contain at a minimum the following elements, placed prominently with such conspicuousness (as compared with other words, statements, or other graphic matter) as to render it likely to be read and understood by an ordinary individual under customary conditions of purchase and use (see FIFRA, sections 2(q)(1)(E) and 12(a)(1)(E)):

(a) Necessary directions for use (see FIFRA, sections 2(q)(1)(F) and 12(a)(1)(E));

(b) Necessary precautionary statements or warnings (see FIFRA, sections 2(q)(1)(G) and 12(a)(1)(E));

(c) Necessary signal words and statements regarding practical treatment (See FIFRA, sections 2(q)(2)(D) and 12(a)(1)(E));

(d) An ingredient statement (see FIFRA, sections 2(q)(1)(A) and 12(a)(1)(E));

(e) The name and address of the producer or person for whom the product is produced (see FIFRA, sections 2(q)(1)(C) (i) and 12(a)(1)(E));

(f) The name, brand or trademark under which the pesticide is sold (see FIFRA, sections 2(q)(2)(A)(i) and 12(a)(1)(E));

(g) The net weight and measure of content of the product (see FIFRA, sections 2(q)(2)(C)(ii) and 12(a)(1)(E)); (and)

(h) The registration number assigned under section 7 to each establishment in which the product was produced (see FIFRA, sections 2(q)(1)(D) and 7).

In addition, the labeling of a product must not contain any statement, design or graphic representation relative thereto to which is false or misleading in any particular (See FIFRA, sections 2(q)(1)(A) and 12(a)(1)(E)), and the product must not be an imitation of, or be offered for sale under the name of, another pesticide (see FIFRA, sections 2(q)(1)(E) and 12(a)(1)(E)).

(2) *Minimum Requirements in Areas Other Than Labeling*

Intrastate pesticide products which are not Federally registered are subject to the following requirements in areas other than labeling:

(a) The product must be contained in a package or other container or wrapping conforming to standards established by the Agency (see FIFRA, sections 2(q)(1)(B) and 12(a)(1)(E)); and

(b) The product must satisfy any requirements concerning coloration by the Agency (See FIFRA, section 12(a)(1)(D)).

In keeping with the general objective of achieving a smooth transition to the new requirements, the Agency intends to apply these requirements in a common sense manner. Generally, enforcement action will be taken when, in the Agency's judgment, deviations from these requirements are significant and might result in serious harm to man or the environment. In addition, the Agency expects to coordinate enforcement actions with state agencies exercising pesticide regulatory responsibilities.

(v) *Establishment Registration Requirement.* Establishments in which intrastate pesticide products are produced have been subject to the establishment registration requirement of section 7(a) of FIFRA since October 21, 1974. See 40 CFR 167.2(d). Accordingly, persons producing intrastate products in unregistered establishments since October 21, 1974, have been in violation of section 7(a), and have been subject to enforcement action under FIFRA section 12(a)(2)(L). In the exercise of its enforcement discretion, and subject to the limitation stated below, the Agency will not take enforcement action under section 12(a)(1)(L) against a person for violating section 7(a) by producing in an unregistered establishment an unregistered intrastate product subject to this subpart (i.e. a product not subject to a State registration requirement), if the person submits an application for establishment registration within ten (10) days after notification that he is subject to the establishment registration requirement. However, the Agency will only afford this grace period in cases where it has determined that the producer did not know about the establishment registration requirement.

IV. Conversion of a Federally Registered Product To A State Registered Product Satisfying the Requirements of 40 CFR 162.17

Currently, many products which possess identical chemical formulations are validly registered with both EPA and State agencies. In some cases, however, the Federal and State labels contain different provisions, reflecting the terms of their respective State or Federal registrations, with regard to the method or rate of application, target pests, protective clothing requirements, or other warning and precautionary statements.

FIFRA section 12(a)(2)(A) makes it unlawful "to detach, alter, deface, or destroy, in whole or in part, any labeling required under this Act." The antecedent to this provision in the 1947 Act (section 3(c)(1); 61 Stat. 163) was interpreted to prohibit most stickering or pasting over of a Federal label by a State label or any removal of a Federal label for replacement by a State label. The accepted alternatives have been (1) to repackage or reformulate and repackage a Federally registered product to produce a State-registered product, or (2) to obtain a Federal registration for the State-registered product, limited to use only in the State in question.

The Agency believes that there is justification for the exercise of prosecutorial discretion regarding certain violations of section 12(a)(2)(A), during the phased implementation period for the new registration requirements. Thus, the Agency will not take enforcement action under section 12(a)(2)(A) against a person who converts a Federally registered pesticide product into a chemically identical State registered product, in the following circumstances:

(1) The resulting State registered pesticide product satisfies the requirements of 40 CFR 162.17. That is, the product must have had a valid State registration or other valid State authorization on August 4, 1976; a notice of application for Federal registration must have been filed before October 3, 1975; and the product must satisfy the minimum requirements in such areas as labeling, packaging and product formulation set out in 162.17(f), and reiterated in Part III of this PEPS.

(2) Conversion is accomplished by

(a) *completely* replacing or covering the Federal label with the State label; or

(b) adding supplementary labeling, approved by the State, which accompanies any movement of the product in commerce. Such supplemental labeling must contain the proper EPA Establishment Number; (and)

(3) No confusion results to the consumer, as to safety cautions, directions for use, ingredients, efficacy and acceptance by various regulating agencies.

It is emphasized that enforcement action will be taken under section 12(a)(2)(A) with respect to persons stickering, partially re-labeling, or performing any other act which only partially obscures the approved label on a Federally registered product. In addition, conversion must result in a product which satisfies all the requirements of 40 CFR 162.17. A conversion which results in any other type of product is outside the scope of this section. Thus, a conversion of a Federally registered product into an intrastate product of the type which is not regulated by the State in which it is to be sold or used (described in Part III (B)(2)(b)(3) of this PEPS) will result in enforcement action under section 12(a)(2)(A) of FIFRA.

V. Public Comment

The Administrative Procedures Act (5 U.S.C. §553(b)) provides that the solicitation of comments is not required of Federal agencies for "interpretative rules, general statements of policy, or rules of agency organization procedure, or practice." EPA has determined that this PEPS falls within this exemption from the requirement to solicit public comment. Accordingly, the Agency is not soliciting public comment regarding matters published in this notice. However, interested persons may submit written comments regarding the policy set forth in this PEPS to the Pesticide Enforcement Division (EN-342), Office of Enforcement, U.S. Environmental Protec-

tion Agency, 401 M St. SW., Room 3624, Washington, D.C. 20460. Three copies of these comments should be submitted to facilitate the work of the EPA and others interested in inspecting such documents.

Dated: March 24, 1976.

STANLEY W. LEGRO,
Assistant Administrator
for Enforcement.

[FR Doc 76 0423 Filed 3 31-76;8:45 am]

UNITED STATES ENVIRONMENTAL PROTECTION AGE
OFFICE OF ENFORCEMENT
OFFICE OF GENERAL ENFORCEMENT
PESTICIDES AND TOXIC SUBSTANCES
ENFORCEMENT DIVISION

PESTICIDE ENFORCEMENT POLICY STATEMENT NO. 4

PREVENTIVE PEST CONTROL TREATMENTS IN THE ABSENCE OF TARGET PESTS

Reprinted from the Federal Register of July 8, 1976
(41 FR 28005)

PESTICIDE ENFORCEMENT POLICY STATEMENT NO. 4

Preventive Pest Control Treatments in the Absence of Target Pests

I. General Background

On May 5, 1975, the Environmental Protection Agency (EPA) published in the FEDERAL REGISTER a document entitled "Institution of Enforcement Policy Statements" (40 Fed. Reg. 19526). It was the Agency's purpose in instituting this series of Pesticide Enforcement Policy Statements (PEPS) to inform the general public and persons engaged in the formulation, distribution, sale, application, or other use of pesticides of the policies adopted by the Agency in the enforcement of the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended in 1972 and 1975 (P.L. 92-516, 86 Stat. 973; P.L. 94-140, 89 Stat. 751; 7 U.S.C. 136 *et. seq.*; hereinafter referred to as FIFRA). PEPS are prepared and published by EPA's Office of Enforcement. Unless otherwise provided, a PEPS indicates how the Agency will exercise its prosecutorial discretion, and does not interpret the law or otherwise define what is and what is not lawful conduct under FIFRA. If the Administrator subsequently promulgates regulations which interpret FIFRA, the Office of Enforcement will revoke or amend any prior PEPS which is inconsistent with such regulations. A detailed explanation of the purpose and scope of the series of PEPS was set forth in the May 5, 1975, FEDERAL REGISTER notice.

Federal regulation of the use of pesticides was established for the first time with the enactment of the 1972 amendments, specifically through the provisions of FIFRA section 3(d)(1), section 4 and section 12(a)(2)(G).[1] Any person who uses a registered pesticide in a manner inconsistent with its labeling is in violation of the Act and may be subject to civil or criminal sanctions.[2] However, as set forth in the legislative history, Congress intended that EPA enforce the prohibition of section 12(a)(2)(G) in a "common sense manner" and not prohibit uses of registered pesticides which are in no way harmful and which have demonstrated beneficial effects.[3]

II. Purpose and Scope of This PEPS

This policy statement concerns the preventive use of registered pesticides on a commodity or crop, or the pesticidal treatment of an environmental area in the absence of a target pest.[4] Whether preventive pest control treatments in the absence of a target pest constitute violations of FIFRA section 12(a)(2)(G) is a question which arises in many categories of pest control including, but not limited to, structural and agricultural pest control.

[1] FIFRA section 3(d)(1) (7 U.S.C. 136 a(d)(1)) provides that as part of the registration of a pesticide, the Administrator shall classify each pesticide for general or for restricted use, or for both general use and restricted use as the administrator, in his discretion, may require. See 40 CFR Part 162.2 (Cc).

FIFRA section 4(a)(1) (7 U.S.C. 136a(a)(1)) empowers the Administrator to prescribe standards for the certification of applicators of restricted use pesticides. The Agency has promulgated regulations establishing certain categories of commercial (professional) applicators and setting forth minimum standards that commercial and private applicators must meet before they are certified to use pesticides classified under section 3 for "restricted use." (40 CFR Part 171).

FIFRA section 12(a)(2)(G) provides that it is unlawful for "any person to use any registered pesticide in a manner inconsistent with its labeling." This section became effective upon the date of enactment of FIFRA and was determined by the Administrator to be self implementing. (FIFRA Implementation Plan 39 Fed Reg 11142). The regulations implementing the registration provisions of the 1972 amendments define pesticide "use" to mean "any act of handling or release of a pesticide, or exposure of man or the environment to a pesticide through acts, including but not limited to:

(1) Application of a pesticide, including mixing and loading and any required supervisory action in or near the area of application;

(2) Storage actions for pesticides and pesticide containers; and

(3) Disposal actions for pesticides and pesticide containers." (40 CFR 162.3(ee)).

This definition of the term "use" has been adopted by the Office of Enforcement in the enforcement of pesticide labeling under FIFRA section 12(a)(2)(G).

[2] House Committee on Agriculture, H.R. Rep. No. 92 511, 92nd Cong., 1st Sess. 16 (1971); Senate Committee on Agriculture and Forestry, S. Rep. No. 92 838, 92nd Cong., 2d Sess. 16 (1972). As the Senate Committee on Agriculture and Forestry noted:

> " " " it is the belief of the Committee that the use of the word "inconsistent" should be read and administered in a way so as to visit penalties only upon those individuals who have disregarded instructions on a label that would indicate to a man of ordinary intelligence that use not in accordance with such instructions might endanger the safety of others or the environment.

[3] Senate Committee on Agriculture and Forestry, S. Rep. No. 92 838, 92d Cong., 2d Sess. 16 (1972). As the Senate Committee on Agriculture and Forestry stated:

> (1)t is not the intention of the Committee to prohibit any use which is in no way harmful, and which has only beneficial effects on man and his environment.

[4] As used in this PEPS, the term, "preventive pest control treatment" means any application or use of a pesticide in the absence of a target pest or use of a pesticide which is primarily intended to prevent, prohibit, discourage, or repel pests which would be reasonably expected to occur in that environment in the absence of the treatment. As used here, "preventive pest control treatment" includes both pretreatments in anticipation of an actual infestation (e.g., at a newly-constructed house) and retreatments to abate a recurring pest problem.

The Agency encourages preventive pest control measures which do not require the use of chemical pesticides, such as good sanitation practices, the establishment of physical barriers to pests, and integrated pest management procedures. However, the use of pesticides in preventive treatments is a commonly recognized and accepted pest control practice (e.g., in the establishment of pesticide barriers against insect damage including impregnation of wood; in the protection against rodents; in protection against plant diseases; and in the use of pre-emergent herbicides). Interested persons have inquired into the circumstances and conditions under which the preventive use of such products is deemed consistent with the purposes and objectives of FIFRA.

Section 2(u) of FIFRA defines the term "pesticide" to mean, in part, "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pests." Many labels, however, do not affirmatively provide for the use of the pesticide as a preventive treatment for pests listed on the label. To protect man and the environment from unreasonable adverse effects of pesticides, the Agency will continue to take enforcement action against those persons who abuse the practice of preventive pest control and unnecessarily introduce chemicals into the environment.

III. Summary of Enforcement Policy Regarding Preventive Pest Control Treatment

In the exercise of its prosecutorial discretion the Agency has determined that it will not generally initiate an enforcement action against a person who uses a registered pesticide in a preventive pest control treatment in the absence of the target pest where all of the following conditions are met:

(A) the label of the pesticide which is used does not affirmatively prohibit preventive treatments; and

(B) the target pest is reasonably expected to infest the treated area; and

(C) the pesticide is normally safe and efficacious against the target pest when used in a preventive capacity.

This PEPS in no way limits enforcement liability for a violation of any affirmative labeling requirement including, but not limited to, dosage rate, application method, and residue tolerances for agricultural commodities.

All of the limiting and defining provisions contained in the paragraphs which follow are an integral part of this policy statement.

IV. Elaboration of Enforcement Policy Regarding Preventive Pest Control Treatments

A. No Affirmative Label Prohibition of Preventive Treatments

Where the EPA-accepted label specifically prohibits preventive pest control treatments, the Agency will strictly enforce the provisions of section 12(a)(2)(G) of the Act. Where the EPA-accepted label is silent regarding preventive treatment, the Agency will make a presumption in favor of such preventive treatments subject to the limitations of section (B) and (C) below.[3]

B. Likelihood of Pest Infestation

Preventive pest control treatments are permissible if the target pest may reasonably be expected to infest the area to be treated. Whether a pest infestation is likely to occur in a given situation will be determined by the Agency on a case-by-case basis. This determination will be based upon the Agency's knowledge of pest infestations in the proposed use site or application environment, and on recognized pest control practices.

C. Safety and Efficacy of Preventive Treatment

Preventive pest control treatments must be performed in a manner which is safe and efficacious and which conforms to good pest control practice. In determining whether a preventive pest control application conforms to good pest control practice the Agency will (a) exercise its legislative mandate to protect man and the environment from unreasonable adverse effects of pesticides in a manner which is consistent with its charge to not prohibit pesticide use which is "in no way harmful, and which has only beneficial effects,"[4] and will (b) consider pest control practices which are commonly relied upon by responsible pest control operators, and which have achieved the desired pest control results when utilized under similar conditions in the past.

[3] For example, products whose accepted labeling direct application "for termite control" may be used in preventive treatments or in regularly-scheduled re-treatments in the absence of active infestations by the target pest. Furthermore, products whose accepted labeling provides for "regularly-scheduled" treatments (in addition to those which stipulate a specific re-treatment interval) may be applied in the absence of an active infestation.

[4] FIFRA section 25(b) requires the Administrator, in evaluating the effects of a preventive pest control treatment on the environment to "take into account the economic, social and environmental costs and benefits of the use of any pesticide." (7 U.S.C. 136(b)(1)); See the Report of the Senate Committee on Agriculture and Forestry, S. Rep. No. 92-838, 92d Cong. 2d Sess. 16 (1972).

V. Public Comment

The Administrative Procedure Act (5 U.S.C. 553(b)) provides that the solicitation of comments is not required of Federal agencies for "interpretative rule, general statements of policy, rules of agency organization, procedure, or practice." EPA has determined that this PEPS falls within this exemption from the requirement to solicit public comment. Accordingly, the Agency is not soliciting public comment regarding matters published in this notice. However, interested persons may submit written comments regarding the policy set forth in this PEPS to the Pesticides and Toxic Substances Enforcement Division (EN-342), Office of Enforcement, U.S. Environmental Protection Agency, 401 M St. SW., Room 3624, Washington, D.C. 20460. Three copies of these comments should be submitted to facilitate the work of EPA and others interested in inspecting such documents.

Dated: July 1, 1976.

STANLEY W. LEGRO,
Assistant Administrator for Enforcement.

[FRL 646-5]

PEST CONTRAL DEVICES AND DEVICE PRODUCERS

Consolidation and Clarification of Requirements

I. Purpose

Requirements applicable to pest l devices and device producers been set forth in various regula- promulgated pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (86 Stat. 973; 89 Stat. 751; 7 U.S.C. 136 et seq.) ("FIFRA" or "the Act"). The purpose of this notice is to provide a consolidation and clarification of all such requirements.

II. Definitions

At section 2(h) of FIFRA (7 U.S.C. 136 (h)) the term "device" is defined to mean:

> * * * any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides when sold separately therefrom.

To more clearly identify the types of products to which the requirements discussed in this Notice apply, the term "device" must be contrasted with the term "pesticide," which is defined at section 2(u) of FIFRA to mean:

> * * * any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and any substance or mixture of substances intended for use as plant regulator, defoliant, or desiccant:

Thus, if an article uses physical or mechanical means to trap, destroy, repel, or mitigate any plant or animal life declared to be a pest at 40 CFR 162.14, it is considered to be a device. If the article incorporates a substance or mixture of substances intended to prevent, destroy, repel, or mitigate any pest, it is considered to be a pesticide.

III. Devices Subject to the Act

Section 25(c)(4) of FIFRA (7 U.S.C. 136w(c)(4)) provides that the Administrator may specify those classes of devices which shall be subject to any provision of paragraph 2(q)(1) (7 U.S.C. 136(q)(1)) or section 7 (7 U.S.C. 136e) of this Act upon his determination that application of such provision is necessary to effectuate the purposes of this Act. On July 3, 1975, the Administrator promulgated regulations (40 F.R. 28242) amending 40 CFR Part 162 pursuant to this authority. 40 CFR 162.15 now provides that devices as defined in FIFRA section 2(h) are subject to the requirements of FIFRA section 2(q)(1)(A)–(G) and to those provisions of FIFRA section 7 which are necessary to effectuate the purposes of FIFRA with respect to devices.

The preamble to these regulations at 40 F.R. 28266 declared that to effectuate the purposes of the Act, devices subject to sections 2(q)(1) and 7 include but are not limited to:

> (A) Certain ultraviolet light systems, ozone generators, water filters and air filters (except those containing substances or mixtures of substances which are pesticides), and ultrasonic devices, for which claims are made to kill, inactivate, entrap, or suppress the growth of fungi, bacteria, or viruses in various sites; (B) certain high frequency sound generators, carbide cannons, foils, and rotating devices, for which claims are made to repel birds; (C) black light traps, fly traps, electronic and heat screens, fly ribbons, and fly paper, for which claims are made to kill or entrap certain insects; and (D) mole thumpers, sound repellents, foils and rotating devices, for which claims are made to repel certain mammals.

The preamble further specifies those instruments declared to be of a character unnecessary to be subject to this Act in order to carry out the purposes of the Act. These include:

> (1) Those which depend for their effectiveness more upon the performance of the person using the device than on the performance of the device itself, and
>
> (2) Those which operate to entrap vertebrate animals.
>
> Products generally falling within these two categories include rat and mouse traps, fly swatters, tillage equipment for weed control and fish traps.

Section 8 of FIFRA (7 U.S.C. 136f) provides for such record-keeping and record inspection requirements as the Administrator determines necessary for effective enforcement of the Act. Section 17 specifies the requirements to be placed on the import and export of devices. In neither of these sections is there a provision that the Administrator declare those classes of devices subject to these sections of the Act; and in the attendant regulations, no specification is made. For purposes of enforcement, the Agency will consider those classes of devices declared to be subject to regulation under section 25(c)(4) of the Act as subject to regulation under sections 8 and 17 as well.

IV. Summary of FIFRA Provisions Applicable to Devices

Any instrument declared to be a device under 40 CFR 162.15 is, upon introduction into channels of trade, subject to the provisions discussed below. Those provisions of the amended FIFRA which pertain to devices are in many respects similar to those under the 1947 FIFRA (61 Stat. 163; 7 U.S.C. 135–135k). In both Acts the Agency is authorized to inspect records showing the delivery, movement, or holding of devices (7 U.S.C. 135c, 136f); to obtain samples of any device in the marketplace (7 U.S.C. 135d, 136g); to seize any misbranded device (7 U.S.C. 135g, 136k); to initiate criminal proceedings against any person violating any provision of the Act (7 U.S.C. 135f, 136l); and, in cooperation with the Secretary of the Treasury, to sample, examine, and detain any imported device which violates the provisions of the Act (7 U.S.C. 135h, 136o).

The differences in the provisions of the two Acts with respect to requirements applicable to devices, lie primarily in the greater specification of jurisdiction and regulatory requirements provided by the 1972 amendments. For example, while a device, unlike a pesticide, is not subject to the section 3 registration requirement of FIFRA, section 12 of the Act makes clear the intent of the Act that subject devices and persons dealing with devices be held responsible for those obligations, other than registration, that are imposed by the Act. Jurisdiction to regulate devices is expanded to intra- as well as interstate commerce (7 U.S.C. 136j(a)(1)). Similarly, section 9(a) of the amended FIFRA specifies that entry for the purpose of inspecting and obtaining samples of devices "packaged, labeled, and released for shipment is permitted into "any establishment or other place where * * * devices are held for distribution or sale (7 U.S.C. 136g(a)).

With respect to affirmative regulatory requirements, section 2(q)(1) of the amended FIFRA expands the definition of misbranding as it applies to devices subject to the Act (7 U.S.C. 136(q)(1)). Section 7 of the amended FIFRA is totally new, requiring the registration of establishments which produce devices declared subject to the Act (7 U.S.C. 136e). In addition to the provisions of the Act allowing the inspection of records kept by producers and distributors of devices, section 8(a) of the amended FIFRA requires producers of devices subject to the Act to maintain such books and records as the Administrator requires by regulation (7 U.S.C. 136f(a)). Finally, section 17(a) of FIFRA, as amended, specifically imposes the same recordkeeping requirements on producers of devices intended for export by making such producers subject to the requirements of section 8.

V. Elaboration of Specific Requirements Applicable to Devices

A. *Section 2(q)(1), Misbranding Provisions (7 U.S.C. 135(q)(1)).* With promulgation of the regulations at 40 CFR [illegible].15, which invoked the authority of [illegible]ion 25(c)(4) to specify devices subject to sections 2(q) and 7 of the Act, the labeling requirements of the 1947 FIFRA to which devices had been subject were expanded (7 U.S.C. 135(z)(1)). Those misbranding provisions of section 2(q)(1) of the amended FIFRA which the Administrator has made applicable to devices are listed at 40 CFR Part 162.15(b). In summary, a device will be subject to enforcement action if

2(q)(1)(A): Its labeling bears any statements, designs, or graphic representations relative thereto or to its ingredients which are false or misleading in any particular;

2(q)(1)(B): Its packaging or wrapping fails to conform with standards established pursuant to section 25(c)(3) (Such standards have not, as of this date, been issued by the Administrator; at such time as they are, the question of their applicability to devices will be addressed);

2(q)(1)(C): It is an imitation of, or is offered for sale under the name of another device;

2(q)(1)(D): Its label fails to bear the establishment number;

2(q)(1)(E): Required information is not prominently displayed on the [illegible];

2(q)(1)(F): It lacks adequate directions for use; or

2(q)(1)(G): It lacks an adequate warning or caution statement.

40 CFR 162.10(a)(5) provides an interpretation of what the term "false and misleading" may include in the content of FIFRA section 2(q)(1)(A) misbranding:

[illegible]se or misleading statement concerning composition of the product;

A false or misleading statement concerning the effectiveness of the product;

A false or misleading statement about the value of the product for purposes other than as a device;

A false or misleading comparison with other devices;

Any statement directly or indirectly implying that the device is recommended or endorsed by any agency of the Federal Government;

A true statement used in such a way as to give a false or misleading impression to the purchaser;

Label disclaimers which negate or detract from labeling statements required under the Act and regulations; or

Non-numerical and/or comparative statements on the safety of the product.

B. Section 7, Registration of Establishments (7 U.S.C. 136e). On November 6, 1973, regulations (40 CFR Part 167) for the implementation of section 7, Registration of Establishments, were published in the FEDERAL REGISTER (38 F.R. 30557). The scope of the requirements is set forth at § 167.2(a): "All establishments, as defined in this part, which produce any pesticide or device subject to the provisions of this section, must be registered pursuant to the requirements of these regulations * * *" At § 167.1(k) the term "device" is defined as "* * * any device or class of devices as defined by the Act and determined by the Administrator pursuant to section 25(c) to be subject to the provisions of section 7 of the Act."

Section 7 imposes three basic requirements: (1) Registration of device-producing establishments, (2) labeling which reflects the EPA establishment number assigned to the establishment in which the device was produced, and (3) submission of annual production reports.

All establishments in which devices subject to the Act are produced must be registered with the Environmental Protection Agency as producing establishments. This includes foreign establishments in which devices shipped to the United States are produced, as well as establishments located in the United States which produce devices for export.

To register establishments, producers should obtain from an EPA regional office the Application for Registration of Pesticide-Producing Establishments (EPA Form 3540-8). The applications require such information as the name and address of the company headquarters and the names and addresses of all device-producing establishments owned and operated by the company. This application must be submitted to the regional office on or before January 18, 1974. Upon receipt of a completed application, the regional office shall register each establishment listed and shall assign each establishment an EPA establishment number. This EPA establishment number must be displayed on all devices released for shipment by the establishment after 90 days after the producer is notified of the assigned number.

The production reports (EPA Form 3540-16) must be submitted to the regional office within thirty days after notification of registration and by February 1 each year thereafter.

C. *Section 8, Books and Records (7 U.S.C. 136f).* On September 18, 1974, regulations (40 CFR Part 169) for the implementation of section 8, Books and Records, were published in the FEDERAL REGISTER (39 F.R. 33512). Pursuant to the authority of section 8(a) of the Act, these regulations (at 40 CFR 162.2) specify those records pertaining to development, testing, production, holding, and distribution, which all producers of devices declared subject to the Act are required to maintain and submit to inspection. These requirements apply to domestic and foreign persons producing devices for sale and distribution in the United States and to domestic producers who export devices.

Specifically, producers of devices subject to the Act are required to maintain the following records:

169.2(b): Records showing the brand names and quantities of devices produced. These records shall be retained for two years.

169.2(c): Records showing the following information regarding the receipt of devices: (1) Brand name of device, (2) Name and address of shipper, (3) Name of delivering carrier, (4) Date received, and (5) Quantities received.

These records shall be retained for two years.

169.2(d): Records showing the following information regarding the shipment of devices: (1) Brand name of device, (2) Name and address of the consignee, (3) Name of originating carrier, (4) Date shipped or delivered for shipment, and (5) Quantities shipped or delivered for shipment.

These records shall be retained for two years.

169.2(e): Inventory records with respect to the types and amounts of devices in stock which he has produced. These records may be disposed of when a more current inventory record is prepared.

169.2(h): In the case of devices intended solely for export to any foreign country, copies of the specifications or directions of the foreign purchaser for the production of the devices. These records shall be retained for two years after expiration of the contract.

Pursuant to the authority of section 8(b) of the Act, 40 CFR 169.3(b) requires that distributors, carriers, dealers or other persons who sell or deliver (or offer to sell or deliver) devices declared subject to the Act, allow inspection of the records they have pertaining to the following:

(1) The delivery or holding of the device and quantity held; (2) Date of shipment and receipt; (3) Name and address of consignee and consignor; and (4) Any guarantees received pursuant to section 12(b)(1).

D. *Section 17, Imports and Exports (7 U.S.C. 136o).* On August 1, 1975, regulations (19 CFR Part 12.1) for the implementation of section 17, Imports and Exports, were published in the FEDERAL REGISTER (40 FR 32321). These regulations require that devices produced by foreign manufacturers and imported into the United States comply with all requirements applicable to domestic producers. In addition, the regulations require an importer to submit to EPA a Notice of Arrival of Pesticides and Devices (EPA Form 3540-1, available at any EPA office) for review and determination as to whether the shipment should be sampled and/or permitted entry into the United States. The Act also provides that samples may be collected and examined and that shipments may be permitted entry, detained until brought into compliance, destroyed, or re-exported.

With respect to devices produced in this country for export, section 17(a) of the FIFRA as amended requires that such devices must be prepared or packed in accordance with the specifications or directions of the foreign purchaser and that producers of such devices must maintain books and records pursuant to section 8(a).

VI. Enforcement Authorities

Section 9(a) (7 U.S.C. 136(g)(a)) of the Act authorizes officers of the Agency to inspect any establishment or other place where a device is held for distribution or sale in order to obtain a sample of the device as packaged, labeled and released for shipment, and samples of any containers or labeling for the device. Officers of the Agency are also authorized

to inspect books and records required to be maintained under section 8(a) and copies of records which are available under section 8(b).

Pursuant to section 12(a)(2)(B) of the Act, it is unlawful for any person to refuse to keep or to permit inspection of books and records, or to refuse to permit inspection of an establishment. Pursuant to section 12(a)(1)(F) of the Act, it is unlawful to sell or distribute any device which is misbranded. Finally, pursuant to section 12(a)(2)(L) of the Act, it is unlawful to violate any provision of section 7.

Upon a finding of any unlawful act, the Administrator may assess a civil penalty pursuant to section 14(a) of the Act or initiate criminal proceedings pursuant to section 14(b) of the Act. If, upon inspection or tests, a device is believed to be in violation of the Act, or if it is believed that a device is intended to be distributed or sold in violation of the Act, a Stop Sale, Use or Removal Order may be issued pursuant to section 13(a). Additionally, section 13(b) authorizes in rem seizure proceedings in a federal district court against any device which is misbranded or which, when used in accordance with the requirements imposed under the Act causes unreasonable adverse effects upon the environment. Finally, the Administrator may seek injunctive relief pursuant to section 16(c) to prevent and restrain violations of the Act.

VII. Public Comment

The Administrative Procedure Act (5 U.S.C. 533(b)) provides that the solicitation of comments is not required of Federal agencies for "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice." EPA has determined that this Notice falls within this exemption from the requirement to solicit public comment. Nonetheless, interested persons may submit written comments regarding the policy set forth in this Notice to the Pesticides and Toxic Substances Enforcement Division (EN-342), Office of Enforcement, U.S. Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460. Three copies of these comments should be submitted to facilitate the work of the EPA and others interested in inspecting such documents.

Dated: November 8, 1976.

STANLEY W. LEGRO,
Assistant Administrator for Enforcement.

[FR Doc.76-34119 Filed 11-18-76;8:45 am]

[FRL 646-8]

PEST CONTROL DEVICES PROCEDURES

Consolidation and Clarification of Requirements

Correction

In FR Doc. 76-34119 appearing on page 51065 in the issue for Friday, November 19, 1976, on page 51066, middle column, third full paragraph, in the 12th line, "January 18, 1976" should have read "January 18, 1977".

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

24 JAN 1977

OFFICE OF ENFORCEMENT

MEMORANDUM

TO: Regional Administrators

FROM: Stanley W. Legro
Assistant Administrator
for Enforcement

Stanley W. Legro

SUBJECT: Enforcement Priorities in Structural Pest Control

a) Establishment Inspections of Pest Control Firms
b) Pesticide Use Inspections
c) Prosecutorial Discretion in Pesticide Use Enforcement

I. Purpose.

This memorandum (a) provides supplemental guidance to the FY 77 Regional Plan and Program Guidance with regard to the performance of establishment inspections of structural pest control firms, and the inspection of pesticide use by structural pest control operators, (b) sets forth criteria to be applied by the Regional Offices in determining which pest control establishments should be the object of establishment inspections, (c) sets forth criteria to be applied by the Regional Offices in determining whether to perform a pesticide use inspection of structural pest control activities, and (d) informs the regions of the manner in which the Office of Enforcement will exercise its prosecutorial discretion in regulating the sale, distribution or use of pesticides in the structural pest control industry.

II. Background.

The implementation of a comprehensive program to regulate pesticide use and to perform pesticide use inspections continues to be an important emphasis of the Agency's pesticide use enforcement program during FY 77. The Agency has determined that its limited inspectional resources should be utilized primarily to observe those activities which present the greatest risks of harm. The Agency intends to exercise its prosecutorial discretion

in a "common sense" manner which will prevent unreasonable adverse effects upon people and the environment, and will foster professionalism and compliance with the law among structural pest control operators. The Office of Enforcement is developing similar supplemental guidance to direct inspectional activities and establish enforcement priorities in agricultural and other non-structural pest control.

All structural pest control firms which supply and apply pesticides for hire are deemed by the Agency to engage in two distinct activities which are subject to regulation under the FIFRA. First, in contracting to perform pest control services, they are deemed to hold pesticides "for distribution or sale" within the meaning of FIFRA section 9(a). Indeed, the price paid by the customer for the application necessarily reflects the cost of the service and the cost of the pesticide. Secondly, while actually applying the use-dilution preparation of the pesticide, they are deemed to "use" pesticides. A relatively small number of these structural pest control firms also engage in a third type of activity, i.e., in the production, formulation, or repackaging and sale of pesticides for use by other persons.

A structural pest control firm which simply supplies and applies pesticides (i.e., a firm which is engaged in the distribution or sale of pesticides while performing pest control applications for hire is subject to enforcement liability as an "other distributor" under the provisions of FIFRA section 14(a)(1), but is exempted from the establishment registration requirements of FIFRA section 7 under the provision of 40 CFR 167.2(a). A structural pest control firm which also engages in the production, formulation, or repackaging and sale of pesticides for use by others, is subject to enforcement liability as a "registrant . . . wholesaler, dealer, (or) retailer" under the provisions of FIFRA section 14(a)(1), and is subject to the establishment registration requirements of FIFRA section 7 as implemented in 40 CFR Part 167.

III. Supplemental Guidance to the FY 77 Regional Guidance and Program Plan.

The FY 77 Regional Program Plan specifies the number of establishment inspections and use observations to be performed by each Region. The Regional Guidance notes that one aspect of the Agency's use enforcement program is the "audit of professional pesticide users such as structural and agricultural pest control operators." The Guidance also provides that the Regions should "devote approximately thirty percent of their pesticide enforcement resources toward ensuring compliance with all use requirements...." Elsewhere, the guidance provides that another thirty percent of the Regional resources will be devoted to assuring industry compliance by performing establishment inspections and other surveillance activities.

Structural pest control operators are constituents of both the pesticide distributing and pesticide using populations. Accordingly, some percentage of each Region's inspectional activities should be devoted to the performance of establishment inspections and use inspections of structural pest control activities. The Office of Enforcement has determined that approximately

fifteen percent of the Region's industry compliance activities should be devoted to the inspection of establishments of structural pest control operators, and that approximately fifteen percent of the Region's audit of professional pesticide users should be devoted to the performance of use inspections of structural pest control activities. This allocation of resources will result in each region expending approximately five percent of its pesticide enforcement resources in performing establishment inspections of structural pest control firms and five percent of its resources in performing use investigations of structural pest control activities. Accordingly, the following number of the establishment inspections and use inspections performed in a Region by EPA personnel or by State personnel functioning pursuant to a Cooperative Agreement should involve structural pest control operators:

ACTIVITY	NUMBER OF INSPECTIONS BY REGION									
	I	II	III	IV	V	VI	VII	VIII	IX	X
Establishment Inspection	8	15	20	44	24	27	26	5	30	15
Use Inspections	10	7	9	30	12	9	11	5	12	18

IV. Establishment Inspection of Structural Pest Control Firms Which Produce, Formulate or Repackage Pesticides.

A. Establishment Inspection of Structural Pest Control Firms Which Engage in Production Activities.

FIFRA Section 9(a) authorizes officers or employees duly designated by the Administrator to conduct administrative inspections of places where pesticides are "held for distribution or sale." Pest control firms which produce, formulate, or repackage pesticides for use by other persons have long been a party to the regulatory process. The pesticides which they produce, formulate, or repackage for use by others are subject to the pesticide registration requirement of FIFRA section 3. Furthermore, their establishments have been subject to the establishment registration requirement of FIFRA section 7 since early 1974.

Inspections of their establishments are conducted for the purpose of inspecting books and records which are required to be maintained under FIFRA section 8(a), and of obtaining samples of pesticides or devices which are packaged, labeled, and released for shipment pursuant to FIFRA section 9(a).

The establishment inspection of such pest control firms is designed to assure compliance with product registration, formulation, packaging, and labeling requirements, to collect and develop evidence to support enforcement actions when violations are found, to determine whether the required books and records are being maintained, and to determine whether procedures for the disposal and storage of pesticides, pesticide wastes, and pesticide containers are being complied with.

The establishment inspection of pest control firms must conform in all respects to the procedures for establishment inspections provided in Chapter 9 of the EPA Inspection Manual. The Consumer Safety Officer (CSO) should discuss with the owner, operator, or agent in charge of the establishment the purpose and potential enforcement ramifications of the inspection.

B. Criteria for Determining Whether to Perform an Establishment Inspection of Structural Pest Control Firms Which Engage in Production Activities.

During FY 77, each region will be expected to conduct establishment inspections of some structural pest control firms which produce, formulate or repackage pesticides. In determining which firms to visit, the region should consider:

1. No Prior Establishment Inspection. The implementation of the registration requirement with respect to pesticides which are sold only in intrastate commerce materially increased the number of establishments which are subject to establishment inspection under FIFRA by virture of their production, formulation or repackaging activities. The Regional Guidance provides that firms which have not previously been inspected will be inspected on a routine basis. Unless re-inspection is dictated by the other criteria, establishments which have once been inspected shall not be re-inspected until other establishments have once been inspected.

2. Suspected Violations. If, on the basis of prior inspections, or of reports from other Federal or State agencies or from the general public, the Region has reason to believe that evidence of violations may be discovered thereby, an establishment inspection of a firm which produces, formulates, or repackages pesticides may be undertaken. Such firms may be inspected as frequently as necessary to assure compliance with registration, formulation, packaging and labeling requirements. As appropriate, the Notice of Inspection must specify that a violation is suspected.

3. Specific Assignment. An establishment inspection should be conducted whenever EPA headquarters, another Region, or another governmental agency requests that such an inspection be performed.

V. Establishment Inspection of Structural Pest Control Firms Which Supply and Apply Pesticides for Hire.

A. Establishment Inspection of Structural Pest Control Firms Which Supply and Apply Pesticides for Hire.

All structural pest control firms which produce, formulate, or repackage pesticides also engage in the sale or distribution of pesticides in the course of supplying and applying pesticides for hire. Such firms are also subject to administrative inspection in their status as distributors. Even though numerous structural pest control firms do not

engage in the production, formulation, or packaging of pesticides for use by others, they nevertheless supply and apply pesticides for hire and are, thus, subject to administrative inspection under the authority of FIFRA section 9(a). Such distributor inspections may be conducted for the purpose of inspecting books and records which are being maintained by the firm as authorized by FIFRA section 8(b), and of obtaining samples of pesticides or devices which are packaged, labeled and released for shipment.1/

The establishment inspection of such pest control firms is designed to determine whether pesticides which are packaged, labeled, and released for shipment conform with all applicable packaging and labeling requirements, to collect and develop evidence to support enforcement actions when violations are found, and to gather information which may be voluntarily supplied by the firm regarding the scope and nature of the firm's program to train and provide technical assistance to its service technicians.

Insofar as the establishment inspection of a firm which only distributes pesticides conforms with the establishment inspection of a firm which produces, formulates, or repackages pesticides for use by others, the procedures for establishment inspections provided in Chapter 9 of the EPA Inspection Manual must be followed. The CSO should discuss with the owner, operator, or agent in charge of the establishment the purpose and potential enforcement ramifications of the inspection. Additional instruction in performing these inspections is provided in part V.C. of this document.

B. Criteria for Determining Whether to Perform an Establishment Inspection of Structural Pest Control Firms Which Supply and Apply Pesticides for Hire.

During FY 77, each region will be expected to conduct establishment inspections of some firms which supply and apply pesticides in the course

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1/ FIFRA section 9(a) does not authorize inspection of any place where pesticides are being held for use or are being used. Accordingly, such places cannot be inspected except pursuant to a search warrant obtained upon a showing of probable cause that a provision of FIFRA has been or is being violated, or pursuant to the voluntary consent of the person in charge of the premises, e.g., the homeowner or restauranteur. The pest control operator who only applies pesticides provided by the customer likewise is not subject to inspection by the Agency under the authority of FIFRA section 9(a).

It is the opinion of the Agency that pesticide concentrates or use-dilution preparations of end use products which have been transferred into service containers are "released for shipment" within the meaning of FIFRA section 9(a). Service containers utilized for the temporary transportation or storage of pesticides must comply with abbreviated labeling requirements of PEPS No. 6. Failure of the service container to bear such abbreviated labeling will constitute a violation of FIFRA section 12(a)(1)(E) which makes it unlawful for any person "to sell . . . offer for sale, (or) hold for sale . . . any pesticide which is . . . misbranded." Under the provisions of PEPS No. 6, such a violation would subject the violator to civil or criminal penalties.

of providing pest control services for hire, but which do not engage in the production, formulation, or re-packaging of pesticides. In determining which firms to visit, the region should consider:

1. No Prior Establishment Inspection. Relatively few establishment inspections of structural pest control firms have been performed since the implementation of the 1972 amendments to FIFRA. The Regional Guidance provides that firms which have not previously been inspected will be inspected on a routine basis. Unless re-inspection is dictated by other criteria, establishments which have once been inspected will not be re-inspected until other establishments have once been inspected.

2. Suspected Violations. If, on the basis of prior inspections, or of reports from other Federal or State agencies or from the general public, the Region has reason to believe that evidence of violations may be discovered thereby, an establishment inspection of a pest control firm which distributes pesticides may be undertaken. As appropriate, the Notice of Inspection must specify that a violation is suspected.

3. Nature of the Pest Control Business. Firms frequently engaging in those pest control activities which are identified in Section VI below as priority areas of enforcement concern should be selected for inspection first. The regional office may have no knowledge of the principal type of pest control business engaged in by the firm prior to its first visit to the firm. Where such information is known, the Regional Offices should assign inspectional priority to firms utilizing the pesticides (or active ingredients), or the application practices outlined in Section VI below.

4. Size of the Pest Control Firm. Regions should seek to inspect firms representing a wide range of business sizes. The inspection of larger firms will maximize the coverage and exposure of our inspectional activities. The inspection of smaller firms will establish an enforcement presence among such firms.

5. Specific Assignment. An establishment inspection should be conducted whenever EPA headquarters, another Region, or another governmental agency requests that such an inspection be performed.

C. Elements of an Establishment Inspection of Structural Pest Control Firms Which Supply and Apply Pesticides for Hire.

1. Elements of Establishment Inspections Which are Authorized by FIFRA Section 9(a).

The following elements of an establishment inspection are authorized purusant to FIFRA Section 9(a), and constitute an integral part of an establishment inspection. All of the procedures for performing establishment inspections provided in Chapter 9 of the EPA Inspection Manual must be complied with in all details, particularly with respect to the requirement to provide proper identification, to give a proper Notice of Inspection, and Receipt

for any samples collected. The results of the analysis will be returned to the establishment from which the sample was collected.

a. Inspection of Books and Records. As needed, the CSO should inspect the books and records which the firm may be maintaining as required by FIFRA to collect and develop evidence to support enforcement actions. Upon specific request for information relevant to an Agency suspension or cancellation proceeding, an in-depth inspection may be undertaken of records showing the delivery, movement or holding of pesticides, as provided in FIFRA section 8(b).

b. Sampling of Pesticide Products. While performing an inspection of a pest control firm, the CSO may collect samples of pesticides which have been packaged, labeled and released for shipment in accordance with the procedures outlined in Chapter 12 of the EPA Inspection Manual.

c. Review of Abbreviated Labeling. The CSO should specifically review the abbreviated labeling which the firm has placed on any service containers containing pesticides which have been released for shipment and which are being used to temporarily store or transport pre-measured quantities of pesticide concentrates, or pre-mixed use-dilution preparations of pesticides. The abbreviated labeling must conform with the standards contained in PEPS No. 6.

2. Discretionary Inspectional Activities Which are Voluntary With the Firm and Which May be Engaged in Only with the Consent of the Company.

The following activities are not a regular part of the establishment inspection conducted pursuant to FIFRA section 9(a). They constitute discretionary activities which the CSO may engage in only with the voluntary consent of the owner, operator, or agent in charge of the establishment.

a. Review of Company Training and Educational Programs. While performing an inspection, the CSO should discuss with company officials whether the company (or its liability carrier) sponsors an on-going training program. The CSO should also determine the extent to which the company has participated in programs to certify appropriate personnel to use restricted use pesticides. This review should be conducted to stress the need to train service technicians regarding such matters as the necessity for use consistent with labeling provisions, pesticide toxicity and hazards to man and common routes of exposure, potential environmental consequences of pesticide use and misuse, factors influencing pest recognition, pesticide formulation and dilution procedures, and factors influencing pesticide toxicity, compatibility, synergism and efficacy, application equipment and methods of procedure. [See 39 FR 36450-51] The CSO should request to receive any available information regarding the company's training and educational program so that appropriate officials at the Regional Office may review the training program to

determine its nature and scope, and to evaluate its general adequacy. The CSO should explicitly advise company officials that the review of the company's training program is voluntary with the company.

b. Collection of Company Technical Bulletins or Manuals. While performing an inspection, the CSO should discuss with company officials their procedures for supplying their service technicians with adequate technical bulletins and manuals to inform them of precise procedures to be followed in performing particular pest control activities. This review should be conducted to stress the need to provide service technicians with technical bulletins or manuals regarding such matters as precautions necessary to guard against injury to people or the environment, factors influencing pest recognition, factors influencing pesticide toxicity, compatibility, synergism and efficacy, the use, calibration and maintenance of application equipment, and specific application procedures used to apply various formulations of pesticides, solutions and gases appropriate to the pest control problem at hand. [See 39 FR 36450-51]. If the company has prepared technical bulletins or manuals, the CSO should request to receive all available materials so that appropriate officials at the Regional Office may determine their nature and scope, and may evaluate their general adequacy. The CSO should explicitly advise company offficials that the review of the company's technical bulletins or manuals is voluntary with the company.

VI. Pesticide Use Inspection of Structural Pest Control Activities.

The Regional Office should perform a pesticide misuse investigation whenever there is reason to believe that provisions of the Act have been (or are being) violated. In the absence of a suspected violation (and as resources permit), the determination to perform a pesticide use inspection will typically be made after the establishment inspection has been completed, and upon a review at the Regional Office of the Establishment Inspection Report.

In performing use inspections of structural pest control treatments, the CSO must follow the procedures provided in Chapter 15 of the EPA Inspection Manual, particularly with respect to the requirement to give a Notice of Use/Misuse Inspection. In determining whether to perform a pesticide use inspection, the Regional Office shall consider:

A. Nature and Scope of the Training and Technical Support Program.

The sponsorship by the firm (or its liability carrier) of a training and technical support program which is adequate, if complied with by the service technicians, to foster good pest control practice will generally mitigate EPA's desire to perform pesticide use inspections. The absence of such a training and technical support program will increase the value to EPA (and to the firm) of performing use investigations. Furthermore, failure by the firm to have performed the training and testing necessary to certify appropriate personnel to use restricted use pesticides will increase the value to EPA of performing pesticide use inspections. Persons who engage in structural pest control as a secondary (or "moonlighting") occupation may warrant particular scrutiny.

B. Nature of Pest Control Activities Engaged In By The Firm.

The Agency intends to scrutinize most carefully the use of (a) those particular active ingredients, or (b) those particular application techniques or methods which pose unique risks of harm or which have been the source of pesticide misuse in the past.

1. Pesticides (or Active Ingredients) Which Warrant Particular Emphasis.

The use of the pesticide class or active ingredient listed below is deemed to warrant particular scrutiny because (a) the products are widely used in structural pest control and have been involved in prior misuse cases, (b) the pesticide is registered for use by application methods which pose inherent risks of harm to children, adults, or domestic animals, or (c) the pesticide or active ingredient is particularly toxic to humans or domestic animals.

The following pesticides have been identified by PTSED as warranting particular emphasis. Accordingly, the CSO should seek to accompany the service technician to observe pest control applications which involve the use of the following pesticides:

a. Phosphorus Paste Products
b. 1080: Sodium monofluoracetate
c. 1081: Fluoracetamide
d. Restricted Use Pesticides
e. Category I Pesticides

[This list may be revised by PTSED, or by a Region upon the concurrenc of PTSED, as dictated by the regulatory objectives of the Agency, or by local pest control practices within the Region].

2. Enforcement of Particular Structural Pest Control Activities or Pesticide Treatment Methods.

The Agency particularly desires to scrutinize application methods which pose serious risks of harm to people or the environment. Accordingly, the CSO should seek to accompany the service technician to observe pest control applications which involve the following pest control activities or treatment methods:

a. Fumigation Treatments: The use of fumigants in the treatment of buildings or other structures such as storage elevators or grain bins;

b. Treatments of Areas or Establishments in Which Food is Processed, Prepared or Handled: The use of appropriately registered pesticides in residential or commerical kitchens or other places where food is processed, prepared or otherwise handled;

c. Rodent Control Treatments: The use of rodent control products in household or public health baiting applications.

[This list may be revised by PTSED, or by a Region upon the concurrenc of PTSED, as dictated by the regulatory objectives of the Agency, or by local pest control practices within the Region].

C. History of Compliance, or Report of Pesticide Misuse.

When the establishment inspection arises out of a history of violations or a report of suspected pesticide misuse, the CSO should seek to accompany the service technician to observe those pest control applications which are similar in nature to those involving prior misuse, or which involve the treatment methods noted above.

VII. Prosecutorial Discretion in Initiating Enforcement Action for Violations of Particular Labeling Provisions By Structural Pest Control Operators.

The Agency's mandate to protect people and the environment from unreasonable adverse effects of pesticides is the overriding consideration in the development of enforcement policy. Any use of pesticides in a manner which results in harm or which poses an unreasonable risk of harm will subject the user to enforcement liability.

PTSED has identified a number of provisions of the Act relating to product registration and labeling which are of particular importance in structural pest control. The violation of these labeling provisions would generally pose particular risks of harm, and have in the past resulted in serious injury to persons exposed to these risks. It is the policy of the Office of Enforcement that any violation of the following provisions will, in most cases, subject the violator to civil or criminal enforcement sanctions:

1. Unregistered Pesticide: The sale or distribution of any unregistered pesticide.

2. Cancelled or Suspended Pesticide: The use, sale, or distribution of any pesticide which contains an active ingredient whose registration has been cancelled or suspended because of human health, environmental or efficacy considerations in a manner inconsistent with the terms of the Final Order.

3. Specific Prohibitions: The use of any registered pesticide in any manner which is specifically prohibited on the label.

4. Use Site: The use of a registered pesticide at a use site not provided on the label.

5. Dosage Rate: The use of a registered pesticide at a higher dosage rate than that provided on the label.

For example, a pesticide is used at a use site which is inconsistent with the labeling if it is used indoors when the label bears use instructions for outdoor applications only, if it is used in hopper cars when the label bears no instructions for use in hopper cars, or if it is applied by a broadcast mechanism when the label provides for use only in cracks and crevices. Additionally, a pesticide will be deemed to have been applied at a higher dosage rate than that provided on the label whenever the amount of active ingredient disbursed (per unit area or per unit time) exceeds that provided on the label.

Most EPA labels bear only affirmative use instructions. Since prohibitory statements are used only where the activity mentioned is strictly prohibited, the violation of any prohibitory statement will, in most cases, subject the user to enforcement sanctions.

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

JUL 11 1977

OFFICE OF ENFORCEMENT

SUBJECT: Enforcement Policy Applicable to Bulk Shipments of Pesticides

TO: Regional Enforcement Division Directors
Pesticide Branch Chiefs

I. Purpose

It has come to our attention that an increasing practice among manufacturers and distributors of pesticides involves the transport and transfer of pesticides in large quantities, i.e., "bulk". 1/ Among the reasons that manufacturers and distributors prefer to handle pesticides in bulk rather than in small individual containers are the following: 1) the need to properly dispose of excess numbers of containers is eliminated; 2) less warehouse space is required: 3) labor and handling costs are reduced; and 4) inventories can be more accurately controlled.

In the interest of energy and resource conservation and of improved safety measures in pesticide handling, it is incumbent upon the Agency to encourage and endorse these practices in so far as they are consistent with the broad purposes of FIFRA. Because the practices involved in "bulk" shipment and transfer are in some cases unclear in or are unaddressed by the Act and regulations, the development of an enforcement policy to define the limits of the "bulk" shipment and transfer practice is needed.

1/ For purposes of this policy, the term "bulk" refers to any volume of pesticide greater than 55 gallons or 100 pounds held in an individual container. Examples of bulk quantities of pesticides are: creosote in barges, weed oil in tank cars, liquid herbicide in tank trucks or rail cars, or any of these in standing storage tanks.

II. Policy and Rationale

A. Policy Summary

For purposes of enforcement of the Act, it is the policy of the Agency that so long as the transfer of a registered pesticide in "bulk" involves only the changing of the product container with no change 1) to the pesticide formulation, 2) to the product's accepted labeling (with exceptions noted in Part III B and C below, and 3) to the identity of the party accountable for the product's integrity, the new product resulting from transfer will be considered as encompassed within the terms of the registration of the product which was transferred. This rationale applies to the transfer of supplementally registered products, as well as to the basic registered product.

B. Rationale

The basis for this policy is published in the Appendix to PEPS No. 6 (41 Fed. Reg. 55932) as follows:

> FIFRA section 3(a) [7 U.S.C. 136a(a)] provides in pertinent part that
>
> > * * * no person * * * may distribute, sell, offer for sale, hold for sale, * * * to any person any pesticide which is not registered with the Administrator.
> >
> > Before a pesticide product which is not encompassed within the terms of an existing registration enters the channels of trade, a separate registration must be obtained. Changes in the formulation of a registered product, changes in accepted labeling, as well as any repackaging of a pesticide into another container will activate the registration requirement, unless the purposes of product registration would be fully met by carrying forward the Federal registration of the constituent product.
> >
> > The broad purposes of the registration process are four fold. First registration of a product provides a mechanism for the review of information regarding the safety and efficacy of the pesticide as proposed for use (and as likely to be used) under widespread and commonly recognized practice. Second, registration of a product provides EPA with the opportunity to review the proposed label and labeling of the product. To support registration, such labeling must clearly communicate the directions for use for the

product and such warnings and precautions as are necessary for the safe and efficacious use of the pesticide. Third, registration of a product identifies the party accountable for its integrity of composition, labeling and effects resulting from use. Fourth, registration of a product is the mechanism which assures that this relevant information is communicated to the ultimate user of the product.

III. Elaboration of Policy Relating to Specific FIFRA Requirements

A. Section 3

The commercial transfer of a pesticide in "bulk" may, at various stages of the shipping or distribution process, involve changing the container of the pesticide. Because "changing the container" or "repackaging" amounts to production within the meaning of 40 CFR 167.1(c), and because the resulting product is a pesticide and is being held for sale and distribution within the channels of trade, it is subject to the registration requirements of section 3. The key to determining the applicability of section 3 to a repackaged bulk product is whether the purposes of registration continue to be satisfied upon further sale and distribution after transfer. These purposes outlined above include: safety and efficacy review, label review, identification of the accountable party, and communication to the user of relevant information. Thus, to the extent that a bulk transfer involves changing the container, e.g., repackaging a registered end-use pesticide with no change to the pesticide formulation, its labeling, or the accountable party, the repackaged product is encompassed within the terms of the original registration. This means that the original registration will have satisfed the purposes of section 3 as to the repackaged pesticide. Conversely, if any of these factors change, the corresponding purpose of registration will be unsatisfied, thereby activating the registration requirement for the repackaged product.

In the context of the bulk transfer practice the most difficult of these criteria to satisfy is accountability. For purposes of this policy, the accountability requirement will be considered as met when a pesticide 1) is transfered in bulk at an establishment owned by the registrant as specified in 40 CFR 162.3(dd)(1), 2/ 2) is transferred

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2/ 40 CFR 162.3(dd) provides:

(dd) The term "operated by the same producer" means (1) another registered establishment owned by the registrant of the pesticide product or (2) another registered establishment operated under contact with the registrant of the pesticide either to package the pesticide product or to use the pesticide as a constituent part of another pesticide product provided that the final pesticide product is registered by the transferor establishment.

at a registered establishment operated under contract with the registrant within the meaning of 40 CFR 162.3(dd)(2), or 3) is transferred at a registered establishment owned by a party not under contract to the product registrant, but who has been furnished written authorization for use of the product label by the registrant. The written authorization may apply to a supplemental registrant's label as well as to a basic product label. If a supplemental registrant's label is involved, the written authorization must still be supplied to all transfer points by the basic registrant. The supplemental registrant cannot satisfy the written authorization requirement.

This provision for satisfying accountability may be utilized at as many points down the chain of distribution as the product registrant cares to authorize. However, at any point where a pesticide is transferred and repackaged in bulk by a person other than the registrant, his agent as provided in 40 CFR 162. 3(dd)(2) or one authorized by the registrant under written agreement with the registrant to transfer the product and to retain use of the registrant's label, the requirement of accountability has not been met. The resulting transferred and repackaged pesticide is considered a different pesticide no longer encompassed within the terms of the original registration and is subject to separate registration under section 3.

Sale and distribution of a pesticide transferred and held for sale under conditions other than the three outlined above and therefore in a manner which fails to satisfy the conditions of registration, will subject the party responsible for such transfer, and for subsequent sale and distribution, to the sanctions of section 12(a)(1)(A) of the Act for sale and distribution of an unregistered pesticide. Failure to supply the required label, with each sale will subject the seller to enforcement liability under section 12(a)(1)(E) for sale and distribution of a misbranded pesticide.

B. Section 2(q)

Section 2(q) lists various types of information which must appear on each pesticide label. In those cases (outlined in Part A above) where the conditions of transferal repackaging do not activate the section 3 registration requirement, the original registered label will be attached to the transferred product; 3/ however, this label must reflect the establishment number of the establishment at which

3/ Label placement must conform to the requirements of 40 CFR 162.10 (a)(4)(ii)(A) and (B)

the product was transferred (unless otherwise specified in part C below) and the appropriate net content statement. Failure to include accurate establishment registration and net content information on the label subjects the tranferor to enforcement liability under section 12(a)(1)(E).

C. Section 7

Regulations pursuant to section 7 (40 CFR Part 167) provide that the act of repackaging constitutes production and thereby activates the need for establishment registration. All establishments, therefore, in which bulk pesticides are transferred or repackaged are subject to section 7.

The Agency has determined, however, that the purposes of the Act are not substantially furthered by enforcing the establishment registration requirement for repackaging or transfer establishments when such repackaging or transfer is performed by an establishment owned by the same person who previously produced the product within the meaning of 40 CFR 162.3(dd)(1). Thus, for purposes of this policy, establishments owned by the registrant which engage only in transfer and repackaging in bulk need not be registered pursuant to section 7 and products transferred and repackaged in such establishments may retain the label showing the number of the establishment in which the original product subject to transfer and repackaging was produced.

However, when the repackaging or transfer is performed in an establishment owned by a person other than the registrant e.g., by a person operating under contract to the registrant pursuant to 40 CFR 162.3 (dd)(2) or by a person authorized by the registrant to use his label on the transferred and repackaged pesticide, that establishment must be registered and the product label must show that establishment number. This label modification may be accomplished by stickering. Failure to register producing transferring establishments as defined at 40 CFR 167 (other than those specifically exempted in this policy statement) and to reflect the establishment number on transferred products, may subject repackagers to the sanctions of section 12(a)(2)(L) of the Act for violation of section 7 and section 12(a)(1)(E) for sale and distribution of a misbranded product.

IV. Examples

A. A registrant ships a bulk pesticide to a new owner (dealer/distributor). The dealer holds the pesticide in labeled storage tanks until the material is sold in bulk quantities to end-use applicators, with the original label accompanying. The dealer's establishment number is on the label or container. The basic registrant has furnished the new owner (dealer) written authorization for use of the registrant's label. The purposes of Section 3 registration are satisfied.

B. A registrant ships a bulk pesticide directly to an end user (custom applicator, farmer, etc.). The label accompanies the shipment and is placed on the user's tank. No new establishment or product registration is needed for the bulk container since the labeled product is fully registered and has been sold intact to the user.

C. A registrant ships a bulk pesticide to a new owner (dealer/ distributor). The registrant furnishes the dealer written authorization for use of the registrant's label only to accompany material from the dealer's tanks to end-use applicators. If the dealer sells from his tanks to a second dealer for subsequent sale to an end user, the purposes of registration are not served by the sale to the second dealer. The accountability requirement will not be considered met by virtue of non-authorization of the registrant's label for such an action. The product will be considered not registered and the dealers will be subject to enforcement sanctions under sections 12(a)(1)(A) and 12 (a)(1)(E) for selling and distributing unregistered and misbranded pesticides.

Responsibility for movement of a product from the registrant to Dealer A to Dealer B and to the user is considered analogous to a registrant that sells a sealed 55-gallon drum of a pesticide to a dealer who sells the drum to another dealer. If the drum was then decanted into 11/5-gallon cans, the registrant could not be held accountable for his product, nor would the decanted product be considered registered.

D. A registrant may wish to have a dealer "operate under contract" for him as a producer. 40 CFR 162.3(dd) allows the registrant to enter formal contractural agreements that, in effect, make the contract producer an extension of the registrant's own production facilities, and both share enforcement liability for the product intergrity. Under this arrangement, the registrant's label would be placed on the bulk pesticide produced and released for shipment by the contract producer (dealer) establishment. Any further transfer of the pesticide in bulk quantities would be subject to the provisions of this policy.

E. A registrant ships a bulk pesticide to a new owner (dealer/ distributor) and refuses to furnish written authorization to use his label. If the dealer sells the pesticide, he will be considered to have sold an unregistered pesticide in violation of Section 12(a)(1)(A) and a misbranded pesticide in violation of Section 12(a)(1)(E). Without such written authorization for the use of the registrant's label, there is no identification of the party accountable for its integrity of composition, labeling, and effects resulting from use.

F. A tank car of pesticide from which commercial applicators meter off into their own tanks, without being put into a dealer's holding tank, would be exempt from new producer establishment registration. It is considered that the original container has not been changed in delivery to the applicator and the tank car label (placard) will bear the producer's establishment number. The commercial applicator would be bound by the general labeling requirements of PEPS VI if the pesticide is transported or stored. The application of PEPS VI to agricultural pest control operators will be elaborated in the enforcement policy for custom blenders and custom applicators.

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

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

22 AUG 1978

OFFICE OF ENFORCEMENT

MEMORANDUM

SUBJECT: Federal Pesticide Act of 1978

TO: Pesticides Branch Chiefs
Enforcement Division Directors

Shortly, Congress is expected to enact, and President Jimmy Carter is expected to sign into law, the Federal Pesticide Act of 1978 (FPA), amending the Federal Insecticide, Fungicide, and Rodenticide Act(FIFRA). Full implementation of these amendments will require extensive participation from your Offices, the regulated industry, and the general public. This memorandum is intended to set forth certain interim enforcement policy prior to development of an overall Agency Implementation Plan. This interim policy is effective immediately upon signature of the legislation. Violations of the Act that arise previous to passage of the FPA should be dealt with in accordance with regulations or policy in effect prior to the effective date of the new amendments.

For purposes of organization, I have grouped this policy under common headings.

a. Actions Affecting Pesticide Users

1. Distributors vs. Applicators. - A previous policy memorandum from this Office (March 25, 1976) considered pesticide applicators who supply and apply registered pesticides in the course of performing pest control services to be sellers and distributors of pesticides. An amendment found in FPA will overturn this policy to some extent. "For hire applicators"1/ are no longer to be considered sellers or

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1/ For purposes of this memorandum "for hire applicators" are those who hold or apply registered pesticides or use dilutions of registered pesticides consistent with section 2(ee) of this Act [definition of the term "to use any registered pesticide in a manner inconsistent with its labeling], only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served.

distributors (and thus subject to §14(a)(1) penalties) unless: 1) they hold or apply an unregistered pesticide, or 2) they deliver any unapplied pesticide to the customer. In either of the above situations, a "for hire applicator" would be considered a seller or distributor for any violation of FIFRA, and subject to the higher penalties set forth in sections 14(a)(1) and 14(b)(1). Because of the Congressionally mandated change in the status of certain "for hire applicators", whereby they can no longer be considered as sellers or distributors, Pesticides Enforcement Policy Statement No. 6, "Use and Labeling of Service Containers for the Transportation or Temporary Storage of Pesticides is no longer applicable to the activities of the "for hire applicator."

2. Commercial Applicators. - Any applicator (except a private applicator) who uses or supervises the use of a restricted use pesticide, whether or not that applicator is certified, is a commercial applicator subject to the higher penalties of sections 14(a)(1) and 14(b)(1).

3. Penalties. - Any "for hire applicator" who violates any provision of FIFRA while holding or applying a registered general use or unclassified pesticide is liable for a maximum fine of $500 for the first offense and $1000 for subsequent offenses in accordance with language amending section 14(a)(2). The new penalty scheme follows:

Applicator Category	GUP2/	RUP3/	Maximum Fine		
			14(a)(2) warning	$500	$5000
Commercial	X			X	
"		X			X
"For Hire"	X			X	
"		X			X
Private	X		X		
"		X	X		
Others	X		X		
"		X			X

2/ General Use or Unclassified Pesticide
3/ Restricted Use Pesticide

Until a new civil penalty matrix is issued, when considering the size of the business, the following interim matrix should be used to determine the maximum penalty:

Category I & II - 1st Offense $250; Subsequent $500

Category III, IV & V - 1st Offense 500; Subsequent $1000

Violations of the Act that arise from independent acts, but which are part of the same series of events, should be assessed as a single offense. As previously stated, it is our position that any violations that occurred prior to the final enactment of the FPA are subject to the provisions and interpretations of the law prior to the amendments. All outstanding cases will continue to proceed on that basis including cases where the civil penalty complaint has not been issued.

4. Use Inconsistent with Labeling. - The term "to use any registered pesticide in a manner inconsistent with its labeling" has been defined, eliminating the need for some Pesticides Enforcement Policy Statements (PEPS). Certain use practices previously covered by PEPS are now permissible without resort to the admininistrative mechanisms found in those PEPS. These include: 1) use of a pesticide at less than labeling dosage (PEPS 1), 2) use of a pesticide for the control of a target pest not named on the labeling, if the site is included on the labeling (PEPS 2 & 5), and 3) use of any application method not prohibited by labeling (PEPS 7). Also, though not the subject of a PEPS, the mixing of a pesticide with another pesticide or with a fertilizer, if not prohibited by labeling, is permissible. In addition, any use of a pesticide in conformance with sections 5, 18, or 24 of FIFRA, will not be considered use inconsistent with labeling.

b. Registration of Establishments

Names of pesticides or active ingredients used in producing pesticides which have been submitted pursuant to section 7(c) of FIFRA are no longer considered as confidential records or information. Requests for such information under the Freedom of Information Act may be granted.

c. Books and Records

The FPA will require that inspectors present their credentials, along with a Notice of Inspection citing the reasons for the inspection prior to conducting a books and records inspection. Since this procedure is required currently by the Pesticides Inspection Manual, no change in procedure is necessary. However, all personnel should be made aware that these procedures are now required by an amendment to section 8 of FIFRA.

d. Unlawful Acts.

An amendment to section 12(a)(2)(F) would permit the sale of restricted use pesticides to uncertified persons for later application by certified applicators under regulations issued by the Administrator. Until such regulations are promulgated, the procedures for permitting such sale found in Part IX of the preamble to the Classification Regulations (43 Fed. Reg. 5783, Feb. 9, 1978) shall govern. In brief, a State must have in effect laws or regulations which 1) require an uncertified person to furnish written evidence that a certified applicator will use the pesticide and 2) require that pesticide dealers keep records of such evidence before uncertified persons could purchase a restricted use pesticide.

I have attached a memorandum, dated July 26, 1978, which discusses, in brief, the FIFRA amendments. This memorandum has an Appendix which contains draft language of the amendments as they would appear when inserted into the FIFRA.

As previously mentioned, a plan for implementing the Federal Pesticide Act of 1978 is currently under development within the Agency. Your input into any regulations, guidance or policy that will flesh out these amendments is strongly encouraged by this Office. Any comments or questions you have concerning the amendments should be directed to Jack Neylan (755-0997).

A. E. Conroy II

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

Attachment

PEPS

[FRL 1243-2]

Pesticides and Toxic Substances Enforcement

On September 30, 1978, the President signed into law S. 1678, the Federal Pesticide Act of 1978 (Pub. L. 95-396, 92 Stat. 819; hereafter "FPA"), which amends the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (Pub. L. 92-516, 86 Stat. 973; Pub. L. 94-140, 89 Stat. 751; 7 USC 136 *et seq*; hereafter referred to as "FIFRA"). As a result of the new amendments, certain of the Pesticide Enforcement Policy Statements (PEPS), which established an administrative mechanism to permit certain pesticide uses which otherwise would have been in violation of FIFRA, are no longer necessary. The purpose of this Notice is to announce the rescission of the affected PEPS and to discuss some of the amendments in the FPA that affect pesticide enforcement policy.

(1) Rescission of Pesticide Enforcement Policy Statements (PEPS) Nos. 1, 2, 5, and 7

On May 5, 1975, the Environmental Protection Agency (EPA) published in the Federal Register a document entitled "Institution of Pesticide Enforcement Policy Statements" (40 *Fed. Reg.* 19538 (1975)). It was the Agency's purpose in instituting this series of Pesticide Enforcement Policy Statements (PEPS) to inform the general public and persons engaged in the formulation, distribution, sale, application or other use of pesticides, of the policies adopted by the Agency in the enforcement of the provisions of the FIFRA. The PEPS were prepared and published by EPA's Office of Enforcement.

Federal regulation of the use of pesticides was established for the first time with the enactment of the 1972 amendments, specifically through the provisions of FIFRA section 3(d)(1), section 4 and section 12(a)(2)(G). Section 12(a)(2)(G) made it unlawful for any person to use a registered pesticide in a manner inconsistent with its labeling. However, as set forth in the legislative history, Congress intended that EPA enforce the prohibition of section 12(a)(2)(G) in a "common sense manner" and left open in many instances exactly what constituted a "use inconsistent with [a pesticide's] labeling."

The FPA broadens the construction of section 12(a)(2)(G) of FIFRA by adding a new subsection 2(ee) which for the first time defines the term "to use any registered pesticide in a manner inconsistent with its labeling."

According to the language of the new subsection, it is a violation of section 12(a)(2)(G) to use a registered pesticide "in a manner not permitted by the labeling" with the exception of four specific areas. The areas specifically excluded from enforcement under § 12(a)(2)(G) include: (a) the use of a pesticide at less than label dosage (PEPS 1);[1] (b) the use of a pesticide for the control of target pests not named on the labeling, if still consistent with site included on the labeling (PEPS 2 and 5); and, (c) the use of any application method not prohibited by labeling (PEPS 7).[2]

Thus, the new section 2(ee) defines by law certain uses which will not be considered inconsistent with labeling that previously were defined by PEPS. The new definition provides exemptions from the strict label language for users/applicators only. Persons who distribute or sell pesticides still may not make oral or written claims for a product which substantially differ from any claims made for the product as a part of the statement required in connection with its registration under section 3 of FIFRA (eg., claims for use not listed on the labeling), or they will be subject to enforcement action under section 12(a)(1)(E).

(2) Actions affecting pesticide users: rescission of PEPS No. 6

The Office of Enforcement issued a policy statement on March 23, 1978 which stated that pesticide applicators who supply and apply registered pesticides in the course of performing pest control services (hereafter "for hire applicators") were considered sellers and distributors of pesticides. Section 2(e)(1) of the FIFRA has been amended so as to generally exclude "for hire applicators" from being considered sellers or distributors of pesticides where they provide the service of controlling pests without delivering any unapplied pesticide to any person so served. "For hire applicators" are no longer considered sellers or distributors (and thus subject to the higher civil penalties in § 14(a)(1)) unless: (a) they hold or apply an unregistered pesticide, or (b) they deliver any unapplied pesticide to the customer. In either of the above situations a "for hire applicator" would be considered a seller or distributor for any violation of FIFRA, and subject to the higher penalties set forth in sections 14(a)(1) and 14(b)(1). Because of the Congressionally mandated change in the status of "for hire applicators," PEPS No. 6, "Use and Labeling of Service Containers for the Transportation or Temporary Storage of Pesticides" is no longer applicable to the activities of the "for hire applicator."

(3) Continuation of Pesticide Enforcement Policy Statements (PEPS) Nos. 3 and 4

Two of the existing PEPS are not affected by the amendments in the FPA and, therefore, are not rescinded by this Notice. They are PEPS No. 3, entitled "Certain Enforcement Policies To Be Followed During the Phased Implementation of FIFRA Section 3" (41 *Fed. Reg.* 13384 (1976)), and PEPS No. 4, entitled "Preventive Pest Control Treatments in the Absence of Target Pests" (41 FR 23005 (1976)).

(4) Commercial Applicators

The FPA also amends the definition of "commercial applicator" in section 2(e)(3) of FIFRA. The new definition provides that the term "commercial applicator" means any applicator (except a private applicator) who uses or supervises the use of a restricted use pesticide, whether or not that applicator is certified. Such persons who violate FIFRA while using *restricted* use pesticides are considered commercial applicators and subject to the higher penalties of section 14(a)(1) and 14(b)(1). On the other hand, any person (excluding those persons subject to the penalty provisions of section 14(a)(1)), as described in section 2 of this Notice) who holds or applies a pesticide registered for *general* use, or a dilution of a pesticide registered for general use and who violates FIFRA, would be subject to the lower penalties as set forth in sections 14(a)(2) and 14(b)(2) of FIFRA.

(5) Definition of "Producer"

The FPA amends the definition of "producer" to add the following:

> The dilution by individuals of formulated pesticides for their own use and according to the directions on registered labels shall not of itself result in such individuals being included in the definition of "producer" for the purposes of this Act.

This amendment makes statutory the Agency's long-standing policy of not considering persons who dilute pesticides as producers unless they engage in the sale and/or distribution of the pesticide.

This notice hereby rescinds PEPS Nos. 1, 2, 5, 6, and 7.

Dated: June 4, 1979.

Jeffrey G. Miller,

Acting Assistant Administrator for Enforcement.

[FR Doc. 79-17970 Filed 6-7-79; 8:45 am]

BILLING CODE 6560-01-M

[1] While PEPS No. 1 excluded certain products which could not be used at less than label dosage—viz. rodenticides, termite control products, and sanitizer/disinfectants—the new definition of section 12(a)(2)(G) does not.

[2] It should be noted that while the FPA amends existing Federal law concerning pesticide misuse, it does not affect State laws. Therefore, before proceeding with any pesticide use in accordance with the exceptions now allowed by the new amendments, pesticide users and applicators should make certain that they will not be in violation of State law.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENFORCEMENT
OFFICE OF GENERAL ENFORCEMENT
PESTICIDES ENFORCEMENT DIVISION

PESTICIDE ENFORCEMENT POLICY STATEMENT NO. 1

USES OF REGISTERED PESTICIDES AT LESS THAN LABEL DOSAGE RATE

Reprinted from the Federal Register of May 5, 1975 (40 FR 19529)
and
September 17, 1975 (40 FR 42914)

Pesticide Enforcement Policy Statement No. 1

USE OF REGISTERED PESTICIDES AT LESS THAN DOSAGE RATE

I. *Background.* On May 6, 1976, the U.S. Environmental Protection Agency published in the FEDERAL REGISTER a document entitled "Notice of the Institution of a Series of Pesticide Enforcement Policy Statements" (PEPS) (40 FR 19526). It was the Agency's purpose in instituting this series of Policy Statements to inform those engaged in the formulation, distribution, sales, application or other use of pesticides, as well as interested segments of the general public, of policies adopted by the Agency in the exercise of its prosecutorial discretion in the enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act as amended (FIFRA). It was suggested in that notice that a large number of these Pesticide Enforcement Policy Statements would involve particular aspects of pesticide use.

These PEPS are prepared and published by EPA's Office of Enforcement. The series of PEPS, insofar as they may regard pesticide use, represent an application of the Agency's prosecutorial discretion. In exercising its prosecutorial discretion, the Agency strives to provide that level of control over regulated activities which is consistent with its public trust and its statutory mandate to protect man and the environment from the hazards associated with the formulation, distribution, sale, application or other use of pesticides.

In making enforcement policy determinations, the Office of Enforcement considers the regulatory purpose to be advanced by compliance with the labeling provisions, customary pesticide application or use practice, the weight of the equities under the totality of the circumstances, and the standard which was imposed by Congress for determining the appropriateness of particular applications or uses of a registered pesticide. This standard was described by the Senate Committee on Agriculture and Forestry when it noted that:

> [I]t is not the intention of the Committee to prohibit any use which is in no way harmful, and which has only beneficial effects on man and his environment (S. Rep. No. 92-838, 92d Cong. 2d Sess. 16 (1972)).

Whether a particular use is to be considered "beneficial" or "harmful" is a determination to be made by the Agency. It is presumed for enforcement purposes that the affirmative provisions of a product label which are accepted by the Agency in conjunction with the product's registration contain allowable uses for the product. Accordingly, an application or other use of a registered pesticide which is not affirmatively provided on the approved label may be considered to be a use of a registered pesticide "in a manner inconsistent with its labeling" and may subject the violator to civil or criminal sanctions.

The Office of Enforcement, in the exercise of its prosecutorial discretion, may determine that some uses or applications which are not affirmatively provided on the label are, nonetheless, to be allowed. The Agency has instituted the series of Pesticide Enforcement Policy Statements to provide public notice of instances in which deviations from the precise language of the product label will not subject the user to enforcement liability. It is understood that no deviation from the affirmative provisions of an approved label shall be allowed which is not explicitly countenanced in a published Pesticide Enforcement Policy Statement.

The legislative history of the 1972 amendments to FIFRA suggests that it was the intent of Congress to ensure that the Agency evaluate the meaning of the term "inconsistent with the label" in a common sense manner. The House of Representatives Committee on Agriculture specifically addressed this issue as it relates to the use of a registered pesticide at a dosage rate lower than that approved on the label:

> It is the intent of this definition that articles designated for general or restricted use may be used by a pesticide applicator at a lower dilution than that specified on the label. While it would obviously be dangerous to permit more concentrated solutions to be used, the Committee recognizes the need to apply the standard of use "inconsistent" with respect to labeling in a common sense manner. Thus for example the use of pesticide solutions in lower amounts for aerial spraying, when otherwise determined to be safe, should be permitted. (H.R. Rep. No. 92-511 92d Cong. 1st Sess., 16 (1971)).

In light of this legislative history, this policy statement regarding the application or use of a registered pesticide at less than the label dosage rate may appear to define the Agency's regulatory jurisdiction under FIFRA. This PEPS does not presume to define the Agency's regulatory jurisdiction, but rather represents the exercise of the Agency's prosecutorial discretion. It defines pesticide application or use prac-

tices which will (or will not) subject the user to prosecution, but does not define pesticide application or use practices which do (or do not) violate FIFRA section 12(a)(2)(G). If the Administrator subsequently promulgates regulations which interpret the scope of the Agency's regulatory jurisdiction, the Office of Enforcement will revoke or amend this PEPS to conform to subsequent regulations.

Recently, many persons have sought permission from the Agency to apply or use pesticides at lower dosage rates than those specified on their accepted labels. Such persons have inquired into the circumstances and conditions under which use at a lower dosage rate may, as a matter of prosecutorial discretion and legislative intent, be deemed to be consistent with the purposes and objectives of FIFRA as amended.

II. *Use of a registered pesticide at less than the label dosage.* The Agency has determined that an application or use of a registered pesticide at a lower dosage rate than that recommended on the accepted label will be permitted if such application or use (a) is recommended in writing by a knowledgeable expert, (b) is efficacious against the target pest, and has only beneficial effects to man and the environment, (c) is performed in accordance with all other label instructions and precautions, and (d) is not repeated at the low dosage rate so frequently as to result in a total pesticide dosage higher than that specified on the approved label.

This policy statement shall apply to the following areas of pesticide use: Agricultural pest control, animal pest control, forest pest control, right-of-way pest control, ornamental and turf pest control, seed treatment, aquatic pest control, industrial, institutional, structural and health related pest control, public health pest control, mosquito control, regulatory pest control, and demonstration and research pest control. Notwithstanding the above, the application or use at a lesser dosage rate of a rodenticide, termite control product or antimicrobial agent such as a disinfectant, sanitizer, or fungicide under any circumstances is prohibited. All of the limiting and defining provisions contained in the paragraphs which follow are an integral part of this policy statement.

III. *Applicability of the Pesticide Enforcement Policy Statement Regarding Lesser Dosages.*—A. *Recommendation of Knowledgeable Expert.* A pesticide applicator or user may apply a registered pesticide at a dosage rate less than that which appears on the accepted label only if the application or use is recommended in writing as safe and efficacious by a recognized expert in pest control practices. This recommendation may be made in a general statement or published document issued by an appropriate State or Federal official or as part of a program developed by an independent and qualified pest management specialist. This written recommendation must be in the possession of the applicator or user prior to the application or use, and must be made available to an official representative of the Agency upon request.

Recognized authorities in the field of pest control are often employed by organizations such as State Cooperative Extension Services, Federal or State departments or agencies, State and Federal Public Health Services. Independent pest management specialists and pest management consultants are also considered to be competent to offer advice regarding dosage rates which will be safe and efficacious in particular environmental circumstances. These recommendations may be made through current scientific journals, textbooks, manuals, technical bulletins or by specific written instructions from a qualified person to the individual.

Responsibility for the safe and efficacious use of the pesticide and for full compliance with the terms of this Pesticide Enforcement Policy Statement may rest with either the user or the recommending expert, or both, as the equities of the circumstance may require. It must be recognized, however, that the Agency has neither assessed nor approved the efficacy of the pesticide application or use at a lower dosage rate.

B. *Product Efficacy and Harmful Effects.* The Agency will construe any application or use at less than the label dosage which is inefficacious or which is in any way harmful to man or the environment to be a use inconsistent with the labeling as prohibited in the Act. Enforcement action will be taken on a case-by-case basis for such violators where repeated abuse of this policy or continued harm to man or the environment has occurred.

An application or use is inefficacious if it results in the control of substantially fewer pests than is normally associated with pesticide use in comparable environmental circumstances or than is intended. The efficacy of any particular pesticide application or use may depend upon the genetic composition of the target pest, pest population dynamics, environmental circumstances, geographic and climatic factors, and the presence of beneficial insects or other organisms.

C. *Directions for Use and Other Precautionary Labeling.* Acceptability of a lesser dosage rate in no way alters or modifies any other label provisions or direction for use. Label provisions which must be complied with at all times (regardless of the application dosage rate) include but are not limited to statements regarding product mixing, loading and preparation, application methods, reentry standards, protective clothing or equipment, product and container transportation, storage and disposal, warning statements, and the minimum application interval before harvest.

No label instruction which affirmatively prohibits use of a lesser dosage may be violated. A pesticide application at a dosage rate which contradicts a specific label minimum dosage rate will be considered to be a violation of the Act.

While dosage rates less than the label levels are considered acceptable, any application or use of any registered pesticide at a dosage rate above the label is strictly prohibited and will subject the user to criminal or civil penalties. In situations where target pests can no longer be controlled with label recommended levels because of pest resistance or other reasons, it will be necessary for the registrant to petition the Agency for an appropriate amendment of the registered labeling. This action is necessary (1) to ensure that proposed increases in label dosages are properly evaluated in respect to human or environmental hazards as required by the amended FIFRA or (2) to determine if the proposed actions may violate tolerance regulations for food or feed crops established under authority of the Federal, Food, Drug and Cosmetic Act (FFDCA).

D. *Total Pesticide Dosage.* This policy which allows the use of lesser dosages in no way permits the application or use (by frequent or repeated applications) of a greater total quantity of pesticide within a period of time where specified on the approved label.

E. *Under-Formulation by Registrant or Producer.* This policy which allows the use of a lesser dosage in no way condones an under-formulation of the pesticide product by the pesticide producer. The allowable formulation of the registered product and the required statement of active ingredients on the label is not affected by this policy statement.

IV. *Duration of Pesticide Enforcement Policy Statement.* This Pesticide Enforcement Policy Statement will remain in effect until amended or modified by subsequent published PEPS or by regulations promulgated by the Administrator. The Agency will evaluate the policy announced herein to determine those areas of pesticide use or those classes of pesticide products in which problems arise. Revocation of the permission to use lesser dosages in specific situations may result from a determination by the Agency that such application or use is either inefficacious or harmful to man or the environment.

V. *Public Comment.* The PEPS relate directly to internal Agency procedures and practice and constitute "interpretive rules" or "general statements of policy". As such, the Agency does not solicit public comment regarding matters published in this series of notices. However, interested persons may submit written comments regarding the policy set forth in this PEPS to the Pesticides Enforcement Division, (EN-342), Office of Enforcement, Environmental Protection Agency, Washington, D.C. 20460. Three copies of the comments should be submitted to facilitate the work of the EPA and others interested in inspecting the document.

Dated: April 30, 1975.

ROBERT L. BAUM,
Acting Assistant Administrator for Enforcement.

Amendment to Pesticide Enforcement Policy Statement No. 1, Use of Registered Pesticides at Less Than Label Dosage Rates

On May 5, 1975, the U.S. Environmental Protection Agency published in the FEDERAL REGISTER Pesticide Enforcement Policy Statement (PEPS) No. 1 entitled "Use of Registered Pesticides at Less Than Label Dosage Rate" (40 FR 19529). This notice informed the pesticide industry and the general public of the Agency's policy permitting the use of a registered pesticide at less than label dosage rates providing that the use is 1) recommended in writing by a knowledgeable expert, 2) is efficacious against the target pest, 3) is performed in accordance with all other label instructions and precautions, and 4) is not repeated at the low dosage rate so frequently as to result in a total pesticide dosage higher than that

[illegible] opted by the Agency and need not remain subject to the requirement for full dosages specified for certain products in PEPS No. 1.

The U.S. Environmental Protection Agency hereby revises Pesticide Enforcement Policy Statement No. 1 (40 FR 19529, May 6, 1975), Section II, Paragraph Two, Sentence Two to read as follows:

Notwithstanding the above, the application or use at a lesser dosage rate of a rodenticide, termite control product, or antimicrobial agent such as a disinfectant or sanitizer which is intended for structural, institutional or domestic use under any circumstances is prohibited.

ROBERT L. BAUM,
Acting Assistant Administrator for Enforcement.

SEPTEMBER 10, 1975.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENFORCEMENT
OFFICE OF GENERAL ENFORCEMENT
PESTICIDES ENFORCEMENT DIVISION

PESTICIDE ENFORCEMENT POLICY STATEMENT NO. 2

USE OF REGISTERED PESTICIDES FOR THE CONTROL OF UNNAMED TARGET PESTS IN STRUCTURAL PEST CONTROL

Reprinted from the Federal Register of September 5, 1975
(40 FR 41175)

PESTICIDE ENFORCEMENT POLICY STATEMENT NO. 2

Use of Registered Pesticides For the Control of Unnamed Target Pests In Structural Pest Control

I. *General Background.*

On May 5, 1975, the Environmental Protection Agency (EPA) published in the FEDERAL REGISTER a document entitled "Institution of Enforcement Policy Statements" (40 FR 19526). It was the Agency's purpose in instituting this series of Pesticide Enforcement Policy Statements (PEPS) to inform the general public and persons engaged in the formulation, distribution, sale, application, or other use of pesticides, of the policies adopted by the Agency in the enforcement of the provisions of the *Federal Insecticide, Fungicide, and Rodenticide Act*, as amended [Pub. L. 92-516; 86 Stat 973; 7 U.S.C. 136 et seq.; hereinafter referred to as FIFRA]. PEPS are prepared and published by EPA's Office of Enforcement. A detailed explanation of the purpose and scope of PEPS was set forth in the May 5, 1975, FEDERAL REGISTER notice.

Federal regulation of the use of pesticides was established for the first time with the enactment of the 1972 amendments, specifically through the provisions of FIFRA section 12(a)(2)(G). Any person who uses a registered pesticide in a manner inconsistent with its labeling is in violation of the Act and may be subject to civil or criminal sanctions. However, as set forth in the legislative history, Congress intended that EPA enforce the prohibition of section 12(a)(2)(G) in a "common sense manner" and not prohibit the use of registered pesticides which are in no way harmful and which have demonstrated beneficial effects. [House Committee on Agriculture, H.R. REP. No. 92-511, 92d Cong., 1st Sess. 16 (1971), and Senate Committee on Agriculture and Forestry, S. Rep. No. 92-838, 92d Cong., 2d Sess. 16 (1972)].

As the Senate Committee on Agriculture and Forestry stated:

> * * * it is the belief of the Committee that the use of the word "inconsistent" should be read and administered in a way so as to visit penalties only upon those individuals who have disregarded instructions on a label that would indicate to a man of ordinary intelligence that use not in accordance with such instructions might endanger the safety of others or the environment. Senate Report, *Id.*

In view of the legislative history concerning the use of registered pesticides for the control of unnamed target pests, this PEPS touches upon matters which may appear to be jurisdictional in nature. It does not, however, presume to define the Agency's regulatory jurisdiction. If the Administrator subsequently promulgates regulations, which interpret the scope of the Agency's regulatory jurisdiction, the Office of Enforcement will revoke or amend this PEPS to conform with such regulations.

This policy statement concerns the use of a registered pesticide in structural pest control for the control of pests which are not named on the product's label. It neither addresses nor in any way affects the requirement of compliance with affirmative provisions of an approved label.

EPA has long been aware of the fact that there exist a host of structural pests which are limited in number and sporadic in their occurrence. These pests are not sufficiently important to justify or in some cases even to permit the collection of sufficient data to meet EPA standards for revision of registration and labeling to include them. Another class of pest problems involves pests which are unpredictable or unprecedented in their occurrence. In the past, pest control operators have commonly used registered pesticides successfully to control pests which, for the reasons described above, were not specifically listed on the pesticide's approved labeling. These pesticide applications against unnamed target pests are conducted with application rates and intervals, and at use sites which conform to those appearing on the approved labeling. However, such a use constitutes a technical violation of section 12(a)(2)(G), in that the target pest differs from that listed on the approved label.

Recently, many interested people have sought permission from EPA to use registered pesticides to control minor or infrequently encountered pests which appear in, on, or adjacent to any structure when such pests are not named on the approved label of the pesticide. Consistent with the legislative history of section 12(a)(2)(G), EPA has determined that under the specified conditions and limitations set forth below, use of a registered pesticide against unnamed pests does not warrant prosecution for violation of section 12(a)(2)(G).

II. *Use of a Registered Pesticide for the Control of Unnamed Target Pests in Structural Pest Control.*

The Agency has determined that the use of a registered pesticide at use sites approved on the label for the control of unnamed target pests in, on, or adjacent to any structure is permitted, provided that:

(A) The pesticide selected is registered for use at the type of site which is to be treated;

(B) Either (1) the user is a knowledgeable expert in structural pest control who has himself recommended the use of a registered pesticide against the unnamed target pest; or (2) the use is recommended in writing by a knowledgeable expert in structural pest control;

(C) No pesticide registered for use against the target pest in, on, or adjacent to any structure is reasonably available in the geographic area in which the pesticide is to be used;

(D) The user complies with all other instructions, warnings, precautions, and prohibitions which appear on the label and labeling of the product which is used; and

(E) The use is efficacious, in that it has beneficial effects, and is not harmful to man or the environment.

All of the limiting and defining provisions contained in the paragraphs which follow are an integral part of this PEPS. Whether the user has reasonably met the criteria set forth in this PEPS will be determined by the Agency on a case-by-case basis. The burden of showing that the criteria set forth herein has been met rests with the person applying or otherwise using a registered pesticide for the control of unnamed target pests in structural pest control.

III. *Applicability of the Pesticide Enforcement Policy Statement Regarding Use of Registered Pesticides for the Control of Unnamed Target Pests.*

A. *Use at the Specific Type of Site Which is to be Treated.*

The policy set forth in this statement allows the use of a registered pesticide against unnamed target pests only when the application is made at the specific type of use site for which the product is registered. This policy applies to the use of registered pesticides in, on, or adjacent to enclosed man-made structures such as human dwellings, institutions (including schools and hospitals), industrial establishments, non-commercial greenhouses and other structures used for the protection of stored, processed, or manufactured products. This PEPS does not, for example, allow any person to use a pesticide which is registered for use in, on, or adjacent to structures to perform any agricultural or other outdoor application or use which is not related to structural pest control. No pesticide registered solely for agricultural use may be used for the control of unnamed target pests in, on, or adjacent to any structure.

B. *Recommendation by a Knowledgeable Expert in Structural Pest Control.*

1. *Definition of the Term "Knowledgeable Expert in Structural Pest Control."*

The term "knowledgeable expert in structural pest control" refers to any person who (1) holds a college or higher level degree in entomology or other science related to pest control; or (2) has five (5) or more years of practical experience in professional pest control; or (3) is the supervisory official of the firm, organization or Agency making the application who is responsible for making technical judgments regarding pest control practice; or (4) is certified by a State pursuant to FIFRA Section 4 to use restricted use pesticides in industrial, institutional, structural or health-related pest control (40 CFR 171.3(b)(7)).

Knowledgeable experts in the field of structural pest control may also include qualified persons employed by organizations such as State Cooperative Extension Services, Federal, State, or local departments or agencies, or public health services.

2. *Use by a Knowledgeable Expert in Structural Pest Control.*

A registered pesticide may be applied or otherwise used for the control of unnamed target pests by a "knowledgeable expert in structural pest control" if that expert himself makes the judgment that such use is efficacious against the unnamed target pest, and that such use is not or will not be harmful to man or the environment.

3. *Recommendation of Knowledgeable Expert in Structural Pest Control.*

A registered pesticide may be applied or otherwise used for the control of unnamed target pests by a person who is not himself a knowledgeable expert in structural pest control only if the application or use has been recommended in writing by a knowledgeable expert.

These recommendations will be made part of the records of pest control activities. Sufficient records must be kept to describe accurately the circumstances of the pest infestation, the pesticide recommended for control of the problem, the results of the treatment, and the name and address of the knowledgeable expert. These records shall be maintained by the person who applies or otherwise uses the pesticide for a period of six (6) months from the date of application or use. Recommendations of a knowledgeable expert in structural pest control may be in the form of articles published in current scientific journals, manuals, or other technical bulletins or specific instructions. The applicator or user must have obtained the written recommendation prior to the time of the application. He must make such recommendations available to an official representative of the Agency upon request.

4. *Enforcement Liability.*

The responsibility for the safe and efficacious use of the pesticide and for full compliance with the terms of this PEPS may rest with either the applicator of the knowledgeable expert in structural pest control or both, as the equities and the circumstances may require.

A knowledgeable expert in structural pest control who personally uses or supervises the use of a registered pesticide against unnamed target pests is responsible for the proper use of the pesticide and for the efficacy of the product against the unnamed target pest. The expert in this position is therefore also subject to enforcement liability for any misuse of the pesticide. In all applications performed by persons other than a knowledgeable expert, the primary responsibility for compliance rests with the person who performs the actual application. Enforcement action will be considered on a case-by-case basis for violations involving significant harm to man or the environment or deviations from the provisions of section II (A) through (E) above.

C. *Reasonable Availability of a Pesticide Registered for Use Against the Target Pest.*

Any registered pesticide currently in the channels of commerce in the geographic area where the user resides or does business is presumed, for purposes of enforcement, to be reasonably available for the control of pests. In determining whether a registered pesticide is reasonably available in the geographic area in which the pesticide is to be used the Agency will consider whether (a) the user had made a reasonable effort to ascertain whether any pesticide had been registered for the control of the target pest, (b) the user had attempted to procure any such pesticide registered for the target pest from his normal sources of distribution, and (c) it was reasonable to conclude that no pesticide registered for the control of the target pest could be obtained within a reasonable period of time from any other structural pest control operator in the geographic area in which the pesticide was to be used.

No claim of unavailability may be made on the basis of excessive cost or non-profitability. Furthermore, a business policy of exclusively using one's own product will not support a claim of unavailability if a pesticide registered for the control of the target pest is available from another registrant or distributor in the geographic area in which the pesticide is to be used.

D. *Directions for Use and Other Precautionary Labeling.*

The use of a registered pesticide for the control of an unnamed target pest neither modifies other label provisions or directions for use, nor authorizes the use of the pesticide in a manner inconsistent with any other label provision, including directions for use, precautionary labeling and warning statements. Label provisions which must be complied with at all times regardless of the target pest include, but are not limited to, statements regarding product mixing, loading and preparation, application methods, label dosage rate (except as provided in PEPS No. 1, 40 FR 19529), structure reentry times, protective clothing or equipment, product and container transportation, and storage and disposal. Although it is not common practice, where a registrant desires expressly to prohibit use of a pesticide against named or unnamed pests and the label so provides, it shall be a violation of FIFRA section 12(a)(2)(G) to use such pesticide for the control of such named or unnamed pest.

E. *Product Efficacy, and Beneficial/Harmful Effects.*

Pesticide use for the control of unnamed target pests must be efficacious and must not be harmful to man or the environment. An application or use will be considered to be efficacious if it has beneficial effects and controls unnamed target pests in a manner which is normally associated with the use of the pesticide in the specific environmental situation.

V. *Public Comment.*

The Administrative Procedures Act (5 U.S.C. § 553(b)) provides that the solicitation of comments is not required

of Federal agencies for "interpretative rules, general statements of policy, rules of agency organization, procedure, or practice." The PEIS relate directly to internal Agency procedures and practice and constitute "interpretive rules" or "general statements of policy." As such, this policy statement falls within the scope of this exemption. However, interested persons may submit written comments regarding the policy set forth in this PEIS to the Pesticides Enforcement Division (EG-342), Office of Enforcement, U.S. Environmental Protection Agency, 401 M St. S.W., Room 3624, Washington, D.C. 20460. Three copies of these comments should be submitted to facilitate the work of the EPA and others interested in inspecting such documents.

Dated: August 29, 1975.

STANLEY W. LEGRO,
Assistant Administrator
for Enforcement.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENFORCEMENT
OFFICE OF GENERAL ENFORCEMENT
PESTICIDES AND TOXIC SUBSTANCES
ENFORCEMENT DIVISION

PESTICIDE ENFORCEMENT, POLICY STATEMENT NO. 5

Use of Registered Pesticides for the Control of Pests Not Named on the Label in Agricultural and Other Non-Structural Pest Control

Reprinted from the Federal Register of September 21, 1976
(41 FR 41142)

PESTICIDE ENFORCEMENT POLICY STATEMENT NO. 5

Use of Registered Pesticides for the Control of Pests Not Named on the Label in Agricultural and Other Non-Structural Pest Control

I. General Background

On May 5, 1975, the Environmental Protection Agency (EPA) published in the Federal Register a document entitled "Institution of Enforcement Policy Statements" [40 FR 19526]. It was the Agency's purpose in instituting this series of Pesticide Enforcement Policy Statements (PEPS) to inform the general public and persons engaged in the formulation, distribution, sale, application, or other use of pesticides of the policies adopted by the Agency in the enforcement of the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended in 1972 and 1975 (Pub. L. 92-516, 86 Stat. 973; Pub. L. 94-140, 89 Stat. 751; 7 U.S.C. 136 et seq.; hereinafter referred to as FIFRA). PEPS are prepared and published by EPA's Office of Enforcement. Unless otherwise expressly provided, a PEPS indicates how the Agency will exercise its prosecutorial discretion, and does not interpret the law or otherwise define what is and what is not lawful conduct under FIFRA. The Office of Enforcement will revoke or amend any PEPS which are inconsistent with regulations interpreting FIFRA which are subsequently promulgated by the Administrator. A detailed explanation of the purpose and scope of PEPS was set forth in the May 5, 1975, Federal Register notice.

Federal regulation of the use of pesticides was established for the first time with the enactment of the 1972 amendments, specifically through the provisions of FIFRA section 3(d)(1), section 4, and section 12(a)(2)(G).[1] Any person who uses a registered pesticide in a manner inconsistent with its labeling is in violation of the Act and may be subject to civil or criminal sanctions.[2] However, Congress intended that EPA enforce the prohibition of section 12(a)(2)(G) in a "common sense manner" and not prohibit uses of registered pesticides which are in no way harmful and which have demonstrated beneficial effects.[3]

II. Purpose and Scope of This PEPS

A. Control of Improbable, Unanticipated, or Other Infrequently Occurring Pests. Pesticides are commonly registered

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[1] FIFRA section 3(d)(1) [7 U.S.C. 136a (d)(1)] provides that as part of the registration of a pesticide, the Administrator shall classify each pesticide for general or for restricted use, or for both general use and restricted use as the Administrator, in his discretion, may require. [See 40 CFR Part 162.2(C)].

FIFRA section 4(a)(1) [7 U.S.C. 136(a)(1)] empowers the Administrator to prescribe standards for the certification of applicators of restricted use pesticides. The Agency has promulgated regulations establishing certain categories of commercial (professional) applicators and setting forth minimum standards that commercial and private applicators must meet before they are certified to the pesticides classified under FIFRA section 3 for "restricted use" [40 CFR Part 171].

[2] FIFRA section 12(a)(2)(G) [7 U.S.C. 136j (a)(2)(G)] provides that it is unlawful for "any person to use any registered pesticide in a manner inconsistent with its labeling." This section became effective upon the date of enactment of FIFRA and was determined by the Administrator to be self implementing [FIFRA Implementation Plan, 89 Fed. Reg. 1142]. The regulations implementing the registration provision of the 1972 amendments define pesticide "use" to mean

"Any act of handling or release of a pesticide, or exposure of man or the environment to a pesticide through acts, including but not limited to:

(1) application of a pesticide, including mixing and loading and any required supervisory action in or near the area of application; and

(2) storage actions for pesticides and pesticide containers; and

(3) Disposal action for pesticides and pesticides containers" [40 CFR 162.3(oo)].

This definition of the term "use" has been adopted by the Office of Enforcement in the enforcement of pesticide labeling standards under FIFRA section 12(a)(2)(G).

[3] House Committee on Agriculture, H.R. Rep. No. 92-511, 92d Cong., 1st Sess. 18 (1971); Senate Committee on Agriculture and Forestry, S. Rept. No. 92 838, 92d Cong., 2d Sess. 18 (1972). The Senate Committee on Agriculture and Forestry suggested the standard that the Agency should apply in enforcing against pesticide misuse:

"* * * it is the belief of the Committee that the use of the word "inconsistent" should be read and administered in a way so as to visit penalties only upon those individuals who have disregarded instructions on a label that would indicate to a man of ordinary intelligence that use not in accordance with such instructions might endanger the safety of others or the environment.

[4] Senate Committee on Agriculture and Forestry, S. Rept. No 92 838, 92d Cong., 2d Sess. 14 (1972). As the Senate Committee on Agriculture and Forestry stated,

"[I]t is not the intention of the Committee to prohibit any use which is in no way harmful, and which has only beneficial effects on man and his environment.

for the control of pests attacking major commodities, crops or treatment areas. Accordingly, many pests which may be encountered in agricultural or other non-structural pest control situations may not be listed on the label of pesticide products registered for use on the commodity, crop, or area where the pest is encountered. EPA is aware that pests may appear which are improbable, unanticipated, or otherwise infrequent in their occurrence. The suddenness of these infestations may not allow sufficient time to enable the registrant to meet EPA standards for registration and labeling. Furthermore, the infrequent or sporadic nature of such unnamed pests limits the economic incentives of the agricultural chemical industry to register these additional pest control uses.

The use of a registered pesticide to control a pest not named on the EPA accepted label would not generally post different risks to man or the environment than would the use of such pesticide to control pests which are named on the label when used in a manner consistent with all other label instructions. Accordingly, it can generally be found that such use against an unnamed pest is as safe as (or is normally no more dangerous than) a properly performed use against the pests named on the label. The primary consideration in the treatment of an unnamed pest is therefore the efficacy of the pesticide, i.e., whether the product achieves, or is likely to achieve, effective control of the unnamed pest. This PEPS sets forth an enforcement policy pursuant to which registered pesticides may be used for the control of improbable, unanticipated, or other infrequently occurring agricultural and other nonstructural pests which are not named on the product's label. This PEPS also establishes an administrative mechanism designed to insure that the anticipated efficacy of proposed uses against unnamed pests will be evaluated by a knowledgeable expert, and that the appropriate State agency will be informed of the recommendation that is made.[1]

B. *FIFRA section 24 (c): State Registrations for "Special Local Needs".* Anticipating that pesticides registered under FIFRA section 3 would not address all pest control problems, Congress provided a statutory mechanism to respond to special local pest control problems. FIFRA section 24(c) (7 U.S.C. 136v(c)) authorizes the Administrator to certify States to issue State registrations of pesticides to respond to "special local needs".[2]

Section 24(c) provides in part:

> A State may provide registration for pesticides formulated for distribution and use within that State to meet special local needs if that State is certified by the Administrator as capable of exercising adequate controls to assure that such registration will be in accord with the purposes of (FIFRA). * * * *

Proposed regulations implementing FIFRA section 24(c) were promulgated on September 3, 1975 (40 FR 40538). The Agency is currently evaluating the comments received and preparing final regulations. The preamble to the proposed regulations announced an interim program of certifying States (found by the Administrator to have established qualifying programs) to issue State registrations pursuant to FIFRA section 24(c). This interim certification program will be in effect during the time period necessary to promulgate final regulations implementing section 24(c). Most States have applied for and have been granted interim certification to issue State registrations for "special local needs" pursuant to section 24(c).[3]

C. *Applicability of the Administrative Mechanism Established in this PEPS.* In addition to the State registrations for "special local needs" provided in FIFRA section 24(c), prosecutorial discretion will be exercised under the conditions specified in this PEPS to resolve problems arising in the control of unnamed pests. The administrative mechanism set forth in this PEPS may be utilized where (a) the unnamed pest is improbable, unanticipated, or infrequent in its occurrence, (b) efficacy data needed to support a registration for the unnamed pest is unavailable, and (c) the failure to control the unnamed pest may be reasonably expected to cause material injury to the commodity or area to be treated.

The administrative mechanism established in this PEPS complements the FIFRA section 24(c) registration program for "special local needs." Notwithstanding this PEPS, the Agency expects that the statutory mechanism for responding to special local pest control needs (i.e., FIFRA section 24(c)) will be utilized to provide State registrations for applications performed for the control of pest infestations which are recurring or persistent in their occurrence.[4]

D. *Further Requirements Imposed by the States.* This PEPS in no way affects the authority of a State, acting pursuant to FIFRA section 24(a), to add further restrictions regarding the use of a Federally-registered product, or in accordance with State law, to prohibit particular uses of Federally-registered pesticides within that State. The Agency anticipates that States may elect to exercise the powers set forth in section 24(a) in the two specific ways elaborated below. The election by a State to impose further restrictions (such as those noted below) upon the use within that State of a Federally-registered product will not affect the Agency's exercise of prosecutorial discretion under FIFRA. An applicator or other person who complies with the requirements set forth in Sections III and IV of this PEPS but who does not comply with the additional requirements established by a State pursuant to FIFRA section 24(a) may be subject to liability only under *State* law. All persons performing applications pursuant to the administrative mechanism set forth in this PEPS are encouraged to familiarize themselves with applicable State regulations.

1. *Election by the State to Designate "Knowledgeable Experts."* Each State may elect to specifically designate competent individuals to be knowledgeable experts within that State by placing their names on a list of knowledgeable experts, or by some other means acceptable to the State. Each State may establish more stringent standards than those which are listed in Section III. C. and IV. C. below. No person will be deemed to be a knowledgeable expert within the meaning of this PEPS unless he meets the minimum standard set forth in Section III. C. and IV. C. below, regardless of having been designated as a knowledgeable expert by a State.

2. *Election by the State to Conduct a Preapplication Review of the Recommendation of the Knowledgeable Expert.* Each State may elect to review individually each recommendation made by a knowledgeable expert prior to the time of the pesticide application for the control of the unnamed pest. States exercising this election will establish their own procedures for performing this preapplication review.

III. Summary of Enforcement Policy Regarding the Use of a Registered Pesticide for the Control of Agricultural or Other Non-Structural Pests Not Named on the Label

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[1] On September 8, 1976, the Office of Enforcement published PEPS No. 2 entitled "Use of a Registered Pesticide for the Control of Unnamed Target Pests in Structural Pest Control" (40 Fed. Reg. 41175). PEPS No. 2 presented the Agency's enforcement policy regarding a pest control matter which is closely associated with the problem addressed in this PEPS. The Agency is currently evaluating differences between the policy and administrative mechanisms established in PEPS No. 2 and this PEPS to determine whether changes in PEPS No. 2 are necessary or appropriate.

[2] It should be noted that FIFRA section 24(c) contains one statutory provision which may be relied upon to address the problem of unanticipated or infrequently occurring pests. A number of other provisions of FIFRA may also be relied upon to alleviate problems of pesticide use which relate to this category of pests. For example, pursuant to FIFRA section 18, Federal or State agencies may obtain emergency exemptions from the registration requirements for the control of pest infestations which constitute a unique crisis, specific emergency, or a threat to public health and for the control of which no pesticide registered for the particular use is available. [40 CFR Part 166].

[3] The legislative history of the 1972 amendments plainly indicates that it was the intention of the Congress that FIFRA section 24(c) be employed to respond to minor or local pesticide use problems. The Senate Committee on Agriculture and Forestry noted that

> (t)he purpose of [section 24(c)] is to give a State the opportunity to meet expeditiously and with less cost and administrative burden on the registrant, the problem of registering for local use a pesticide needed to treat a pest infestation which is a problem in such State but is not sufficiently widespread to warrant the expense and difficulties of Federal registration.

Senate Report No. 92-838, dated June 7, 1972, and Part II of the same Report, dated October 8, 1972; See also House of Representatives Report No. 92-511, dated September 25, 1971.

[4] States may be certified to register pesticide products for local or minor pest problems under the following circumstances:

> There is no EPA-registered pesticide product for the use in question, or there is an EPA-registered pesticide product, but it is not available, e.g., cannot be obtained in sufficient quantity, or there is an EPA-registered pesticide product which, nominally, is suitable but, if used in accordance with the label, would not be as safe or as efficacious under local conditions [40 FR 40539; September 3, 1976].

[5] It should be noted that the availability of the administrative mechanism provided in this PEPS in no way limits the right of any person authorized to do so to seek a State registration pursuant to FIFRA section 24(c) for the use of a Federally registered pesticide for the control of improbable, unanticipated, cyclical, or other infrequently occurring pests.

The use of a registered pesticide to control pests not named on the label or labeling constitutes a violation of FIFRA section 12(a)(2)(G) in that it is a "use of a registered pesticide in a manner inconsistent with its labeling." In the exercise of its prosecutorial discretion, however, the Agency will not initiate enforcement action against a person who uses a registered pesticide for the control of appropriate categories of agricultural or other non-structural pests which are not named on the product's label where all of the following conditions are met:

(A) The unnamed pest to be treated is improbable, unanticipated, or infrequent in its occurrence, and is not a bacterium, fungus, virus or other microbial life form which is pathogenic to man or other animals;

(B) The selected pesticide is registered for use at the type of site or application environment and on the commodity, crop, or area which is to be treated;

(C) The use is recommended in writing by an individual who is a knowledgeable expert in the appropriate area of agricultural or other non-structural pest control;

(D) The recommendation of the knowledgeable expert is submitted to the State Control Agency;

(E) No pesticide registered for use against the agricultural or other non-structural pest is reasonably available in the geographic area in which the pesticide is to be used;

(F) The user complies with all instructions, warnings, precautions, and prohibitions on the label and labeling of the product which is used, other than those pertaining to the pests against which the pesticide is to be used;

(G) The selected pesticide does not contain an ingredient included in a product whose registration is the subject of a notice of intent to cancel or suspend, or whose registration has been suspended or cancelled because of human health, environmental or efficacy considerations with respect to such ingredient; and

(H) The use is efficacious or may reasonably be expected to be efficacious in the control of the unnamed pest.

All of the limiting and defining provisions contained in the paragraphs which follow are an elaboration of conditions A through H above, and as such are an integral part of this PEPS. Whether the user has reasonably met the criteria set forth in this PEPS will be determined by the Agency on a case-by-case basis. The burden of showing that the criteria set forth herein have been met rests with the person applying or otherwise using a registered pesticide for the control of agricultural or other non-structural pests which are not named on the approved product label.

IV. Elaboration of Conditions Regarding Use of Registered Pesticides for the Control of Agricultural or Other Non-Structural Pests Not Named on the Label

A. *Treatment of Improbable, Unanticipated or Other Infrequently Occurring Pests (except Bacteria, Fungi, Viruses or Other Pathogens).* The administrative mechanism set forth in this PEPS may be utilized only to control pests which are improbable, unanticipated or otherwise infrequent in their occurrence. The knowledgeable expert who makes the recommendation must certify that the unnamed pest to be treated is appropriately addressed by this PEPS. The use of a registered pesticide against unnamed pests which are not improbable, unanticipated, or otherwise infrequent in their occurrence will subject the knowledgeable expert and/or the user to civil or criminal sanctions as noted in Section IV. C.4 of this PEPS.

The administrative mechanism established in this PEPS may not be utilized if the pest to be controlled is a bacterium, fungus, virus or other microbial life form which is pathogenic to man or animals. In effect, this limitation removes from the scope of this PEPS antimicrobial agents (See 40 CFR 162.2(ff)) and fungicides (See 40 CFR 162.3(ff)) intended for preventing, destroying, repelling or mitigating human or animal pathogens. Therefore, in order to control an unnamed human or animal pathogen, it will be necessary to obtain an amended registration under FIFRA. This limitation upon the scope of this PEPS is based upon a finding that the efficacy of disinfectants, sanitizers, sterilizers, bacteriostats, or other antimicrobial products used against human or animal pathogens has unique significance, in that especially serious consequences may result if such a pesticide is not in fact efficacious in the treatment of this category of unnamed pests.

B. *Use at the Specific Type of Site or Application Environment and on the Commodity, Crop, or Area Which is to be Treated.* The policy set forth in this PEPS applies to the use of a registered pesticide for the control of unnamed agricultural or other non-structural pests only when the application is made at the specific type of use site or application environment and on a commodity, crop, or area which appears on the EPA-accepted label of the product used.[a] For example, this PEPS in no way authorizes the use of a pesticide which is registered for use in, on, or adjacent to structures for any agricultural or other out-door application which is not related to structural pest control.

This policy applies to the use of registered pesticides in agricultural applications for the production of agricultural crops,[b] in outdoor or indoor applications on animals,[c] in forest pest control,[d] in ornamental and turf pest control,[e] in seed treatments, in right-of-way pest control,[f] and in public health and regulatory pest control.[g]

C. *Recommendation of a Knowledgeable Expert in Agricultural or Other Non-Structural Pest Control*—1. *Meaning of the Term "Knowledgeable Expert"*—(a) *Qualifications of Knowledgeable Experts.* The Agency intends in this PEPS to allow the use of registered pesticides for the control of unnamed pests where such applications provide efficacious control of the unnamed pest. To achieve this end, the Agency requires all persons seeking to control unnamed pests to obtain the written recommendation of a knowledgeable expert. To be considered to be a knowledgeable expert within the meaning of this PEPS an individual must have obtained sufficient technical education and/or practical experience in the particular pest control area in which the recommendation is being made. Persons who have any of the following combinations of qualifying technical experience and education may qualify to be knowledgeable experts within the meaning of this PEPS.

Qualifying Experience:	Qualifying Education
6 years	Less than Baccalaureate Degree.
3 years	Baccalaureate Degree.
2 years	Masters Degree.
1 year	Doctorate.

As used in this PEPS, the terms "qualifying experience" and "qualifying education" refer to practical pest control experience or formal academic training in the particular pest control area or academic discipline in which the recommendation is made as a result of which the knowledgeable expert has become familiar with the following elements of pest control practice:

(i) *Pesticide:* the pesticide (or active ingredient) to be used to control the unnamed pest;

(ii) *Use Site and Pest Control Environment:* the commodity, crop or area to be treated; and the climatic, seasonal, and geographic characteristics of the locale;

(iii) *Pest:* the class and nature of the unnamed pest to be controlled;

(iv) *Application Method:* the method of preparing and applying the pesticide as instructed on the label of the pesticide selected for use.

(b) *Examples of "Knowledgeable Experts".* Qualified persons employed by such organizations as State Cooperative Extension Services, State land grant colleges, Federal, State, or local agricultural departments or agencies, or public health agencies may be considered to be "knowledgeable experts." Others may include pest management specialists or consul-

[a] An evaluation of the behavior of pesticide residues on the commodity or crop to which a pesticide is applied is an integral part of the registration of any pesticide. Strict conformity with all other conditions of this PEPS will not prevent the quarantine seizure of the commodity or crop if illegal residues are discovered thereon.

[b] Agricultural commodity and crop applications include, without limitation, tobacco, peanuts, cotton, feed grains, soybeans and forage vegetables, small fruits, tree fruits and nuts, as well as on grasslands and non-crop agricultural lands.

[c] Animal applications include, without limitation, beef cattle, dairy cattle, swine, sheep, horses, goats, poultry and livestock. Pesticidal treatments made to places in which such animals are confined must be made in accordance with the provisions on the label of the pesticide used in the treatment, or in accordance with the provisions of PEPS No. 2.

[d] Forest pest control includes without limitation pesticide applications to forests, forest nurseries, and forest seed producing areas.

[e] Ornamental and turf pest control includes, without limitation, applications on ornamental trees, shrubs, flowers, and turf. It includes applications in greenhouses.

[f] Right-of-way pest control includes, without limitation, applications on roads, electric powerlines, pipelines, and railway rights-of-way.

[g] Public health and regulatory pest control includes pest control activities engaged in by State, Federal or other governmental employees using or supervising the use pesticides in public health programs for the management and control of pests having medical and public health importance, or in the control of other regulated pests.

tants. Qualified academicians employed by private institutions and scientists employed by a company owning or managing the farm or other application site may also be knowledgeable experts. Additionally, scientists and other persons employed by a manufacturer, distributor, formulator, or user will be deemed to be knowledgeable experts within the meaning of this PEPS if such persons are responsible for making technical judgments regarding the development and use of particular pesticides for active ingredients) or regarding particular pest control practices.

(c) *Limitations.* Notwithstanding the above, no person whose principal function or primary source of personal income (e.g., sales commission) is directly derived from promoting the sale or distribution of the pesticide (or active ingredient) which is recommended for use may provide the recommendation required of a knowledgeable expert under this PEPS. Under no circumstances may any sales representative, marketing employee, or advertising agent of any manufacturer, distributor or formulator or any other person who has a primary personal economic interest in promoting the sale or distribution of a product provide the recommendation required of a knowledgeable expert."

2. *Contents of the Recommendation of the Knowledgeable Expert.* Each recommendation made by a knowledgeable expert for the use of a registered pesticide for the control of unnamed agricultural and other non-structural pests shall be made in writing and shall be signed and dated. In making the recommendation the knowledgeable expert must assure himself that the pest to be treated is improbable, unanticipated or infrequent in its occurrence within the meaning of this PEPS. The recommendation of the knowledgeable expert must specify (e.g., by county) the geographic location in which the use against the unnamed pest will be allowed, the commodity, crop or area on which the application is to be made, the dates or duration for which the recommendation is applicable, the pesticide to be used, and the unnamed pest which is to be controlled.

The recommendation of the knowledgeable expert must refer to either (a) the particular pesticide product which is to be used to control the unnamed pest (identified by proprietary name and by EPA Registration Number), or (b) the particular formulation of active ingredient (identified by the percentage of active ingredient) to which the recommendation applies. If the recommendation refers to a particular formulation of active ingredient, the proprietary product used to control the unnamed pest must contain that exact formulation. The applicator or user must have obtained the written recommendation of the knowledgeable expert prior to the time of the application. He must make a copy of such recommendation available to an official representative of EPA upon request. Unless otherwise provided therein, the recommendation of a knowledgeable expert shall remain in effect for the duration of the pest infestation or pest control problem out of which the need for the control of an unnamed pest arose, but no longer than the growing season in which the recommendation was made. If the infestation or pest control problem persists past the initial growing season, any subsequent application should be made as a result of a State registration issued pursuant to FIFRA section 24(c), or an EPA registration issued pursuant to FIFRA section 3.

The recommendation of the knowledgeable expert will be valid only in the State wherein the recommendation was given, and the pesticide is to be applied.

3. *Liability of the Knowledgeable Expert.*—a. *FIFRA Enforcement Liability.* The responsibility for the efficacious use of the pesticide and for full compliance with the terms of this PEPS may rest with either the applicator or the knowledgeable expert in agricultural or other non-structural pest control or both, as the equities and the circumstances may require. Pursuant to FIFRA section 12 (a)(2)(G), it is unlawful for any person to "use any registered pesticide in a manner inconsistent with its labeling." FIFRA enforcement liability for the misuse of pesticides falls primarily upon the pesticide user or applicator. Particularly where the pesticide application involves a deviation from the uses which are allowed on the accepted label, any person who mixes, loads, applies, stores, or disposes of any registered pesticide in a manner inconsistent with its labeling may be subject to civil or criminal sanctions under FIFRA."

The knowledgeable expert who personally uses a registered pesticide against unnamed pest is responsible for the proper use of the pesticide and for the efficacy of the product against the unnamed pest. In addition, the expert who personally supervises the actual use or application is himself considered to "use" the pesticide within the meaning of FIFRA section 12(a)(2)(G), and is thus subject to FIFRA enforcement liability for any misuse of the pesticide which occurs under his supervision." The responsibility for compliance with all applicable labeling requirements, and with all of the provisions of this PEPS is assumed by the person who uses or supervises the use of the product.

b. *Civil Liability.* It is not the intention of the Office of Enforcement that this PEPS should in any way affect the civil liability in damages of a knowledgeable expert. This PEPS is not intended to increase the risk of liability beyond that which is inherent in the ordinary execution of one's duties in offering pest control advice to users, or in supervising pesticide applications. Nor is this PEPS intended to exempt the expert from possible civil liability for damages arising out of his own negligence. Any knowledgeable expert may be liable for damages which result from a recommendation which he makes if that recommendation evidences a careless or negligent disregard for commonly applied principles in the area of his expertise, and upon which the user relies to his detriment.

D. *Notification of the State Control Agency.*—1. *Meaning of the Term "State Control Agency".* As used in this PEPS the term "State Control Agency" refers to that agency which has been designated within each State to regulate the use of pesticides in agricultural (plant and animal), forest, ornamental, seed treatment, or right-of-way pest control, respectively. In most cases the State Control Agency will be the State agency which has been designated by the Governor to be the State Lead Agency pursuant to the provisions of FIFRA section 4, and the State plan submitted pursuant to 40 CFR Part 171. Where the State Lead Agency is not the State Control Agency within the meaning of this PEPS, the State Lead Agency (or the State's Department of Agriculture) will be able to direct interested individuals to the appropriate State Control Agency.

2. *Notification of the State Control Agency.* Except as otherwise provided by States electing to review each recommendation of its knowledgeable experts, each recommendation which is made by a knowledgeable expert pursuant to this PEPS must be forwarded by the knowledgeable expert to the State Control Agency of the State in which the application is to occur. The State Control Agency for each State will determine its own procedures and policies for this process, subject to the requirements for the kind of information to be provided, as stated in section IV.C.2. of this PEPS. This requirement to notify the State Control Agency shall serve to (a) inform the State Control Agency of pest control activities being performed within the State, and (b) provide an experimental basis for evaluating the need for a State registration issued pursuant to FIFRA section 24(c) to respond to identified special local pest control needs.

The State Control Agency shall maintain a record of the recommendation of the knowledgeable expert for two (2) years from the date of the recommendation.

E. *Availability of a Pesticide Registered for Use Against the Pest.* Any registered pesticide which is currently in the channels of commerce in the geographic area where the user resides or does business is presumed, for purposes of enforcement, to be reasonably available for the control of all pests named on the label. In determining whether a pesticide which is registered for use

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* This prohibition is consistent with the provisions of FIFRA section 12(a)(1)(B), which makes it unlawful 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 registered pesticide if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration under section 3 [Emphasis added; 7 U.S.C. 136j(a)(1)(B)].

It is noted, however, that professional pest control operators who are deemed by the Agency to hold pesticides "for distribution or sale" within the meaning of FIFRA may be deemed to be knowledgeable experts within the meaning of this PEPS if they meet the educational or experiential standards set forth in this PEPS.

** Where the recommendation of the knowledgeable expert does not refer to a proprietary pesticide product, but refers instead to a formulation with a stipulated percent active ingredient, it is the responsibility of the person who uses or applies the pesticide to select a proprietary product which contains the stipulated percent of active ingredient and which is registered for use at the use site or in the application environment in which an unnamed pest appears.

*** Many State pesticide laws prohibit the recommendations of the use of a registered pesticide in a manner inconsistent with its accepted labeling. This PEPS in no way affects the liability under applicable State law of a knowledgeable expert who recommends the use of a pesticide in a manner inconsistent with its labeling.

against the target pest is reasonably available, the Agency will consider whether:

(a) The user has contacted officials of State or Federal agencies which exercise regulatory authority in the area of pesticide use, or has otherwise made a reasonable effort to ascertain whether any pesticide has been registered for the control of the pest;

(b) The user has attempted to procure any such pesticide registered for the pest from his normal sources of distribution; and

(c) It is reasonable to conclude that no pesticide registered for the control of the pest could be obtained within a reasonable time from another distributor in the geographic area in which the pesticide was to be used.

No claim of unavailability may be made on the basis of cost or profitability.

F. *Directions for Use and Other Precautionary Labeling.* The use of a registered pesticide for the control of unnamed pests in accordance with the provisions of this PEPS neither modifies other label provisions or directions for use, nor authorizes the use of the pesticide in a manner inconsistent with any other label provisions, including, without limitation, directions for use, and precautionary labeling and warning statements. Under no circumstances does this PEPS permit any activity which is expressly prohibited on the label. Label provisions which must be complied with at all times regardless of the pest treated include, without limitation, statements regarding product mixing, loading and preparation, application methods, label dosage rates (except as provided in another published PEPS), application frequency or pre-harvest intervals, field reentry intervals, protective clothing or equipment requirements, product packaging and transportation requirements, and storage and disposal practices. Although it is not common, where the label of a registered pesticide expressly prohibits use of the pesticide against unnamed pests, it shall be a violation of FIFRA section 12(a)(2)(G) to use such pesticide for the control of unnamed pests.

G. *Cancellation or Suspension of a Pesticide Ingredient.* The administrative mechanism established in this PEPS may not be utilized to authorize the use against an unnamed pest of a pesticide which contains an ingredient which is included in a product whose registration is the subject of a notice of intent to cancel or suspend, or whose registration has been cancelled or suspended because of human health, environmental, or efficacy considerations with respect to such ingredient.[*]

The decision to cancel or suspend the registration of a pesticide for certain uses is based upon a careful balancing of the costs incurred and the benefits derived from those uses.[**] The decision to cancel or suspend certain uses of pesticide products containing a given ingredient or ingredients, and not to cancel or suspend certain other uses reflects a carefully considered judgment that the benefits of the uses which have not been cancelled or suspended outweigh the risks. Necessarily, no such finding will have been made by the Administrator with respect to the use of pesticide products containing the ingredients in question against pests which are not named on the label of the product; the use of the product cannot be extended to unnamed pests unless and until the Administrator has determined through the registration process that the benefits of the use outweigh the risks.

Somewhat different considerations warrant the exclusion from the scope of this PEPS of products containing ingredients included in products subject to a notice of intent to cancel or suspend. The issuance of such a notice indicates that a substantial question of safety exists with respect to the use of products containing the ingredient in question. Until this question of safety has been thoroughly explored in the cancellation or suspension hearing, prudent public policy dictates that the products be restricted to those uses which are expressly provided for on the product label.

H. *Product Efficacy.* The pesticide application for the control of unnamed pest must be efficacious, or must reasonably be expected to be efficacious in the control of the unnamed pest. An application or use will be considered to be efficacious if it has the beneficial effect of controlling the unnamed pest.

V. Public Comment

The Administrative Procedure Act (5 U.S.C. 553(b)) provides that the solicitation of comments is not required of Federal agencies for "interpretative rules, general statements of policy, rules of agency organization, procedures, or practice." EPA has determined that this PEPS falls within this exemption from the requirement to solicit public comment. Accordingly, the Agency is not soliciting public comment regarding matters published in this notice. However, interested persons may submit written comments regarding the policy set forth in this PEPS. These comments may be addressed to the Pesticides and Toxic Substances Enforcement Division (EN-342), Office of Enforcement, U.S. Environmental Protection Agency, 401 M Street, S.W., Room 3024, Washington, D.C. 20460. Three copies of these comments should be submitted to facilitate the work of the Agency and of others interested in inspecting such documents.

Stanley W. Legro,
Assistant Administrator for Enforcement.

September 18, 1978.

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[*] It should be noted that this same category of pesticides was explicitly exempted from the special local needs registration program under FIFRA section 24(c). See proposed regulations at 40 CFR 162.153(c)(2)(ii).

[**] Registered uses of a pesticide are cancelled only upon a finding that such uses pose an "unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of (each use)." (7 USC 136(bb)) The decision to suspend the registration of a pesticide for certain uses is based upon a finding that such uses pose an "imminent hazard", i.e., "that the continued use of the pesticide during the time required for cancellation proceedings would be likely to result in unreasonable adverse effects on the environment * * *" (7 U.S.C. 136(l)). Applying this statutory standard in determining whether or not to suspend the registration of certain uses of a pesticide also involves a careful balancing of the costs and benefits of the uses in question.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF ENFORCEMENT

OFFICE OF GENERAL ENFORCEMENT

PESTICIDES AND TOXIC SUBSTANCES

ENFORCEMENT DIVISION

PESTICIDE ENFORCEMENT POLICY STATEMENT NO. 6

STRUCTURAL PEST CONTROL

Use and Labeling of Service Containers for the Transportation or Temporary Storage of Pesticides

Reprinted from the Federal Register of December 23, 1976

(41 FR 55932)

Use and Labeling of Service Containers for the Transportation or Temporary Storage of Pesticides

I. *General Background.*

On May 5, 1975, the Environmental Protection Agency (EPA) published in the FEDERAL REGISTER a document entitled "Institution of Enforcement Policy Statements" (40 FR 19528). It was the Agency's purpose in instituting this series of Pesticide Enforcement Policy Statements (PEPS) to inform the general public and persons engaged in the formulation, distribution, sale, application, or other use of pesticides of the policies adopted by the Agency in the exercise of its prosecutorial discretion in the enforcement of the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended in 1972 and 1975 (Pub. L. 92-516; 86 Stat. 973; Pub. L. 94-140; 89 Stat. 751; 7 U.S.C. 136 et seq.; hereinafter referred to as FIFRA). PEPS are prepared and published by EPA's Office of Enforcement. Unless otherwise expressly provided, a PEPS indicates how the Agency will exercise its *prosecutorial discretion, and does not interpret* the law or otherwise define what is and what is not lawful conduct under FIFRA. The Office of Enforcement will revoke or amend any PEPS which is inconsistent with regulations interpreting FIFRA which are subsequently promulgated by the Administrator.[1] A detailed explanation of the purpose and scope of PEPS was set forth in the May 5, 1975, FEDERAL REGISTER notice.

II. *Subject and Scope of This PEPS.*

This PEPS addresses two pesticide transportation and storage practices which are commonly engaged in by professional structural pest control operators. The first practice consists of transferring or repackaging portions of a pesticide concentrate[2] into a service container[3] for the purpose of transporting it to the application site, or of temporarily storing the pesticide prior to application. This practice allows the pest control operator to purchase large quantities of a pesticide concentrate and then mix, store, and transport smaller portions for actual application.

The second practice addressed in this PEPS involves the utilization of service containers for the pre-measure and premixture of quantities of use-dilution preparations[4] of pesticides at a storage site prior to application, and for the transportation of such use-dilution preparations to the application site. These practices lessen the possibility of spillage at the application site, and help to insure that accurate and consistent dosage levels are used with each application.

III. *Jurisdiction to Regulate the Use and Labeling of Service Containers.*[5]

It is the opinion of the Agency that professional pest control operators who

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[1] The Agency anticipates that the exemption from enforcement sanctions which is outlined in this PEPS will be superseded by regulations having the same effect, published pursuant to section 25(b) of the Act.

[2] As used in this PEPS, the term "pesticide concentrate" means any formulation of chemicals which has not been diluted or altered as specified on the label or labeling for the purpose of producing the concentration of the pesticide required for a particular purpose or effect provided on its accepted label or labeling.

[3] As used in this PEPS, the term "service container" means any container utilized to hold, store, or transport a pesticide concentrate or a pesticide use-dilution preparation, other than (a) the original labeled container provided by the manufacturer, (b) the measuring device, or (c) the application device. Containers used for the recovery and disposal of pesticides and target pests (e.g., containers used to recover rodent bait apparatuses together with dead rodents) are not deemed to be service containers within the meaning of this PEPS. Pesticides in such containers must be handled and disposed of in a manner consistent with the disposal instructions on the EPA-accepted label or pursuant to the *Recommended Procedures for* Disposal and Storage issued by the Agency pursuant to FIFRA section 19.

[4] As used in this PEPS, the term "use-dilution preparation" means a pesticidal preparation which is mixed with a diluent and at a rate specified on the label or labeling which produces the concentration of the pesticide for a particular purpose or effect provided on such accepted label or labeling.

[5] This part of PEPS No. 8 represents an outline of the Agency's legal interpretation of the effect of the 1972 amendments and the implementing regulations on the authority of the Agency to regulate the activities of pest control operators with respect to the use of service containers. As indicated above, PEPS *generally describe how the Agency will* exercise its prosecutorial discretion under FIFRA. As to this instance, any portion of a PEPS which interprets the law will be accompanied by an express indication that the portion is in fact interpretive. All interpretive portions of a PEPS have the concurrence of the Agency's Office of General Counsel. For a more detailed exposition of the Agency's jurisdiction to regulate the use and labeling of service containers, see the Appendix to this PEPS.

supply and apply pesticides for hire engage in the distribution or sale of pesticides within the meaning of FIFRA.[6] FIFRA section 9(a) authorizes the Agency to perform without a warrant the administrative inspection of places where pesticides are "held for distribution or sale." These inspections may be performed for the purpose of obtaining samples of pesticides, including the contents of service containers, of reviewing labeling on pesticides, including the abbreviated labeling on service containers, and of inspecting books and records which the firm may maintain regarding the delivery, movement, or holding of pesticides, as authorized by FIFRA section 8(b).

FIFRA section 12(a)(1)(E) provides that it is unlawful "* * * to distribute, sell, offer for sale, (or) hold for sale * * * any pesticide which is * * * misbranded." The sale or distribution of a pesticide concentrate or of a use-dilution preparation[7] in a container other than the original container bearing the EPA-accepted labeling constitutes a literal violation of FIFRA section 12(a)(1)(E). Thus, it is technically illegal for a structural pest control operator performing pest control services for hire to utilize service containers to store or transport pesticides.[8]

IV. *Summary of Enforcement Policy Regarding the Use and Labeling of Service Containers.*

The Agency finds that the utilization of service containers has generally beneficial effects and need not cause unreasonable risks of harm to man or the environment. However, to require each service container to bear a full end-use label may materially inhibit the utilization of service containers by structural pest control operators. Accordingly, the Office of Enforcement, in the exercise of its prosecutorial discretion, has determined that it will refrain from prosecuting structural pest control operators under FIFRA section 12(a) for the utilization of service containers to transport or temporarily store end-use pesticides, *if all of the following conditions and limitations are met:*

(A) An abbreviated label, securely attached to the service container, includes the following information:

1. *Pesticide Concentrate.* If the pesticide to be transported or stored in the service container is a pesticide concentrate:

a. The name, address, and telephone number of the pest control firm;

b. Product name;

c. EPA Registration number;

d. Name and percentage of active ingredients; and

e. Signal word from registered label.

2. *Use-dilution Preparation.* If the pesticide to be transported or stored in the service container is a use-dilution preparation of the product an end-use pesticide:

a. The name, address, and telephone number of the pest control firm;

b. Product name, preceded by the word "Diluted";

c. EPA registration number, preceded by the words "Derived from";

d. Name and percentage of active ingredient as diluted; and

e. Signal word from the registered label.

(B) A reference copy of the EPA-accepted labeling for the registered product is in the *possession of the firm at its place of business* at the time of the application and is made available to an appropriate regulatory official of the Agency upon request; and

(C) The user complies with all use instructions, warnings, precautions, and prohibitions which appear on the EPA accepted label or labeling of the registered product; and

(D) The service container conforms in all respects with any applicable container or packaging requirements for pesticide products; and

(E) The pesticide in the service container is not sold, distributed or given away for application or other use by another person.

The limiting and defining provisions contained in section V of this PEPS are an elaboration of the conditions A through E above. Whether the user has reasonably met the requirements set forth in this PEPS will be determined by the Agency on a case-by-case basis. The *burden of showing that the requirements* set forth herein have been met rests with the person engaging in the transportation or temporary storage of a registered pesticide in a service container.[9]

V. *Elaboration of the Pesticides Enforcement Policy Regarding Use and Labeling of Service Containers.*

A. *Abbreviated Labeling for Pesticide Concentrates or Use-Dilution Preparations of Pesticides.*

The abbreviated labeling noted above is designed to assure that adequate information regarding the particular formulation and/or dilution of the product can be ascertained in case of medical emergency. The abbreviated label must include the signal word (e.g., "Warning," "Caution," "Poison," together with skull and cross bones) which appears on the accepted label of the end-use product, or which is appropriate to the use-dilution preparation of that product if specified on the accepted label. No other written or graphic material may appear on the service container. This service container labeling is subject to the FIFRA prohibitions against false or misleading statements on product labels.

The abbreviated label must be clearly legible and securely attached to the service container throughout the active life of the container or until the container has been properly disposed of or recycled. The abbreviated label must be replaced as frequently as necessary to meet these requirements.[10]

When several service containers, each containing pesticide concentrates or use-dilution preparations, are stored or contained in a larger compartment or carrying case, each individual service container must bear the abbreviated label described above.

B. *Reference Copy of EPA-Approved Label.*

A reference copy of the EPA-accepted end-use label bearing use instructions, precautionary statements, and medical treatment instructions must be retained by the firm at its place of business. It is the responsibility of the firm as well as of the service technician who performs each pest control application to assure that pesticides are used in the manner specified on the accepted labeling. To achieve this goal, the firm should train the service technician regarding the provisions and precautions which appear on the end-use label, and provide technical application instructions as necessary.

C. *Directions for Use and Other Precautionary Labeling.*

All directions for use and all warning and precautionary statements which appear on the end use label pertain to the use of the pesticide in a service container. This includes, without limitation, those label statements pertaining to application site, target pests, product mixing and preparation procedures, application method and dosage rate, protective clothing or equipment requirements, storage and disposal practices, or other precautionary labeling and warning statements.[11] If a label expressly prohibits the transfer of a product from the original container into a service container, any violation of that prohibition will constitute a violation of FIFRA section 12(a)(2)(G), and may subject the user to enforcement sanctions.

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[6] This construction of FIFRA (and the regulatory consequences it implies) is consistent with the regulatory scheme of FIFRA which subjects pest control professionals to more regulatory scrutiny than persons who are not in the business of supplying or applying pesticides. Further rationale for this interpretation of FIFRA appears in the Appendix to this PEPS.

This construction of FIFRA is not meant to affect the construction of other Federal, State, or local laws or regulations such as laws or regulations dealing with sales tax, employment licensing, vehicle licensing, liability bonding, or other similar matters.

[7] This policy statement applies only to the utilization of service containers by structural pest control operators for the transportation or temporary storage of "end-use" pesticides which (a) bear on their label directions for use-dilution preparation and for end-use application, or (b) are already prepared in a use-dilution preparation for the control of pests. No pesticide which is intended solely for use in manufacturing may be transferred for transportation or temporary storage into a service container.

[8] FIFRA section 12(a)(1)(E) is generally designed to assure that the formulation of the product (whether in the original unbroken container or transferred into a service container) conforms to the strength, purity or other standards of quality which were accepted by the Agency in the registration process; that labeling adequate to clearly communicate use instructions and necessary warning precautions to persons handling the pesticide accompanies the product in the channels of trade; and that the identity of the person responsible for the integrity of the product and its labeling is always ascertainable.

[9] This PEPS in no way affects the authority of a State, acting pursuant to FIFRA section 24(a), to add further restrictions regarding the sale or use of a Federally-registered product, or in accordance with State law, to prohibit particular activities involving Federally-registered pesticides within that State. The election by a State to impose further restrictions upon the sale or use within that State of a Federally-registered product will not affect the Agency's exercise of prosecutorial discretion under FIFRA. An applicator or other person who complies with the requirements set forth in Sections IV and V of this PEPS but who does not comply with the additional requirements established by a State pursuant to FIFRA section 24(a), may be subject to liability under State law. All persons utilizing service containers pursuant to this PEPS are encouraged to familiarize themselves with applicable State laws or regulations.

[10] The label may be of any appropriate material, such as paper, gummed paper, metal foil imprinted by hand or by typewriter, or a metal tag requiring stamping. As needed to maintain clear legibility, the label may be covered with a clear plastic film or seal, or placed in a cellophane, glassine, or other transparent covering. The labels may be attached by any practical means, such as with wire, chain, plastic latch or cord, as required to withstand the [illegible] or the [illegible] or [illegible] container.

D. *Container Size and Packaging Requirements.*

The service container must conform in all respects with any applicable container and packaging requirements for service containers established by EPA or by any other agency exercising statutory jurisdiction.[*] Containers which have been used for food, feed, beverages, drugs or cosmetics or which are in any significant way (e.g., by shape, size, or markings) identified with food, feed, beverages, drugs or cosmetics may not be used as service containers for pesticides. Service containers and their caps or closures must be of such construction and design as to withstand hazards of normal usage without breaking, rupturing, or leaking. The design must also be such as to facilitate the removal of the pesticide without risk of spillage.

E. *Prohibition Against Further Sale or Distribution.*

The service container holding the pesticides must remain in the sole and actual possession of the firm utilizing the service container. It may neither be sold, distributed, nor given away for use by another person. Any such sale, distribution, or gift of a pesticide for use by another person would require compliance with the registration requirements of FIFRA section 3, and the establishment registration requirement of FIFRA Section 7. Any sale or distribution of a pesticide in a service container for use by another person will subject the seller or distributor to liability under FIFRA sections 12(a)(1)(A) and 12(a)(2)(L).

VI. *Public Comment.*

The Administrative Procedure Act (5 U.S.C. 553(b)) provides that the solicitation of comments is not required of Federal agencies for "interpretative rules, general statements of policy, rules of agency organization, procedure, or practice." EPA has determined that this PEPS falls within this exemption from the requirements to solicit public comment. Accordingly, the Agency is not soliciting public comment regarding matters published in this notice. However, interested persons are invited to submit written comments regarding the policy set forth in this PEPS. These comments should be addressed to the Pesticides and Toxic Substances Enforcement Division (EN-342), Office of Enforcement, U.S. Environmental Protection Agency, 401 M Street, S.W., Room 3624, Washington, D.C. 20460. Three copies of these comments should be submitted to facilitate the work of the EPA and others interested in inspecting such documents.

Dated: December 17, 1976.

STANLEY W. LEGRO,
Assistant Administrator for Enforcement.

APPENDIX REGARDING EPA'S JURISDICTION TO REGULATE THE USE AND LABELING OF SERVICE CONTAINERS

It is the opinion of the Agency that the terms "distribute", "sell", "offer for sale" and "hold for sale" as they are used in FIFRA apply to the typical service work of structural pest control operators who supply and apply Federally registered pesticides for hire.[1] The Agency finds that this construction of FIFRA (and the regulatory consequences which it implies) is consistent with the regulatory scheme of FIFRA and with its legislative history. The Senate Committee on Agriculture and Forestry envisioned that the level of regulatory scrutiny to which people would be subject under FIFRA should be in proportion to their level of knowledge about pesticides. It suggests that persons who supply and apply pesticides for hire were intended to be the objects of more rigorous regulation than were non-professional pesticide users. The Committee noted that because of their "greater knowledge of the dangers of pesticides and greater familiarity with the law regulating their use," higher civil penalties would be assessed "for an offense by person(s) in the business of making, or applying pesticides."[2]

I. *FIFRA Section 3—Registration of Pesticides.*

FIFRA section 3(a) (7 U.S.C. 136a(a)) provides in pertinent part that

> * * * no person * * * may distribute, sell, offer for sale, hold for sale, * * * to any person any pesticide which is not registered with the Administrator.

Before a pesticide product which is not encompassed within the terms of an existing registration enters the channels of trade, a separate registration must be obtained. Changes in the formulation of a registered product, changes in accepted labeling, as well as any repackaging of a pesticide into another container will activate the registration requirement, unless the purposes of product registration would be fully met by carrying forward the Federal registration of the constituent product.[3]

The Agency finds that a pesticide concentrate or a use-dilution preparation of a registered end-use pesticide which remains within the sole and actual possession of the repackager/reformulator throughout its distribution, sale and use is encompassed within the terms of the registration of the constituent product and is thereby itself a registered pesticide.[4] On the other hand, pest control operators who hold pesticides in inventory and sell pesticides for application by other persons are considered to "distribute," "sell," "offer for sale," or "hold for sale." [5] In selling inevitably activates the registration requirements of FIFRA section 3 and section 7. Failure to comply with these requirements will subject such producers to liability under FIFRA section 12(a)(1)(A) and section 12(a)(2)(L).

It is the opinion of the Agency that the transfer into a service container of a pesticide concentrate or a use-dilution preparation of a registered pesticide, (in accordance with its end-use labeling) does not require the separate registration of the new formulation so long as the transferred pesticide concentrate or the use-dilution preparation remains within the sole and actual possession of the pest control operator performing the transfer. In such cases, the transferred quantity of the pesticide concentrate or the use-dilution preparation is encompassed within the terms of the registration of the constituent product; thus, the purposes of FIFRA section 3 have been satisfied by the registration of the original product. It would serve no purpose to require each transferred quantity of the already registered pesticide or each use-dilution preparation to be separately registered.[6]

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[*] The service container must be disposed of in a manner consistent with the disposal instructions on the EPA-approved product label or pursuant to the Recommended Procedures for Disposal and Storage of Pesticides issued by the Agency pursuant to FIFRA section 19. Furthermore, the service container must be used and re-used in a manner which will avoid the contamination of the pesticide concentrate or use-dilution preparation of the pesticide. Any contamination due to faulty rinsing procedures will be a violation of FIFRA section 12(a)(1)(E) and may subject the user to enforcement sanctions.

FIFRA section 25(c)(3) empowers the Administrator * * * to establish standards (which shall be consistent with those established under the authority of the Poison Prevention Packaging Act (Public Law 91-601)) with respect to the package, container, or wrapping in which a pesticide or device is enclosed for use or consumption, in order to protect children and adults from serious injury or illness resulting from accidental ingestion or contact with pesticides or devices regulated by this Act as well as to accomplish the other purposes of this Act;

However, no such containering or packaging requirements have yet been promulgated by the Administrator. Compliance with the provisions of this PEPS does not necessarily satisfy applicable requirements of Interim Regulations regarding the transportation of hazardous materials which have been promulgated by the U.S. Department of Transportation at 49 CFR Parts 171.177. [41 FR 43245; September 27, 1976].

[1] In the event that the customer himself supplies the pesticide which is to be used, and the pest control operator is hired *solely* to perform the pesticide application, the pest control operator would not be considered to be distributing, selling, or holding for distribution or sale the pesticide which he applies.

[2] Emphasis added. Supplemental Report to S. Rep. No. 92-838, 92d Cong. 2d Sess. 23 (1972). It is also noted that the pest control operator sells not only the pesticide application service, but also sells the pesticide used in performing the application. The price paid by the customer reflects both the cost of the service and the cost of the pesticide. As such, the pest control operator is engaged in the sale and distribution of a pesticide in the course of (and in addition to) the application of the pesticide.

[3] The broad purposes of the registration process are four fold. First, registration of a product provides a mechanism for the review of information regarding the safety and efficacy of the pesticide as proposed for use (and as likely to be used) under widespread and commonly recognized practice. Second, registration of a product provides EPA with the opportunity to review the proposed label and labeling of the product. To support registration, such labeling must clearly communicate the directions for use for the product and such warnings and precautions as are necessary for the safe and effectious use of the pesticide. Third, registration of a product identifies the party accountable for its integrity of composition, labeling and effects resulting from use. Fourth, registration of a product is the mechanism which assures that this relevant information is communicated to the ultimate user of the product.

[4] The pesticide concentrate and use-dilution preparation of an end-use pesticide which is transferred into a service container in which it is stored or transported by the structural pest control operator, is itself a pesticide within the meaning of FIFRA. However, the fact that structural pest control operators distribute or sell pesticides does not, standing alone, require the registration of any pesticide product resulting from the reformulation or repackaging by an operator of a currently registered product. The requirement that the product which is reformulated by the operator be registered is activated when the new formulation is not encompassed within the terms of an existing registration, and when the purposes of Federal registration are not otherwise satisfied with respect to the operator's formulation.

[5] Where the new pesticide product remains at all times within the sole and actual possession of the pest control operator, he will be the party accountable for the formulation in the service container. The safety and efficacy of the formulation will have been assessed and appropriate label directions, warnings and precautions will have been provided as necessary to insure that the pesticide when used in accordance with directions will not generally cause unreasonable adverse effects on man or the environment. The directions, warnings and precautions of the accepted label will have been communicated to the ultimate user of the pesticide, since the distributor/seller and applicator of the pesticide remains in actual possession of the pesticide.

It is noted that this policy applies only to end-use pesticides. Any reformulation or repackaging of a registered technical grade pesticide approved only for manufacturing uses for the purpose of further distribution or sale, will activate the registration requirement of FIFRA. The sale or distribution of such a product prior to approval of a separate registration is a violation of FIFRA section 12(a)(1)(A).

II. *FIFRA Section 12(a)(1)(E)—Pesticide Labeling.*

Structural pest control operators who supply and apply pesticides in performing pest control services are deemed to "distribute," or "sell," pesticides within the meaning of FIFRA section 12(a)(1). Under section 12(a)(1)(E) [7 U.S.C. 136j(a)(1)(E)], it is unlawful for any person in any state to distribute, sell, offer for sale, hold for sale, * * * to any person * * * (E) any pesticide which is * * * misbranded.

A pesticide concentrate or a use-dilution preparation is misbranded if its labeling fails to meet the standards set forth in FIFRA section 2(q). The sale or distribution by a structural pest control operator of pesticides in service containers whose labels do not conform with the requirements of FIFRA section 2(q) constitutes a violation of FIFRA section 12(a)(1)(E) and may subject the violator to civil or criminal penalties under FIFRA, except as otherwise provided in PEPS No. 6.

III. *FIFRA Section 9(a)—Inspection of Establishments.*

FIFRA section 9(a) authorizes the Agency to enter, for the purpose of conducting routine inspections, "any establishment or other place where pesticides * * * are held for distribution or sale." FIFRA section 2(d) defines an establishment as "any place where a pesticide or device is produced, or held for distribution or sale." This provision authorizes warrantless inspections of the business premises (including service vehicles, service containers, or application devices) of pest control operators who supply and apply pesticides for hire.*

FIFRA section 9(a) further provides that such inspections may be performed "for the purpose of inspecting and obtaining samples of any pesticides * * * packaged, labeled and released for shipment, * * *." Such inspections may include the product sampling and label review of pesticide products held for distribution or sale by the structural pest control operator, including the sampling of pesticide concentrates or use-dilution preparations in service containers, and the review of the abbreviated labeling which is affixed to such service containers.[7]

IV. *FIFRA Section 12(a)(2)(G)—Pesticide Preparation and Use.*

While the provisions of FIFRA section 12(a)(1) apply to the distribution and sale of the product, the provisions of FIFRA section 12(a)(2) apply to the individuals handling and/or using the product. It has been noted above that the registration of the constituent end-use product which is transferred into a service container carries over to the transferred product. The use (including the mixing, loading, storage, application, or disposal) of the product in the service container in a manner inconsistent with the provisions of the EPA-accepted end-use labeling is, therefore, a violation of FIFRA section 12(a)(2)(G) and may subject the user to civil or criminal sanctions.

It is noted that the act of pre-measuring or pre-mixing a pesticide as provided on the end-use labeling constitutes an act of pesticide use within the meaning of FIFRA section 12(a)(2)(G). Accordingly, such pre-measuring and pre-mixing of end-use pesticides in making use-dilution preparations must conform with all applicable label instructions.

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*It is the opinion of the Agency that FIFRA section 9(a) does not authorize the administrative inspection of places where pesticides are held for use, or are actually being used. The administrative inspection of such places may be performed only upon the knowing and voluntary consent of the property owner, or under the authority of a search warrant issued pursuant to FIFRA section 9(b) upon a showing to a court of competent jurisdiction that the provisions of FIFRA have been violated.

[7] Routine establishment inspections may also include a review of any books and records regarding the formulation, production or repackaging of pesticides which the structural pest control operator may be required to keep pursuant to FIFRA section 8 and the regulations promulgated thereunder at 40 CFR Part 167. Section 8(b) also empowers the Agency to inspect records which the firm may maintain regarding the delivery, movement, or holding of pesticides.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENFORCEMENT
OFFICE OF GENERAL ENFORCEMENT
PESTICIDES AND TOXIC SUBSTANCES
ENFORCEMENT DIVISION

PESTICIDE ENFORCEMENT POLICY STATEMENT NO. 7

PESTICIDE ENFORCEMENT POLICY STATEMENT NO. 7 AERIAL APPLICATION OF REGISTERED PESTICIDES

Reprinted from the Federal Register of APRIL 27, 1977
(42 FR 21198)

PESTICIDE ENFORCEMENT POLICY STATEMENT NO. 7 AERIAL APPLICATION OF REGISTERED PESTICIDES

I. General Background

On May 5, 1976, the Environmental Protection Agency (EPA) published in the FEDERAL REGISTER a document entitled "Institution of Enforcement Policy Statements" (40 FR 18526). It was the Agency's purpose in instituting this series of Pesticide Enforcement Policy Statements (PEPS) to inform the general public and persons engaged in the formulation, distribution, sale, application or other use of pesticides, of the policies adopted by the Agency in the enforcement of the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended in 1972 and 1975 (Pub. L. 92-516; 86 Stat. 973; Pub. L. 94-140, 89 Stat. 751; 7 U.S.C. 136 et seq.; hereinafter referred to as FIFRA). PEPS are prepared and published by EPA's Office of Enforcement. Unless otherwise expressly provided, a PEPS indicates how the Agency will exercise its prosecutorial discretion, and does not interpret the law or otherwise define what is and what is not lawful conduct under FIFRA. If the Administrator subsequently promulgates regulations which interpret FIFRA, the Office of Enforcement will revoke or amend any prior PEPS to conform with such regulations. A detailed explanation of the purpose and scope of PEPS was set forth in the May 5, 1975, FEDERAL REGISTER notice.

II. Purpose and Scope of This PEPS

This PEPS sets forth the Agency's enforcement policy regarding the aerial application of pesticides whose labels bear the respective types of application instructions which are listed in Section V below. It reiterates established policy prohibiting aerial application where label instructions specifically prohibit such use. It also establishes an administrative mechanism pursuant to which pesticides whose labels bear no affirmative instructions for aerial application may, under conditions enunciated herein, be applied by air without incurring Federal enforcement actions. This administrative mechanism assures that (a) the proposed aerial application will be evaluated by a knowledgeable expert to ascertain the efficacy and safety of the application, and that (b) the appropriate State agency will be informed of the pesticide formulations which are being recommended for aerial application within the State. The administrative mechanism set forth in this PEPS is applicable only to products bearing application instructions described in Category V or Category V. in Section V below.

III. Regulation of the Use of Registered Pesticides

A. Federal Jurisdiction to Regulate Pesticide Use[1]

Federal regulation of the use of pesticides was established for the first time with the enactment of the 1972 FIFRA amendments, specifically through the provisions of FIFRA section 3(d)(1), section 4, and section 12(a)(2)(G).[2] Any

[1] This part of PEPS No. 7 represents an outline of the Agency's legal interpretation of the effect of the 1972 amendments and implementing regulations on the authority of the Agency to regulate the use of registered pesticides, including the method of application of such pesticides. As indicated above, PEPS generally describe how the Agency will exercise its prosecutorial discretion under FIFRA. As in this instance, any portion of a PEPS which interprets the law will be accompanied by an express indication that the portion is in fact interpretive. All interpretive portions of a PEPS have the concurrence of the Agency's Office of General Counsel.

[2] FIFRA section 3(d)(1) (7 U.S.C. 136a (d)(1)) provides that as part of the registration of a pesticide, the Administrator shall classify each pesticide for general use or for restricted use, or for both general use and restricted use as the Administrator, in his discretion, may require. (See 40 CFR Part 162.2(C).)

FIFRA section 4(a)(1) (7 U.S.C. 136b(a)(1)) empowers the Administrator to prescribe standards for the certification of applicators of restricted use pesticides. The Agency has promulgated regulations establishing certain categories of commercial (professional) applicators and setting forth minimum standards that commercial and private applicators must meet before they are certified to use pesticides classified under section 3 for "restricted use." (40 CFR Part 171.)

FIFRA section 12(a)(2)(G) (7 U.S.C. 136j (a)(2)(G)) provides that it is unlawful for "any person to use any registered pesticide in a manner inconsistent with its labeling." This section became effective upon the date of enactment of FIFRA and was determined by the Administrator to be self implementing (FIFRA Implementation Plan, 39 FR 1162). The regulations implementing the registration provision of the 1972 amendments define pesticide "use" to mean: Any act of handling or release of a pesticide, or exposure of man or the environment to a pesticide through acts, including but not limited to: (1) Application of a pesticide, including mixing and loading and any required supervisory action in or near the area of application; (2) Storage actions for pesticides and pesticide containers; and (3) disposal actions for pesticides and pesticide containers. (40 CFR 162.3(ou).)

This definition of the term "use" has been adopted by the Office of Enforcement in the enforcement of pesticide labeling under FIFRA section 12(a)(2)(G).

person who uses a registered pesticide in a manner inconsistent with its labeling is in violation of the Act and may be subject to civil or criminal sanctions.

It is the opinion of the Agency that the aerial application of a pesticide whose label bears no affirmative instruction for aerial application constitutes a violation of section 12(a)(2)(G), in that the method of application is inconsistent with that which appears on the EPA accepted label. This is the case even where aerial application of that pesticide may have become a common pest control practice. However, as set forth in the legislative history, Congress intended that EPA enforce the prohibition of section 12(a)(2)(G) in a "common sense manner,"[4] and not prohibit uses of registered pesticides which are in no way harmful and which have demonstrated beneficial effects.[5]

B. PESTICIDE REGISTRATION UNDER THE 1972 FIFRA AMENDMENTS

Regulations implementing the registration provision of the 1972 FIFRA amendments require applicants for new registrations to submit data regarding the efficacy, chemistry, and hazard of the pesticide desired to be registered (40 CFR 162.8(b)).[6] Review of these data constitutes one of the steps necessary to accomplish the broad purposes of product registration.[7]

In considering a product for registration, the Agency makes specific efficacy and safety evaluations with respect to application techniques, including an analysis of the proposed application equipment, method, timing, and site. Pesticide products which do not provide directions for a particular use or application method, have generally not been subject to safety and efficacy review by the Agency with respect to such use or application method. Accordingly, it is the policy of the Office of Enforcement that pesticides bearing Category V and Category VI labels may be applied by air only pursuant to the safeguards established in this PEPS.

C. IMPACT OF THE FIFRA REREGISTRATION PROCESS

On July 3, 1975, the Agency promulgated regulations governing the registration, reregistration and classification of pesticides pursuant to FIFRA section 3 (40 CFR Part 162). These regulations prescribe procedures and policies governing the Federal pesticide registration program, and are designed to implement the changes to that program which were mandated by Congress in the 1972 amendments.

As a part of the reregistration process, every pesticide product which may be legally applied by air will bear affirmative instructions for aerial application. The aerial application of a registered pesticide which has been through the reregistration process, but whose label bears no affirmative instructions for aerial application, shall be deemed to be a use of the pesticide in a manner inconsistent with its labeling and may subject the user to civil and criminal sanctions.[8]

IV. REGULATORY ROLE OF THE STATES

This PEPS in no way affects the authority of a State, acting pursuant to FIFRA section 24(a), to add further restrictions regarding the use of a Federally registered product, or, in accordance with State law, to prohibit particular uses of Federally-registered pesticides within that State. The Agency anticipates that States may elect to exercise the powers set forth in section 24(a) in the two specific ways elaborated below. The election by a State to impose further restrictions upon the use within that State of a Federally-registered product will not affect the Agency's exercise of prosecutorial discretion under FIFRA. An applicator or other person who complies with the requirements set forth in Sections VI and VII of this PEPS to avoid liability under FIFRA, but who does not comply with the additional requirements established by a State pursuant to FIFRA section 24(a), may be subject to liability under State law. All persons performing applications pursuant to the administrative mechanism set forth in this PEPS are encouraged to familiarize themselves with applicable State regulations.

A. ELECTION BY THE STATE TO DESIGNATE "KNOWLEDGEABLE EXPERTS"

Each State may elect to specifically designate competent individuals to be knowledgeable experts within that State by placing their names on a list of knowledgeable experts, or by some other means acceptable to the State. Each State may establish more stringent standards than those which are listed in Section VII(B) below. No person will be deemed to be a knowledgeable expert within the meaning of this PEPS unless he meets the minimum standards set forth in Section VII(B) below, regardless of having been designated as a knowledgeable expert by a State.

B. ELECTION BY THE STATE TO CONDUCT A PREAPPLICATION REVIEW OF THE RECOMMENDATION OF THE KNOWLEDGEABLE EXPERT

Each State may elect to review individually each recommendation made by a knowledgeable expert pursuant to this PEPS prior to the aerial pesticide application. States exercising this election will establish their own procedures for performing this pre-application review.

V. CATEGORIZATION OF LABELS BASED UPON PROVISIONS FOR APPLICATION METHOD

Whether a specific pesticide may be aerially applied depends upon the application instructions which appear on the EPA-accepted label. Common characteristics of pesticide label instructions facilitate the grouping of pesticide labels into six general categories:[9]

Category I.—Labels which bear explicit and adequate application instructions and other precautionary labeling for aerial application.[10]

Category II.—Labels which bear an explicit prohibition against the aerial application of the pesticide.[11]

Category III.—Labels which bear only affirmative instructions for ground application, and which bear other dilution or dosage rate instructions and accompanying precautionary statements which are inconsistent with aerial application as a matter of pest control practice and application technology.[12]

Category IV.—Labels which bear no affirmative ground or aerial application instructions, but which bear dilution or dosage rate instructions and precautionary statements which are inconsistent with aerial application as a matter of pest control practice and application technology.[13]

Category V.—Labels which bear only affirmative instructions for ground application, but which bear dilution or dosage rate

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[4] House Committee on Agriculture, H.R. Rep. No. 92 511, 92nd Cong., 1st Sess. 16 (1971); Senate Committee on Agriculture and Forestry, S. Rep. No. 92 838, 92nd Cong., 2d Sess. 14 (1972). As the Senate Committee on Agriculture and Forestry noted:

> * * * It is the belief of the Committee that the use of the word "inconsistent" should be read and administered in a way so as to visit penalties only upon those individuals who have disregarded instructions on a label that would indicate to a man of ordinary intelligence that use not in accordance with such instructions might endanger the safety of others or the environment.

[5] House Committee on Agriculture, H.R. Rep. No. 92 511, 92nd Cong., 1st Sess. 16 (1971); Senate Committee on Agriculture and Forestry, S. Rep. No. 92 838, 92nd Cong., 2d Sess. 167 (1972). As the Senate Committee on Agriculture and Forestry stated:

> [I]t is not the intention of the Committee to prohibit any use which is in no way harmful, and which has only beneficial effects on man and his environment.

[6] The regulations implementing the registration provision of the 1972 amendments require applicants to gather data by performing laboratory and/or field-tests which simulate actual use conditions. There tests "will vary according to the characteristics of the chemical, the type of formulation, the target pest, the use patterns, and the methods and time of application." (40 CFR 162.8 (b)(2).)

[7] The broad purposes of the registration process are four fold. First, registration of a product provides a mechanism for the view of information regarding the safety and efficacy of the pesticide as proposed for use (and as likely to be used) under widespread and commonly recognized practice. Second, registration of a product provides EPA with the opportunity to review the proposed label and labeling of the product. To support registration, such labeling must clearly communicate the directions for use for the product and such warnings and precautions as are necessary for the safe and efficacious use of the pesticide. Third, registration of a product identifies the party accountable for its integrity of composition, labeling, and effects resulting from use. Fourth, registration of a product is the mechanism which assures that this relevant information is communicated to the ultimate user of the product.

[8] This PEPS is intended as a temporary adjunct to and not a replacement for the section 3 registration/reregistration process, or for the program authorized under FIFRA section 24(c) pursuant to which States may issue registrations for "special local needs." Upon the completion of the reregistration process, these statutory mechanisms will provide the only means of approving the aerial application of any pesticide.

[9] The application instructions which appear on each registered pesticide will conform to one of the six categories of label provisions set forth herein. A number of FIFRA provisions may be utilized to amend the registration of a product with respect to acceptable application method, thus removing that pesticide from one label category and placing it, for the purposes of this PEPS, in another label category. These statutory means of amending a registration to authorize the aerial application of such pesticides include the issuance of a State registration under FIFRA section 24(c), or amending the existing registration under FIFRA Section 3.

[10] For example, a label may provide: "For aerial application to brush along utility right-of-ways apply ½ to 1 gallon (product) in 12 to 15 gallons of water per acre using the appropriate type of boom or other low-drift equipment."

[11] For example, a label may provide: "Do not apply by air."

[12] For example, a label may provide: "Apply at 2 gallons per acre in 200 gallons of water, using ground equipment."

[13] For example, a label may provide: "Apply at 2 gallons per acre in 200 gallons of water."

instructions and other precautionary statements which are consistent with aerial application as a matter of pest control practice and application technology."

Category VI.—Labels which bear no affirmative ground or aerial application instructions, but which bear other dilution or dosage rate instructions and other precautionary statements which are consistent with aerial application as a matter of pest control practice and application technology."

VI. Summary of Enforcement Policy Regarding the Aerial Application of Each Label Category of Registered Pesticides

A. Enforcement Policy Regarding Category I Labels

Products bearing the labeling described in Category I above may be legally applied by air when such application is performed in accordance with all aerial application instructions.

B. Enforcement Policy Regarding Category II Labels

Products bearing the labeling described in Category II above may not be legally applied by air under any circumstances.

C. Enforcement Policy Regarding Category III and Category IV Labels

Products bearing the labeling described in Category III or Category IV above may not be legally applied by air except if such aerial application is authorized under a State registration issued pursuant to FIFRA section 24(c), or some other statutory mechanism.

D. Enforcement Policy Regarding Category V and Category VI Labels

In the exercise of its prosecutorial discretion, the Agency will not initiate enforcement action a person who aerially applies a registered pesticide which bears Category V or Category IV labeling where all of the following conditions are met:

1. The selected pesticide is registered for use at the type of site or application environment and on the commodity, crop, or area which is to be treated.

2. The use is recommended in writing by an individual who is a knowledgeable expert in the appropriate area of agricultural or other outdoor pest control;

3. The recommendation of the knowledgeable expert is submitted to the State Control Agency;

[14] For example, a label may provide: "Apply at 2 gallons per acre in 40 gallons of water, using ground equipment."

[15] For example, a label may provide: "Apply at 10 pounds per acre."

4. The user complies with all instructions, warnings, precautions, and prohibitions on the label and labeling of the product which is used, other than those pertaining to the application method, and except as provided in other published PEPS;

5. The pesticide is efficacious, or may reasonably be expected to be efficacious, when properly applied.

VII. Elaboration of Enforcement Policy Regarding Category V and Category VI Labels

The limiting and defining provisions contained in the paragraphs which follow are an elaboration of the enforcement policy with regard to Category V and Category VI labels and of the conditions 1 through 5 above. They constitute an integral part of this PEPS. Whether the user has reasonably met the criteria set forth in this PEPS with regard to Category V and Category VI labels will be determined by the Agency on a case-by-case basis. The burden of showing that the criteria set forth herein have been met rests with the person who aerially applies a registered pesticide whose label bears a Category V or Category VI label.

A. Use at the Specific Type of Site or Application Environment and on the Commodity, Crop, or Area Which is To Be Treated

The policy set forth in this PEPS applies to the aerial application of registered pesticides bearing Category V and Category VI labels when the application is made at the specific type of use site or application environment and, as applicable, on a commodity, crop, or area which appears on the label of the product used.[16] For example, this PEPS in no way authorizes the agricultural or other outdoor application of a pesticide which is registered solely for use in structural pest control.

This policy applies to the use of registered pesticides in agricultural applications for the production of agricultural

[16] An evaluation of the behavior of pesticide residues on the commodity or crop to which a pesticide is applied is an integral part of the registration of any pesticide. The aerial application of a pesticide for which no data regarding aerial application have been submitted to and analyzed by EPA may result in illegal residues. Strict conformity with all other conditions of this PEPS will not prevent the quarantine or seizure of the commodity or crop if illegal residues are discovered thereon.

crops," in forest pest control," in ornamental and turf pest control," in right-of-way pest control," and in public health and regulatory pest control."

B. Recommendation of a Knowledgeable Expert in Agricultural or Other Outdoor Pest Control

1. *Meaning of the Term "Knowledgeable Expert"—(a) Qualifications of Knowledgeable Experts.* The Agency intends in this PEPS to allow the aerial application of registered pesticides bearing Category V or Category VI labels where such aerial application is safe and efficacious. Persons seeking to aerially apply pesticides bearing such labels must obtain the written recommendation of a knowledgeable expert. To be considered to be a knowledgeable expert within the meaning of this PEPS, an individual must have achieved one of the following combinations of qualifying experience and/or qualifying education:

Qualifying Experience and Qualifying Education
6 years with Less than Baccalaureate.
3 years with Baccalaureate.
2 years with Masters Degree.
1 year with Doctorate.

As used in this PEPS, the terms "qualifying experience" and "qualifying education" refer to practical pest control experience or formal academic training in the particular pest control area or academic discipline in which the recommendation is made, as a result of which the knowledgeable expert has become knowledgeable about the following elements of pest control practice:

(i) *Pesticide:* the pesticide product (or active ingredient) to be used;

[17] Agricultural commodity and crop applications include, without limitation, tobacco, peanuts, cotton, soybeans and forage vegetables, small fruits, tree fruits and nuts, as well as grasslands and non-crop agricultural commodity applications.

[18] Forest pest control includes, without limitation, pesticide applications to forest, forest nurseries, and forest seed producing areas.

[19] Ornamental and turf pest control includes, without limitation, application on ornamental trees, shrubs, flowers, and turf.

[20] Right-of-way pest control includes, without limitation, applications on roads, electric powerlines, pipelines, and railway right-of-ways.

[21] Public health and regulatory pest control includes, without limitation, pest control activities engaged in by State, Federal or other governmental employees using or supervising the use of pesticides in public health programs for the management and control of pests having medical and public health importance, or in the control of other regulated pests.

(ii) *Use Site and Pest Control Environment:* the commodity, crop or area to be treated, and the climatic, seasonal, geographic, and ecological characteristics of the local;

(iii) *Pest:* the class and nature of the pest to be controlled, and

(iv) *Application Method:* the method of preparing and applying the pesticide selected for use, and the risks which may attend the aerial application of the pesticide.

(b) *Examples of Knowledgeable Experts.* Qualified persons employed by such organizations as State Cooperative Extension Services, State land grant colleges, Federal, State, or by private institutions and scientists employed by companies owning or managing farms or other application sites may also be knowledgeable experts. Additionally, scientists and other persons employed by a manufacturer, distributor, formulator, or user, including the user himself, will be deemed to be knowledgeable experts within the meaning of this PEPS if such persons are responsible for making technical judgments regarding the development and use of particular pesticides products (or active ingredients) or regarding particular pest control practices, including application technology.

(c) *Limitations.* Notwithstanding the above, no person whose principal function or significant source of personal income (e.g., sales commission) is directly derived from promoting the sale or distribution of the pesticide product (or active ingredient) which is recommended for use may provide the recommendation required of a knowledgeable expert under this PEPS. Under no circumstances may any sales representative, marketing employee, or advertising agency of any manufacturer, distributor or formulator, or any other person who has a significant personal economic interest in promoting the sale or distribution of a product provide the recommendation required of a knowledgeable expert."

[22] This prohibition is consistent with the provisions of FIFRA section 12(a)(2)(B), which make it unlawful 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 registered pesticide if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration under section 3. (Emphasis added; 7 U.S.C. 136j (a)(2)(B).)

It is noted, however, that persons who supply and apply pesticides for hire are deemed by the Agency to hold pesticides "for dis-

3. *Contents of the Recommendation of the Knowledgeable Expert.* Each recommendation made by a knowledgeable expert for the aerial application of pesticides bearing Category V or Category VI labels shall be made in writing and shall be signed and dated. The recommendation of the knowledgeable expert must specify the pesticide (or active ingredient) to be used,[9] the geographic location (e.g., identified by county, terrain, topography, or ecological character) in which the aerial application will be allowed, the commodity, crop or area on which the aerial application is to be made, the pest to be controlled, and the dates or duration for which the recommendation is applicable. The recommendation must also supply all appropriate instructions regarding dilution rate, mixing and loading method, aerial application equipment to be used and its calibration, airplane speed, wind velocity, pesticide drift, and environmental or ecological precautions.

The applicator or user must have obtained the written recommendation of the knowledgeable expert prior to the time of the application. He must make a copy of such recommendation available to an official representative of EPA upon request. Unless otherwise provided therein, the recommendation of a knowledgeable expert shall remain in effect for the growing season or application period in which the recommendation was made.

The recommendation of the knowledgeable expert will be valid only in the State in which the recommendation was given and in which the aerial application is to occur. A recommendation which has been properly executed pursuant to this PEPS may be relied upon by other pesticide applicators within the State, provided that all of the terms and conditions (e.g., pest, topography, application site) set forth in the recommendation are met by such other applicators. Persons seeking to learn whether a prior recommendation which meets their pest control needs has been issued should contact the State Control Agency of the State in which the application is to occur.

3. *Liability of the Knowledgeable Expert*—(a) *FIFRA Enforcement Liability.* The responsibility for the safe and efficacious aerial application of the pesticide and for full compliance with the terms of this PEPS may rest with either the applicator or the knowledgeable expert or both, as the equities and the circumstances may require. FIFRA enforcement liability for the misuse of pesticides falls primarily upon the pesticide user or applicator, and not upon the knowedgeable expert who has recommended such use. Particularly where the pesticide application involves a deviation from the uses which are allowed on the accepted label, any person who mixes, loads, applies, stores or disposes of any registered pesticide in a manner inconsistent with its labeling may be subject to civil or criminal sanctions under FIFRA.[10] The knowledgeable expert who both recommends and aerially applies a registered pesticide which bears a Category V or Category VI label is personally responsible for the proper use of the pesticide and for the safety and efficiency of the product. In addition, the expert who recommends and personally supervises the aerial application of such a pesticide is himself considered to "use" the pesticide within the meaning of FIFRA section 12(a)(2)(C), and is, thus, subject to FIFRA enforcement liability for any misuse of the pesticide which occurs under his supervision.[11]

(b) *Civil Liability.* It is not the intention of the Office of Enforcement that this PEPS should in any way affect the civil liability in damages of a knowledgeable expert. This PEPS does not increase the risk of liability beyond that which is inherent in the ordinary execution of one's duties in offering pest control advice to users, or in supervising pesticide applications. Nor does this PEPS exempt a knowledgeable expert from possible civil liability for damages arising out of his own negligence. Any knowledgeable expert may be liable pursuant to relevant State law for damages which result from a recommendation which he makes.

C. NOTIFICATION OF THE STATE CONTROL AGENCY

1. *Meaning of the Term "State Control Agency".* As used in this PEPS the term "State Control Agency" refers to that agency which has been designated within each State to regulate the use of pesticides in agricultural, forest, ornamental, turf, right-of-way, or regulatory pest control, respectively. In most cases the State Control Agency will be the State agency which has been designated by the Governor to be the State Lead Agency pursuant to the provisions of FIFRA section 4, and the State Plan submitted pursuant to 40 Part 171. Where the State Lead Agency is not the State Control Agency within the meaning of this PEPS, the State Lead Agency (or the State's Department of Agriculture) will be able to direct interested individuals to the appropriate State Control Agency.

2. *Notification of the State Control Agency.* Except as otherwise provided by States electing to review each recommendation of its knowledgeable experts, each recommendation which is made by a knowledgeable expert pursuant to this PEPS must be forwarded by the knowledgeable expert to the State Control Agency of the State in which the application is to occur prior to the time of the application. The State Control Agency for each State may adopt its own procedures and policies for this process, subject to the requirements regarding the contents of the recommendation set forth in Section VIII.B. of this PEPS. This requirement to notify the State Control Agency will (a) inform the State Control Agency of pest control activities being performed within the State, (b) provide an experimental basis for evaluating applications for State registrations issued pursuant to FIFRA section 24(c) in response to local pest control needs. The appropriate EPA Regional Office will receive recommendations of knowledgeable experts in those States which do not establish procedures to receive such recommendations.

The State Control Agency should maintain a record of the recommendation of the knowledgeable expert for two (2) years from the date of the recommendation. Each State shall adopt its own policies and procedures for informing pesticide users or applicators of the recommendations which have been made, so such other users may aerially apply Category V or Category VI pesticides for which a prior recommendation has been executed pursuant to this PEPS.

D. DIRECTIONS FOR USE AND OTHER PRECAUTIONARY LABELING

The aerial application of a registered pesticide which bears a Category V or Category VI label pursuant to the provisions of this PEPS neither modifies other label provisions or directions for use, nor authorizes the use of the pesticide in a manner inconsistent with any other label provisions, including, without limitation, other directions for use and precautionary labeling, or other warning statements. Under no circumstances does this PEPS permit any activity which is expressly prohibited on the label. Label provisions which must be complied with at all times regardless of the application method, include, without limitation, statements regarding product mixing, loading and preparation, target pests (except as provided in other published PEPS), application frequency or intervals, field reentry intervals, protective clothing or equipment requirements, product packaging and transportation requirements, and storage and disposal practices.

E. PRODUCT SAFETY EFFICACY

The aerial application of a product pursuant to the administrative mechanism established in this PEPS must be safe and efficacious, or must reasonably be expected to be safe and efficacious. An application or use will be considered to be safe and efficacious if it has beneficial effects when applied by air and achieves that level of pest control which is normally associated with the use of the pesticide, and does not cause harm to people or the environment.

VIII. PUBLIC COMMENT

The Administrative Procedure Act (5 U.S.C.§ 553(b)) provides that the solicitation of comments is not required of Federal agencies for "interpretative rules, general statements of policy, rules of agency organization, procedures, or

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tribution or sale" within the meaning of FIFRA. Such professional applicators may be deemed to be knowledgeable experts within the meaning of this PEPS if they meet the standards of qualifying experience and/or qualifying education set forth in this PEPS.

[9] The recommendation of the knowledgeable expert must refer to either (a) the particular pesticide product which is to be aerially applied (identified by proprietary name and by EPA Registrant Number), or (b) the percentage of active ingredient to which the recommendation applies. If the recommendation refers to a particular formulation of active ingredient, the proprietary product used must bear Category V or Category IV labeling and must contain that exact formulation.

[10] Where the recommendation of the knowledgeable expert does not refer to a proprietary pesticide product, but refers instead to a percent of active ingredient, it is the responsibility of the person who uses or applies the pesticide to select a proprietary product which (a) bears Category V or Category VI labeling, (b) contains the stipulated percent of active ingredient, and (c) is registered for use at the use site or in the application environment in which aerial application is to occur.

[11] Many State pesticide laws prohibit the recommendation of the use of a registered pesticide in a manner inconsistent with its accepted labeling. This PEPS in no way affects the liability under applicable State law of a knowledgeable expert who recommends the use of a pesticide in a manner inconsistent with its labeling.

practice." EPA has determined that this PEPS falls within this exemption from the requirement to solicit public comment. Accordingly, the Agency is not soliciting public comment regarding matters published in this notice. However, interested persons are invited to submit written comments regarding the policy set forth in this PEPS. These comments should be addressed to the Pesticides and Toxic Substances Enforcement Division (EN-342), Office of Enforcement, U.S. Environmental Protection Agency, 401 M Street SW., Room 3624, Washington, D.C. 20460. Three copies of these comments should be submitted to facilitate the work of the Agency and of others interested in inspecting such documents.

STANLEY W. LEGRO,
Assistant Administrator
for Enforcement.

APRIL 20, 1977.

therefore entitled to purchase the volume of motor gasoline equal to the amount furnished by Addie during the corresponding months of the November 1977 through October 1978 base period.

Atlantic Richfield Co., Los Angeles, Calif., DRO-0229, motor gasoline

On June 8, 1979, the Atlantic Richfield Company, 515 S. Flower Street, Room 3077, Los Angeles, California 90071 (ARCO), filed a Notice of Objection in which it indicates that it will contest an Interim Remedial Order for Immediate Compliance (IROIC) which the DOE Office of Special Counsel issued to it on May 25, 1979. In the IROIC, the Special Counsel found that (i) during May 1979 ARCO violated the DOE Mandatory Petroleum Allocation Regulations by refusing to supply Meier Oil Service, Inc. of Ashkum, Illinois (Meier) with volumes of motor gasoline which Meier had certified as necessary to supply its customers that are engaged in agricultural production, (ii) the violation was continuing, and (iii) Meier's customers would be irreparably harmed unless an IROIC were issued immediately. The IROIC directed ARCO to make available to Meier 100,000 gallons of motor gasoline.

Tenneco Oil Co., Houston, Tex., DRO-0226, crude oil

On June 5, 9179, Macmillan Ring-Free Oil Co., Inc., 90 Park Avenue, New York, New York 10016, filed a Notice of Objection to an Interim Remedial Order for Immediate Compliance which the DOE Southwest District Office of Special Counsel issued to Tenneco Oil Company on May 24, 1979. In the Interim Remedial Order for Immediate Compliance, the Office of Special Counsel ordered Tenneco to make available to Kern County Refinery 5,000 barrels per day of crude oil from its Yowlumne Field properties, in addition to the 2,000 barrels per day of crude oil which Tenneco is already supplying to Kern.

Wilshire Oil Co., of Tex., Oklahoma City, Okla., DRO-0225, crude oil

On June 5, 1979, Wilshire Oil Company of Texas, (Wilshire), 7th Floor, 200 North Harvey, Oklahoma City, Oklahoma 73102, filed a Notice of Objection to a Proposed Remedial Order which the DOE Southwest Enforcement District issued on April 27, 1979. In the Proposed Remedial Order, the Enforcement District found that during the period from February 1976 through December 1976, Wilshire committed pricing violations in connection with the production and sale of crude oil. According to the Proposed Remedial Order, Wilshire's violations resulted in overcharges to its customers of $119,685.

[FR Doc. 79-21573 Filed 7-11-79; 8:45 am]

BILLING CODE 6450-01-M

ENVIRONMENTAL PROTECTION AGENCY

[FRL 1270-5]

Enforcement Policy Regarding Failures To Report Information Under Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act

AGENCY: Environmental Protection Agency.

ACTION: Notice setting forth a general statement of the Agency's policy concerning the exercise of its enforcement discretion to regard as unactionable some failures to report, or delays in reporting, information required to be reported by Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA), 7 U.S.C. § 136 d(a)(2).

SUMMARY: This Notice describes a number of circumstances in which the Agency will not seek or recommend civil or criminal penalties against pesticide registrants who fail to report information concerning the risks or benefits of their registered pesticide products, despite the fact that reporting is required according the Agency's interpretation of FIFRA § 6(a)(2).

DATES: July 12, 1979.

Effective Date:

Comments will be most helpful if they are received on or before October 10, 1979.

FOR FURTHER INFORMATION CONTACT:

John J. Neylan III, Office of Enforcement (EN-342), Environmental Protection Agency, 401 M Street, S.W., Room 3632, Washington, D.C. 20460, Telephone: (202) 755-0630.

or

Edward C. Gray, Office of General Counsel (A-132), Environmental Protection Agency, 401 M Street, S.W., Room 535, Washington, D.C. 20460, Telephone: (202) 755-0638.

SUBMIT COMMENTS TO: John J. Neylan III, Office of Enforcement (EN-342), Environmental Protection Agency, Washington, D.C. 20460.

SUPPLEMENTARY INFORMATION:

Introduction

Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136d(a)(2), provides that

> If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, he shall submit such information to the Administrator.

On August 23, 1978, EPA published in the Federal Register a memorandum prepared by the EPA General Counsel and adopted by the Administrator entitled "Agency Interpretation of Requirements Imposed on Registrants by Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act." 43 FR 37611 *et seq.* The memorandum, which was prepared in response to a directive by the Administrator, explained in detail the Agency's views concerning proper interpretation of the statutory reporting requirement established by Section 6(a)(2).

The conclusions in the August, 1978 memorandum were based on the pertinent legislative history and on the principle that the language of Section 6(a)(2) should be construed consistently with the overall regulatory approach established by Congress. The General Counsel concluded that section 6(a)(2) requires each registrant to submit any item of information in his possession which pertains to a pesticide product for which he holds a registration and which, if true, would be relevant to an evaluation of the risks and benefits of the pesticide product, unless such information consists solely of unsolicited lay opinion or has been previously submitted.

Though the August, 1978 memorandum rejected the notion that Congress intended that Section 6(a)(2) be given a narrow or restrictive interpretation, the memorandum noted that

> The Agency might conclude that although information of a certain kind is subject to the § 6(a)(2) reporting requirement (as interpreted by this memorandum), registrant reporting of that kind of information is not essential to the Agency's functions * * * In such a case, it would be appropriate for the Agency to announce publicly (by Federal Register notice or otherwise) that it will not consider a registrant's failure to submit that kind of information to be an actionable violation of § 6(a)(2).

This Notice constitutes EPA's first statement regarding particular types of information which, though arguably pertinent to evaluation of risks and benefits and otherwise reportable under section 6(a)(2), are not currently needed by EPA in order to properly discharge its statutory responsibilities under FIFRA, and thus need not be submitted by registrants. By publishing this Notice, EPA does not intend to alter or amend in any way its interpretation of the requirements imposed on registrants by section 6(a)(2), but rather to specify, until further notice, certain instances in which a registrant's failure to submit information to EPA will not be treated as an actionable violation of section 6(a)(2).

The provisions of this Notice are based to a large extent on assumptions about the resources EPA will have available in the near term future for the review of information submitted under FIFRA § 6(a)(2), and on the Agency's plans concerning review of the continued registrability of currently-registered pesticides. We have attempted in this Notice to discriminate between information we feel can be usefully reviewed, given currently-available resources, and information which could only be properly reviewed if the Agency had considerably more resources. Routine examination of all information concerning a registered pesticide's risks and benefits would serve useful purposes. However, given a level of resources which does not permit this degree of day-to-day scrutiny, it would not be appropriate to require registrants to submit information that could not be reviewed promptly because other matters are of higher priority.

This Notice is designed to give clear and explicit guidance to registrants in determining whether or not EPA will regard failure to submit a given item of information concerning any toxicological study, incomplete toxicological study, epidemiological study, efficacy study, incident involving toxic or adverse effects, incident involving failure of efficacy, or other matter as an actionable violation of section 6(a)(2). EPA may issue supplementary notices later concerning types of information not specifically considered in this Notice.

A registrant who violates FIFRA § 6(a)(2) commits an unlawful act, see FIFRA § 12(a)(2(N), 7 U.S.C. 136j(a)(2)(N), and is subject to civil or criminal penalties under FIFRA § 14, 7 U.S.C. 1361. Whenever this Notice states that a given failure to submit information will not be treated by EPA as an actionable violation of Section 6(a)(2), it means that EPA will not recommend or seek to impose a civil or criminal penalty, under Section 14 or otherwise, on the grounds that such a failure to submit information violates Section 6(a)(2).

Effective immediately, in exercise of its enforcement discretion, EPA will not commence any civil penalty action based on FIFRA § 6(a)(2), or seek criminal prosecution of any registrant based on FIFRA § 6(a)(2), with regard to any failure by a registrant to submit any information which this Notice says need not be submitted, until at least 30 days after modification or revocation of this Notice. This Notice will be modified or revoked only by publication in the Federal Register of a supplementary notice which clearly states which failures to submit information which were previously permitted will subsequently be treated as actionable violations of section 6(a)(2). Any modification of this Notice will be applied prospectively only.

This policy will be effective on July 12, 1979. Because this Notice is a "general statement of policy," it is exempted from the notice and comment provisions of the Administrative Procedure Act by 5 U.S.C. 553(b)(3)(A). Nevertheless, interested parties are encouraged to submit comments on or suggested modifications of this policy. We are especially interested in receiving comments and recommendations pertaining to the types of information discussed in Section III of this Notice. Comments will be most helpful if they are received on or before October 10, 1979. After expiration of the ninety day period, EPA will evaluate the comments which have been received and consider appropriate modifications of this Notice.

I. Study and Experimental Data Reporting

A. Toxicological Studies

Policy

Failure to submit information to EPA which concerns the results of a completed study of the toxicity to any organism of a registered pesticide product or any of its ingredients, impurities, metabolites, or degradation products and which is otherwise reportable according to the "Agency Interpretation of Requirements Imposed on Registrants by Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act," 43 FR 37611, will not be considered an actionable violation of FIFRA § 6(a)(2) unless the information concerns any study in which:

(1) The substance tested was associated with a kind of toxic or adverse effect, or an effect on an organ or tissue type, not observed in any study concerning the substance previously reported to EPA;

(2) The substance tested was associated with any toxic or adverse effect at a lower dosage, after a shorter exposure period, or after a shorter latency period than in any study concerning that effect of the substance previously reported to EPA;

(3) The substance tested was associated with a more severe toxic or adverse effect, or a higher incidence or frequency of a toxic or adverse effect, than in any study concerning that effect of the substance previously reported to EPA;

(4) The substance tested was associated with a toxic or adverse effect in a different species, strain, sex, or generation of test organism than in any study concerning that effect of the substance previously reported to EPA;

(5) The substance tested was associated with a toxic or adverse effect involving a route or medium of exposure not associated with such an effect in any study concerning the substance previously reported to EPA, if humans or other non-target organisms could conceivably be exposed to the substance by that route or medium during manufacture or distribution, or by an approved manner of use, of the pesticide product;

(6) It appears that a substance produced a toxic or adverse effect by means of a pharmacokinetic, metabolic, or biological mechanism different than any mechanism postulated or proposed for that effect in any study concerning the substance previously reported to EPA; or

(7) The substance tested was associated with *any* toxic or adverse effect, if the substance is a pesticide, or an ingredient, impurity, metabolite, or degradation product of a pesticide, which is the subject of a reregistration proceeding, generic standard proceeding, Rebuttable Presumption Against Registration proceeding, suspension proceeding, or cancellation proceeding.

EPA will not consider a delay in submission of information on a completed study which is otherwise reportable under paragraphs (1)–(7) above to be an actionable violation of FIFRA § 6(a)(2) if the delay is for a reasonable period, no longer than 30 days from the date the registrant first receives the apparently reportable information. In addition, EPA will not consider failure to submit such information to be an actionable violation of FIFRA § 6(a)(2) if, prior to the expiration of the period mentioned in the preceding sentence:

(i) The registrant discovers that any analysis, conclusion, or opinion which would have caused the information to be reportable was predicated on data that were erroneously generated, recorded, or transmitted, or on computational errors;

(ii) Every author of each such analysis, conclusion, or opinion has acknowledged in writing that the analysis, conclusion, or opinion was improper because of the use of the erroneous data, and has corrected the original analysis, conclusion, or opinion accordingly; and

(iii) After such corrections, the information no longer need be reported under any provision of this Notice.

Discussion

The result of any controlled study in which exposure to a pesticidal substance is associated with a toxic or adverse effect are clearly pertinent to evaluation of risk and are thus legally reportable under Section 6(a)(2). However, unless new toxicological information suggests that reliance on material previously submitted to EPA may have resulted in underestimation of risk, or that prior information was otherwise inaccurate, misleading, or incomplete, submission of such new information is not likely to materially affect the registration status of products containing the substance tested. EPA will not treat failure to submit toxicological information which is essentially corroborative as an actionable violation of Section 6(a)(2), but will insist on submission of any toxicological data which indicates that a pesticide may present different or greater hazards than previously identified.

However, when a particular pesticide product is involved in an RPAR proceeding under 40 CFR 162.11, or in suspension or cancellation proceedings under FIFRA § 6(b) or 6(c), or where reregistration is underway, the scope of EPA's information needs is considerably broader. In such circumstances, the ultimate status of the pesticide depends on a comprehensive Agency reevaluation of the pesticide's risks and benefits, including an assessment of the reliability of previously submitted material and extent to which it has been corroborated. Thus, if a particular substance is the subject of a reregistration, RPAR, suspension, or cancellation proceeding, EPA will treat failure to submit any toxicological information linking that substance with any toxic or adverse effect as an actionable violation of Section 6(a)(2), regardless of whether or not such information merely confirms or corroborates prior data.

By the time a study is "completed", checking and validation of data should normally also be complete. We will nonetheless allow the registrant a reasonable period, not to exceed 30 days, to check for data errors which the registrant believes may have formed the basis for an opinion about what the data signify, and to seek a corresponding modification of the opinion.

On the other hand, if it is not the data, but the expert analysis, conclusion, or opinion *itself* with which the registrant disagrees, the registrant's remedy is not to withhold the information from EPA, but to submit with the § 6(a)(2) report his own analysis of the information's significance.

B. Incomplete Toxicological Studies

Policy

Failure to submit information to EPA which concerns the results of an incomplete study of the toxicity to any organism of a registered pesticide product or any of its ingredients, impurities, metabolites, or degradation products and which is otherwise reportable according to the "Agency Interpretation of Requirements Imposed on Registrants by Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act," 43 FR 37611, will not be considered an actionable violation of FIFRA § 6(a)(2) unless the information concerns:

(1) An acute effects study or other study utilizing a testing regimen lasting 90 days or less, in which all testing has been completed, a preliminary data analysis or gross pathological analysis has been conducted, final analysis has not been completed, and a reasonable period for completion of the final analysis (not longer than 90 days following completion of testing) has elapsed, if comparable information concerning the results of a complete controlled study would be reportable under paragraphs I. A(1)–(7) of this Section:

(2) A chronic effects study or other study utilizing a testing regimen lasting more than 90 days, in which all testing has been completed, a preliminary data analysis or gross pathological analysis has been conducted, final analysis has not been completed, and a reasonable period for completion of final analysis (not longer than one year following completion of testing) has elapsed if comparable information concerning the results of a completed controlled study would be reportable under paragraphs I. A(1)–(7) of this Section: or

(3) Any study in which testing or analysis of results is not yet complete but in which serious adverse effects have already been observed which may reasonably be attributed to exposure to the substance tested, because the affects observed in exposed organisms differ from effects observed in control organisms, are atypical in view of historical experience with the organism tested, or otherwise support a reasonable inference of causation.

Discussion

In developing a policy regarding which failures to submit otherwise reportable information from incomplete toxicological studies should be treated as actionable violations of Section 6(a)(2), EPA has determined that it is not necessary at this time to require submission of preliminary or incomplete toxicological information, except in certain specific circumstances. The criteria selected are designed to accomplish two fundamental regulatory objectives. The first objective is to provide an incentive to registrants to complete analysis of toxicological data within a reasonable time, especially if a preliminary appraisal suggest that a pesticide may present different or greater hazards than previously identified. The second objective is to insure that any preliminary findings are reported to EPA as soon as there is a reasonable basis for concern, even though further testing or analysis may be necessary before the observed hazard can be defined or quantified.

We do not believe that it would be currently useful to insist on submission of preliminary or inconclusive data on a routine basis. On the other hand, no registrant who fears that submission of a completed study might jeopardize any of its registrations should be permitted to indefinitely defer or postpone completion of analysis of potentially significant data. Accordingly, we have designated an appropriate period—up to 90 days for acute studies, up to one year for chronic studies—during which the registrant may engage in further analysis designed to refine the data prior to submission.

Example

A registrant conducts the first study of the acute effects of ingestion of a certain pesticide on rabbits. A prior acute study of the same pesticide using mice found that exposed mice experienced increased mortality due to liver damage. The registrant notes increased mortality of unknown origin in the exposed rabbits. Following completion of the test regimen, the registrant may take a reasonable period, not exceeding an additional 90 days, for investigation of the significance and cause of the increased mortality. After that period has elapsed, failure to submit information concerning the study to EPA will be treated as an actionable violation of Section 6(a)(2), regardless of whether or not the analysis is yet complete, because information concerning a completed study in which toxic effects have been observed in a different species than previously reported would be reportable. Of course, the registrant will always be entitled to supplement any initial submission with the results of subsequent analysis.

Certain types of preliminary experimental observations and findings are sufficiently serious that they should be reported to EPA immediately. In general, we will not treat failure to submit information concerning any incomplete study in which testing is still underway, or for which the prescribed period for analysis of results has not yet expired, as an actionable violation of Section 6(a)(2) unless serious adverse effects have been observed which are sufficiently different from effects observed in control organisms or in prior experience with the species tested that the registrant may reasonably assume that the adverse effects are associated with the pesticidal substance being tested. Even though preliminary information may not always be sufficiently complete or definitive to warrant immediate regulatory action, preliminary data may indicate a need for immediate modifications of or additions to the study protocol, provide a basis for requests for further information under FIFRA § 3(c)(2)(B), or convince EPA to conduct or sponsor additional research.

Examples

(1) A registrant conducts a two-year study of the effects of chronic exposure to a certain pesticide on rats. Nine months after the study commences, study personnel observe that a large percentage of the exposed rats have developed ocular opacity of the type associated with formation of cataracts. None of the control mice exhibit a comparable abnormality. Though the test is incomplete and the evidence that the pesticide is inducing cataracts is not yet definitive, the registrant may reasonably conclude that the ocular abnormalities are attributable to exposure to the pesticide, and the observed effects must be reported to EPA.

(2) A registrant conducts a two-year controlled study of the effects of chronic exposure to a certain pesticide on mice. Six months after the study commences, several of the exposed animals die. Upon dissection, study personnel observe that the dead animals have developed a type of tumor which is rarely observed in the strain of mice being tested. Though a substantial portion of the test regimen has not been completed, pathological evaluation of the tumors is also incomplete, and the evidence that the pesticide is tumorogenic is not definitive, a reasonable inference arises that the unusual tumors are attributable to exposure to the pesticide, and the observed effects must be reported to EPA.

C. Epidemiological Studies

Policy

Failure to submit information to EPA which concerns any completed epidemiological study (or portion thereof) involving correlation or association between exposure to a registered pesticide (or any of its ingredients, impurities, metabolites, or degradation product) and adverse effects in humans, and which is reportable according to the "Agency Interpretation of Requirements Imposed on Registrants by Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act." 43 FR 37611, will be considered an actionable violation of FIFRA § 6(a)(2) regardless of whether or not the registrant considers any observed correlation or association to be significant.

Discussion

Unlike most studies, which can be designed and controlled in advance, epidemiological studies are generally retrospective in character. As a consequence, it is often difficult to assess the impact of various uncontrolled variables on the magnitude of any observed correlation, and competent experts can reasonably disagree regarding the practical significance of epidemiological findings. On the other hand, epidemiological studies can be an indispensable source of information on the critical issue of the risks associated with human exposure. Thus, it is important that EPA be able to independently examine for relevance any epidemiological information concerning pesticide exposure, and we will consider any failure to submit such information to be an actionable violation of Section 6(a)(2). Registrants may supplement any submission of epidemiological information with a statement describing any reservations they might have concerning the information's validity or significance.

D. Efficacy Studies

Policy

Failure to submit information to EPA which concerns any study of the efficacy of a registered pesticide product and which is otherwise reportable according to the "Agency Interpretation of Requirements Imposed on Registrants by Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act," 43 FR 37611, will not be considered an actionable violation of FIFRA § 6(a)(2) unless:

(1) The information demonstrates that the pesticide may not perform in accordance with any claim by the registrant regarding use to control organisms which may pose a risk to human health, including any of the uses identified in 40 CFR 162.10-2(d)(2), (3)(i), 44 FR 27932, 27942, May 11, 1979; or

(2) The information concerns any deficiency or reduction in the claimed efficacy of any use of a registered pesticide, if such use is subject to a Rebuttable Presumption Against Registration proceeding, suspension proceeding, or cancellation proceeding.

EPA will not consider a delay in submission of information which is otherwise reportable under paragraph (1) or (2) above to be an actionable violation of FIFRA § 6(a)(2) if the delay is for a reasonable period, no longer than 30 days from the date the registrant first receives the apparently reportable information. In addition, EPA will not consider failure to submit such information to be an actionable violation of FIFRA § 6(a)(2) if, prior to the expiration of the period mentioned in the preceding sentence:

(i) The registrant discovers that any analysis, conclusion, or opinion which would have caused the information to be reportable was predicated on data that were erroneously generated, recorded, or transmitted, or on computational errors;

(ii) Every author of each such analysis, conclusion, or opinion has acknowledged in writing that the analysis, conclusion, or opinion was improper because of the use of the erroneous data, and has corrected the original analysis, conclusion, or opinion accordingly; and

(iii) After such corrections, the information no longer need be reported under any provision of this Notice.

Discussion:

In most instances, EPA will not treat the failure to submit information concerning the efficacy of a registered pesticide product as an actionable violation of Section 6(a)(2) unless such information indicates that the pesticide may not perform as claimed when used to control organisms which pose a potential threat to human health. We have taken the position that the utility and efficacy of many pesticide products can best be verified by the mechanism of the marketplace. See 44 FR 27932, 27938-40, May 11, 1979. However in some instances where use of a particular pesticide appears to involve substantial hazards, EPA must evaluate the efficacy of the pesticide, in addition to the magnitude and value of its use and the feasibility of substitutes, before determining whether or not the risks associated with use of the pesticide are acceptable. Accordingly, whenever any use of a registered pesticide is the subject of an RPAR, suspension, or cancellation proceeding, EPA will treat failure to submit any study which concerns any deficiency or reduction in the efficacy of the product for the use in

question as an actionable violation of Section 6(a)(2).

II. Incident Reporting

A. Toxic or Adverse Effects

Policy

Registrants may receive information, other than the results of controlled studies, concerning specific incidents in which toxic or adverse effects have been attributed to exposure to the registrant's pesticide product. This information may come to the registrant's attention through a variety of sources, including but not limited to: product liability claims and complaints; information obtained directly, or through field representatives, from dealers, growers and pesticide users; reports from agricultural extension agents and federal and state regulatory agencies; information received from the general public; information received from a poison control center; and information reported by plant managers and employees. Failure to submit information of this type which is otherwise reportable according to the "Agency Interpretation of Requirements Imposed on Registrants by Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act," 43 FR 37611, will not be considered an actionable violation of FIFRA § 6(a)(2) unless one of the following three sets of criteria apply:

(1) *Human Incidents.* The information concerns an incident in which: (a) The registrant has been informed that some person suffered an adverse physiological or behavioral effect (other than local damage to or irritation of the skin of the type commonly associated with dermal exposure, when the lable provides adequate notice of such a hazard);

(b) The registrant has been informed that the affected person may have been exposed to the pesticide, or to one or more of its ingredients;

(c)(i) The registrant has verified that the person did suffer an adverse effect and was exposed to the pesticide, *or*

(ii) The registrant has received sufficient information to enable investigation of whether or not the reported adverse effect and exposure occurred, a reasonable period of time for investigation has elapsed, and the registrant is not aware of facts which establish that the reported adverse effect or reported exposure did not occur; and

(d)(i) The registrant has concluded that the effect may have resulted from the exposure, *or*

(ii) The registrant has been advised by any individual whose opinion is reportable under Section 6(a)(2)—i.e., and employee, consultant, or qualified expert—that the effect may have resulted from the exposure, and is not aware of facts which conclusively establish that the reported adverse effect and reported exposure were unrelated.

(2) *Incidents Involving Other Non-Target Organisms.* The information concerns an incident in which:

(a) The registrant has been informed of an adverse effect on non-target fish or wildlife, domestic animals, or plants;

(b) The registrant has been informed that the affected fish, wildlife, domestic animals, or plants may have been exposed to the pesticide, or to one or more of its ingredients;

(c)(i) The registrant has verified that the reported adverse effect and exposure did occur, *or*

(ii) The registrant has received sufficent information to enable investigation of whether or not the reported adverse effect and exposure occurred, a reasonable period of time for investigation has elapsed, and the registrant is not aware of facts which establish that the reported adverse effect or reported exposure did not occur; and

(d)(i) The registrant has concluded that the effect may have resulted from the exposure, *or*

(ii) The registrant has been advised by any individual whose opinion is reportable under Section 6(a)(2)—i.e. an employee, consultant, or qualified expert—that the effect may have resulted from the exposure, and is not aware of facts which conclusively establish that the reported adverse effect and reported exposure were unrelated; *and*

(e)(i) The registrant cannot demonstrated that the pesticide exposure resulted from improper use, *or*

(ii) The labeling of the pesticide does not provide reasonable notice of the risk of adverse effects of the kind reported.

(3) *Series of Incidents.* The information concerns any *series* or *pattern* of individual incidents as to which:

(a) The registrant has been informed of the same kind of adverse effect on humans, non-target fish and wildlife, domestic animals, or plants;

(b) The registrant has been informed that the affected organisms may have been exposed to the same pesticide or to one or more of its ingredients;

(c) For each individual incident, either

(i) The registrant has verified that the reported adverse effect and reported exposure did occur, *or*

(ii) The registrant has received sufficient information to enable investigation of whether or not the reported adverse effect and exposure occurred, a reasonable period of time for investigation has elapsed, and the registrant is not aware of facts which establish that the reported adverse effect or reported exposure did not occur;

(d) For each individual incident, the registrant is not aware of facts which conclusively establish that the reported adverse effect and reported exposure were unrelated; and

(e) The series or pattern of incidents would not be expected unless the reported adverse effects were caused by the reported exposures.

Discussion

Information concerning incidents in which toxic or adverse effects are attributed to pesticide exposure varies considerably in specificity and accuracy. Some reports received by registrants are so vague or implausible that they would be unlikely to provide a basis for administrative action. On the other hand, some incident reports may contain unique and valuable information on the hazards and environmental impacts associated with actual use and practice, information which cannot be readily derived from laboratory data alone. Thus, we have endeavored to select sets of criteria which will give practical assistance to each registrant in identifying those types of incident information which are currently needed by EPA in order to properly discharge its statutory responsibilities. Each set criteria contains the following elements: (1) a report of a toxic or adverse effect, (2) a report of pesticide exposure, (3) an opportunity for investigation of the accuracy of the reports, and (4) a basis for an inference that the toxic effect and the pesticide exposure were related.

Demonstrably inaccurate incident information need not be submitted to EPA under Section 6(a)(2). If a registrant can clearly demonstrate that a reported toxic effect or pesticide exposure did not occur, or that the effect and exposure were unrelated, we will not treat any failure to report an alleged incident as an actionable violation of Section 6(a)(2). However, failure to investigate the accuracy of any report or allegation which could be investigated will not be considered to excuse non-compliance with Section 6(a)(2). By adopting this policy, EPA does not intend to attempt to impose any sort of

duty or obligation on the registrant to investigate incident reports, but rather to accord the registrant a reasonable opportunity to investigate incident information. In any event, the responsibility for determining the significance of any potentially useful incident information which has not been either verified or rebutted must ultimately reside with EPA.

Information concerning incidents in which humans exposed to a pesticide have experienced toxic or adverse effects is extremely useful in, e.g., evaluating the occupational risks associated with pesticide use, or deciding whether a method of applying the pesticide should be prohibited. Receipt of incident information regarding adverse effects in humans is particularly important because of the ethical unacceptability of deliberate clinical exposure and the difficulties associated with predicting human toxicity on the basis of animal data. Thus, we may consider any failure to submit incident information concerning any toxic or adverse effect in humans (except for local skin damage or irritation warned against on the label) which includes the basic elements previously identified and which is otherwise reportable under Section 6(a)(2) to be an actionable violation of FIFRA, regardless of the circumstances which resulted in the pesticide exposure. In contrast, we will not treat failure to submit information on any single incident involving toxic or adverse effects on other non-target organisms as an actionable violation of Section 6(a)(2) if the registrant can demonstrate that (1) the pesticide was used improperly, and (2) the label provides reasonable notice of the risk of adverse effects of the kind reported.

Incident information concerning toxic or adverse effects has little current utility for regulatory purposes and need not be submitted to EPA under Section 6(a)(2) unless the information is predicated on a conclusion, opinion, or reasonable inference that the reported effects were related to pesticide exposure. Failure to submit information regarding any *single* incident of this type will not be treated as a violation of Section 6(a)(2) unless the registrant has concluded that the reported effect may have been caused by the reported pesticide exposure, or has been advised by any individual whose opinion is reportable (according to the "Agency Interpretation of Requirements Imposed on Registrants by Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act," 43 FR 37611) that a causal relationship may have existed.

Examples

(1) A registrant receives a report from an unidentified source indicating that an agricultural employee experienced respiratory difficulties after working in a field where a pesticide manufactured by the registrant had recently been applied. The report is sufficiently detailed to enable investigation of its accuracy. A few days later, the registrant discusses the alleged incident with a toxicologist, who states that, in his opinion, the reported respiratory symptoms could have been caused by exposure to the registrant's pesticide. The registrant will be given a reasonable time to investigate the incident. If the registrant subsequently discovers facts which establish that the reported adverse effects or reported exposure did not occur, or which conclusively establish that the respiratory difficulties experienced by the exposed individual were caused exclusively by some factor other than pesticide esposure, the incident need not be reported. Otherwise, information concerning the incident must be submitted to EPA, because the toxicologist is a qualified expert whose opinion is reportable under Section 6(a)(2).

(2)A registrant receives a report from an agricultural extension agent indicating that fish were killed in a creek adjacent to a field where a pesticide manufacture by the registrant had recently been applied. After investigation, the registrant concludes that the reported fish kill probably resulted from exposure to the registrant's pesticide. However, the registrant also discovers facts which establish that the pesticide was improperly applied, by an individual who disregarded a statement on the label expressly warning against use in circumstances where contamination of surface waters might result. Any *single* incident of this sort need not be reported under Section 6(a)(2).

If a registrant has been informed of a series or pattern of incidents in which the same kind of toxic or adverse effects have followed exposure to the same pesticide, a reasonable inference of a causal relationship may arise from the existance of the series or pattern itself, even in the absence of a specific conclusion or expert opinion to that effect. In such circumstances, any requirement that the registrant specifically conclude or be advised that a causal relationship exists is superflous, and registrants will be held legally accountable under Section 6(a)(2) for failure to submit information regarding any significant series or pattern of incidents involving the same kind of toxic or adverse effect and the same pesticidal substance. Moreover, even if a series or pattern consists of incidents which would otherwise not be reportable under this policy, because each incident involves predictable effects on nontarget organisms resulting from improper use, we will likely treat failure to report such information in an aggregate form as an actionable violation of Section 6(a)(2). EPA needs this type of incident information because the existence of widespread or routine misuse of pesticide products may be a basis for changes in labeling, additional restrictions on use, or other regulatory action.

Example

The registrant has received a number of reports, from various sources, of unusually high mortality in birds feeding in or near fields where the registrant's pesticide has been applied. Though some of these reports were not specific enough to enable investigation of their accuracy, the registrant has identified a series of specific investigable incidents in which it appears that an unusual number of birds died following use of the registrant's pesticide. However, the registrant has not determined whether or not the pesticide was responsible for the observed increase in bird mortality, and no employee, consultant, or qualified expert has indicated that a causal relationship may exist. Nevertheless, if the existence of the series of unexplained incidents is sufficient to support a reasonable inference of a causal relationship, failure to submit information concerning the incidents will be considered an actionable violation of Section 6(a)(2).

B. Failure of Efficacy

Policy

Registrants may also receive information concerning specifc incidents in which it is asserted that the registrant's pesticide product failed to perform as claimed against designated target organisms. Failure to submit information of this type which is otherwise reportable according to the "Agency Interpretation of Requirements Imposed on Registrants by Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act," 43 FR 37611, will not be considered an actionable violation of FIFRA § 6(a)(2) unless one of the following two sets of criteria apply:

(1) *Immediate Hazard to Life.* The information concerns an incident in which:

(a) The registrant has been informed that a pesticide product did not perform as claimed against target organisms;

(b)(i) The registrant has verified that the reported failure of efficacy did occur, *or*

(ii) The registrant has received sufficient information to enable investigation of whether or not the reported failure of efficacy occurred, a reasonable period of time for investigation has elapsed, and the registrant is not aware of facts which establish that the reported failure of efficacy did not occur; and

(c) The failure of the pesticide to perform as claimed involved any use against organisms which, unless controlled, may pose an immediate hazard to human life.

(2) *Health Risk.* The information concerns any *series* or *pattern* of individual incidents as to which:

(a) The registrant has been informed of the same type of failure to perform as claimed against target organisms;

(b) For each individual incident, either

(i) The registrant has verified that the reported failure of efficacy did occur, *or*

(ii) The registrant has received sufficient information to enable investigation of whether or not the reported failure of efficacy occurred, a reasonable period of time for investigation has elapsed, and the registrant is not aware of facts which establish that the reported failure of efficacy did not occur; and

(c) The failure of the pesticide to perform as claimed involved any use to control organisms which may pose a risk to human health, including any of the uses identified in 40 CFR 162.18-2(d)(2), (3)(i).

Discussion

We will not treat any failure to submit information concerning incidents in which a pesticide did not perform as claimed against target organisms as an actionable violation of Section 6(a)(2) unless the reported failure of efficacy involved organisms which pose a potential threat to human health. This policy reflects a judgement by EPA that the efficacy of pesticide products which are not used to protect public health can usually be adequately tested by the dictates of a competitive marketplace. See 44 FR 27932, 27938-40, May 11, 1979. Moreover, except in those instances where a reported failure of efficacy involved use against organisms which may pose an immediate hazard to human life, it is not likely that we would consider any single reported incident of failure of efficacy to be a proper basis for regulatory action. Therefore, we will not treat any failure to submit incident information concerning failure of efficacy against organisms which may pose a risk to public health, but do not pose an immediate hazard to human life, as an actionable violation of Section 6(a)(2) unless such information concerns any significant series or pattern of comparable failures of efficacy. As in the case of incident information involving toxic or adverse effects, registrants will be afforded a reasonable opportunity to investigate any reported failure of efficacy before such information will be considered reportable.

III. Reporting of Other Information

Policy

EPA will not consider failure to submit information of any kind other than those kinds of information described in Sections I and II of this Notice as an actionable violation of FIFRA § 6(a)(2) even though such information would otherwise be reportable according to the "Agency Interpretation of Requirements Imposed on Registrants by Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act," 43 FR 37611, unless:

(1) After a reasonable period of time for verification or investigation of the information has elapsed, the registrant is not aware of facts which establish that the information is incorrect; and

(2) The registrant knows, or reasonably should know, that if the information should prove to be correct, EPA would regard the information, alone or in conjunction with other information about the pesticide, as raising serious questions about the continued registrability of one or more uses of any of the registrant's pesticide products, or about the proper terms and conditions of registration of any such product.

Discussion

In Sections I and II of this Notice, we have established policies concerning the types of information which, insofar as we are aware, have been the subject of most of the inquiries made and concern expressed by registrants with regard to FIFRA § 6(a)(2). There are, however, many other categories of information which may be reportable under FIFRA § 6(a)(2), including additional information concerning: the identity and amount of impurities and degradates of pesticide products in the product as sold; degradation and fate of pesticides in the environment after application or use; soil, plant, and animal metabolism; bioaccumulation by various life forms; identity and quantity of pesticide residues on raw and processed agricultural commodities and foods; levels of exposure to applicators, farm workers, bystanders, food consumers, and other persons; drift of pesticides to non-target areas; and a variety of other information which might affect EPA decisions concerning the continued registrability of a product or the appropriate terms and conditions of registration.

In this Notice we have not attempted to establish with specificity, for each category of such information, which failures to report information we will not treat as actionable violations of FIFRA § 6(a)(2). In part, this is because we are interested in receiving the views of the pesticide industry and other interested persons concerning what our policy regarding such information should be. It is likely that we will modify this Notice in the future to announce a more specific Section 6(a)(2) enforcement policy concerning some or all of these types of information.

However, in order to provide some immediate guidance to registrants, we have set forth in this Notice a general policy covering all information not described by Sections I and II of the Notice. It allows registrants a reasonable period to verify or investigate apparently reportable information, prior to actual submission. In deciding whether a delay in reporting was reasonable, we will take into account the seriousness of the problem suggested by the information, as well as the kind and amount of verification that would be desirable. If, during this period, the registrant learns of facts showing that the information is incorrect, the information need not be submitted and failure to report will not be considered an actionable violation of Section 6(a)(2).

In addition, we will not treat a failure to report information as an actionable violation of FIFRA § 6(a)(2) unless the registrant knew, or reasonably should have known, that EPA would regard the information as pertinent to the question of whether the product's registrations should be cancelled, suspended, or modified in some respect.

Example

The registrant knows that the original EPA decision to register his product for use as a soil insecticide in corn fields (the only registered use) was based on the belief that no residues of a particular, highly-toxic metabolite of the product would appear in corn planted in fields treated with the product during the spring. In January the registrant learns of a study conducted by a university scientist showing that residues of the metabolite in question have appeared in corn grown in fields which were properly treated with the product. If true, this report would indicate that use of the product may pose a serious hazard to food consumers. Accordingly, the information must be reported to EPA unless, during a reasonable period of time for investigation or verification, the registrant learns of facts establishing it is untrue. One means of verification would be to conduct independent field trials during the coming growing season. However, waiting for the results of field trials would require a delay of at least 9-10 months in reporting. Given the serious import of the information already available, a 9-month

delay would be unreasonably long. Alternatively, the registrant could contact the scientist who conducted the study and review the raw data for errors. A review of this type would probably require 10 days or less. The Agency would regard the latter delay as reasonable, since, even though the information could conceivably warrant an emergency suspension of the product's registration, this could be accomplished in time to prevent use of the product during the growing season.

IV. Previously Reported Information

Any information shall be considered to have been previously reported to EPA under Section 6(a)(2) of FIFRA for the purposes of this notice if such information is contained completely in:

(1) Documents previously submitted to EPA by the registrant;

(2) Any scientific article or publication which has been abstracted in Biological Abstracts, Chemical Abstracts, Index Medicus, or Pesticides Abstracts, if the abstract in question clearly identified the active ingredient or the registered pesticide(s) to which the information pertains. [Information received by or known to the registrant prior to publication of an abstract concerning the information must be reported and may not be withheld pending such publication.];

(3) EPA publications, EPA hearing records, or publications cited in EPA Federal Register notices;

(4) Reports or publications which have been made available to the public by any of the following federal agencies: Center for Disease Control, Consumer Products Safety Commission, Department of Agriculture, Department of Interior, Food and Drug Administration, National Institutes of Health, or Occupational Safety and Health Administration. [Otherwise reportable information concerning research which was performed, sponsored, or funded by the registrant which may also appear in a forthcoming government report or publication must be reported and may not be withheld pending publication.]; or

(5) Any other documents which are contained in the official files and records of the EPA Office of Pesticide Programs.

Discussion

Section 6(a)(2) applies only to "additional" information. Thus, if a registrant has previously submitted information concerning a given study, document, or incident, the same information need not be submitted again. In addition, we do not believe that it would serve any useful purpose to insist that registrants submit information which is already in EPA files or is otherwise readily accessible to EPA. Accordingly, we have specified a number of objectively defined categories of information which need not be submitted. Failure to submit information in any of these categories will not be treated as an actionable violation of Section 6(a)(2). While the specified categories are not intended to encompass all information which could conceivably come to the attention of Agency personnel, they do indicate which types of information are most likely to be routinely examined or reviewed by EPA.

V. Case-by-Case Exercise of Prosecutorial Discretion

EPA will not automatically seek or recommend civil or criminal penalties whenever it discovers an apparent violation of FIFRA § 6(a)(2) of a type which is considered actionable under this Notice. Decisions in such cases will be based on a careful evaluation of all pertinent information, including any explanation offered by the registrant.

Dated: July 6, 1979.

Marvin B. Durning,

Assistant Administrator for Enforcement.

[FR Doc. 79-21564 Filed 7-11-79; 8:45 am]

BILLING CODE 6560-01-M

[FRL 1270-6]

Illinois State Implementation Plan; Notice of Deficiency

AGENCY: U.S. Environmental Protection Agency.

ACTION: Notice of Deficiency; Illinois State Implementation Plan.

SUMMARY: As a result of Illinois Appellate Court action on September 27, 1978 which vacated regulations pertaining to particulate and sulfur dioxide emission standards USEPA finds the Illinois State Implementation Plan to be deficient.

FOR FURTHER INFORMATION CONTACT: Maxine Borcherding, Air Programs Branch, Air and Hazardous Materials Division, U.S. Environmental Protection Agency, 230 South Dearborn Street, Chicago, Illinois 60604, (312) 353-2205.

SUPPLEMENTAL INFORMATION: This notice contains a summary of the findings of the EPA Regional Administrator for Region V from an assessment of deficiency of the implementation plan for the State of Illinois.

On May 31, 1972 (37 FR 10862) under Section 110 of the Clean Air Act and 40 CFR Part 51, the Administrator substantially approved Illinois' control strategy for the attainment and maintenance of the national primary and secondary standards for sulfur dioxide emissions and particulate emissions in the State of Illinois. In April of 1972, the Illinois Pollution Control Board (PCB) initially adopted regulations numbers 203 (particulate emission standards) and 204 (sulfur dioxide emission standards). These regulations were adopted pursuant to the Illinois Environmental Protection Act of 1970, *Ill. Rev. Stat.*, ch. 111 1/2 sections 1001 *et seq.* (1975) and superseded other air quality regulations promulgated under prior acts.

The validation of Rules 203(g)(1), 204(a)(1) and 204(c)(1)(A) was challenged in court and, as a result, the Illinois Appellate Court found that the PCB had not followed the correct procedure in its adoption of those Rules. The Court remanded the cause to the PCB for further consideration. (*Commonwealth Edison Co.* v. *Pollution Control Board*, 25 Ill. App. 3d 271, 323 N.E. 2d 84.) The Illinois Supreme Court affirmed the Illinois Appellate Court's decision instructing PCB to validate Rules 203(g)(1), 204(a)(1) and 204(c)(1)(A) according to Section 27 of the Illinois Environmental Protection Act or to prepare proper rules as substitutes. (*Commonwealth Edison Co.* v. *PCB*, 62 Ill. 2d 494, 343 N.E. 2d 459 (January, 1976).)

On August 2, 1976, the EPA Regional Administrator, Region V, formally issued a Notice of Deficiency requesting that a revision to the Illinois State Implementation Plan (SIP) be developed or that appropriate action be taken to correct the SIP deficiencies noted by the Illinois courts. (41 FR 149, August 2, 1976.) Authority for the Notice of Deficiency was provided in Sections 110(a)(2)(H) and 110(c) of the Clean Air Act.

On July 7, 1977, the Illinois PCB issued an order "validating" Rules 203(g)(1), 204(a)(1) and 204(c)(1)(A), to become effective September 1, 1977. The validation of the regulation was subject to a public comment period running 45 days from the date of the order. This action by the PCB was challenged by Ashland Chemical Company, one of the sources affected by the Rules.

On September 27, 1978, the *Illinois Chemical Company* v. *Pollution Control Board* (No. 77-362), —— Ill. App. 3d ——. The Court held that the PCB did not follow the instructions of the Illinois Supreme Court in *Commonwealth Edison Co., supra*, for either "revalidating" the rules or adopting "substitute" rules. The Court found that

FEDERAL REGISTER

WEDNESDAY, AUGUST 23, 1978
PART IV

ENVIRONMENTAL PROTECTION AGENCY

PESTICIDE REGISTRANT REPORTING REQUIREMENTS

Agency Interpretation and Revocation of Interpretative Rule

[6560-01]

Title 40—Protection of Environment

CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY

[FRL 952-2]

PART 162—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

Revocation of Interpretative Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Revocation of interpretative rule.

SUMMARY: EPA revokes a regulation containing an Agency interpretation of the reporting requirement imposed on registrants by section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA). This revocation is issued because the Agency has concluded that the regulation inadequately expresses the Agency's interpretation of the requirement imposed by FIFRA section 6(a)(2).

EFFECTIVE DATE: August 23, 1978.

FOR FURTHER INFORMATION CONTACT:

Edward C. Gray, Office of General Counsel (A-132), U.S. Environmental Protection Agency, 401 M [illegible] et SW., Room 425 West Tower, Washington, D.C. 20460, telephone 202-755-0638.

SUPPLEMENTARY INFORMATION: The Agency has concluded that 40 CFR 162.8(d)(2) inadequately expresses the Agency's interpretation of the requirement imposed by FIFRA section 6(a)(2). The Agency's review was prompted by currently pending litigation seeking to have the regulation set aside (*Chemical Specialties Manufacturing Association and National Agricultural Chemicals Association* v. *EPA*, CA No. 77-1938, U.S. District Court for the District of Columbia).

The Agency's General Counsel recently issued a memorandum concerning the requirements of FIFRA section 6(a)(2), which the Agency has adopted as its interpretation of those requirements. That memorandum appears in this same separate part of the FEDERAL REGISTER.

Notice-and-comment procedures are not being used in connection with this action because (1) the regulation being revoked is an interpretative rule, (2) the public interest would be served by prompt revocation of an interpretation which inadequately reflects the Agency's views, and (3) the expeditious resolution of the previously-mentioned litigation depends on prompt revocation of the regulation. For the same reasons, the effective date of this action shall be August 23, 1978.

The U.S. Department of Agriculture has reviewed this regulation in accordance with FIFRA section 25(a)(2)(B). By letter dated July 31, 1978, the Department informed the Agency that it did not object to publication of the regulation, and that the reporting contemplated by the interpretative memorandum did not appear to be unreasonable. Copies of the regulation and accompanying memorandum also were submitted to the Senate Committee on Agriculture, pursuant to FIFRA section 25(a)(3). In accordance with FIFRA section 25(d), copies of the regulation and memorandum were furnished to the FIFRA Scientific Advisory Panel; by letter dated July 18, 1978, the Panel notified the Agency that it would not conduct scientific review and comment on the regulation.

The Agency has determined that this document is not a "significant" regulation under the Agency's criteria for implementing Executive Order 12044.

This action is authorized by FIFRA section 25(a), 7 U.S.C. 136w(a), and by 5 U.S.C. 552, 553.

Accordingly, Part 162, Chapter I, Title 40 of the Code of Federal Regulations, is hereby amended by deleting the text of section 162.8(d)(2) and by designating that paragraph as "Reserved."

Dated: August 14, 1978.

DOUGLAS M. COSTLE,
Administrator.

[FR Doc. 78-23552 Filed 8-22-78; 8:45 am]

[6560-01]

ENVIRONMENTAL PROTECTION AGENCY

[FRL 952-3]

PESTICIDE REGISTRANT REPORTING REQUIREMENTS

Agency Interpretation of Requirements Imposed on Registrants by Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act

This notice sets forth the Environmental Protection Agency's interpretation of the reporting requirements imposed on registrants of pesticides by section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA), 7 U.S.C. 136d(a)(2). The memorandum of the Agency's General Counsel dated June 30, 1978, which is set forth below, is hereby adopted as the Agency's position.

Dated: August 14, 1978.

DOUGLAS M. COSTLE,
Administrator.

[Memorandum]

Subject: Nature of reporting requirement under FIFRA section 6(a)(2).
From: Joan Z. Bernstein, General Counsel (A-130).
To: The Administrator (A-100).
Through: AX (A-101).

JUNE 30, 1978.

BACKGROUND

This memorandum sets forth in detail this Office's views concerning the proper interpretation of the registrant reporting requirements imposed by Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA). It responds to your May 10 directive that such a discussion be prepared. Since we merely state here what we believe the statute requires, publication of this memorandum would not by itself impose any new or additional requirements, but would constitute a statement of the Agency's position with respect to the matter.

QUESTION

What information must a registrant submit to EPA in order to comply with the requirement of FIFRA Section 6(a)(2)?

ANSWER

In our opinion, FIFRA Section 6(a)(2) imposes the following requirement:

A registrant must submit an item of information to EPA if:

(1) The registrant possesses the information and it pertains to a pesticide for which that registrant holds a registration under FIFRA; *and*

(2) The information, if true, would be relevant to an Agency decision regarding the risks and benefits of the pesticide, i.e., an Agency decision regarding the registrability of the pesticide or regarding the proper terms and conditions of the registration of the pesticide.

(b) Notwithstanding (a) above, information need not be submitted to the Agency to the extent that it consists solely of opinion(s) or conclusion(s) expressed by persons *other than* any person:

(1) who was employed or retained (directly or indirectly) by the registrant to express an opinion or conclusion which relates in any way to the pesticide's properties, effects, risks or benefits; *or*

(2) from whom the registrant requested the opinion(s) or conclusion(s) in question; *or*

(3) who by virtue of his knowledge, skill, experience, training or education would be permitted to testify to the opinion(s) or conclusion(s) under Rule 702 of the Federal Rules of Evidence.[1]

(c) Notwithstanding (a) and (b) above, information need not be submitted to the Agency if it has previously been submitted to the Agency in writing or if it has been accurately tabulated or summarized in a previous written submission to the Agency.

DISCUSSION

I. THE STRUCTURE OF FIFRA AND THE ROLE OF SECTION 6(a)(2)

The Federal Insecticide, Fungicide, and Rodenticide Act, as amended in 1972 by the Federal Environmental Pesticide Control Act (hereafter referred to as "FIFRA"), completely restructured the Federal pesticide regulatory scheme and redefined its thrust. FIFRA was changed "from a labeling law into a comprehensive regulatory statute that will henceforth more carefully control the manufacture, distribution, and use of pesticides."[2] As the House Committee on Agriculture summarized in its Committee Report:

> The Committee found the greatest need for revision of existing laws to be in the areas of strengthening regulatory controls on the uses and users of pesticides, speeding up procedures for barring pesticides found to be undesirable; streamlining procedures for making valuable new control measures, procedures, and materials broadly available; strengthening enforcement procedures to protect against misuse of these biologically effective materials; and creating an administrative and legal framework under which continued research can produce more knowledge about better ways to use existing pesticides as well as developing alternative materials and methods of pest control.[3]

It is clear that Congress' primary purpose in enacting the 1972 amendments was to insure that pesticide use would be subject to a thorough environmental and human health hazard review.[4]

Under FIFRA, with certain exceptions no pesticide may be distributed, sold or otherwise placed in commerce unless it has been registered. FIFRA section 3(a), § 12(a)(1)(A). Extensive information on the risks and benefits of using the pesticide must be submitted to the Administrator before it can be registered, FIFRA section 3(c). A pesticide is eligible for registration only if the Administrator determines that it will perform its intended function without "unreasonable adverse effects on the environment," particularly "when used in accordance with widespread and commonly recognized practice," and that it is otherwise effective and properly labelled, FIFRA section 3(c)(5).

If it appears to the Administrator that a registered pesticide no longer meets the registration requirements, he may initiate proceedings to either cancel the registration or change its classification if he finds that the pesticide "generally causes unreasonable adverse effects on the environment," FIFRA section 6(b). The Administrator also may suspend the registration of a pesticide pending completion of cancellation proceedings, if he finds that an "imminent hazard" exists, FIFRA section 6(c)(1). An immminent hazard is defined as "a situation which exists when the continued use of a pesticide during the time required for cancellation proceeding would be likely to result in unreasonable adverse effects on the environment or will involve an unreasonable hazard to the survival of • • • [an endangered species]." FIFRA section 2(l). In some cases of emergency, the Administrator may even issue a suspension order which takes effect immediately, prior to a hearing, FIFRA section 6(c)(3).

In each instance where a determination is required for registration, cancellation or suspension, the controlling standard is the same, i.e., whether the pesticide causes or is likely to cause "unreasonable adverse effects on the environment." A pesticide which was originally registered on the basis that it would perform its intended function without unreasonable adverse effects

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[1] Rule 702 provides: If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

[2] House Committee on Agriculture, H. Rept. No. 92-511, 92d Cong., 1st sess. 4 (1971) (hereafter "House Report").

[3] House Report at 4.

[4] House Report at 13, 20, and Senate Committee on Agriculture and Forestry, S. Rept. No. 92-838, 92d Cong., 2d sess. 5 (1972) (hereafter "Senate Agriculture Report").

on the environment might subsequently be found to violate that standard if the registration was based on an incorrect evaluation of the information available at the time registration occurred or if new information raised questions about the continued registrability of the pesticide. The need for information relating to the risks and benefits of a pesticide after registration is, therefore, just as important for effective administration of FIFRA as the need for information to initially register a pesticide.

Accordingly, FIFRA provides the Administrator with a variety of tools to insure that he is kept current on information relating to the risks and benefits of registered pesticides. One of these is section 6(a)(2), which requires registrants to submit information after registration to the Administrator.[5] Since approximately 35,000 pesticide products are currently registered with EPA, it is not difficult to understand why Congress imposed such a duty to keep the Administrator informed on registrants. Section 6(a)(2) of FIFRA prescribes the registrant's responsibility as follows:

> Information—If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, he shall submit such information to the Administrator.

It is an accepted canon of statutory construction to interpret the language of a statute in a manner which is consistent with the overall goals of the statute. The U.S. Court of Appeals for the District of Columbia, in interpreting a statute administered by the Federal Trade Commission, expressed this principle as follows:

> In determining the legislative intent, our duty is to favor an interpretation which would render the statutory design effective in terms of the policies behind its enactment and to avoid an interpretation which would make such policies more difficult of fulfillment, particularly where * * * that interpretation is consistent with the plain language of the statute. See *Bird* v. *United States*, 187 U.S. 118, 124, 23 S. Ct. 42, 47 L. Ed. 100 (1902); *United States* v. *Blasius*, 2d Cir., 397 F. 2d 203, 207 n. 9 (1968), cert. dismissed, 393 U.S. 1008, 89 S. Ct. 615, 21 L. Ed. 2d 557 (1969). "[I]n the absence of an unmistakable directive," we cannot "construe the Act in a manner which runs counter to the broad goals which Congress intended it to effectuate." *FTC* v. *Fred Meyer, Inc.*, 390 U.S. 341, 349, 88 S. Ct. 904, 908 19 L. Ed 2d 1222 (1968). *National Petroleum Refiners Association* v. *FTC*, 482 F. 2d 672, 689 (D.C. Cir. 1973).

From the plain language of section 6(a)(2) we know that the submission requirement of that section applies to persons holding registrations; that it refers to information concerning the registered pesticides; that if refers to "additional" information, i.e., information which has not previously been submitted to the Agency; and that it refers only to information which the registrant itself possesses. From there the inquiry must focus on the meaning of the terms "regarding unreasonable adverse effects on the environment" and "factual information."

II. WHAT IS "INFORMATION REGARDING UNREASONABLE ADVERSE EFFECTS ON THE ENVIRONMENT"?

Some registrants have argued for a restrictive interpretation of the section 6(a)(2) disclosure requirement by advancing the notion that the section leaves to the registrant the determination whether an item of information *shows* that the pesticide *causes* "unreasonable adverse effects on the environment." However, this position overlooks not only the plain language of section 6(a)(2) and its legislative history but also the role of section 6(a)(2) in the FIFRA statutory scheme.

The language of § 6(a)(2) plainly states that the information to be submitted is factual information "regarding" unreasonable adverse effects on the environment. In other words, to be covered by the requirement, the information need only *pertain*[6] or *relate* to unreasonable adverse effects on the environment; it does not have to indicate, establish, or prove the existence of such effects.

The statutory scheme clearly requires the determination of whether effects are unreasonably adverse to be made by the Administrator, not by the individual registrant. The term "unreasonable adverse effects on the environment" is defined in § 2(bb) of FIFRA as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." In other words, it calls for the Administrator to balance the benefits of use of a pesticide against the risks of its use.[7] Plainly there is no finite scale for measuring where the balance should be struck. In interpreting the Administrator's authority to conduct a risk-benefit assessment under FIFRA, the U.S. Court of Appeals for the District of Columbia has emphasized repeatedly that "'FIFRA confers broad discretion' on the Administrator to find facts and 'to set policy in the public interest.' *Wellford* v. *Ruckelshaus*, 142 U.S. App. D.C. 88, 91, 439 F.2d 598, 601 (1971). See, also, *EDF* v. *EPA*, * * * 150 U.S. App. D.C. at 354, 465 F.2d at 534 (1972)." *Environmental Defense Fund* [hereafter "EDF"] v. *Environmental Protection Agency* [hereafter "EPA"], 510 F.2d 1292, 1297 (D.C. Cir. 1975; *EDF* v. *EPA*, 548 F.2d 998, 1005 (D.C. Cir. 1976); and see *EDF* v. *Ruckelshaus*, 439F. 2d 584 (D.C. Cir. 1971). This broad discretion is necessary in part because there is frequently great uncertainty concerning just what the risks and benefits are.[8] Even more important, however, is the fact that in balancing risks and benefits the Administrator is performing a task which is intrinsically policymaking in nature. In deciding, for example, whether a health risk should be borne by one group in order for another group to enjoy the benefits of a pesticide product, the Administrator is performing a public, official function which no private group is qualified to perform.[9]

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[5] The Administrator also has authority to require registrants to conduct studies relevant to assessing the risks and benefits of a pesticide, and to report the results thereof to the Agency. See 40 CFR 162.8(d)(1) and FIFRA section 6(b)(1). See also FIFRA section 20, which authorizes the Administrator to conduct research to carry out the purposes of the Act and to undertake monitoring.

[6] The legislative history is clear on this point. According to the Senate Committee on Commerce, "Paragraph (2) of subsection (a) requires a registrant to furnish information to the Administrator regarding unreasonable adverse effects on the environment after his pesticide is registered. While this provision allows the registrant to judge whether the information *pertains* to any unreasonable adverse effect, he will be subject to the penalties of section 14 should he possess such information and not make it available to the Administrator. Senate Committee on Commerce, S. Rept. No. 92-970, 92d Cong., 2d sess. 37 (1972) (hereafter "Senate Commerce Report")." A proposal by the National Agricultural Chemicals Association (NACA), which would have required the registrant to submit "factual information *indicating* that the registered pesticide *has* substantial adverse environmental or health effects," was adopted in one of the early House Committee prints but was later dropped in favor of the present "regarding" language. Committee Print No. 2, H.R. 4152 (June 22, 1971 (emphasis added). Had Congress adopted the NACA proposal, the restrictive interpretation of section 6(a)(2) advanced by some registrants would be more worthy of consideration.

[7] House Report at 14; and Senate Agriculture Report at 4.

[8] The Administrator must often rely on extrapolations from laboratory data, animal studies, and clinical studies in order to assess the risks, and he must rely on estimates of economic impact in order to assess the benefits. The risks and benefits (with their associated uncertainties) must then be balanced to arrive at a final decision.

[9] Various practical considerations also point out the fallacy of the idea that the individual registrant is to make a risk/benefit balancing decision in order to know whether an item of information the registrant possesses must be submitted under section 6(a)(2). For instance, if a registrant were required to submit information under section 6(a)(2) *only* if he had first concluded that the information showed that his pesticide caused unreasonable adverse effects on the environment, he would in effect be conceding that the pesticide should be cancelled, and there would be no need for further adversary proceedings of the type contemplated by section 6(b)-(d). Clearly the statute is not intended to function in this manner.

Moreover, pesticide regulatory decisions involve much more than whether or not a pesticide should be registered at all; the Administrator is required to make a number of decisions about the terms and conditions of registration which are not expressly stated in terms of "unreasonable adverse effects on the environment." Among these are decisions concerning the pesticide's labeling and packaging,[10] and decisions concerning whether additional restrictions beyond labeling should be imposed.[11] Decisions concerning these and other terms of registration must be made when the Administrator registers a pesticide product in the first instance. However, the Administrator has the option of changing some or all of these terms or conditions after registration, as remedies short of outright cancellation, in situations where he determines that without such changes, the pesticide would generally cause unreasonable adverse effects.[12]

It is in this context that the registrant must decide [13] whether to submit the information. If the information would be relevant to an *Agency* decision on the continued registrability of the pesticide or to the proper terms and conditions of the pesticide's registration, and the other requirements of section 6(a)(2) are satisfied, the registrant is required by section 6(a)(2) to submit the information to the Agency.[14] Naturally the registrant is under a duty to make such decisions about the relevance of the information in an objective manner and to be informed concerning the kinds of information upon which the Agency may wish to rely in making regulatory decisions.

A broad range of information normally would be relevant to the Administrator's decisions concerning the registrability of a pesticide product, including the terms and conditions of registration. As discussed above, the basic test of registrability under FIFRA is whether the pesticide causes "unreasonable adverse effects on the environment"—in other words, whether use of the pesticide poses risks which are greater than its benefits. Accordingly, any information on either risks or benefits relevant either to the terms and conditions of registration or to the question whether the pesticide should be registered at all is information "regarding unresonable adverse effects" which must be submitted if the other requirements of section 6(a)(2) are satisfied.

III. WHAT IS "FACTUAL INFORMATION"?

This term is not defined in the Act, and its meaning must therefore be derived from ordinary usage in light of the broad goals which Congress intended to effectuate by passage of the 1972 amendments.

Unfortunately, the legislative history does not contribute much to the analysis. An early version of what eventually became section 6(a)(2) required the registrant to submit "any information." [15] Thereafter, the National Agricultural Chemicals Association sponsored an amendment changing the wording to "factual information." [16] This change was eventually adopted by the House without explanation,[17] and the entire section underwent further revision in other respects before enactment. Thus, there is no recorded legislative history that explains what Congress intended by the term "factual information."

The legislative history also does not indicate whether these changes were made in conjunction with changes in the companion provisions governing the preregistration disclosure requirements imposed on the registration applicant. Although the terms "information" and "scientific information" appear elsewhere in the Act, there is no indication that Congress attached any particular significance to the word "factual" in section 6(a)(2). Section 3(c), which prescribes procedures for registration, authorizes the Administrator to specify the kinds of "information" required to support registration and to require that "additional information" be submitted. Within 30 days after registration the Administrator must make public the data called for in the registration statement together with such other "scientific information" he deems relevant to his decision. Congress never discussed the wording differences in the two provisions, so there is no indication that it intended any significant distinction between the type of information the two provisions require. On the contrary, there are sound reasons for reading sections 3(c) and 6(a)(2) together. Congress clearly intended that the Administrator's evaluation of a pesticide's effects on the environment be a continuing process. The language of section 6(a)(2) emphasizes this by requiring the registrant to submit information "additional" to that previously submitted under section 3(c).

Nor is the dictionary of much assistance. One dictionary defines *factual* as "of or containing facts" and *information* as "something told; news; intelligence; word" or "knowledge acquired in any manner; facts; data; learning; lore." [18] *Fact*, itself is defined as "a thing that has actually happened or that is really true" or "the state of things as they are; reality; actuality; truth [*fact* as distinct from *fancy*]." [19] However, in the present context, these approaches are too abstract to provide meaningful distinctions between the information that must be submitted under section 6(a)(2) and the information that need not be. For example, some of these definitions might be interpreted as suggesting the exclusion of expert opinion from the scope of section 6(a)(2). However, since such opinions form a large part, if not the preponderance, of the information upon which EPA routinely relies in making regulatory decisions under FIFRA, such an interpretation is utterly implausible and clearly not intended by Congress.

Accordingly, the appropriate interpretation is one based upon the function of section 6(a)(2) in the context of the FIFRA regulatory scheme. The proper focus is not the scope of the phrase "factual information" as an abstract concept, but the informational needs of EPA in regulating pesticides to protect the public health and the environment. As a result, the standard stated in this memorandum defines the scope of section 6(a)(2) in terms of information which, either by itself or in conjunction with other information, might, be relevant and probative in regulatory decisionmaking. Since EPA considers a wide range of information and FIFRA provides a wide variety of regulatory options, the standard set forth above excludes only the unsolicited opinions of persons who are not employed or retained by the registrant to express the opinion and whose opinions would not be admissible under the Federal Rules of Evidence as "expert" opinion. This approach is premised on the fact that if a registrant solicits an opinion it may be entitled to some weight with respect to a regulatory decision. If the registrant employs or retains the person giving the opinion to express such an opinion, the same logic applies. Finally, if a person's opinion would be admissible under the Federal Rules of Evidence, it may pro-

[10] See, e.g., FIFRA sections 2(q), 3(c)(5)(B), and 25(c)(3).

[11] See FIFRA sections 3(d) and 4.

[12] See, e.g., FIFRA sections 3(d) and 6(d).

[13] See footnote 6, supra.

[14] This does not require a registrant to anticipate future advances in scientific knowledge, however. The relevance of information is to be assessed by contemporary standards. Nonetheless, an advance in scientific knowledge may require the submission under section 6(a)(2) of older information which was not previously relevant. For example, see hypothetical number 5, infra.

[15] H.R. 4152, 92d Cong., 1st sess., section 5(a) (1971) and S. 745, 92d Cong., 1st sess., section 5(d) (1971).

[16] Hearings on H.R. 26, H.R. 1077, H.R. 1722, H.R. 45152, H.R. 5182, H.R. 6576, and H.R. 6761 before the House Committee on Agriculture, 92d Cong., 1st sess., March 9, 1971, at 342.

[17] House Report at 53; 1170 Cong. Rec. H10674-10680, H10726-10774 (Nov. 8-9, 1971).

[18] Webster's New World Dictionary (Complete Reference Edition (1972)).

[19] Id.

vide an appropriate basis for regulatory decision by the Agency.

This approach requires the submission of information which EPA may ultimately determine to be insufficient, when considered in light of all other information bearing on risks and benefits, to warrant regulatory action. In this connection, it has been argued that the registrant should be permitted to delay submission until it has verified the accuracy or reliability of the information. That argument ignores a fundamental aspect of the regulatory scheme: the assessment of the accuracy or reliability of information as a basis for regulatory action is to be made by the Administrator, not the registrant.

Moreover, in providing procedures for the suspension and cancellation of pesticide registrations, Congress recognized that protection of the health of the public and the environment cannot wait until evidence of unreasonable adverse effects becomes conclusive or universally accepted. By granting the Administrator authority to suspend pesticide registrants to prevent an "imminent hazard", Congress clearly anticipated that the Administrator would have to act swiftly (either before a hearing or after an expedited hearing) upon new information, even before the information could be definitively evaluated. The Act defines an imminent hazard as a situation that "would be *likely* to result in unreasonable adverse effects", FIFRA sections 2(l) and 6(c), and the courts have repeatedly recognized that "the function of the suspension decision is to make a preliminary assessment of evidence, and probabilities, not an ultimate resolution of difficult issues". *EDF* v. *EPA*, 510 F. 2d at 1298, quoting *EDF* v. *EPA*, 465 F. 2d 528, 537 (D.C. Cir. 1972).

Congress imposed on registrants the responsibility to submit to the Administrator information he may need to prevent imminent hazards. The Act would be subverted if registants were permitted to withhold information merely because they doubted its validity, or because the information had not yet been verified to their own satisfaction, or because the information was contained in a "preliminary", "interim" or "partial" report.

The same principles apply to determinations the Administrator must make regarding cancellation. The Act does not permit the Administrator to wait until conclusive proof on adverse effects has been developed. Rather, cancellation proceedings (or hearings to determine whether a pesticide registration should be cancelled or changed) must be initiated "[i]f *it appears* to the Administrator that a pesticide generally causes unreasonable adverse effects on the environment," FIFRA, section 6(b). (Emphasis added).[21] Even after the conclusion of the cancellation proceedings, the Administrator may act on evidence that is disputed. *EDF* v. *EPA*, 489 F. 2d 1247, 1252 (D.C. Cir. 1973). The Act's adversary hearing provisions recognize that the accuracy or validity of information submitted will frequently be subject to vigorous dispute by the registrant. The purpose of the adversary hearings is to ventilate and resolve such disputes. But the hearing process would be undermined if registrants could unilaterally withhold from the Administrator information that he could properly consider at a hearing, merely because the information could be subject to legitimate dispute.[22]

IV. EXAMPLES OF INFORMATION WHICH MUST BE, AND INFORMATION WHICH NEED NOT BE, REPORTED UNDER SECTION 6(a)(2)

The following examples illustrate the foregoing discussion (these are only examples, and by no means constitute a complete listing of the kinds of information which must be reported):

1. The registrant receives a report that a degradation product of his registered pesticide causes an adverse health effect. This information must be reported, since it clearly pertains to the effects of the registered pesticide. Similar information concerning any impurity or metabolite of the pesticide would also have to be reported.

2. The registrant receives a report that an aerial applicator, contrary to label directions, applied registrant's contact herbicide in a manner that allowed the pesticide to drift onto adjacent fields, causing harm to the nontarget vegetation. This information must be reported.

3. The registrant learns that a person intentionally drank a pesticide in a suicide attempt, and suffered severe liver damage as a result. The fact that the ingestion resulted from the person's desire to commit suicide need not be disclosed, since the registrant could reasonably conclude that the Agency will not make regulatory decisions about pesticides on the basis of attempting to prevent persons from using pesticides to commit suicide. However, the information concerning the toxicological effects of the pesticide on the person must be reported, because information on a pesticide's toxicity to humans is relevant to regulatory decisionmaking. Such information can be utilized, for example, to verify the estimates of potential human toxicity derived from animal studies which supported the decision to register the pesticide. Moreover, the information could permit follow-up contacts with a treating physician who could provide information on the feasibility of treatment options.

4. It is well known that chemical X induces tumors in laboratory animals when the registrant becomes aware of new evidence which indicates, for the first time, that X may be a degradation product of pesticide A, for which he holds a registration. The registrant is not in violation of section 6(a)(2) for previously failing to submit the information regarding X with respect to this registration of A. However, once the relevance of that information is discovered, section 6(a)(2) requires the submission of all information regarding chemical X, including the information which indicates that it may be a degradation product of A.

5. The registrant receives an unsolicited report claiming that a man died of cancer as a result of being exposed to a pesticide three days earlier. The report was made by a relative with no pertinent scientific expertise. This incident does not have to be reported, the causal relationship between the exposure to the pesticide and the cancer death is the opinion of a person: (1) who is not retained or employed by the registrant; (2) from whom the registrant did not request the opinion; and (3) who lacks the knowledge, skill, experience, training and education which would entitle his opinion to be admissible under the Federal Rules of Evidence.

6. Two registrants jointly sponsor a study and each receives a copy of the final report; both recognize that the study is subject to the reporting requirement of section 6(a)(2). One registrant submits the final report to the appropriate official at EPA and sends a copy of the cover letter, which adequately identifies the study and report, to the second registrant. The second registrant need not submit the report, since it has been previously submitted; it is not "additional" information.

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[21] One of the most fundamental and well settled concepts in the FIFRA regulatory scheme is that the burden of proof of registrability always rests with the registrant, and not with the Agency. See, e.g., *EDF* v. *EPA*, 510 F. 2d at 1297.

[22] One reason some registrants may be reluctant to submit information under section 6(a)(2) is concern that the Agency may misinterpret it, or that actions may be taken by the Agency based on it, despite the fact the information has not yet been verified. A related concern is that the information may be disclosed under the Freedom of Information Act to the public, and that unwarranted conclusions about risks might be drawn by the public. It should be noted that any registrant with such concerns may submit, with the information, a statement describing his reservations concerning the information's validity or significance. The Administrator would take that statement into account in assessing the information. The statement of reservations would also be available for public disclosure.

V. INFORMATION THE AGENCY DETERMINES REGISTRANTS NEED NOT SUBMIT

The agency might conclude that although information of a certain kind is subject to the section 6(a)(2) reporting requirement (as interpreted by this memorandum), registrant reporting of that kind of information is not essential to the Agency's functions. (The Agency might, for instance, conclude that information of a certain kind available from sources other than registrants is sufficient for Agency decision-making, and thus that information of that kind which registrants may also possess is not needed by the Agency.) In such a case, it would be appropriate for the Agency to announce publicly (by FEDERAL REGISTER notice or otherwise) that it will not consider a registrant's failure to submit that kind of information to be an actionable violation of section 6(a)(2).

Of course, it is for the Agency, not the registrant, to decide that alternative information sources are adequate for the Agency's needs. Until the Agency announces that it will not seek to enforce its section 6(a)(2) right to obtain a particular kind of information, that information must be reported by registrants.

[FR Doc. 78-23553 Filed 8-22-78; 8:45 am]

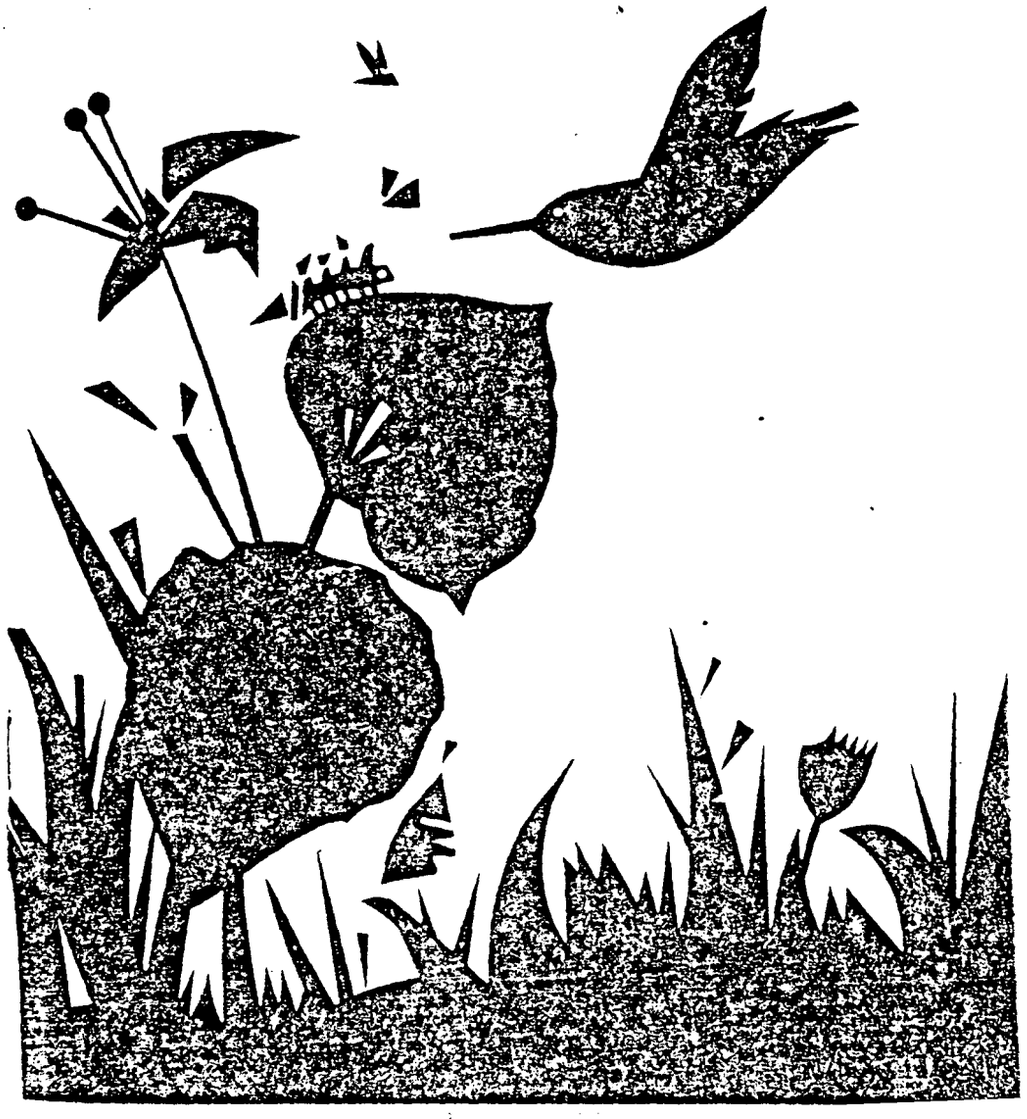
United States
Environmental Protection
Agency

Office of
Public Awareness (A-107)
Washington DC 20460

Second Revision October 1979 OPA 159/9

EPA

Suspended and Cancelled Pesticides



Suspension and Cancellation List

Prepared by
Pesticides and
Toxic Substances
Enforcement
Division

This booklet has been compiled for the purpose of summarizing and clarifying Agency actions on those pesticides which have been suspended, cancelled, or otherwise restricted. It excludes cancellations on those use patterns that were cancelled by Pesticide Registration Notices based on "residues," "no residues," and zero tolerances," as well as notices of cancellations to single registrants. Pesticides which have been voluntarily cancelled by some but not all registrants, and have not met or exceeded "risk criteria" established by the Special Pesticide Review Division are also excluded.

This list is not a statement of Agency policy, but is primarily designed as a quick reference guide to be used by Regional EPA inspectors. However, the list can also serve as a general reference for anyone involved or interested in pesticide regulatory work.

Material for this edition of the booklet was compiled as of October 1979. This is the third edition of this publication. Future Agency actions will necessitate updating and republishing this booklet, and this will continue to be done periodically.

Comments on the accuracy and completeness of this list should be sent to:

Pesticides and Toxic Substances
Enforcement Division (EN-342)
Environmental Protection Agency
Washington, D.C. 20460

Pesticide/Use Affected	Action	Reference
Aldrin	Cancelled, all uses *except* those in the following list: 1. subsurface ground insertion for termite control. 2. dipping of non-food roots and tops. 3. moth-proofing by manufacturing processes in a closed system.	PR Notice 71-4 *March 18, 1971;* Accelerated Decision of the Chief Administrative Law Judge *May 27, 1975 and* the order Declining Review of the Accelerated Decision of the Administrative Law Judge issued by the Chief Judicial Officer *June 30, 1975;* 39 FR 37246 *October 18, 1974.*
Arsenic Trioxide	In excess of 1.5%, labeling which bears directions for home use is unacceptable, and a warning against home use is required. The following statements must appear in a prominent position: *"Do not use or store in or around the home" and "Do not allow domestic animals to graze treated area."*	PR Notice 67-2 *August 1, 1967;* Interpretation No. 25 *August 1968*
Basic Copper Arsenate	Voluntary cancellation, all products. The sale, distribution and use of existing stocks is permited.	42 FR 18422 *April 7, 1977*
BHC	All registered products have been eliminated. In some instances these products were voluntarily cancelled, in others lindane was substituted for BHC non-gamma isomers. These non-gamma isomers may be sold, manufactured or distributed for use in the United States.	43 FR 31432 July 21, 1978
Bithionol	Cancelled, products intended for: 1. direct contact with the skin or can be expected to be in direct or continuous contact with the skin. 2. use in textiles or other materials likely to come in contact with the skin. 3. household use.	PR Notice 68-13 *August 14, 1968*
Chloranil	Voluntary cancellation, all products.	42 FR 3702 *January 19, 1977*
Chlordane	Under the provisions of the Administrator's acceptance of the settlement plan to phase out certain uses of the pestcides chlordane and heptachlor, most registered products containing chlordane will be effectively cancelled or their applications for registration denied by December 31, 1980. A summary of those uses not affected by this settlement, or a previous suspension, as well as a summary of those uses affected (Phase Out Uses) by this settlement, including the pest to the controlled,	PR Notice 74-11 *December 2, 1974* 41 FR 7552 *February 19, 1976* FIFRA Docket No. 336, et. al. *March 6, 1978* PR Notice 78-2 March 28, 1978

Pesticide/Use Affected	Action	Reference
Chlordane *(continued)*	the site of application, the end-use dates and use restrictions, follows: 1. Uses not affected: a. subsurface ground insertion for termite control (clarified by 40 FR 30522, July 21, 1975, 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). b. dipping of roots or tops of nonfood plants. 2. Uses affected (Phase Out Uses): a. Registrations for control of ants on citrus in the States of California and Texas will be effectively cancelled or denied by December 31, 1979. Restricted to use on acreage under an Integrated Pest Management program involving the release of beneficial insects (parasites and predators) to maintain populations of harmful insects (scales, mites, mealybugs) at an acceptable level. In California, this use is permitted only pursuant to the provisions of the appropriate State of California permit and prescription use programs. b. Registrations for control of imported fire ants on lands not presently used or to be used for food or feed production or grazing for a period of two years following treatment are effectively cancelled or denied by December 31, 1980. Distribution and use is restricted to nine states (AL, AR, FL, GA, LA, MS, NC, SC and TX). Use shall be restricted to mound treatment; broadcast or aerial application is prohibited. c. Registrations for control of cutworms on grapes in the State of California will be effectively cancelled or denied by July 1, 1980. This use shall be restricted to application by ground equipment only. Use shall be permitted only pursuant to the provisions of the appropriate State of California permit and prescription use programs. d. Registrations for control of grasshoppers on flax were effectively cancelled or denied by October 1, 1978. e. Registrations for control of white grubs, strawberry rootworm, strawberry root weevil or crown girdler, strawberry crown borer and black vine weevil on strawberries were effectively cancelled or denied by August 1, 1979. This use was permitted in California only pursuant to the provisions of the appropriate State of California permit and prescription use programs.	

Chlordane *(continued)*	f. Registrations for control of imported fire ants and Japanese beetle larvae on nursery stock, for compliance with Federal or State Quarantines, *and* for control of the black vine weevil on nursery stock for compliance with State Nursery Certification Regulations will be effectively cancelled or denied by December 31, 1979. Restricted to use on land with nursery stock grown for balled and burlapped, bare root or container stock. Use on turf is prohibited. ☐ Note: *Phase Out Uses listed above may be applied by certified applicators only. The end-use dates for Phase Out Uses should be those dates listed above, unless the production limitations imposed by FIFRA Docket No. 326 et. al. is exceeded earlier. Pesticide products in existence 90 days before the effective date of cancellation or denial of a Phase Out Use may: (1.) be distributed, sold or otherwise moved in commerce, and used; provided that the pesticide shall not be used inconsistent with its labeling, and (2.) may be relabeled by or under the authority of a registrant for another Phase Out Use not already cancelled or denied, and any pesticide product so produced shall not count against the production limitation for the other Phase Out Use.*	
Chlorobenzilate	Cancellation and denial of registrations of chlorobenzilate products for uses other than citrus uses in Florida, Texas, California, and Arizona. Notwithstanding the above, registration of chlorobenzilate products for citrus use in these four states will also be cancelled or denied unless registrants or applicants for new registrations modify the terms or conditions of registration as follows: 1. Classification of chlorobenzilate products for these citrus uses for restricted use, for use only by or under the supervision of certified applicators. 2. Modification of the labeling of chlorobenzilate products for these citrus uses to include the following: a. *Restricted Use Pesticide* — For retail sale to and use only by certified applicators or persons under their direct supervision and only for those uses covered by the certified applicator's certification. b. *General Precautions* — 1.) Take special care to avoid getting chlorobenzilate in eyes, on skin, or on clothing. 2.) Avoid breathing vapors or spray mist.	44 FR 9548 February 13, 1979

Pesticide/Use Affected	Action	
Chlorobenzilate *(continued)*	3.) In case of contact with skin, wash as soon as possible with soap and plenty of water. 4.) If chlorobenzilate gets on clothing, remove contaminated clothing and wash affected parts of body with soap and water. If the extent of contamination is unknown, bathe entire body thoroughly. Change to clean clothing. 5.) Wash hands with soap and water each time before eating, drinking, or smoking. 6.) At the end of the work day, bathe entire body with soap and plenty of water. 7.) Wear clean clothes each day and launder before reusing. c. *Required Clothing and Equipment for Application* — 1.) One-piece overalls which have long sleeves and long pants constructed of finely-woven fabric as specified in the USDA/EPA *Guide for Commercial Applicators.* 2.) Wide-brimmed hat. 3.) Heavy-duty fabric work gloves. 4.) Any article which has been worn while applying chlorobenzilate must be cleaned before reusing. Clothing which has been drenched or has otherwise absorbed concentrated pesticide must be buried or burned. 5.) Facepiece respirator of the type approved for pesticide spray applications by the National Institute for Occupational Safety and Health. 6.) Instead of the clothing and equipment specified above, the applicator can use an enclosed tractor cab which provides a filtered air supply. Aerial application may be conducted without the specified clothing and equipment. d. *Handling Precautions* — Heavy duty rubber or neoprene gloves and apron must be worn during loading, unloading, and equipment clean-up.	
DBCP	Suspended, all registrations of end use products, *except* for the use on pineapples in Hawaii. The sale, distribution or movement in commerce for all suspended uses is prohibited.	FIFRA Docket Nos 398, 399 and 400, October 27, 1977; 42 FR 57543, November 3, 1977 FIFRA Docket No. October 29, 1979.
DDD (TDE)	Cancelled, all products containing DDD, a metabolite of DDT.	PR Notice 71-5 *March 18, 1971*

DDT	Cancelled, all products, *except* the following list of uses: 1. the U.S. Public Health Service and other Health Service Officials for control of vector diseases. 2. the USDA or military for health quarantine. 3. in drugs, for controlling body lice. (To be dispensed only by a physician.) 4. in the formulation for prescription drugs for controlling body lice.	PR Notice 71-1 *January 15, 1971* and 37 FR 13369 *July 7, 1972*
2,4-D	Products bearing directions for use on small grains (barley, oats, rye, or wheat) must bear the following label precaution: *Do not forage or graze treated grain fields within 2 weeks after treatment with 2,4-D.*	PR Notice 67-7 *October 12, 1967* Reregistration Guidance package 23-4
Dieldrin	Most uses cancelled. See Aldrin for uses allowed.	PR Notice 71-4 *March 18, 1971;* Accelerated Decision of the Chief Administrative Law Judge *May 27, 1975 and* the order Declining Review of the Accelerated Decision of the Administrative Law Judge issued by the Chief Judicial Officer *June 30, 1975* 37 FR 37246 *October 18, 1974.*
Disinfectants	Cancelled, products bearing labeling claims involving the terms "germ proofing," "germ proofs," and "germ proof."	PR Notice 69-13 *August 8, 1969*
Endrin	1. Cancellation of uses on: a. Tobacco. b. Cotton in all areas east of Interstate Highway #35 (includes all states east of the Mississippi River, Arkansas, Louisiana, Missouri, and portions of Texas and Oklahoma). c. Small grains to control all pests other than the army cutworm, the pale western cutworm, and grasshoppers. d. Apple orchards in Eastern States to control meadow voles. e. Sugarcane to control the sugarcane borer. f. Ornamentals. 2. Denial of application for new registrations for the above uses (1. b.-e.), as well as for the use of endrin in unenclosed bird perch treatment.	Unnumbered PR Notice May 20, 1964 44 FR 43632 July 25, 1979

Endrin *(continued)*	3. Cancellation of the following registrations of endrin products *unless* registrants modify the terms and conditions of registration as specified below: a. Use on cotton west of Interstate Highway #35 (must modify label to add statements 5. a., b., c., d., e., f., and g.). b. Use on small grains to control army cutworms and pale western cutworms (must modify label to add statements 5. b., c., d., e., f., and h.). c. Use on apple orchards in Eastern States to control the pine vole and in Western States to control meadow voles (must modify label to add statements 5. q., c., i., r., j., k., and l.). d. Use on sugarcane to control the sugarcane beetle (must modify label to add statements 5. q., c., m., and n.). e. Use for conifer seed treatment (must modify label to add statement 5. o.). f. Use in enclosed bird perch treatments (must modify label to add statements 5. t., c., and p.). 4. Denial of applications for new registrations for any of the above endrin uses (3. a.-f.), as well as for the following endrin uses *unless* the applications are modified to meet the terms and conditions specified herein. a. As a tree painting (in Texas) — must modify label to add statements 5. s. and c. b. On alfalfa and clover seed crops (in Colorado) — must modify label to add statements 5. b., c., d., e., and f. c. On small grains to control grasshopper (in Montana) — must modify label to add statements 5. b., c., d., e., f., and h. 5. Label Statements: a. For use in areas west of Interstate Highway #35 only. b. *Required Clothing for Female Workers* — Female ground applicators, mixers and loaders and flagpersons must wear long-sleeved shirts and long pants made of a closely woven fabric, and wide-brimmed hats. Mixers and loaders must also wear rubber or synthetic rubber boots and aprons. c. *Warning to Female Workers* — The United States Environmental Protection Agency has determined that endrin causes birth defects in laboratory animals. Exposure to endrin during pregnancy should be avoided. Female workers

esticide/Use Affected	Action	Reference
ndrin *continued)*	must be sure to wear all protective clothing and use all protective equipment specified on this label. In case of accidental spills or other unusual exposure, cease work immediately and follow directions for contact with endrin. d. *Equipment* — 1.) Ground Application — For use with boom-nozzle ground equipment. Apply at not less than 5 gallons total mixture, water and chemical, per acre. Do not use nozzle liquid pressure at greater than 40 psi (pounds per square inch). Do not use cone nozzle size smaller than 0.16 gallons per minute (gpm), at 40 psi such as type D2-25 or TX-10, or any other atomizer or nozzle giving smaller drop size. 2.) Aerial Application — Do not apply at less than 2 gallons total mixture of water and chemical per acre. Do not operate nozzle liquid pressure over 40 psi or with any fan nozzle smaller than 0.4 gpm or fan angle greater than 65 degrees such as type 6504. Do not use any cone type nozzles smaller than 0.4 gpm nor whirl plate smaller than #46 such as type D4-46 or any other atomizer or nozzle giving smaller drop size. Do not release this material at greater than 10 feet height above the crop. e. *Application Restrictions* — Do not apply this product within 1/8 mile of human habitation. Do not apply this product by air within 1/4 mile or by ground within 1/8 mile of lakes, ponds, or streams. Application may be made at distances closer to ponds owned by the user but such application may result in excessive contamination and fish kills. Do not apply when rainfall is imminent. Apply only when wind velocity is between 2 and 10 mph. f. *Procedures To Be Followed if Fish Kills Occur or if Ponds are Contaminated* — In case of fish kills, fish must be collected and disposed of by burial. Ponds in which fish kills have occurred, and user-owned ponds exposed to endrin by application at distances closer than otherwise prohibited, must be posted with signs stating: "Contaminated: No Fishing." Signs must remain for one year after a fish kill has occurred or for six months after lesser contamination unless laboratory analysis shows endrin residues in the edible portion of fish to be less than 0.3 parts per million (ppm).	

Pesticide/Use Affected	Action	Reference
Endrin *(continued)*	g. *Prophylactic Use* — Unnecessary use of this product can lead to resistance in pest populations and subsequent lack of efficacy. h. *Pests for Which This Product May be Applied* — This product may be applied to control the following pests only: army cutworm; pale western cutworm; grasshoppers. (Currently grasshoppers may only be included on endrin products for use in Montana.) i. *Application Restrictions* — Do not apply this product within 50 feet of lakes, ponds or streams. Do not apply this product within 50 feet of areas occupied by unprotected humans. Do not apply when rainfall is imminent. j. *Equipment* — Apply by ground equipment only. Use a very coarse spray with minimum pressure necessary to penetrate ground cover. Do not apply as fine spray. Power air blast equipment must be modified to meet the above application restriction. Consult the State recommendations for acceptable methods of adapting equipment. k. *Prophylactic Use* — Unnecessary use of this product can lead to resistance in the vole population and subsequent lack of efficacy. l. *Pests for Which This Product May be Applied* — This product may be applied to control the following pests only: Eastern United States — Pine Vole (*Microtus pinetorum*) Western United States — Meadow Voles (*Microtus* species) m. *Application Restrictions* — Apply only with low-pressure ground equipment. Cover furrows with soil promptly after application. n. *Pests for Which This Product May Be Applied* — This product may be applied only to control the sugarcane beetle. o. *Application Restrictions* — Do not sow treated seed when large numbers of migratory birds are expected. p. *Special Warning* — Do not use within one mile of roosting sites or within two miles of nesting sites of peregrine falcons, as identified by the United States Fish and Wildlife Service.	

Pesticide/Use Affected	Action	Reference
Endrin *(continued)*	q. *Required Clothing for Female Workers* — Female applicators, mixers and loaders must wear long-sleeved shirts and long pants made of a closely woven fabric, and wide-brimmed hats. Mixers and loaders must also wear rubber or synthetic rubber boots and aprons. r. *Procedures To Be Followed if Fish Kills Occur* — In case of fish kills, fish must be collected promptly and disposed of by burial. Ponds in which fish kills have occurred must be posted "Contaminated: No Fishing." Signs must remain for one year after a fish kill has occurred unless laboratory analysis shows endrin residues in the edible portion of fish to be less than 0.3 ppm. s. *Required Clothing for Female Workers* — Female workers handling or applying this product must wear long-sleeved shirts and long pants made of a closely woven fabric, wide-brimmed hat, and rubber or synthetic rubber boots and aprons. t. *Required Clothing for Female Workers* — Female workers handling this product must wear long-sleeved shirts and long pants made of a closely woven fabric, wide-brimmed hats, and rubber or synthetic rubber aprons.	
Fluoroacetamide	Labeling amended to allow use *only* inside of sewers against the Norway and roof rat. This use is restricted and may be applied only by a certified applicator or a competent person acting under the instructions and control of a certified applicator.	Label amendment accepted by OPP November 2, 1979
Heptachlor	Under the provisions of the Administrator's acceptance of the settlement plan to phase out certain uses of the pesticides heptachlor and chlordane, most registered products containing heptachlor will be effectively cancelled, or their application for registration denied by July 1, 1983. A summary of those uses not affected by this settlement or a previous suspension, as well as a summary of those uses affected (Phase Out Uses) by the settlement, including the pest to be controlled, the site of application, the use restrictions, and end-use dates, follows: 1. Uses not affected: see chlordane 2. Uses affected (Phase Out Uses): a. Registrations for control of cutworms on field corn will be effectively cancelled or denied	PR Notice 74-11 *December 2, 1974* 41 FR 7552 *February 19, 1976* FIFRA Docket No. 336, et. al. *March 6, 1978* PR Notice 78-2 March 28, 1978

Pesticide/Use Affected	Action	References
Heptachlor *(continued)*	by August 1, 1980 in States with EPA approved restricted-use permit programs and *immediately* in all other States *unless* and until those States obtain and maintain EPA approved restricted use permit programs. Use shall be by *certified applicators* only, and shall be applied only by soil broadcast or soil incorporation. The following crops shall not be grown in a field treated with heptachlor in the year of treatment or the following year: legumes (including soybeans, alfalfa, clover, peas, peanuts and other beans); root crops (including potatoes, sugar beets and rutabagas); oil crops (including cotton and safflower); vegetable crops; tobacco or pumpkins. Silage shall not be cut from a field treated with heptachlor in the year of treatment or the following year. Corn which has been treated with heptachlor shall not be followed with any other dairy or meat animal forage crop nor shall livestock be permitted to have access to treated land for a period of two years following treatment. b. Registrations for control of seed corn beetle, seed corn maggot, wireworm, false wireworm, southern corn rootworm and kafir ant on: (1.) barley, oats, wheat, rye and corn will be effectively cancelled or denied by September 1, 1982; and (2.) sorghum will be effectively cancelled or denied on July 1, 1983. May be used by commercial seed treatment companies only. c. Registrations for control of citrus root weevil larvae and Feller's rose beetle larvae on citrus in the State of Florida will be effectively cancelled or denied by December 31, 1979. Use shall be by *certified applicators* only, and may be applied by soil incorporation only. d. Registrations for control of ants on pineapples in the State of Hawaii will be effectively cancelled or denied by December 31, 1982. To be applied by *certified applicators* only. e. Registrations for control of narcissus bulb fly on narcissus bulbs will be effectively cancelled or denied by December 31, 1980. Use shall be by *certified applicators* only. The following protective procedures will be required for persons engaged in treating narcissus with heptachlor: 1.) wear heavy natural rubber gloves and clean water proof protective clothes and goggles. 2.) bathe immediately after work and change all clothing, wash clothing thoroughly with soap and warm water before reuse. 3.) in case of contact, immediately remove	

Heptachlor *(continued)*	contaminated clothes and wash thoroughly with soap and warm water. 4.) wear a pesticide respirator jointly approved by the Mining Enforcement and Safety Administration and by the National Institute of Occupational Safety and Health under provisions of 30 CFR Part II. ☐ Note: *The end-use dates for Phase Out Uses should be those dates listed above, unless the production limitations imposed by FIFRA Docket No. 326 et. al. is earlier exceeded. Pesticide products in existence 90 days before the effective date of cancellation or denial of a Phase Out Use may: (1.) be distributed, sold or otherwise moved in commerce, and used; provided that the pesticide shall not be used inconsistent with its labeling, and (2.) may be relabeled by or under the authority of a registrant for another Phase Out Use not already cancelled or denied, and any pesticide product so produced shall not count against the production limitation for the other Phase Out Use.*	
Kepone	All registered products containing Kepone were effectively cancelled by May 1, 1978. A summary of Kepone products, their registration numbers, effective cancellation dates, and disposition of uses of existing stocks follows: 1. Inaccessible Products a. Antrol Ant Trap, Reg. No. 475-11; Black Flag Ant Trap, Reg. No. 475-82; Grant's Ant Trap, Reg. No. 1663-21; Grant's Roach Trap, Reg. No. 1663-22; Grant's Ant Control, Reg. No. 1663-24; and Dead Shot Ant Killer, Reg, No. 274-23 were cancelled as of May 11, 1977. Distribution, sale, and use of existing stocks formulated prior to May 11, 1977, was permitted until such stocks were exhausted. b. Black Leaf Ant Trap, Reg. No. 5887-63; Hide Roach and Ant Trap, Reg. No. 3325-4; Lilly's Ant Trap With Kepone, Reg. No. 460-17; T.N.T. Roach and Ant Killer, Reg. No. 2095-2; Johnston's No-Roach Traps, Reg. No. 2019-19; Mysterious Ant Trap With Kepone, Reg. No. 395-19; Magikil Ant Trap With Kepone, Reg. No. 395-21; Magikil Roach Trap With Kepone, Reg. No. 395-25; Ant-Not Ant Trap, Reg. No. 358-20; Nott Roach Trapp, Reg. No. 358-129; E-Z Ant Trap Contains Kepone, Reg. No. 506-109; Tat Ant Trap, Reg. No. 506-126; and Ant Check Ant Trap, Reg. No. 506-129 were effectively cancelled on May 1, 1978. Kepone already in the formulation process may be formulated into inaccessible products between now and May 1, 1978. Distribution, sale and use	41 FR 24624 *June 17, 1976;* 42 FR 18885 *April 11, 1977* 42 FR 38205 *July 27, 1977;* FIFRA Dockets Nos. 392 et. al. October 27, 1977; and the affirmation of FIFRA Dockets Nos. 392 et al. by the Judicial Officer *December 13, 1977*

Pesticide/Use Affected	Action	Reference
Kepone *(continued)*	of kepone products formulated prior to May 1, 1978 was permitted until such stocks were exhausted. 2. Accessible Products: all of these products were cancelled as of December 13, 1977. Distribution, sale, and use of these products is now unlawful. ☐Note: *the following definitions are included in order to distinguish between the two categories of Kepone products.* 1. Inaccessible products: includes those enclosed Kepone traps made from metal or plastic as well as metal stakes containing enclosed Kepone bait which are hammered into the ground. 2. Accessible products: includes those which, in normal use, would be removed from their containers, as well as foil or cardboard covered traps.	
Lindane	Cancelled, for use in vaporizers.	PR Notice 69-9 *April 28, 1969* IF and R Docket 19 *December 2, 197*
Mercury	Cancelled, all uses *except* the following: 1. as a fungicide in the treatment of textiles and fabrics intended for continuous outdoor use. 2. as a fungicide to control brown mold on freshly sawn lumber. 3. as a fungicide treatment to control Dutch elm disease. 4. as an in-can preservative in water-based paints and coatings. 5. as a fungicide in water-based paints and coatings used for exterior application. 6. as a fungicide to control "winter turf diseases" such as *Sclerotinia borealis,* and gray and pink snow mold subject to the following— a. the use of these products shall be prohibited within 25 feet of any water body where fish are taken for human consumption. b. these products can be applied only by or under the direct supervision of golf course superintendents. c. the products will be classified as restricted use pesticides when they are reregistered and classified in accordance with section 4(c) of FEPCA. ☐ Note: *For purposes of the settlement agreements, "winter diseases" refer to the forms of snow mold which can attack and damage the fine turf of greens, tees, and aprons.*	PR Notice 72-5 *March 22, 1972* FIFRA Docket Nc et al. *December 22, 19* 41 FR 16497 *April 19, 1976* 41 FR 26742 *June 29, 1976* 41 FR 36068 *August 26, 1976*

Pesticide/Use Affected	Action	Reference
Metaldehyde	Labeling for metaldehyde snail and slug baits must have the following statement on the front panel of the product label: *This pesticide may be fatal to children and dogs or other pets if eaten. Keep children and pets out of treated area.*	PR Notice 74-7 *July 1, 1974*
Mirex	All registered products containing Mirex were effectively *cancelled* on December 1, 1977. (A technical Mirex product made by Hooker Chemical Company is unaffected by this Settlement Agreement. However, since Mirex produced under this registration may be used only in the formulation of other pesticide products, the registration was useless after December 1, 1977). All existing stocks of Mirex within the continental U.S. was not to be sold, distributed, or used after June 30, 1978. Harvester Bait 300, Reg. No. 38962-5, may only be used for the control of the pheidole ant, Argentine ant, and fire ant on pineapples in Hawaii. The effective date of *cancellation* for these uses was December 1, 1977; existing stocks as of December 1, 1977 may not be applied aerially after December 31, 1977, but may be sold and used (other than aerially) indefinitely. The application of Harvester Bait 300 is subject to the following restrictions: 1. Aerial Application: No longer permitted. 2. Ground Application a. Permissible in all areas of infestation provided that there is no ground application to aquatic and heavily forested areas or areas where run-off or flooding will contaminate such areas. b. Treatment shall be confined to areas where the imported fire ants are causing significant problems. ❑ Note: *the following definition is included in order to clarify the ground application restrictions:* Aquatic areas: encompasses without limitation estuaries, rivers, streams, wetlands (those land and water areas subject to inundation by tidal, riverine, or lacustrine flowage), lakes, ponds, and other bodies of water.	FIFRA Docket No. 293 *October 20, 1976* 41 FR 56694 *December 29, 1976*
OMPA	Voluntary cancellation, all products.	41 FR 21859 *May 28, 1976*
10, 10'-Oxybisphenoxarsine	Product labels amended to eliminate use in windbreakers and baby pants.	Special Pesticide Review Division's Position Document on 10, 10'-Oxybisphenoxarsine Approved April 20, 1978

Pesticide/Use Affected	Action	Reference
Parathion (Ethyl)	1. Registration of ethyl parathion limited to those packed in one gallon containers or larger. 2. Manufacturers and formulators of registered ethyl parathion should be in compliance with the standardized safety label that was enclosed with PR 71-2.	PR Notice 71-2 *April 5, 1971*
PCB'S	Elimination (all use as active or inactive ingredients).	PR Notice 70-25 *October 29, 1970*
Phenarzine Chloride	Voluntary cancellation, all uses.	42 FR 59976 *November 21, 197*
Polychlorinated Terphenyls	Elimination (all use as active or inactive ingredients).	PR Notice 70-25 *October 29, 1970*
Predacides	All agency heads are to prevent the use of chemical toxicants in any *Federal* mammal/bird damage control program or on any *Federal lands* where the field use of such toxicant is being employed to kill a *predatory* mammal or bird, or where the field use of such toxicants causes any secondary poisoning effects on mammals, birds, or reptiles. However, chemical toxicants can be used on an emergency basis when no other method is available and the use of the toxicants is essential to protect human health and safety, to preserve a wildlife species threatened with extinction, or to prevent substantial irretrievable damage to nationally significant natural resources. Notwithstanding these provisions, agency heads may authorize the use of *sodium cyanide in Federal* programs or on *Federal* lands subject to the 26 restrictions cited in this booklet.	Executive Order 37 FR 2876 *February 9, 1972.* Executive Order 40 FR 30611 *July 22, 1975;* Executive Order 41 FR 22239 *June 2, 1976*
Quaternary Ammonium Compounds	Cancelled, for use as a sanitizer in poultry drinking water.	PR Notice 73-5 *August 29, 197*
Safrole	Voluntary cancellation, all uses. The distribution, sale, and use of existing stocks of Surf-Kote Pet Repellent, Reg. No. 1811-8, and Scram Dog Repellent Spray, Reg. No. 239-2057, are permitted only by persons other than the registrants.	42 FR 11039 *February 25, 1:* 42 FR 16844 *March 30, 197* 42 FR 29957 *June 10, 1977*
Seed Treatments	Cancelled, all registrations of these products not containing a dye or discoloring agent which will impart an unnatural color to the seed. Exceptions to this are products bearing directions for use solely as planter box treatments.	PR Notice 70- *June 26, 1970* PR Notice 70- *October 28, 1.*

		References
Silvex	Chlorodioxin contaminants not allowed. Suspended, all pesticide products containing silvex for forestry uses, rights-of-way uses, pasture uses, home and garden uses, commercial/ornamental turf uses, and aquatic weed control/ditch bank uses. ☐ Note: *The only allowable uses for silvex are on rice, rangeland, sugarcane (field and stubble), preharvest fruit drop of apples, prunes, and pears, and non-crop uses.* Non-crop uses *of silvex include use on or around non-crop sites, including fencerows, hedgerows, fences (not otherwise included in suspended uses, e.g., rights-of-way, pasture); industrial sites or buildings (not otherwise included in suspended uses, e.g., rights-of-way, commercial/ornamental turf); storage areas, waste areas, vacent lots, and parking areas. The following definitions are included in order to help clarify the suspension orders for 2,4,5-T and silvex —* Range *is non-pasture grazing land on which forage is produced through native species, or on which introduced species are managed as native species. This precludes land on which regular cultural practices of the nature contained in the pasture definition are followed.* Pasture *is 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. Fence rows enclosing pastures are include as part of the pasture.*	PR Notice 70-22 *September 28, 1970* 44 FR 15917 March 15, 1979 44 FR 41536 July 17, 1979
Sodium Arsenite	Unacceptable for home use if compound is in excess of 2.0%, and the following warning statements must appear on the label: *"Do not use or store in or around the home" and "Do not allow domestic animals to graze treated area."*	PR Notice 67-2 *August 1, 1967* Interpretation No. 25 *August 1968*
Sodium Cyanide	Cancelled and suspended, all uses for mammalian predator control *except;* the registration of sodium cyanide capsules for use in the M-44 device is allowed for the purpose of controlling certain wild canid predators subject to the following 26 restrictions: 1. Use of the M-44 device shall conform to all applicable Federal, State, and local laws and regulations. 2. The M-44 device shall be used only to take wild canids suspected of preying upon livestock and poultry.	PR Notice 72-2 *March 9, 1972* 10th Circuit Court's Vacation of the Wyoming District Court's Predcide Injunction *December 2, 1975* 40 FR 44726 *September 29, 1975* 41 FR 21690 *May 27, 1976* 42 FR 8406 *February 10, 1977*

Pesticide/Use Affected	Action
Sodium Cyanide *(continued)*	3. The M-44 device shall not be used solely to take animals for the value of their fur. 4. The M-44 device shall only be used in instances where actual livestock losses due to predation by wild canids are occurring. M-44 devices may also be used prior to recurrence of seasonal depredation, but only when a chronic problem exists in a specific area. In each case, full documentation of livestock depredation, including evidence that such losses were caused by wild canids, will be required before appliation of the M-44 is undertaken. 5. The M-44 device shall not be used in: (1) National or State Parks; (2) National or State Monuments; (3) Federally-designated Wilderness areas; (4) Wildlife refuge areas; (5) Prairie dog towns; (6) Areas where exposure to the public and family pets is probable. 6. The M-44 shall not be used in areas where threatened or endangered species might be adversely affected. Each applicator shall be issued a map which clearly indicates such areas. 7. The M-44 device shall not be placed within 200 feet of any lake, stream, or other body of water. 8. The M-44 device shall not be placed in areas where food crops are planted. 9. M-44 devices shall not be placed within 50 feet of public rights of way. 10. The maximum density of M-44's placed in any 100-acre pastureland area shall not exceed 10; and the density in any one square mile of open range shall not exceed 12. 11. The M-44 device may be placed in the vicinity of draw stations (livestock carcasses), provided that no M-44 device shall be placed within 30 feet of a carcass; no more than 4 M-44 devices shall be placed per draw station; and no more than 3 draw stations shall be operated per square mile. 12. M-44 devices shall be inspected at least once a week to check for interference or unusual conditions and shall be serviced as required. 13. Used sodium cyanide capsules shall be disposed of by deep burial or at a proper landfill site. 14. An M-44 device shall be removed from an area if, after 30 days, there is no sign that a target predator has visited the site. 15. Damaged or non-functional M-44 devices shall be removed from the field. 16. In all areas where the use of the M-44 device is anticipated, local hospitals, doctors, and clinics shall be notified of the intended use and informed of the antidotal and first-aid measures required for treatment of cyanide poisoning.

		Reference
Sodium Cyanide *(continued)*	17. Bilingual warning signs in English and Spanish shall be used in all areas containing M-44 devices. All such signs shall be removed when M-44 devices are removed. a. Main entrances or commonly used access points to areas in which M-44 devices are set shall be posted with warning signs to alert the public to the toxic nature of the cyanide and to the danger to pets. Signs shall be inspected weekly to insure their continued presence and insure that they are conspicuous and legible. b. An elevated sign shall be placed within 6 feet of each individual M-44 device warning persons not to handle the device. 18. Registrations for sodium cyanide capsules to be used in the M-44 device may be granted to persons other than State and Federal agencies; provided, that such persons shall be authorized to sell said capsules only to State and Federal registrants, except that Indian governing authorities on reservations not subject to State jurisdictions are also eligible to obtain registrations. Only State, Federal, and Indian registrants shall be permitted to sell, give or otherwise distribute sodium cyanide capsules to individual applicators. Such State, Federal and Indian registrants of sodium cyanide capsules shall be responsible for insuring that the restrictions set forth herein are observed by individual applicators to whom such registrants sell or distribute such capsules and/or M-44 devices. State, Federal and Indian registrants shall train applicators, and such training shall include, but need not be limited to: (1) Training in safe handling of the capsules and placement of the device; (2) Training in the proper use of the antidote kit; (3) Instructions regarding proper placement of the device; and (4) Instructions in recordkeeping. 19. Each authorized M-44 applicator shall keep records dealing with the placement of the device and the results of each placement. Said records shall include, but need not be limited to: a. The number of devices placed. b. The location of each device placed. c. The date of each placement, as well as the date of each inspection. d. The number and location of devices which have been discharged and the apparent reason for each discharge. e. The species of animal taken. f. All accidents or injuries to humans or domestic animals. 20. M-44 devices and sodium cyanide capsules shall not be sold or transferred to, or entrusted to the care of, any person not authorized or licensed by, or under the supervision or control of a Federal, Indian, or State registrant. 21. All persons authorized to possess and use	

Pesticide/Use Affected	Action	Reference
Sodium Cyanide *(continued)*	M-44 capsules and devices shall store said devices under lock and key. 22. Each authorized or licensed applicator shall carry an antidote kit on his person when placing and/or inspecting M-44 devices. The kit shall contain at least six pearls of amyl nitrate and instructions on their use. Each authorized or licensed applicator shall also carry on his person instructions for obtaining medical assistance in the event of accidental exposure to sodium cyanide. 23. One person other than the individual applicator must have knowledge of the exact placement location of all M-44 devices in the field. 24. Supervisors shall periodically check the records, signs, and devices of each applicator to verify that all applicable restrictions, laws, and regulations are being strictly followed. 25. In areas where more than one governmental agency is authorized to place M-44 devices, the agencies shall exchange placement information and other relevant facts to insure that the maximum number of M-44's allowed is not exceeded. 26. Registrants and applicators shall also be subject to such other restrictions as may be prescribed from time to time by the U.S. Environmental Protection Agency.	
Sodium Fluoride	Cancelled, for home use if the product contains more than 40% of this compound.	PR Notice 70-14 *June 1, 1970*
Sodium Fluoroacetate	Cancelled and suspended for use in mammalian predator control. Label should have instructions for predator use blocked out.	PR Notice 72-2 *March 9, 1972* 10th Circu[illegible] vacation [illegible] ing District [illegible] Predicide Injunc[illegible] *December 2, 197[illegible]*
Sodium Hypochlorite	The following label requirements should be made in order to correct deficiencies in active ingredients: 1. Products bearing label claims for 7.0% sodium hypochlorite or less: no change requirements. 2. Products bearing label claims for more than 7.0% to 12.5% soldium hypochlorite, add this label statement. *"Degrades with age. Use a test kit and increase dosage as necessary to obtain required level of available chlorine."* Such products packaged in containers less than one gallon are not acceptable. 3. Products bearing label claims for more than 12.5% sodium hypochlorite are not acceptable for registration. In some cases overformulation to maintain claimed concentrations is necessary; however, such overformulation should not exceed 25% of the claimed concentrations.	PR Notice 70-16 *June 25, 1970*

Pesticide/Use Affected	Action	Reference
Strobane	Voluntary cancellation, all products.	41 FR 26607 June 28, 1976
Strychnine	Cancelled and suspended for use in mammalian predator control. Label should have instructions for predator use blocked out.	PR Notice 72-2 *March 9, 1972* 10th Circuit Court's vacation of the Wyoming District Court's Predacide Injunction *December 2, 1975*
2,4,5-T	Chlorodioxin contaminants not allowed.	PR Notice 70-22 *September 28, 1970*
	Suspended, the following list: 1. all uses in lakes, ponds, or in ditch banks. 2. liquid formulations for use around the home, recreation areas and similar sites. 3. all uses in forestry, rights-of-way and pastures.	PR Notice 70-11 April 20, 1970 44 FR 15874 March 15, 1979 44 FR 41531 July 17, 1979
	☐ Note: *The only allowable uses for 2,4,5-T are for rice, rangeland and non-crop uses.* Non-crop uses *include uses at 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). For definitions of* range *and* pasture *see silvex.*	PR Notice 70-13 *May 1, 1970*
	Cancelled, the following list: 1. all granular formulations for use around the home, recreation areas and similar sites. 2. all uses on food crops intended for human consumption. *(Note:* use on rice not finally cancelled*).*	
Thallium Sulfate	Cancelled and suspended, all products.	PR Notice 72-3 *March 9, 1972*
Toxaphene	Cancelled, all uses of toxaphene products bearing directions for use on lettuce and cabbage *except* the following: 1. Cabbage at application rates of 4.0 lbs. actual/acre must have the warning statement *"Do not apply after heads start to form."* 2. Lettuce at application rates of 5.0 lbs. actual/acre must have the warning statement *"Do not apply after seedling stage on leaf lettuce. Do not apply after heads begin to form on head of lettuce.*	PR Notice 69-5 *February 14, 1969*
Vinyl Chloride	Cancelled and suspended, all pesticide products containing this compound, whether an active or inert ingredient, for uses in the home, food handling establishments, hospitals or in enclosed areas.	PR Notice 74-5 *April 30, 1974* 40 FR 3494 *January 22, 1975*

Cross Index

4-Allyl-1, 2-methylenedioxybenzene: See Safrole
Aroclor: See Polychlorinated Biphenyls and Polychlorinated Terphenyl
Arsenous Oxide: See Arsenic Trioxide
Benzene Hexachloride, other Isomer of: See BHC
Benzene Hexachloride, gamma isomer: See Lindane
Compound 1080: See Sodium Fluoroacetate
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1,2-Dibromo-3-chloropropane: See DBCP
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Dichloro diphenyl trichloroethane: See DDT
Dodecachlorooctahydro—1,3,4-metheno-1H-cyclobuta[cd]pentalene: See Mirex
Ethyl 4, 4'-dichlorobenzilate: See Chlorobenzilate
Heptachlorotetrahydro-4,7-methanoindene: See Heptachlor
Hexachloroepoxyoctahydro-endo, endodemethanonaphthalene: See Endrin
Hexachloroepoxyoctahydro-endo, exo-dimethanonaphthalene 85% and related compounds 15%: See Dieldrin
Hexachlorohexahydro-endo, exo-dimethanonaphthalene 95% and related Compounds 5%: See Aldrin
60% Octachloro-4,7-methanotetra-hydroindane and 40% related compounds: See Chlordane
Octamethylpyrophosphoramide: See OMPA
O,O-Diethyl o-p-nitrophenyl phosphorothioate: See Parathion
Polychlorinated Biphenyls: See PCB's
Technical Chlorinated Camphene (67-69% chlorine): See Toxaphene
Terpene polychlorinates (65% or 66% chlorine) consists of chlorinated camphene, pinene, and related polychlorinates: See Strobane
Tetrachloro-p-benzoquinone: See Chloranil
2,2'-Thiobis (4,6-dichlorophenol): See Bithionol
2,4,5-Trichlorophenoxyacetic acid: See 2,4,5-T
2,-(2,4,5-Trichlorophenoxy) propionic acid: See Silvex
1081: See Fluoroacetamide

ENVIRONMENTAL PROTECTION AGENCY

[OPP-00035A; FRL 1350-4]

Pesticide Use and Production by Veterinarians; Statement of Policy on the Applicability of the Federal Insecticide, Fungicide, and Rodenticide Act to Veterinarians

AGENCY: Office of Pesticide Programs/ Office of Enforcement, Environmental Protection Agency (EPA).

ACTION: Notice of a policy for implementation of the Federal Insecticide, Fungicide, and Rodenticide Act as amended, with respect to veterinarians.

SUMMARY: This notice explains EPA's policy for enforcement of various provisions of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA) (7 U.S.C. 136 et seq.), and regulations thereunder, with regard to Doctors of Veterinary Medicine (veterinarians) who use, mix, or prescribe pesticides.

FOR FURTHER INFORMATION CONTACT: Ralph Colleli (TS-766), Office of Pesticide Programs, (202) 755-8030.

SUPPLEMENTARY INFORMATION: On Thursday, March 15, 1979, EPA's Office of Pesticide Programs and Office of Enforcement published a proposed statement of policy for the regulation of veterinarians who use or dispense pesticides in the course of their practice (44 FR 15768). That proposed policy statement pointed out that veterinarians who deal with pesticides are subject, to some extent, to legal responsibilities imposed by FIFRA and regulations thereunder, including regulations for pesticide applicator certification, product registration, establishment registration, and special (child-resistant) packaging. The March 15 notice also stated that the purpose of the proposed policy was to describe EPA's plan for applying these statutory and regulatory requirements to veterinarians. This plan would allow veterinarians to continue their usual practices without having to comply with all the procedural requirements to which they are technically subject, provided that they comply with certain minimal safety precautions specified in the policy statement. These conditions would not extend or augment in any way the legal responsibilities or liabilities of veterinarians. However, compliance with these precautions would permit EPA to allow beneficial and customary veterinary practices to continue, free from restraints which would otherwise apply.

The March 15 notice invited the public to comment on the proposed policy. The deadline for submitting comments was April 30, 1979. Only two commenters responded to this notice. One commenter (No. 1(00086)), speaking for the California Department of Food and Agriculture, objected generally to the idea that veterinarians should be treated any differently under this policy than other pesticide users. The commenter specifically stated that "Veterinarians should comply with applicator certification requirements and use registered pesticides in accordance with registered labeling."

EPA must reject this objection since, as the March 15 notice pointed out, veterinarians are exempted from certification requirements by regulations promulgated in 1975 (40 CFR 171.4(e)), and *not* by this policy. Also, as the proposed policy statement, and this final notice, expressly state, "veterinarians, like all other persons, must use all pesticides . . . consistently with their registered labeling."

The other commenter (No. 2(00083)) raised several points. First, he stated that this policy might set a precedent for other pesticide user and producer groups, and that the policy statement should be written with that consideration in mind. EPA has considered this issue and notes that this policy is not intended as a precedent for treatment of any persons other than practicing veterinarians. This policy was specifically developed to recognize the special status granted to veterinarians by regulation, and to obtain for the public the unique benefits this group can provide, while maintaining an acceptable level of safety in the use, production, and distribution of pesticides by veterinarians. This statement cannot, therefore, be extended to any other groups.

The same commenter also suggested that veterinarians who mix and dispense special pesticide blends for treating unusual cases should be required to keep special records on such treatments. This comment was rejected since most of the information specified by the commenter is routinely kept by veterinarians in their office files, and since the incremental benefits obtainable from such records would not justify imposing such a requirement on veterinarians.

These comments are available for public inspection in the Chemical Information Division (TS-793), Office of Toxic Substances, EPA, Room E-447, 401 M Street, S.W., Washington, D.C. 20024, from 9:00 a.m. to 4:00 p.m., Monday through Friday.

Certain minor changes in the policy statement have been made since its proposal, however, in order to clarify or correct certain deficiencies in the proposed policy. For example, the sections relating to *Repackaging and Dispensing of Pesticides* and *Production of Special Pesticide Formulas* have been modified to require that the basic labeling information described therein be physically attached to the pesticide package, if space permits. In addition, in cases where the size of the package precludes insertion of human safety precautionary statements on the package itself, certain specific precautions must appear on a tag attached to the package.

Also, the final policy statement clarifies that veterinarians dispensing special pesticides formulations will be covered by the exemptions described herein only when the special blend is formulated for use on an affected animal. Special blends intended for other purposes (e.g., space sprays) are not covered by the exemption and must be registered by the veterinarian.

Accordingly, notice is hereby given that the Office of Pesticide Programs and the Office of Enforcement intend to implement immediately a policy on the subject of veterinarians using and dispensing pesticides, as described below.

Use of Restricted Use Pesticides

Under sections 3, 4, and 12(a)(2)(F) of FIFRA, no individual may use a restricted use pesticide unless he is an applicator certified under a plan approved by EPA, or is under the direct supervision of a certified applicator, or is expressly exempted from the certification requirement. Regulations promulgated under section 4 in 1974 established an exemption from the certification requirement for veterinarians who use restricted use pesticides in "the course of their normal practice" (40 CFR 171.4(e)). The regulations explained, however, that this

exemption does *not* apply to veterinarians who are "in the business of applying pesticides for hire, publicly holding themselves out as pesticide applicators, or engaged in large-scale use of pesticides" (40 CFR 171.3(b)(1)(ii)). Activities such as these would not be part of "normal practice," and veterinarians would have to be certified to use restricted use pesticides for such purposes. Although the meaning of a "normal practice" is broad and may vary according to local needs, some activities clearly do not come within the scope of that term. For instance, application of pesticides by a veterinairian as a "principal or regular occupation" (39 FR 36447 (October 1, 1974)), or solicitation of pesticide application business by veterinarians, is not considered part of a "normal practice." Veterinarians who use restricted use pesticides for such purposes, or in any other manner which is not part of their "normal practice," are required to become certified under an appropriate approved State or Federal certification plan, unless they use such pesticides under the direct supervision of a certified applicator.

Although EPA strongly recommends that veterinarians keep abreast of advances in pesticide use and technology through appropriate professional continuing education, veterinarians who practice within the bounds of 40 CFR 171.4(e) are exempt from the certification requirement. EPA interprets this exemption as also extending to regular employees of a veterinarian when applying restricted use pesticides "under the direct supervision" of the veterinarian. Such supervision requires, unless the pesticide labeling specifies otherwise, that the employee be a competent individual, acting under the supervision and control of a veterinarian who is available if and when needed, even though the veterinarian is not physically present at the time (section 2(e)(4) of FIFRA). Veterinarians are, however, subject to civil and criminal penalties for violations of FIFRA, including misuse of pesticides, committed by employees under their supervision (see section 14(b)(4) of FIFRA). Additionally, veterinarians (unless they have become certified applicators) are not authorized to supervise the use of restricted use pesticides by uncertified persons other than their employees.

Similarly, under section 12(a)(2)(F) of FIFRA, veterinarians, as all other persons, are forbidden to dispense restricted use pesticides to uncertified persons, including their clients, unless expressly allowed by EPA regulations. However, EPA will consider the need of veterinarians to dispense a particular pesticide to clients as part of any future decision on whether to restrict use of such a pesticide.

Finally, veterinarians, like all other persons, must use all pesticides, including those not classified for restricted use, consistently with their registered labeling. As authorized by section 2(ee) of FIFRA, this includes use against a pest not specified on the labeling as long as the animal or site treated *is* so specified, unless use against that pest is expressly forbidden by the Administrator of EPA.

Any veterinarian who uses or dispenses pesticides in violation of the provisions of FIFRA, as described above, may be penalized under section 14 of FIFRA for such actions.

Repackaging and Dispensing of Pesticides

Sections 3(a) and 7(a) of FIFRA, and regulations thereunder, require every "producer" of pesticides to register all pesticides produced by him, and to register the establishment in which they are produced, prior to sale or distribution of such pesticides. By regulation, the term "producer" includes all persons who "repackage or otherwise change the container of any pesticide * * *" (40 CFR 167.1(c) and (d)). Therefore, a veterinarian who prescribes or otherwise dispenses a pesticide in a new container, or a container which he has altered by changing the package or its labeling, after receipt of the original product, is considered a "producer." The veterinarian is then legally responsible for registering such a product with EPA (even though the original product may already have been registered by its producer); for registering his establishment; for complying with all applicable labeling and packaging standards established by EPA; and for keeping all records required of producers under section 7(c) of FIFRA and 40 CFR 167.5.

However, EPA recognizes the substantial benefits which may be gained by permitting veterinarians who obtain pesticides in bulk containers to dispense such pesticides to clients in individual containers better suited to the specific case for which each pesticide is prescribed. EPA also recognizes the care with which most veterinarians prescribe, repackage, and distribute pesticides. Therefore, EPA, as a matter of policy, will not subject veterinarians who prescribe and dispense repackaged pesticides to the requirements imposed on "producers," provided that the following minimal conditions are met:

1. The repackaged pesticide is registered by EPA for a use consistent with the use for which the pesticide is prescribed, and the EPA registered use is not classified as restricted.

2. The veterinarian supplies the client with labeling for the pesticide which contains:

(a) The common or trade name(s) and percentage(s) of the active ingredient(s);

(b) The EPA product registration number;

(c) Use directions for the use prescribed;

(d) The name and address of the veterinarian;

(e) An antidote statement;

(f) Directions for disposal of the pesticide and the package dispensed to the client; and

(g) Human safety precautionary statements, including but not limited to:

(i) "For application to animals only."

(ii) "Keep out of reach of children."

(iii) "In case of accident, contact local physician immediately."

If there is sufficient space on the package dispensed to the client, all of the information specified in (a)–(g) above must be physically attached to the package.

If space on the package is not sufficient to permit direct attachment of labeling containing all the information in (a)–(g), then, at a minimum, the information specified in (a), (b), (c), and (d) must be physically attached to the package. In addition, in such a case, the human safety precautionary statement specified in (g) above must be physically affixed to the container by wire, plastic, or similar means.

The information required by (e) and (f) above may be supplied to the client in the form of supplemental labeling, which may, if appropriate, consist of the original labeling of the pesticide as received by the veterinarian.

3. The container in which the pesticide is dispensed to the client is a child-resistant package as described in 40 CFR 162.16 of the "Special Packaging" rule (44 FR 7695), unless the veterinarian has determined that there is no reasonable possibility that the package will come within the reach of children.

4. The pesticide is prescribed and dispensed to the client for the treatment of a specific pest problem, on a case-by-case basis, as part of the veterinarian's "normal practice."

In addition to meeting the above requirements, all veterinarians distributing pesticides are urged to discuss labeling directions with the client at the time the pesticide is dispensed.

Any veterinarian who repackages and dispenses pesticides, and who does not satisfy conditions (1) through (4) above, must comply with all federal registration and recordkeeping requirements for "producers," and may be penalized under section 14 of FIFRA for failure to do so.

Producing and Dispensing Special Pesticide Formulas

Veterinarians who prepare their own special products for treatment of pests, other than by mere dilution of a registered pesticide in accordance with its labeling, may also be "producers." If the product formulated by the veterinarian is a "new animal drug" (as defined in 21 U.S.C. 321(w) and 321(g)(1)), the product and the veterinarian are subject to regulations of the U.S. Food and Drug Administration. If, however, the product is not a "new animal drug," or an animal feed containing a new animal drug, and is intended to prevent, repel, mitigate, or destroy any pest, it is a pesticide (section 2(u) of FIFRA) and is subject to the primary jurisdiction of EPA. The veterinarian is then considered a "producer" under FIFRA section 2(w).

As described above, "producers" are ordinarily required to register products and establishments, to keep records, and to meet labeling and packaging standards. If, however, the veterinarian produces a special pesticide blend solely for his own use, or use by persons in his presence and under his immediate supervision, then the veterinarian is exempt from these requirements (*see, e.g.*, 40 CFR 162.3(gg); 162.5(a); 167.2(a)). Nevertheless, when mixing or using special pesticide blends, veterinarians are still required to comply with the labeling directions of any registered pesticides used. In addition, EPA recommends that labeling meeting the minimum standards of 40 CFR Part 162 accompany the special blend, in order to promote safe use, storage, and disposal of such pesticides by the veterinarian and his employees. Also, when applying a special blend which may leave a residue in or on an animal intended for use as food, the veterinarian must ensure that the ingredients used have been granted necessary clearances under the Federal Food, Drug, and Cosmetic Act.

On the other hand, veterinarians who formulate special pesticide mixtures for distribution to others are legally subject to all registration, labeling, and packaging requirements imposed on producers. However, EPA recognizes the benefits which may be obtained by allowing veterinarians to formulate products to meet unusual cases. Therefore, EPA will not subject veterinarians who dispense such products to these requirements if:

1. The special pesticide blend is produced by mixing two or more pesticides already registered by EPA, or by adding new substances to an EPA registered persticide.

2. Special blends made from registered pesticides classified for restricted use by EPA are not dispensed to uncertified persons.

3. The special blend is formulated and dispensed in accordance with recognized clinical practices and not primarily for purposes of experimentation.

4. The product is prescribed solely for application to an affected animal consistent with the labeling of any registered product used as an ingredient, and the use directions in the labeling for the registered ingredient do not prohibit the mixing performed by the veterinarian.

5. The special product is prescribed and dispensed to individual clients of the veterinarian on a case-by-case basis to meet specific pest problems.

6. The veterinarian supplies the client with labeling for the special product which contains:

(a) The common or trade name(s) and percentage(s) of active ingredient(s);

(b) The EPA registration number for each registered product used as an ingredient;

(c) Use directions for the use prescribed, which are consistent with the directions found in the original labeling for the registered products used as ingredients;

(d) The name of the veterinarian;

(e) An antidote statement;

(f) Directions for disposal of the pesticide and its container; and

(g) Human and environmental safety precautionary statements including, but not limited to:

(i) "For application to animals only."

(ii) "Keep out of reach of children."

(iii) "In case of accident, contact local physician immediately."

If there is sufficient space on the package dispensed to the client, all of the information specified in (a)–(g) above must be physically attached to the package.

If space on the package is not sufficient to permit attachment of labeling containing all the information in (a)–(g), then, at a minimum, the information specified in (a), (b), (c), and (d) must be physically attached to the package. In addition, in such a case, the human safety precautionary statements specified in (g) above must be physically affixed to the container by wire, plastic, or similar means.

If the original labeling or any of the ingredients would satisfy the requirements of (e) and (f), copies of that labeling may be supplied to the client to fulfill those requirements.

7. The container in which the special product is sold to the client is a child-resistant package, as described by the "Special Packaging" rule, unless the veterinarian has determined that there is no reasonable possibility that the package will come within the reach of children.

In addition to meeting the above requirements, all veterinarians distributing their own special products are encouraged to discuss labeling instructions for the special product with the client at the time the pesticide is dispensed.

Veterinarians who do not meet these conditions when distributing specially formulated pesticides must comply with all registration, recordkeeping, labeling, and packaging requirements established for "producers." Failure to comply may result in the imposition of penalties under section 14 of FIFRA.

Special Packaging

As mentioned above, it is expected that veterinarians who "produce" pesticides for their clients' use will frequently be subject to the requirements of the "Special Packaging" rule by its own terms. That is, a veterinarian producing a pesticide which meets the toxicity requirements of the "Special Packaging" rule, and which is intended for "residential application", as defined by that rule, *must* package the product in a child-resistant container before dispensing it to a client.

In addition, in those cases where that rule will not apply by its own terms, but the prescribed pesticide may come within the reach of children, use of child-resistant packaging by the veterinarian is a prerequisite to exemptions from registration, recordkeeping, and labeling requirements described in the preceding sections of this policy.

These facts, coupled with the practical difficulty that some veterinarians may have in determining whether a prescribed pesticide is subject to the terms of the "Special Packaging" rule, make it to the veterinarians' advantage to comply with the rule whenever there is a reasonable possibility that a prescribed pesticise may come within the reach of children. Therefore, EPA strongly encourages veterinarians to voluntarily comply with packaging standards established by the rule when dispensing any repackaged or specially blended pesticides.

State Regulation of Veterinarians

This policy statement concerns only EPA policy under FIFRA and federal regulations. It does not affect State or local regulatory restrictions covering veterinarians who deal with pesticides. Therefore, all veterinarians should consult their local professional associations, licensing offices, and State and local pesticide regulatory agencies for detailed information on local requirements.

Dated: October 16, 1979.

Edwin L. Johnson,

Deputy Assistant Administrator for Pesticide Programs.

Dated: October 24, 1979.

Richard O. Wilson,

Deputy Assistant Administrator for General Enforcement.

[FR Doc. 79-33835 Filed 10-31-79; 8:45 am]

BILLING CODE 6560-01-M

[OPP-30000/33A; FRL 1350-1]

Rebuttable Presumption Against Registration and Continued Registration of Pesticide Products Containing EPN; Extension of Period for Submission of Rebuttal Evidence and Comments

AGENCY: Environmental Protection Agency (EPA), Office of Pesticide Programs.

ACTION: Extension of comment period.

SUMMARY: EPA has extended the period for submittal of rebuttal evidence and other comments in regard to the rebuttable presumption against registration (RPAR) of pesticide products containing O-ethyl O-(p-nitrophenyl) phenylphosphonothioate (EPN).

DATE: The comment period closes on December 28, 1979.

FOR FURTHER INFORMATION CONTACT: Mr. Patrick Miller, Special Pesticide Review Division (TS-791), Office of Pesticide Programs, Room 722, Crystal Mall Building #2, 1921 Jefferson Davis Highway, Crystal City, Virginia 22202, Telephone: 703/557-7973 Ext. 24. The file supporting the Agency's presumption against EPN is available for public inspection at this location.

SUPPLEMENTARY INFORMATION: On September 4, 1979, EPA issued an RPAR against EPN. This notice was published in the Federal Register on September 19, 1979 (44 FR 54304). The regulations governing RPAR's provide that the applicant or registrant of these pesticide products shall have forty-five days from the date this notice is sent to submit evidence in rebuttal of the presumption. If good cause is shown, however, an additional sixty days may be granted in which to submit evidence (40 CFR 162.11(a)(1)(i)).

The deadline for submitting rebuttal evidence in the RPAR notice was October 29, 1979. Requests for an additional sixty days in which to submit evidence to EPA have been received from registrants and others who were affected by the notice of presumption. They have specified a need for additional time to respond to the risk presumptions set forth in the September 19 notice (i.e., delayed neurotoxicity in test animals and acute toxicity to aquatic organisms) and to assess properly the benefits of EPN.

The Agency concludes that additional time would be beneficial to ensure the submission of complete and accurate responses to this notice of presumption. Therefore, all registrants, applicants, for registration, and other interested persons shall have until December 28, 1979, to submit rebuttal evidence and other comments or information. These submissions should be sent to the Document Control Officer, Chemical Information Division (TS-793), Office of Toxic Substances, EPA, Room 447, East Tower, 401 M Street, SW., Washington, D.C. 20460.

All comments should bear the identifying notation "OPP-30000/33A." Comments received on or before December 28, 1979, will be considered before the Agency decides whether a notice shall be issued under 40 CFR 162.11(a)(5)(ii) and 7 U.S.C. 136(d)(B)(1). Comments received after December 28, 1979, shall be considered only to the extent feasible, consistent with the time limits imposed by 40 CFR 162.11(a)(5)(ii). All written comments filed will be available for public inspection in the office of the Document Control Officer at the above address from 8:30 a.m. to 4 p.m. on normal business days.

Dated: October 26, 1979.

Edwin L. Johnson,

Deputy Assistant Administrator for Pesticide Programs.

[FR Doc. 79-33838 Filed 10-31-79; 8:45 am]

BILLING CODE 6560-01-M

FEDERAL COMMUNICATIONS COMMISSION

Canadian Standard Broadcast Stations; Notification List

List of new stations, proposed changes in existing stations, deletions, and corrections, in assignments of Canadian standard broadcast stations modifying the assignments of Canadian broadcast stations contained in the appendix to the recommendations of the North American Regional Broadcasting Agreement Engineering Meeting Jan. 30, 1941.

September 19, 1979.

Canadian List No. 309

Call letters	Location	Power kW	Antenna	Schedule	Class	Antenna height (feet)	Ground system		Proposed date of commencement of operation
							Number of radials	Length feet	
				800 kHz					
CSQ	Thunder Bay, Ontario, N. 48°18'38", W. 89°21'30" (In operation with changed antenna radiation pattern)	10D/5N	DA-1	U	II				
				1050 kHz					
CHRS	Longueuil, Quebec, N. 45°19'17", W. 73°18'36" (Change of studio location from St. Jean)	10	ND-180	D	II		120	300(ave)	

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

DEC 19 1979

OFFICE OF ENFORCEMENT

SUBJECT: Enforcement Actions Concerning Nonhazardous Pesticide Devices

TO: Pesticide Branch Chiefs
Enforcement Division Directors

Section 13 of the Pesticides Case Proceedings Manual states that the issuance of a Stop-Sale, Use or Removal Order is mandatory for devices whose labeling bears false, misleading, or fraudulent claims. 1/ This guidance is based on section 13 of FIFRA, which grants EPA the authority to prevent the further distribution and sale of any pesticide or device found to be in violation of the Act. However, the question has been raised in a case involving an electromagnetic rodent repelling device whether a section 13 Stop Sale Order is an unconstitutional seizure and deprivation of a person's property without due process of law because of the absence of an opportunity for an administrative determination as to the validity of the Order. As a result, PTSED is developing a regulation governing the issuance of Stop Sale, Use or Removal Orders covering certain classes of pesticide devices. The regulation being developed would provide persons who are distributing or selling nonhazardous devices which do not present immediate human health or environmental risks, with an opportunity for an administrative review of the validity of the Stop Sale Order. This review would take place prior to and independent of the adjudication of the alleged violation through the civil penalty process.

Until such a regulation is implemented, it is the Office of Enforcement's policy that in any case of a misbranding violation involving a nonhazardous pesticide device, it will be necessary to complete civil penalty proceedings before issuing any Stop Sale Order. Thus, in cases involving nonhazardous devices regulated by FIFRA, a Civil Penalty Notice should be issued and, if a hearing is requested, the adjudicatory proceedings completed before issuing a Stop Sale, Use or Removal Order. If the respondent fails to request a timely hearing once he has received a Civil Penalty Notice, a Stop Sale Order

1/ Case Proceedings Manual, Section 13(I)(B)(2)(a)(3), TN 76-2 (10-76)

can be imposed. A Stop Sale Order can also be imposed once a Final Order has been issued pursuant to a Consent Agreement with the regional office. However, any Consent Agreement concerning a misbranded device should require as a minimum the immediate halt to any further sale or distribution of the devices. If the respondent does request a hearing pursuant to section 14 and the regulations set forth in 40 CFR Part 168, a Stop Sale Order should not be imposed until the completion of the administrative proceedings and the issuance of a Final Order. However, it is not necessary to wait for the respondent to exhaust all avenues of appeal (i.e., appeal to the appropriate U.S. Court of Appeals) before issuing a Stop Sale Order.

It should be noted that this policy extends only to those devices found not to pose an immediate human health or environmental risk but whose labeling is found to bear false, misleading, or fraudulent claims. Other classes of devices, especially those which do pose human health or environmental risks, will continue to be treated under the mandatory provisions of the guidance found in section 13 of the Case Proceedings Manual. An example of a device which would still warrant the mandatory issuance of a Stop Sale Order, notwithstanding the discretionary policy outlined in this memorandum, is a water treatment device whose labeling makes false, misleading, or fraudulent claims to purify raw well water or other untreated water supplies. A more detailed classification of devices subject to this policy will be outlined in the proposed regulation.

Nevertheless, in certain cases involving nonhazardous devices it may be necessary or appropriate to take further action to prevent the continued distribution and sale of the devices before the completion of the civil penalty proceedings. In such cases it may be appropriate to seize the devices pursuant to the authority in section 13(b) and/or to seek an injunction pursuant to the authority in section 16(c) to prevent their further distribution and sale pending the outcome of the civil penalty proceedings. These actions require the prior concurrence of EPA Headquarters as outlined in sections 13(II)(A) and 18(D)(3) of the Case Proceedings Manual, and must be referred to the Department of Justice for prosecution. 2/

2/ The authority to institute in rem (seizure) proceedings is vested concurrently in the Regional Administrator and Assistant Administrator for Enforcement [Chapter 10-2, EPA Delegations Manual].

If you have any questions about the policy or procedures outlined in this memorandum, or need assistance on a case-by-case basis in prosecuting persons for the sale and distribution of misbranded, nonhazardous pesticide devices please contact Joseph Virgilio of PTSED at 202-472-3701.

A. E. Conroy II

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

JAN 16 1980

MEMORANDUM

SUBJECT: Federal Facilities Compliance

TO: Clyde B. Eller, Director
Enforcement Division, Region IX

This is in response to your memorandum of December 19, 1979, requesting a further determination on the issue of civil compliance against Federal facilities. Your memorandum stemmed from earlier telephone conversations between our staffs in which we indicated a preference for more informal enforcement actions when dealing with other Federal executive agencies.

Executive Order 12088 (copy attached) sets forth policies governing compliance with environmental standards by Federal facilities. The thrust of E.O. 12088 is that the Administrator should notify an Executive Agency when it has been found to be in violation of a pollution control standard. That agency, in turn, should promptly consult with the Administrator and provide a plan to achieve and maintain compliance with the pollution control standard. The Administrator is directed to make every effort to resolve conflicts regarding the violation. If the Administrator cannot resolve the conflict, he is directed to request the Office of Management and Budget to resolve the conflict between the agencies. Section 1-604 further provides that these conflict resolution procedures are in addition to, and not in lieu of, other enforcement procedures.

It is the express policy of the Agency to make every effort to resolve such conflicts with other Executive agencies in accordance with E.O. 12088. This policy is consistent with the thrust of E.O. 12088 in favoring inter-agency settlement over more formal enforcement actions. This is so in the context of administrative procedings as well as in the context of in-court litigation where the Department of Justice has indicated it would not allow the EPA to file suit against another Executive Agency.

CONCURRENCES

EN342	EN342	EN342					
[illegible]	J.F. / for [illegible]	T Hurst					
1/11/80	1/11/80	1/11/80					

1320-1 (12-70) OFFICIAL FILE COPY

It is the policy of the Department of Justice (DOJ) not to involve the Judicial Branch in resolving Executive Branch problems. DOJ would intervene against EPA if we attempted any such filings on our own behalf.

The goal in negotiating settlements when an Executive Agency is found to be in violation of a pollution control standard is not to assess penalties but to obtain compliance. Expeditious compliance might be obtained solely on the basis of such settlement between the agencies. To the extent that every effort to resolve such conflicts with other Executive agencies has not yet been made, the consideration of other enforcement options would be inappropriate.

An example of one such agreement is the Federal Facilities Compliance Agreement between EPA and the Department of the Army (copy enclosed). This agreement established expeditious compliance schedules for the Department of the Army Material Development and Readiness Command (DARCOM) facilities which were in violation of provisions of the Clean Water Act and the Clean Air Act. As outlined in an April 13, 1979, memorandum from the Director, OE Office of Program and Management Operations, to the Regional Enforcement Division Directors, this agreement will serve as a model for resolving similar problems with Executive agencies in the future.

I hope that this information will be of help to you. If I can be of any further assistance, please contact me at (202) 755-0970.

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

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: December 19, 1979

SUBJECT: TSCA Civil Complaints Against Federal Facilities

FROM: Clyde B. Eller
Director
Enforcement Division, Region IX

TO: ~~A. E. Conroy II~~
Director
Pesticides and Toxic Substances Enforcement Division

In telephone conversations with your staff, we have been informed that PTSED will not concur in a civil complaint against a federal facility. Because of Executive Order 12088, PTSED prefers that a settlement with a federal facility be embodied in an informal compliance agreement.

It is our position that a federal facility should be treated in the same manner as any private company. A civil complaint should be issued against a federal facility which violates TSCA and any settlement should be embodied in a consent agreement.

Our position is not inconsistent with Executive Order 12088, which states:

> "These conflict resolution procedures are in addition to, not in lieu of, other procedures, including sanctions, for the enforcement of applicable pollution control standards."

Because a number of completed federal facility inspection reports are awaiting enforcement action, we request a prompt resolution of this issue.

If you have any questions, please contact me or Keith Takata of my staff at (415) 556-8008.

U.S. ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D. C.

Department of the Army

and

U.S. Environmental

Protection Agency

Federal Facility

Compliance

Agreement

The Environmental Protection Agency (EPA) and the Department of the Army (Army) are the parties to this agreement which is entered into pursuant to Executive Order 12088, October 13, 1978 (43 FR 47707). The Office of Management and Budget and the Department of Justice take cognizance of this agreement pursuant to their respective duties to assure compliance with the environmental laws under Executive Order 12088 and the particular statutes herein addressed.

SCOPE

1. This agreement is entered into by the parties to assure compliance by the Department of Army Materiel Development and Readiness Command (DARCOM) with the Clean Air Act (CAA) (42 USC 7401 et seq.) and the Clean Water Act (CWA) (33 USC 1251 et seq.), and implementing regulations.

2. This agreement is not and shall not be construed as a permit under the CWA nor shall it relieve the Army of any legal obligations under the

CWA which are in addition to or different from matters covered in this agreement. This agreement does not modify the terms of the State Implementation Plan (SIP) governing each subject facility, nor shall it relieve the Army of such SIP responsibility under the CAA. This agreement in no way affects requirements for each facility to apply to the appropriate EPA regional office and State or regional environmental agency for all applicable air quality permits.

Authorities

3. The duties of the Army to operate its facilities in compliance with the Clean Air Act and the Clean Water Act are prescribed in section 118 of the Clean Air Act (42 USC 7418) and section 313 of the Clean Water Act (33 USC 1323). Executive Order 12088 was promulgated to ensure Federal compliance with applicable pollution control standards. This agreement contains a "plan" as described in section 1-601 of Executive Order 12088 to achieve and maintain compliance with applicable air and water pollution control standards.

Statement of Facts

4. The following DARCOM facilities are owned, operated, or under the control of the Army:

a. Sewage Treatment and Industrial Wastewater, Aberdeen Proving Ground, Aberdeen, Maryland.

b. Sewage Treatment and Industrial Wastewater Anniston Army Depot, Anniston, Alabama.

c. Industrial Waste Treatment, Holston Army Ammunition Plant, Kingsport, Tennessee.

d. Industrial Waste Treatment, Lone Star Army Ammunition Plant, Texarkana, Texas.

e. Pink Water Treatment, Milan Army Ammunition Plant, Milan, Tennessee.

f. Sewage Treatment and Industrial Wastewater, New Cumberland Army Depot, New Cumberland, Pennsylvania.

g. Industrial Waste Treatment, Pine Bluff Arsenal, Pine Bluff, Arkansas.

h. Industrial Waste Treatment, Radford Army Ammunition Plant, Radford, Virginia.

i. Sewage Treatment Plant, Redstone Arsenal, Alabama.

j. Sewage Treatment Plants, Seneca Army Depot, Romulus, New York.

k. Sewage Treatment Plant, Industrial Wastewater, and Boiler Plant, Tobyhanna Army Depot, Tobyhanna, Pennsylvania.

l. Industrial Waste Treatment and Deactivation Furnace, Lake City Army Ammunition Plant, Independence, Missouri.

m. Contaminated Waste Process, Iowa Army Ammunition Plant, Middleton, Iowa.

n. Boiler Plant, Rock Island Arsenal, Rock Island, Illinois.

o. Demilitarization Facility, Savanna Army Depot, Savanna, Illinois.

5. Twelve DARCOM facilities named in paragraph 4(a) through (l) are presently in violation of the statutory compliance deadline of the Clean Water Act, to wit, CWA section 301 (33 USC 1311).

Four DARCOM facilities named in paragraph 4(l) through (o) presently have state granted variances from the operative SIP. However, these variances have not been submitted to or approved by EPA as a modification of the SIP.

The compliance status under the CAA of the Tobyhanna AD identified in paragraph 4(k) is undetermined at this time because of measures presently being undertaken at the facility. It has been in periodic, marginal violation in the past.

Compliance Schedules

6. The Compliance Schedules for the fifteen DARCOM facilities named in paragraph 4 are intended to achieve compliance as expeditiously as practicable, pursuant to section 1-601 of E.O. 12088, and are set forth as Attachments a through o to this agreement. The attachments are incorporated into and made a part of this agreement. The schedules were determined after consultation between the Army and EPA. The schedules contain interim requirements reflecting design and construction milestone dates. Wherever reasonably possible, the Army will expedite the schedules.

Funding

7. The Army shall request all funds and/or authorizations from the Congress necessary to achieve the compliance schedules. These schedules are fixed and definite except to the extent that the Congress of the United States may fail to approve budget and/or authorization requests for these projects. Steps to be taken in seeking funding shall be consistent with Sections 1-4 and 1-5 of Executive Order 12088 as implemented by the Office of Management and Budget Circular A-106 (as amended).

Reporting Requirements

8. The Army shall submit a progress report no later than ten days after the date for achievement of each incremental step in the compliance schedules and upon the final compliance date as set forth in the Attachments. The progress reports will be submitted to the EPA Regional office responsible for the particular facility and the appropriate State or regional environmental agency, as identified on the Attachments. The status reports shall indicate compliance or non-compliance with the schedule. In the event of non-compliance, the report shall include the cause of non-compliance and any remedial actions taken.

If delay is anticipated in meeting any schedule date the Army shall immediately notify the EPA Regional office and the State or regional environmental agency, in writing, of the anticipated delay, describing in detail the anticipated length of delay, the precise cause or causes

of the delay, the measures taken and to be taken by the Army to prevent or minimize the delay and the timetable by which the measures shall be implemented. The Army will take action to minimize any delay. The Regional Administrator shall make a determination whether the compliance schedule set forth in the Attachment will be revised. If the Army disagrees with this determination, the Conflict Resolution procedure described herein shall control.

Additionally, beginning three months after the date for achievement of the first milestone specified on each Attachment the Army shall submit a status report to the appropriate EPA Regional office and the State or regional environmental agency detailing the progress made during that quarter. These reports shall be submitted quarterly until compliance has been achieved.

9. In the event that there is an amendment of the CAA or CWA, or in the event that changes to the regulations promulgated under those statutes change the technology necessary to achieve compliance pursuant to this agreement, the schedules will be renegotiated to effect changed law or regulations. Such renegotiation shall be governed by Executive Order 12088. Any disagreements in renegotiations shall be resolved by the Conflict Resolution provisions of this agreement. During the pendency of any request for renegotiation, the attached compliance schedules, to the extent they do not conflict with statutory or regulatory changes, shall remain in effect unless specifically waived by EPA.

10. On the date for final compliance as shown on the attachments, compliance with air and water standards must be demonstrable by testing and positive reporting of the achievement of compliance, rather than by the mere completion of construction of pollution abatement facilities.

Upon the Army's demonstration of compliance, there will be a continuing obligation to comply with applicable discharge and emission limitations under the CWA and CAA respectively. These limitations are embodied in each facility's National Pollutant Discharge Elimination System permit under the CWA and in the pertinent State Implementation Plan under the CAA.

Conflict Resolution

11. Anticipated non-compliance with, or alleged violations of, this agreement shall be brought to the attention of the Administrator of the Environmental Protection Agency for resolution by EPA and the Army. If necessary, the Director, Office of Management and Budget shall be notified pursuant to sections 1-602 and 1-603 of Executive Order 12088. The Director, Office of Management and Budget shall consider such steps as are necessary to resolve any conflicts and remedy the violations.

Sanctions

12. In the event of violations of air or water standards or the terms of this agreement by the Army, sanctions under the authority of section 1-604 of Executive Order 12088, as well as enforcement procedures

established by the Clean Air Act and the Clean Water Act are available as enforcement mechanisms in addition to the conflict resolution procedures cited in paragraph 11.

13. Provided that the Compliance Schedules, as attached, are met, this agreement is considered to be in lieu of any other EPA or Federal enforcement action with regard to the DARCOM facilities named in paragraph 4, for the pollution indicated in paragraph 5. This agreement in no way modifies section 303 of the CAA and section 504 of the CWA.

14. This agreement in no way addresses potential liability of the Army regarding non-compliance penalties under section 120 CAA by the facilities subject to this agreement.

Signed: _____

Alan J. Gibbs
Assistant Secretary of the Army
for Installations, Logistics
and Financial Management

30 MAR 1979

_____

Marvin B. Durning
Assistant Administrator for
Enforcement
Environmental Protection Agency

Attachment a

NPDES Permit #

Facility

Aberdeen Proving Ground Harford Co, MD MD0021237

Project Description

This project involves upgrading of the main sewage treatment plant and connection of 67 separate discharges to the sewer system.

Compliance Schedule

1.	Final design start	May 1978
2.	Final design complete	March 1979
3.	Construction award	June 1979
4.	Construction complete	June 1981
5.	Achieve compliance	September 1981

Remarks

NONE

Progress Reports

EPA, Region III
Curtis Building
6th & Walnut Streets
Philadelphia, Pennsylvania 19106

Water Resource Administration
Thomas Andrews, Director
Tawes State Office Building
Annapolis, Maryland 21401

Facility	NPDES Permit #
Anniston Army Depot Lowndes Co., AL	AL0002658

Project Description

This project involves upgrading of the industrial waste treatment facility and the existing sewage treatment plant.

Compliance Schedule

1. Final design start	March 1979
2. Final design complete	December 1979
3. Construction award	March 1980
4. Construction complete	November 1981
5. Achieve compliance	February 1982

Remarks

None

Progress Reports

EPA, Region IV
345 Courtland Street, N.E.
Atlanta, Georgia 30308

Alabama Water Improvement Commission
James W. Warr, Director
State Office Building
Montgomery, Alabama 36130

Attachment C

Facility | NPDES Permit #

Holston Army Ammo Plant Kingsport, TN | TN0002381

Project Description

This project will involve construction of a new treatment facility for collection and treatment of all liquid industrial wastes at Holston AAP.

Compliance Schedule

1. Final design start	August 1975
2. Final design complete	April 1979
3. Construction award	September 1979
4. Construction complete	May 1982
5. Achieve compliance	November 1982

Remarks

None

Progress Reports

EPA, Region IV
345 Courtland Street, N.E.
Atlanta, Georgia 30308

Division of Water Quality Control
Tennessee Department of Public Health
621 Cordell Hull Building
Nashville, Tennessee 37219

Attachment d

Facility	NPDES Permit #
Lone Star Army Ammo Plant Texarkana, TX	TX0021768

Project Description

This project consists of the upgrading of the waste treatment facility for lead removal from electroplating discharges, in addition to several minor miscellaneous source controls.

Compliance Schedule

1. Final design start	September 1980
2. Final design complete	June 1981
3. Construction award	October 1981
4. Construction complete	June 1982
5. Achieve compliance	August 1982

Remarks

The scope and compliance schedule of this facility shall be subject to revision within 90 days pending the negotiation of a less stringent NPDES permit limit for lead with EPA Region VI and the State of Texas.

Progress Reports

EPA, Region VI
First International Building
1201 Elm Street
Dallas, Texas 75270

Texas Dept. of Water Resources
Harvey Davis, Director
P.O. Box 13087 Capitol Station
Austin, Texas 78711

Attachment e

Facility	NPDES Permit
Milan Army Ammo Plan Milan, TN	TN0000060

Project Description

This project will involve upgrading of the existing industrial waste treatment plant to treat pink water discharges from munitions manufacturing.

Compliance Schedule

1. Final design start	September 1977
2. Final design complete	February 1979
3. Construction award	May 1979
4. Construction complete	December 1980
5. Achieve compliance	March 1981

Remarks

None

Progress Reports

EPA, Region IV
345 Courtland Street, N.E.
Atlanta, Georgia 30308

D. Elmo Lunn, Director
Division of Water Quality Control
621 Cordell Hull Building
Nashville, Tennessee 37219

Attachment f

Facility NPDES Permit #

New Cumberland Army Depot Fairfield, PA PA0038385

Project Description

This project involves the upgrading of the existing sewage treatment plant to increase phosphate removal.

Compliance Schedule

1. Final design start	NA
2. Final design complete	June 1979
3. Construction award	August 1979
4. Construction complete	May 1980
5. Achieve compliance	July 1980

Remarks

None

Progress Reports

EPA, Region III
Curtis Building
6th & Walnut Streets
Philadelphia, Pennsylvania 19106

Department of Environmental Resources
William Middendorf, Director
P.O. Box 2063
Harrisburg, Pa. 17120

Attachment g

Facility	NPDES Permit #
Pine Bluff Arsenal Pine Bluff, AR	AR0034622

Project Description

This project involves the tie-in of drainage systems in 35 buildings to the existing waste treatment facility.

Compliance Schedule

1. Final design start	March 1979
2. Final design complete	July 1979
3. Construction award	September 1979
4. Construction complete	March 1980
5. Achieve compliance	April 1980

Remarks

Compliance schedule based on FY 79 funds being successfully reprogrammed.

Progress Reports

EPA, Region IV
First International Building
1201 Elm Street
Dallas, Texas 75270

Arkansas Department of Pollution Control
& Ecology
Jarrell E. Southall, Director
8001 National Drive
Little Rock, Arkansas 72209

Attachment h

Facility | NPDES Permit #

Radford Army Ammo Plant Montgomery Co., VA VA0000248

Project Description

This project will upgrade the existing industrial waste treatment facility to improve treatment of effluent from munitions manufacturing.

Compliance Schedule

1. Final design start	NA
2. Final design complete	March 1978
3. Construction award	June 1978
4. Construction complete	December 1980
5. Achieve compliance	January 1981

Remarks

None

Progress Reports

EPA, Region III
Curtis Building
6th & Walnut Streets.
Philadelphia, Penn. 19106

Virginia State Water Control Board
Robert Davis, Director
2111 No. Hamilton Street
Richmond, Va. 23230

Attachment 1

Facility	NPDES Permit #
Redstone Arsenal Redstone, AL	AL0000019

Project Description

This project will upgrade three existing sewage treatment plants and connect miscellaneous discharges to the sanitary sewer system.

Compliance Schedule

1. Final design start	NA
2. Final design complete	January 1980
3. Construction award	April 1980
4. Construction complete	November 1981
5. Achieve compliance	February 1982

Remarks

None

Progress Reports

EPA, Region IV
345 Courtland Street, N.E.
Atlanta, Georgia 30308

Alabama Water Improvement Commission
James W. Warr, Director
State Office Building
Montgomery, Alabama 36130

Attachment j

Facility | NPDES Permit

Seneca Army Depot Romulus, NY | NY0021296

Project Description

This project will upgrade two minor existing sewage treatment plants to meet an advanced waste water treatment requirement.

Compliance Schedule

1.	Final design start	February 1979
2.	Final design complete	February 1980
3.	Construction award	April 1980
4.	Construction complete	November 1981
5.	Achieve compliance	December 1981

Remarks

None

Progress Reports

EPA, Region II
26 Federal Plaza
Room 1009
New York, N.Y. 10007

Dept. of Environmental Conservation
Region VII
100 Elmwood Davis Road
No. Sysacuse, N.Y. 13212

federal register

Monday
July 28, 1980

Part VI

Environmental Protection Agency

Statement of Policy on the Labeling Requirements for Exported Pesticides, Devices, and Pesticide Active Ingredients and the Procedures for Exporting Unregistered Pesticides

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175, 176, 177, 178, 179, and 180

[FRL 1546-5]

Statement of Policy on the Labeling Requirements for Exported Pesticides, Devices, and Pesticide Active Ingredients and the Procedures for Exporting Unregistered Pesticides

AGENCY: Office of Enforcement, Environmental Protection Agency (EPA or the Agency).

ACTION: Notice of policy statement.

SUMMARY: The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or the Act) was amended by the Federal Pesticide Act of 1978 on September 30, 1978. Section 17(a) of the Act was modified so that pesticides, devices, and active ingredients used in producing pesticides which are manufactured for export must now bear certain minimal labeling, and the producers of such products are now subject to the requirements of both FIFRA sections 7 (establishment registration) and 8 (books and records). In addition, unless a pesticide is registered under section 3 is being sold under section 6(a)(1) it annot be lawfully exported unless, prior to export, (1) the foreign purchaser has signed a statement acknowledging that the purchaser understands that the pesticide is unregistered and therefore cannot be sold in the United States, and (2) a copy of that statement has been transmitted to EPA for transmittal to the appropriate officials of the importing country. This foreign purchaser acknowledgement statement must be acquired by the exporter and transmitted to EPA for the first shipment of each unregistered pesticide to a particular purchaser for each importing country, annually.

This notice informs the public of the scope of the new labeling requirements and of the procedures that an exporter of unregistered pesticides must follow to acquire acknowledgement statements which will be transmitted by the U.S. Government to the government of the importing country.

EFFECTIVE DATES: *Labeling.* Labeling requirements for exported pesticides, devices, and pesticide active ingredients became effective March 29, 1979, (Federal Pesticide Act of 1978, Pub. L. 95-396, 92 Stat. 833). Therefore, exported products which fall within the purview of this notice must now bear labels which comply with the statutory requirements of FIFRA section 17(a)(1).

Purchaser Acknowledgement Statements. After thirty days from the date of this notice, exporters of unregistered pesticides will be in violation of FIFRA if the foreign purchaser acknowledgement statements have not been acquired before shipment and transmitted to EPA in accordance with this policy.

FOR FURTHER INFORMATION CONTACT: John J. Neylan III, Office of Enforcement, Pesticides and Toxic Substances Enforcement Division (EN-342), EPA, 401 M Street, S.W., Washington, D.C. 20460 (202) 755-1212.

SUPPLEMENTARY INFORMATION: On Wednesday, July 18, 1979, EPA's Office of Enforcement published a proposed statement of policy on the labeling requirements for exported pesticides, devices, and pesticide active ingredients and the procedures for exporting unregistered pesticides, [44 FR 41955]. That proposed policy statement explained in some detail what information would be required to appear on the labels or labeling of pesticides, devices, or pesticide active ingredients destined for export in order to be considered in compliance with the law. It also described the procedures for acquiring from a foreign purchaser of unregistered pesticides a statement in which the purchaser acknowledges the registration status of the pesticide. Both of these requirements became effective 180 days after the date of enactment of the Federal Pesticide Act of 1978 (March 29, 1979).[1]

The July 18 notice invited the public to comment on the proposed policy before September 17, 1979. Twenty-three comments were received. Following is a summary of the major modifications to the policy statement made as a result of the comments.

(1) A more detailed explanation was included of which products will be considered as not registered for use in the United States, for purposes of this policy statement.

(2) The policy statement explains in greater detail what labeling is expected to appear on exported pesticides, devices, and pesticide active ingredients.

Appendix A contains summaries of the comments made to the July 18, 1979 policy statement and the Agency's response to them.

Accordingly, the Office of Enforcement's general statement of policy on the labeling requirements for exported pesticides, devices, and pesticide active ingredients and the procedures for exporting unregistered pesticide are set forth below.

Dated: July 10, 1980.

Jeffrey G. Miller,

Acting Assistant Administrator for Enforcement.

I. Summary of Policy

Pesticides, devices, and active ingredients used in producing pesticides which are manufactured for export must now bear labeling which will serve to both identify the product and the producer and to protect persons who come in contact with the product. Certain of the label items must be written in both the English language and in the language of the importing country. These bilingual labeling requirements apply to the product's ingredient statement and its warning and precautionary statements. Exporters of pesticides which are not registered for use in the United States (in accordance with this policy) must obtain a statement from the foreign purchaser of the pesticide in which the purchaser acknowledges the registration status of the product. The pesticide must also bear labeling to indicate that it is not registered in the United States. For purposes of this policy an unregistered pesticide is one which (1) contains an active ingredient not found in a federally registered product; or (2) bears labeling for a use which is currently subject to denial or cancellation of registration; or (3) is not similar in composition and use pattern to a federally registered product.

The acknowledgement statement must (1) identify the purchaser, the exporter, the product's identity and the product's destination; (2) be obtained for the first shipment of a particular pesticide to a particular purchaser for each importing country, annually; (3) be obtained *before* exportation takes place; and (4) be transmitted to EPA within seven (7) days of receipt by the exporter.

II. Labeling Requirements

Section 17(a) of FIFRA has been amended to provide as follows:

(a) Pesticides and Devices Intended for Export.—notwithstanding any other provision of this Act, no pesticide or device or active ingredient used in producing a pesticide intended solely for export to any foreign country shall be deemed in violation of this Act—

(1) when prepared or packaged according to the specifications or directions of the foreign purchaser, except that producers of such pesticides and devices and active ingredients used in producing pesticides shall be subject to sections 2(p), 2(q)(1)(A), (C), (D), (E), (G), and (H), 2(q)(2)(A), (B), (C)(i) and (iii), and (D), 7, and 8 of this Act;

[1] Pub. L. 95-396, 92 Stat. 819, September 30, 1978, Section 18(b).

Every exported pesticide, device, and active ingredient used in producing a pesticide must bear a label or labeling, in English or in the language of the importing country, which meets the requirements of FIFRA section 17(a)(1). In addition, certain information which will satisfy FIFRA sections 2(q)(1)(E), (G), and (H) and 2 (q)(2)(A) and (D) must also appear on the label or labeling so as to provide bilingual (in other words, in English and in the language of the importing country) information to anyone who handles or comes in contact with these products. Any language in which official government business is conducted in the country or which is the predominately spoken language of the country, is acceptable as the second language on the label.

Pursuant to Section 17(a)(1), all exported pesticides, devices, and active ingredients used in producing pesticides must bear labels or labeling which:

(a) bear EPA Establishment Numbers;

(b) have ingredient statements;

(c) have the name and address of the producer or registrant;

(d) have statements of net weight or measure;

(e) if highly toxic, bear skull and crossbones and statements of practical treatment in case of poisoning;

(f) include warning and caution statements;

(g) do not make false representations;

(h) are not in imitation of other products; and

(i) in the case of unregistered pesticides, bear the statement "Not Registered for Use in the United States of America." All such required statements must be conspicuous and readable.

To satisfy FIFRA section 2(q)(1)(E), the labeling provisions set forth below must appear in the English language and in the language of the importing country. This section specifies that required statements must be represented ". . . in such terms as to render it likely to be read and understood by the ordinary individual . . ." Therefore, the following information must appear bilingually on exported product labeling:

(a) the warning and caution statements;

(b) the ingredient statement;

(c) where required, the word "poison" and the statement of practical treatment; and

(d) the statement "Not Registered for Use in the United States of America."

The following may provide more specific guidance on particular elements which must appear on the label or labeling of each exported product:

a. *EPA Establishment Number.* The Establishment Number may appear anywhere on the label or immediate container in accordance with the establishment registration labeling requirements set forth in 40 CFR § 162.10(f).

b. *Precautionary Statements.* Warning or caution statements must be biligual and must be adequate for the protection of persons handling the pesticide, particularly with respect to general toxicological hazards and environmental, physical, or chemical hazards. Where the bilingual translation is obviously inappropriate to protect residents of the importing country, (for example, where a label calls for a gas mask meeting the specification of the U.S. Bureau of Mines) an equivalent caution may be substituted.

c. *Unregistered Products.* Labels of pesticides which are not registered under FIFRA (See *Products Subject to the Requirement for an Acknowledgement Statement* below) must prominently display the following statement: "Not Registered for Use in the United States of America." This statement must appear bilingually.

d. *Ingredient Statement.* The ingredient statement must appear bilingually unless the ingredients are easily identifiable despite their being listed in a foreign language.

e. *Use Classification Statement.* The statement of use classification (Restricted Use Pesticide or General Use Pesticide) must appear on the labeling of the pesticide; however, summary statements regarding the terms of the restriction, e.g., "For retail sale to and application only by Certified Applicators . . ." are not required.

f. *Identity of Parties.* Name and address of the producer, registrant, or person produced for must appear in the labeling.

g. *Net Weight.* The net weight must appear on the labeling in either conventional English units or metric units.

h. *Highly Toxic Pesticides.* If the pesticide is highly toxic, the skull and crossbones, the word "Poison", and a statement of practical treatment must appear on the labeling. The word "Poison" and the statement of practical treatment shall be bilingual. The skull and crossbones may be in red or black. For guidance on what pesticides are highly toxic, see 40 CFR § 162.10 (h).

The Agency is concerned that labeling required by FIFRA not conflict with labeling requirements of the importing country. Such a situation might arise, for example, where pesticides are being exported to a foreign country with strict labeling and registration laws such as this country has. To avoid such potential conflicts, yet still meet the statutory requirements of FIFRA, exporters may use supplemental labeling. Pesticides, devices, and active ingredients used in producing pesticides may, therefore, bear a label with the appropriate information required by FIFRA section 17(a)(1) or may be accompanied by supplemental labeling in instances where FIFRA required labeling is in contravention of foreign labeling requirements. Supplemental labeling may be attached to or accompany the product container or shipping container.

III. Foreign Purchaser Acknowledgment Statement

Section 17 of FIFRA has been further amended to provide as follows:

(a) Pesticides and Devices Intended for Export.—Notwithstanding any other provision of this Act, no pesticide or device or active ingredient used in producing a pesticide intended solely for export to any foreign country shall be deemed in violation of this Act—

(2) In the case of any pesticide other than a pesticide registered under section 3 or sold under section 6(a)(1) of this Act, if, prior to export, the foreign purchaser has signed a statement acknowledging that the purchaser understands that such pesticide is not registered for use in the United States and cannot be sold in the United States under the Act. A copy of that statement shall be transmitted to an appropriate official of the government of the importing country.

This notice also delineates what pesticide products are affected by this provision and procedures EPA believes would satisfy the purposes of section 17(a)(2).

IV. Products Subject to the Requirements for an Acknowledgment Statement

Many pesticides which are produced in the United States solely for export contain active ingredients that are also registered as components of pesticides used within the United States. However, the export formulations in many cases contain slightly different percentages of active ingredients and are labeled differently. Several factors dictate these minor modifications in formulation and labeling, such as different systems of measurement, pests to be controlled which are different from those for which the same or a similar pesticide product is used in the United States, and requirements for labeling in a language other than English.

The Agency believes that Congress did not intend the requirement for obtaining an acknowledgement statement which is applicable to "unregistered" pesticides to apply to products which are minor variations on formulations registered in the United States and which contain only active

ingredients w[illegible] United States [illegible] Agency's view that the export [illegible]ments were meant to apply in cases in which either (1) an adverse decision concerning the use of the pesticide in the United States has been made, or (2) no decision has been made concerning use of the pesticide. The requirement for obtaining an acknowledgement statement from a foreign purchaser will apply to pesticide products in which:

(a) The pesticide active ingredient has been judged to pose "unreasonable adverse effects" to man or the environment, and the registrations of products with that active ingredient have been cancelled or denied; or

(b) Either, (1) no assessment or no conclusive assessment of the hazard resulting from use of the pesticide has been made by EPA (while the pesticide may have been used under limited experimental or emergency conditions), (2) the pesticide has never been registered under section 3 because registration for the pesticide active ingredient has not been sought or has not yet been granted, or (3) the pesticide is being exported for a use which is substantially different from any currently registered use of that pesticide (e.g., a pesticide which is registered in this country for use as a termiticide is exported bearing directions for use on food crops).

Consequently, the Agency interprets section 17(a)(2) to apply to:

(a) All pesticide products which contain an active ingredient that is not found in a federally registered product;

(b) All pesticide products bearing labeling for a use which is currently subject to denial or cancellation of registration (section 17(a)(2) will also apply to uses not considered by the Administrator during a cancellation or denial determination); and

(c) All pesticide products which are not similar in composition and use pattern to a federally registered product.

To be considered similar in composition and use pattern, a pesticide product must contain only the same ingredient or combination of active ingredients and must have the same category of toxicity as a federally registered product. Also, the use pattern must be similar to the use pattern of the federally registered pesticide to which it is being compared. Registrations involving changes in use patterns such as changes from non-food to food use, outdoor to indoor use, terrestrial to aquatic use, or non-domestic to domestic use, are not considered to qualify as similar use patterns. Pesticide uses which were never reviewed during a cancellation or denial of registration determination (such as a pesticide use in a crop which is not grown in the United States) also do not qualify as a similar use.

Pesticide products which are subject to the requirements of section 17(a)(2) must also bear the label statement, "Not Registered for Use in the United States of America" stipulated by section 2(g)(1)(H) of this Act.

A pesticide product which has been registered under Section 24(c) of FIFRA will be considered as registered for purposes of this policy. A pesticide product which may be legally used only under an experimental use permit (Section 5) or an emergency exemption (Section 18) will not be considered as federally registered. Nor will a pesticide product whose distribution and use are legal in intrastate commerce because the producer has filed an application for federal registration in accordance with the procedures found in 40 CFR § 162.17. Technical grade and manufacturing use pesticides which are not federally registered will be considered as registered for purposes of this policy, if they qualify as being similar in composition to a registered formulation use pesticide, (i.e., if the products have the same active ingredients and category of acute toxicity).

V. Procedures

Section 17(a)(2) requires that before a pesticide which is not registered for use in the United States can be exported, the foreign purchaser of the pesticide must acknowledge in writing that he understands the registration status of the pesticide and that the pesticide cannot be sold in the United States. An exporter of unregistered pesticides must have received the required acknowledgement statement *before* the product is released for shipment. The Agency feels that requiring exporters to have in hand the purchaser acknowledgement statement before exportation takes place is the only way to assure that foreign purchasers comply with these new FIFRA export requirements. The Agency recognizes that this requirement may cause some disruption in the export of pesticides. However, any such delays will be visited only upon exporters of unregistered pesticides, and then only for the *first* shipment to a foreign purchaser, in a particular country, annually. The information required on the acknowledgement statement, along with a certification signed by the exporter, must be transmitted to the Environmental Protection Agency within seven days of receipt by the exporter, or by the date of export, whichever occurs first. The certification must state that the shipment did not take place before the exporter had the signed acknowledgement statement in hand.

The Agency will consider the receipt of purchaser acknowledgement statements by local company representatives in foreign countries to be receipt by the exporter. Nevertheless, the information required by the acknowledgement statement must still be transmitted to EPA within seven days of receipt, or by the date of export, whichever occurs first. Acknowledgement statements may be acquired at any time in advance of shipment. For example, an exporter that ships to the same foreign purchasers year after year may acquire at the beginning of a year all of the acknowledgement statements which are anticipated to be needed.

The Agency will transmit the acknowledgement statements to appropriate foreign officials through the Department of State. Statements will be transmitted promptly after receipt.

The Agency believes that the purpose of the purchaser acknowledgement statement is to advise foreign governments that pesticides which have been judged by the United States to be hazardous to human health or the environment, or pesticides for which no hazard assessment has been made, are being exported by U.S. producers to their country. Foreign governments may then use such information as they desire, perhaps, for example, in evaluating the risk of continued use of the pesticide in that country versus the benefits that pesticide provides. The Agency does not consider that the acknowledgement statement is primarily intended to serve as preshipment notification to foreign governments in order that they may intercept shipments of such pesticides. Nevertheless, because of the Agency's concern that acknowledgement statements reach foreign governments in a timely manner, the information contained in the acknowledgement statement will be forwarded to foreign governments promptly upon receipt by EPA.

As an information mechanism, the purchaser acknowledgement statement serves the purpose of alerting the foreign government that a certain pesticide is entering its country. The Agency believes that the first notice fulfills this purpose; repetitive notices would be of only marginal value, and in cases of a high volume of exports to a foreign country, might result in a flood of paper. After considering the administrative burdens placed on exporters, EPA, and foreign governments and the value of repetitive notices, the Agency has concluded that each exporter should

complete and have signed a purchaser acknowledgement statement, for the first shipment of a particular product to a particular purchaser for each importing country, annually. A shipment of the same product to a different purchaser or to the same purchaser for disposition to a different importing country would also trigger the requirement for obtaining a signed acknowledgement statement from the foreign purchaser. A second shipment, during the same calendar year, involving the same product, purchaser, and importing country would not trigger this requirement. Any change in the variables—different purchaser, different product, different importing country—will result in the need for obtaining a new purchaser acknowledgement statement.

In summary, the procedures that an exporter of unregistered pesticides must follow in obtaining and transmitting foreign purchaser acknowledgement statements are:

(a) The exporter must provide the foreign purchaser with instructions about the required information on an acknowledgement statement and inform the foreign purchaser that shipment of the pesticide cannot be undertaken unless the exporter has received from the foreign purchaser a properly completed, signed, and dated acknowledgement statement;

(b) The exporter must secure, prior to shipment, an acknowledgement statement which contains the information outlined in the *Required Information* section of this notice. Such a statement must be secured for the first purchase each year of a particular pesticide product by a foreign purchaser destined for a particular country;

(c) The exporter must forward the information required on the acknowledgement statement, along with the certification that exportation did not take place until a signed acknowledgement statement was received, within seven (7) days of receipt, or by the date of exportation, whichever occurs first, to the following address: Environmental Protection Agency, Pesticides and Toxic Substances, Enforcement Division (EN-342), 401 M Street SW., Washington, D.C. 20460.

Attention: Export Acknowledgement Statement.

VI. Required Information

As previously stated, a foreign purchaser of a pesticide which is not registered for use in the United States must sign a statement acknowledging his understanding that the product is unregistered and cannot be sold in this country. The Agency does not intend to prescribe a format for this acknowledgement statement. However, the statement must include the following information:

(a) Name and address of the exporter;

(b) Name and address of the foreign purchaser;

(c) Name of the product and the active ingredient and an indication that the purchaser understands that the product is not registered for use in the United States;

(d) Destination of the export shipment, if different than purchaser's address;

(e) Signature of the foreign purchaser; and

(f) Date of the foreign purchaser's signature.

VII. Confidentiality

Persons submitting the information specified in Part VI may assert a claim of business confidentiality by marking this information as "FIFRA Confidential Business Information." Information so marked will not be disclosed, with the exception of disclosure to the foreign government, except in accordance with the procedures set forth in 40 CFR Part 2, 7 USC 136h, and this policy statement. If such claim is not asserted, EPA may disclose the information to the public without providing notice of disclosure or an opportunity to object. Notwithstanding any claim of confidentiality, the acknowledgement statement will be forwarded to the appropriate foreign government in its entirety as required by section 17.

VIII. Relationship to Other Statutory Requirements

Producers of pesticides, devices, and active ingredients used in producing pesticides which are intended for export are subject to the establishment registration procedures, including the report requirements, as well as the record keeping requirements of FIFRA. The Agency has proposed amendments to the regulations which are promulgated under the authority of those parts of the Act (sections 7 and 8) to bring them into conformity with the newly amended FIFRA. These regulations are found at 40 CFR Part 167 and Part 169, respectively.

Pesticides, devices, and pesticide active ingredients for export are not considered to be in violation of FIFRA when produced according to the directions of the foreign purchaser, when properly labeled and, in the case of unregistered pesticides, when the foreign purchaser has signed a statement in which he acknowledges that he understands the registration status of the pesticide and the exporter has forwarded the statement to EPA. Exported pesticides, devices, and active ingredients used in producing pesticides which do not bear labels or labeling in compliance with FIFRA section 17(a)(1) will be considered to be misbranded. Exporters of such products will be subject to civil or criminal liabilities for violation of FIFRA sections 12(a)(1) (D) or (E)—misbranding. Exporters of unregistered pesticides will be subject to civil or criminal liabilities for violation of FIFRA section 12(a)(1)(A)—selling or distributing a pesticide which is not registered—if they fail to secure, prior to export, a properly completed, signed, and dated acknowledgement statement from the foreign purchaser of the pesticide. Falsification of the required certification may subject an exporter to sanctions under 18 U.S.C. 1001.

Appendix A.—Significant Comments and Responses

General Comments

Comment No. 1. Applicability of Rulemaking Procedures. Two commenters stated that the Agency should have implemented the export provisions of FIFRA through the procedures established by the Administrative Procedures Act for the promulgation of "substantive" rules. The Agency disagrees. As mentioned previously, these requirements for export labeling and purchaser acknowledgement statements were statutorily effective March 29, 1979, 180 days from enactment of the Federal Pesticide Act of 1978. The law lists the type of information required on an exported pesticide's labeling and the legislative history makes it clear that purchaser acknowledgement statements are to be transferred to foreign governments in the same manner that cancellation notices are furnished. The Agency's position, therefore, is that there is no need for rulemaking but rather there is a need for a general statement of policy on such matters as: (a) what would constitute minimally acceptable labeling, (b) how such labeling could be attached or accompany shipments, and (c) how foreign purchaser acknowledgement statements are to be transmitted to foreign governments.

Comment No. 2. Use of Suspended and Cancelled Pesticides List. Another commenter suggested that foreign countries can be adequately informed of the hazards of U.S. manufactured pesticides through an expansion of the Suspended and Cancelled Pesticides List. This is not the intended function of the Suspended and Cancelled Pesticides List. That list constitutes only a guide

for Government officials; it is not the final authority on the status of a given pesticide. It is the intent of Congress that the procedures that are followed for notifying foreign governments of the suspension or cancellation of pesticides be those which are also used to inform them that an unregistered pesticide will be entering their country. Therefore, the channel of communication described in this policy is derived from the procedures already used to notify foreign governments of major suspension or cancellation actions.

Comment No. 3. Scope of the FIFRA Section 17 Requirements. A number of commenters addressed the definition contained in this policy statement of an unregistered pesticide. The Agency agrees that clarification on this point is necessary. It is not EPA's intent to limit export of a chemical if it is properly labeled and the exporter complies with the procedures for obtaining and transmitting to EPA a properly executed acknowledgement statement. A more detailed explanation of which products will be regarded as unregistered for the purposes of this policy has been given. One commenter objected to including products with denied or cancelled uses and products with different composition or use patterns with products which contained no registered active ingredient. In drafting this policy statement, EPA adopted a broad interpretation of the registration status of a pesticide.

The Agency could have required exporters of all pesticide products that were not registered under section 3 to acquire an acknowledgement statement from the foreign purchaser. The effect of this would be that an acknowledgement statement would have been required for the overwhelming majority of exported pesticides since most exports differ slightly in formulation or directions for use from the U.S. registered product, or the labels are written in a foreign language. The EPA clearly stated in the proposed policy statement that in its view Congress did not intend that exported products with minor variations from EPA registered pesticides be subject to the export notification procedures. However, products with cancelled uses or with substantial differences in composition or use patterns cannot be considered products with minor variations. The Agency must, therefore, reject this comment.

Comment No. 4. Status of Certain Unregistered Pesticides. One commenter suggested that experimental use products be treated as registered products; another commenter thought that products with temporary tolerances should be considered as if they were registered. Since registration data for such products are not complete, it has consistently been Agency policy to treat experimental use products and products with temporary tolerances as unregistered products. Products which bear registrations under section 24(c) of FIFRA will, however, be treated as registered products. Products undergoing Rebuttable Presumption Against Registration will be considered in accordance with their registration status at the time of export. It was suggested by one commenter that those pesticides which were registered by a foreign country should not be subject to the requirement for an acknowledgement statement. In order to adequately enforce a policy which took this approach, the EPA would have to evaluate the internal registration procedures conducted by other countries and to regulate exports based upon the policies of the *importing* country. Thus, EPA policy would be different for similar shipments going to different countries. The Agency rejects this comment. Not only would it be administratively difficult to operate such an export program, but such a policy fails to recognize the point of having the acknowledgement statement: To inform foreign governments of the U.S. registration status of a pesticide.

Comment No. 5. Non-Commercial Exportation. Another commenter requested clarification on the application of the notice provision to pesticides which are exported without a commercial transaction. There are two possible categories of products to which this comment might apply: the first would be small amounts of pesticide exported for research purposes only; the second would be large shipments exported to a foreign establishment of the domestic company which manufactures it. Research quantities are subject to the labeling rules of this policy but not to the acknowledgement statement requirement. Large shipments transferred from a domestic facility to a foreign facility of the same company will be treated in accordance with their U.S. registration status. That is, if the product is registered (in accordance with the use of that term in this policy), no acknowledgement statement is required; if the product is not registered, an acknowledgement statement will be required.

Comment No. 6. Technical and Multiple Use Chemicals. Some commenters asked for clarification of the impact of this policy upon formulated and technical grade products and multi-use products. Formulated and technical grade products which are subject to FIFRA are subject to this policy. The label on the exported product must comply with section 17 of FIFRA. A multi-use product for which no pesticide claims are made and which is not an active ingredient in any pesticide product in the United States is not subject to this policy, even if it is subsequently processed into a pesticide in another country.

Labeling Comments

Comment No. 7. Use of Bilingual Labeling. A number of commenters stated that the law did not require bilingual labeling. The law states that an exported pesticides, device, or pesticide active ingredient must bear labeling in conformance with FIFRA section 2(q)(1)(E). The FIFRA states in section 2(q)(1)(E) that a pesticide is misbranded if:

> Any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon . . . in such terms as to render it *likely to be read and understood by the ordinary individual* under customary conditions of purchase and use; (Emphasis added.)

The EPA interprets this passage to apply to ordinary individuals in the importing country as well as in the United States. Thus, the bilingual requirements are meant to communicate some basic information about the product to as many handlers of the pesticide as possible. International symbols, suggested by one commenter, could not adequately communicate all the required label elements, although they may be used in addition to the required wording. Commenters asked for guidance regarding EPA's enforcement of the bilingual requirement in two specific instances: when the importing country has several official dialects, or when English is an official government language. Any language in which official government business is commonly conducted in the country, or which is the predominately spoken language of the country, is acceptable as the second language on the label. If English is one of these languages, then a bilingual label is optional, except as may be required by the importing country. One commenter asked if a translation of the U.S. label would be satisfactory. Such a label would be acceptable if the necessary elements appeared both in English and in the foreign language.

Comment No. 8. Foreign Labeling Requirements. Several commenters asked about the application of this policy to labels which comply with the laws of the importing country. It is not

the intention of this policy to supersede the labeling requirements of foreign governments. However, FIFRA now requires that exported pesticides, devices, and pesticide active ingredients bear certain minimal labeling. If the labeling which currently appears on exported pesticides does not meet the minimum FIFRA requirements, even though it may meet the foreign country's requirements, additional labeling must be added to satisfy U.S. law.

Comment No. 9. Supplemental Labeling. Several commenters suggested that supplemental labeling be liberally allowed. The Agency intends to be as flexible as possible in this respect. Exporters will be permitted to use a variety of types of labeling to comply with the FIFRA export requirements. The Agency's principal interest will be to ascertain that products to which this policy applies bear labels or labeling which, taken together, conform to the FIFRA section 17(a)(1) requirements.

Comment No. 10. Establishment Numbers. One commenter requested the option of substituting another code for the EPA Establishment Number on the label. The Act clearly requires that an Establishment Number appear on the label. The Agency must reject this suggestion since permitting other means of identifying the production establishment would negate the usefulness of such numbers.

Comment No. 11. Restricted Use Pesticides. Several commenters requested guidance on label requirements for exported restricted use pesticides. If the product is a restricted use pesticide, then the statement "Restricted Use Pesticide" must appear on the label or labeling. The supplementary statement of the terms and conditions of restriction is not required.

Acknowledgment Statement

Comment No. 12. Prior Possession of Acknowledgement Statements. A number of commenters questioned the requirement that the acknowledgement statements be in the exporter's possession before shipment of the pesticide can take place. Other commenters stated that in their opinion foreign importers, through oversight or bureaucratic inefficiency, will not comply with the acknowledgement statement requirement. In the proposed policy statement, the Agency clearly recognized the problem of non-compliance by foreign importers. For this precise reason, EPA must reject the contention that acknowledgement statements should not be required to be in the exporter's control *before* shipment can take place. A more liberal interpretation of what constitutes receipt of the acknowledgement statements has been provided in the final policy statement to facilitate compliance. One commenter suggested that a signed acknowledgement in the hands of a local company representative be considered a receipt by the exporter. The Agency agrees that this would be acceptable so long as the information required on the acknowledgement statement is sent to EPA within the stated time period. If a company anticipates several orders in a year, the acknowledgement statements may be obtained in advance of the actual order. One commenter stated that the requirement that acknowledgement statements be sent to EPA within seven days of receipt by the exporter was too restrictive. This commenter suggested that transmittal of the acknowledgement statement should be tied to the date of shipment. The Agency disagrees. Where possible, acknowledgement statements will be sent to foreign governments as far in advance of shipment as possible. This will provide the government some time to review the information received. The Agency feels more timely notification will occur if transmittal of the acknowledgement statement is tied to date of receipt.

Comment No. 13. Certifications. Some commenters objected to filing, along with the acknowledgement statement, a certification that the order was not shipped before the acknowledgement statement was received. The Agency believes that a certification statement is necessary. While some monitoring of compliance will be through inspection of required books and records, a certification requirement will serve to remind exporters that shipment must wait until the acknowledgement statement has been received.

Comment No. 14. Destination of Shipment. One commenter suggested that there was no need to include in the acknowledgement statement the destination of the export shipment, if different than the purchaser's address. This comment is rejected because without this information the Agency would be unable to determine if the labeling complied with the bilingual requirements nor would it know the proper place to send the acknowledgement statement.

Comment No. 15. Annual Reporting. Several commenters stated that the requirement that a new acknowledgement statement be acquired each year that a particular product is exported is overly burdensome. They point out that the law requires an acknowledgement statement only once per country, not once per country, per year. The Agency must reject this comment. Although FIFRA is not clear on this point, the law seems to indicate that an acknowledgement statement should be acquired for each export shipment of an unregistered pesticide. It is the Agency's position that imposing such a requirement would be a burden for all parties concerned—exporters, importers, and the U.S. Government, as well as foreign governments—beyond any regulatory purpose it may serve. The requirement to send an acknowledgement statement once per year, which is similar to that being considered under the Toxic Substances Control Act, is not overly burdensome, and yet accomplishes the purpose of regular notification to foreign governments.

Comment No. 16. Notification of Foreign Governments. Several commenters questioned the procedure for notifying foreign governments. It was suggested that either the foreign purchaser or the exporter should directly notify the foreign government. The EPA rejects this proposal. First, it would be difficult, if not impossible, for the Agency to monitor compliance under such a procedure. Second, as previously explained, the procedure for transmitting acknowledgement statements parallels that of the notification of foreign governments of suspended or cancelled registrations. It is the understanding of the Agency that such a procedure, namely government-to-government contact, was the intent of Congress.

Comment No. 17. Problems with Importing Countries. Two commenters suggested that the policy be different for socialist or communist countries. These commenters cited their experience exporting pesticides to these countries where the "importer" is an agency of the government. These import agencies are said by the commenters to be staffed by very conservative bureaucrats who are reluctant to sign unusual requests. As has been discussed earlier, it is not the intent of this Agency to write a different export policy for different countries. However, should numerous problems arise with any particular country, the Agency will work with industry and the Department of State to solve them.

[FR Doc. 80-22055 Filed 7-25-80; 8:45 am]

BILLING CODE 6560-01-M

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

JUL 30 1980

OFFICE OF ENFORCEMENT

MEMORANDUM

SUBJECT: Request Procedures for Pesticide Samples and Followup on Pesticide Complaints

FROM: John S. Seitz, Chief
Compliance Monitoring Branch

TO: PTSED Staff

Recent confusion regarding requests for pesticide samples or investigations has resulted in a need to formalize procedures for making such requests. This memorandum and attachments describe the new procedures.

Situations which are referred to the regions can be divided into three major categories: 1) pesticide sample or label required, 2) complaint followup required, and 3) requests for large numbers of any type of sample or investigation. Attachment 1 outlines subcategories and appropriate responses for each.

1. Pesticide Sample or Label Required

Initiator of the request should complete EPA Form 8500-1 "Special Request for Sample" (attachment 2) according to directions in attachment 3. This form should be given to the Chief, Compliance Monitoring Branch. The request will be reviewed, authorized, and transmitted to the region by the compliance monitoring coordinator for that region.

2. Complaint Followup Required

Initiator should write down all pertinent information including who made the complaint, when and where he/she can be reached, complete description of the problem, and any memos, labels, advertising, references, etc. that are pertinent. This information (which can be handwritten if it's readable) should be given to the Chief, Compliance Monitoring Branch. The compliance monitoring coordinator will forward the information to the region.

3. Large Numbers of Samples or Investigations

Initiator should provide all pertinent information to the Chief, Compliance Monitoring Branch. Mike Wood will act as coordinator for all large requests. Mr. Conroy will authorize the forwarding of these requests to the regions.

Attachment I

PROCEDURES
PESTICIDE SAMPLE REQUESTS AND REFERRALS

SITUATION	PAPER WORK	APPROVING OFFICIAL	SENT TO
. Pesticide Sample Required			
. Physical sample required for chemical or efficacy testing	Sample request form (8500-1) -need registration number -check ERSS for establishment address and recent production -health hazards are "urgent"	CMB STAFF	Regional contact*
Documentary sample required: label, pamphlets or advertising to be reviewed	Sample request form as above except note: Documentary sample per manual	CMB STAFF	Regional contact
[redacted]plaint: [redacted]egistered product, mis-branding, claims differ	Sample request form, documentary sample (see above)	CMB STAFF	Regional contact
Complaint Followup Required			
Marketplace investigation: suspended/cancelled, health hazard	Buck slip forwarding information for investigation; phone call to notify	Chief, CMB	Pesticides Branch Chief Regional contact
Complaint: advertising followup	Buckslip or memo forwarding complaint: please investigate and document as necessary	CMB STAFF	Regional contact
Incident report: [redacted]soning, ill-[redacted]s, crop damage, [redacted]isuse	Memo forwarding information, and/or phone call, depending on severity or public interest	AS NECESSARY	AS NECESSARY

SITUATION	PAPER WORK	APPROVING OFFICIAL	SENT TO
3. Large Numbers of Samples or Investigations Required			
a. Large number of samples required	Contact Mike Wood (472-3701) for instructions	Director, PTSED	Enforcement Division Director Pesticide Branch Chief
b. Large numbers of investigations/ inspections required	Contact Mike Wood (472-3701) for instructions	Director, PTSED	Enforcement Division Director Pesticide Branch Chief
c. Multi-region request for samples, inspections	Contact Mike Wood (472-3701) for instructions	Director, PTSED	Enforcement Division Director Pesticide Branch Chief

*REGIONAL CONTACTS

REGION	CONTACT	PESTICIDES BRANCH CHIEF
REGION I	C. Lincoln	C. Lincoln
REGION II	S. Fenichel	S. Fenichel
REGION III	J. Smith	N. Davis
REGION IV	R. Clark	R. Clark
REGION V	G. Marsh	M. Wrich
REGION VI	A. Anderson	N. Dyer
REGION VII	J. Wicklund	J. Wicklund
REGION VIII	B. Harding	L. Johnson
REGION IX	R. Mandel	R. M. Stenburg
REGION X	D. Donaldson	R. Poss

FOLLOWUP

Originals of sample request form and copies of referrals will be kept in a regional pesticide sample/referral file.

When a sample is picked up, the region will return the acknowledgement copy to the originator. This will contain ID number and date of inspection. This copy will be filed with original.

If a physical sample is analyzed by a laboratory, one copy of the results of analysis form should be sent to the originator of the sample request. This will be filed with sample request copy.

PEMS followup should be made periodically to determine status of sample.

Phone calls to regional contact should be made when PEMS followup is not possible or should no action.

Attachment 3

Directions For Completing Form 8500-1 Special Request For Sample

lock 1: DATE OF REQUEST

lock 2: From: Compliance Monitoring Branch
Pesticides & Toxic Substances
Enforcement Division EN-342
Washington, D.C.

lock 3: NAME OF ECONOMIC POISON

lock 4: NAME AND MAILING ADDRESS OF REGISTRANT
This name and address should be the site at which the pesticide is actually manufactured, formulated or distributed. It should include a street address which the inspector can use to locate the company and the establishment number if available. Please check with Carol Buckingham, Establishment Registration Support System coordinator (755-2047), to make sure of the address, establishment number, and to verify that the product was actually produced recently at that site. This is to save state and regional inspectors unnecessary trips to sites that do not produce the pesticide requested.

lc LAB TO RECEIVE SAMPLE
If a physical sample is requested for chemical or efficacy testing, a laboratory address should be specified. This laboratory may be a state pesticide lab, NEIC, Beltsville or a contractor.

.ock 6: SPECIFIC SAMPLE SIZE REQUESTED
Unless there is a specific reason for a large sample, "MINIMUM" should be specified in this block. If documentary samples are requested, this block should read "DOCUMENTARY."

.ock 7: DATE SAMPLE REQUIRED
Samples needed in less than 60 days should be marked "URGENT" and justification given in Block 9. All others will be collected when the region or state can reasonably collect them. In this case, this block should remain blank.

.ock 8: REGISTRATION NUMBER
This number should be obtained from label, fiche or Registration Division.

.ock 9: REASON FOR COLLECTION
This block should contain all relevant information which resulted in the request for collection of a sample. The phrases "complaint", "unregistered product" "misleading advertising" are not adequate. Reference to letters or memos should be included as needed. This block should also contain the name, organization and phone number of the requestor in case questions or problems arise.

Block 10-15: Should remain blank. The region or state will complete these block:

Block 16: SIGNATURE OF APPROVING OFFICIAL
This block will be completed by the Compliance Monitoring Branch regional liaison, Branch Chief or the PTSED Director, as appropria

* U. S. GOVERNMENT PRINTING OFFICE: 1972—722—709

ATTACHMENT 2.

SPECIAL REQUEST FOR SAMPLE	NOTE: Use a separate form for each product request.	DATE OF REQUEST: 1

TO:
Director, Pesticide Enforcement Division
Environmental Protection Agency
Washington, D.C. 20250
Attn: National Sampling and Recall Section

FROM: 2

NAME OF ECONOMIC POISON *(Must be same product as on label - do not list active ingredients)*: 3

NAME AND MAILING ADDRESS OF REGISTRANT *(Include ZIP code)*: 4

LAB TO RECEIVE SAMPLE: 5

SPECIFIC SAMPLE SIZE DESIRED *(Specify minimum coverage if size unknown)*	DATE SAMPLE REQUIRED *(Minimum of 60 days from request unless specified, urgent)*	REGISTRATION NO.
6	7	8

REASON FOR COLLECTION: 9

SAMPLE IDENTIFICATION

PREVIOUS		NEW	
NAME OF INSPECTOR: 10	ID NO.: 11	Any correspondence should refer to the Registration No. above and the ID No. below.	
LOCATION OF COLLECTION: 12		ID NO.: 13	DATE: 14
SIGNATURE OF APPROVING OFFICIAL: 15	DATE	NAME OF INSPECTOR	

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 raw water 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, without 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-PTSED 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-PTSED 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. into 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.

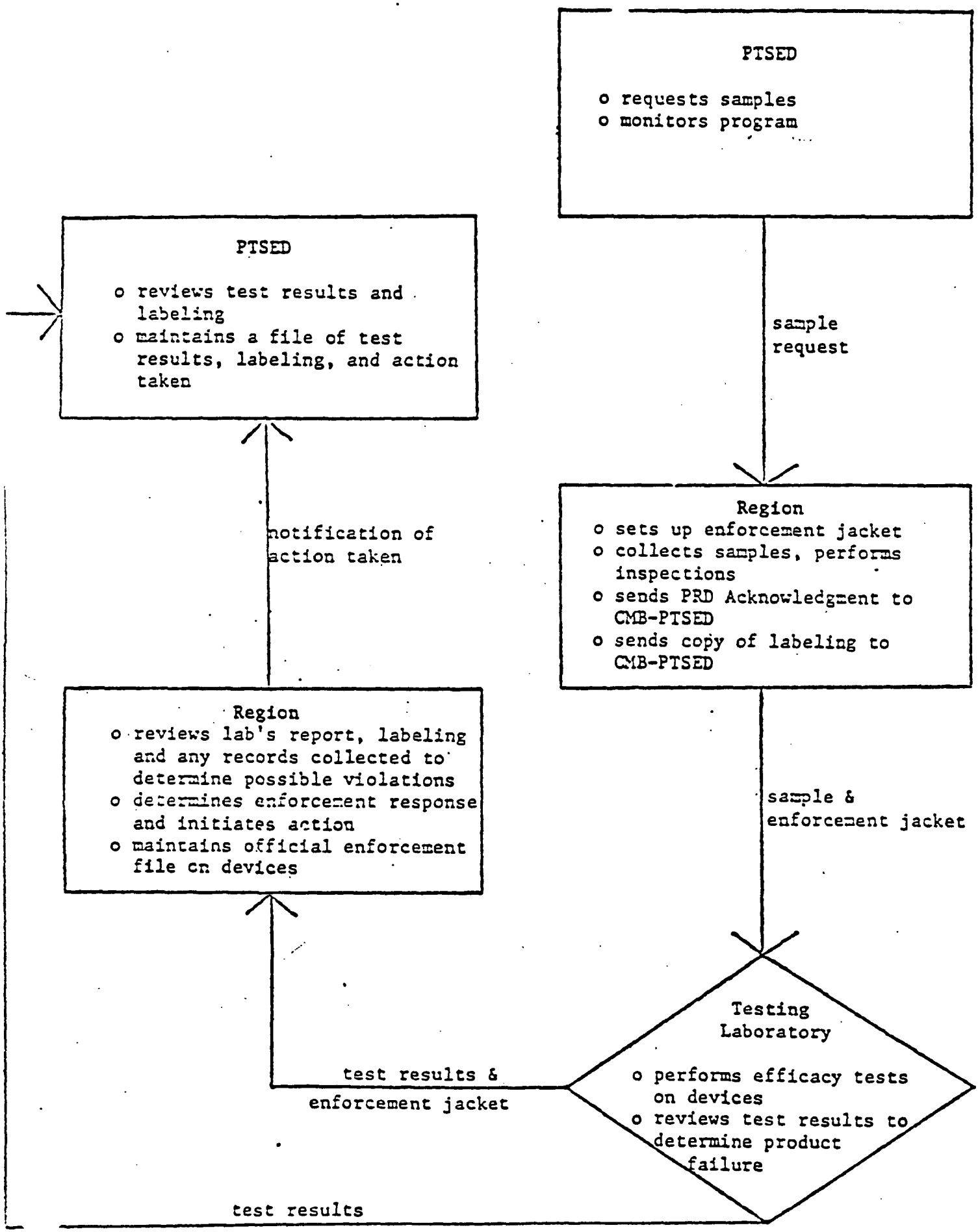
A press release has also been prepared announcing the program to the public and notifying industry of the establishment registration requirements (Appendix III-A)

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 will proceed in accordance with the Case Proceedings Manual. The Regions are advised to avail themselves 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.	
3. 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; send a 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	10. Publicity
• Start of Program - Press Release - Letters to manufacturers and trade associations.	• Release of information about individual cases in the same manner as other pesticide ca cases.
• 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.	

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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 regulated 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-186 (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).

A-1. Excerpts from FTC v. 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-1966C
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

---

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)).

[FRL 646-5]

PEST CONTRAL DEVICES AND DEVICE PRODUCERS

Consolidation and Clarification of Requirements

I. Purpose

Requirements applicable to pest control devices and device producers have been set forth in various regulations promulgated pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (86 Stat. 973; 89 Stat. 751; 7 U.S.C. 136 et seq.) ("FIFRA" or "the Act"). The purpose of this notice is to provide a consolidation and clarification of all such requirements.

II. Definitions

At section 2(h) of FIFRA (7 U.S.C. 136 (h)) the term "device" is defined to mean:

> • • • any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides when sold separtely therefrom.

To more clearly identify the types of products to which the requirements discussed in this Notice apply, the term "device" must be contrasted with the term "pesticide," which is defined at section 2(u) of FIFRA to mean:

> • • • any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and any substance or mixture of substances intended for use as plant regulator, defoliant, or desiccant.

Thus, if an article uses physical or mechanical means to trap, destroy, repeal, or mitigate any plant or animal life declared to be a pest at 40 CFR 162.14, it is considered to be a device. If the article incorporates a substance or mixture of substances intended to prevent, destroy, repeal, or mitigate any pest, it is considered to be a pesticide.

III. Devices Subject to the Act

Section 25(c)(4) of FIFRA (7 U.S.C. 136w(c)(4)) provides that the Administrator may specify those classes of devices which shall be subject to any provision of paragraph 2(q)(1) (7 U.S.C. 136(q)(1)) or section 7 (7 U.S.C. 136e) of this Act upon his determination that application of such provision is necessary to effectuate the purposes of this Act. On July 3, 1975, the Administrator promulgated regulations (40 F.R. 28242) amending 40 CFR Part 162 pursuant to this authority. 40 CFR 162.15 now provides that devices as defined in FIFRA section 2(h) are subject to the requirements of FIFRA section 2(q)(1)(A)–(G) and to those provisions of FIFRA section 7 which are necessary to effectuate the purposes of FIFRA with respect to devices.

The preamble to these regulations at 40 F.R. 28266 declared that to effectuate the purposes of the Act, devices subject to sections 2(q)(1) and 7 include but are not limited to:

> (A) Certain ultraviolet light systems, ozone generators, water filters and air filters (except those containing substances or mixtures of substances which are pesticides), and ultrasonic devices, for which claims are made to kill, inactivate, entrap, or suppress the growth of fungi, bacteria, or viruses in various sites; (B) certain high frequency sound generators, carbide cannons, foils, and rotating devices, for which claims are made to repel birds; (C) black light traps, fly traps, electronic and heat screens, fly ribbons, and fly paper, for which claims are made to kill or entrap certain insects; and (D) mole thumpers, sound repellents, foils and rotating devices, for which claims are made to repel certain mammals.

The preamble further specifies those instruments declared to be of a character unnecessary to be subject to this Act in order to carry out the purposes of the Act. These include:

> (1) Those which depend for their effectiveness more upon the performance of the person using the device than on the performance of the device itself, and
>
> (2) Those which operate to entrap vertebrate animals.
>
> Products generally falling within these two categories include rat and mouse traps, fly swatters, tillage equipment for weed control and fish traps.

Section 8 of FIFRA (7 U.S.C. 136f) provides for such record-keeping and record inspection requirements as the Administrator determines necessary for effective enforcement of the Act. Section 17 specifies the requirements to be placed on the import and export of devices. In neither of these sections is there a provision that the Administrator declare those classes of devices subject to these sections of the Act; and in the attendant regulations, no specification is made. For purposes of enforcement, the Agency will consider those classes of devices declared to be subject to regulation under section 25(c)(4) of the Act as subject to regulation under sections 8 and 17 as well.

IV. Summary of FIFRA Provisions Applicable to Devices

Any instrument declared to be a device under 40 CFR 162.15 is, upon introduction into channels of trade, subject to the provisions discussed below. Those provisions of the amended FIFRA which pertain to devices are in many respects similar to those under the 1947 FIFRA (61 Stat. 163; 7 U.S.C. 135–135k). In both Acts the Agency is authorized to inspect records showing the delivery, movement, or holding of devices (7 U.S.C. 135c, 136f); to obtain samples of any device in the marketplace (7 U.S.C. 135d, 136g); to seize any misbranded device (7 U.S.C. 135g, 136k); to initiate criminal proceedings against any person violating any provision of the Act (7 U.S.C. 135f, 135l); and, in cooperation with the Secretary of the Treasury, to sample, examine, and detain any imported device which violates the provisions of the Act (7 U.S.C. 135h, 136o).

The differences in the provisions of the two Acts with respect to requirements applicable to devices, lie primarily in the greater specification of jurisdiction and regulatory requirements provided by the 1972 amendments. For example, while a device, unlike a pesticide, is not subject to the section 3 registration requirement of FIFRA, section 12 of the Act makes clear the intent of the Act that subject devices and persons dealing with devices be held responsible for those obligations, other than registration, that are imposed by the Act. Jurisdiction to regulate devices is expanded to intra- as well as interstate commerce (7 U.S.C. 136j(a)(1)). Similarly, section 9(a) of the amended FIFRA specifies that entry for the purpose of inspecting and obtaining samples of devices "packaged, labeled, and released for shipment is permitted into "any establishment or other place where • • • devices are held for distribution or sale (7 U.S.C. 136g(a)).

With respect to affirmative regulatory requirements, section 2(q)(1) of the amended FIFRA expands the definition of misbranding as it applies to devices subject to the Act (7 U.S.C. 136(q)(1)). Section 7 of the amended FIFRA is totally new, requiring the registration of establishments which produce devices declared subject to the Act (7 U.S.C. 136e). In addition to the provisions of the Act allowing the inspection of records kept by producers and distributors of devices, section 8(a) of the amended FIFRA requires producers of devices subject to the Act to maintain such books and records as the Administrator requires by regulation (7 U.S.C. 136f(a)). Finally, section 17(a) of FIFRA, as amended, specifically imposes the same recordkeeping requirements on producers of devices intended for export by making such producers subject to the requirements of section 8.

ABORATION OF SPECIFIC REQUIREMENTS APPLICABLE TO DEVICES

ection 2(q)(1), *Misbranding Pro-* (7 *U.S.C. 136(q)(1)*). With pro- on of the regulations at 40 CFR invoked the authority of 4) to specify devices sub- ns 2(q) and 7 of the Act, beling requirements of the 1947 to which devices had been sub- ere expanded (7 U.S.C. 135(z)(1)). misbranding provisions of section) of the amended FIFRA which dministrator has made applicable ices are listed at 40 CFR Part b). In summary, a device will be to enforcement action if

(1)(A): Its labeling bears any state- designs or graphic representations thereto or to its ingredients which e or misleading in any particular;
(1)(B): Its packaging or wrapping conform with standards established nt to section 25(c)(3) (Such stand- are not as of this date, been issued Administrator at such time as they e question of their applicability to will be addressed);
(1)(C): It is an imitation of, or is for sale under the name of another

(1)(D): Its label fails to bear the ishment number;
(1)(E): Required information is not ently displayed on the label;
(1)(F): It lacks adequate directions ; or
(1)(G): It lacks an adequate warning tion statement.

CFR 162.10(a)(5) provides an in- tation of what the term "false and ding" may include in the context FRA section 2(q)(1)(A) misbrand-

lse or misleading statement concern- e composition of the product;
lse or misleading statement concern- e effectiveness of the product;
lse or misleading statement about the of the product for purposes other than ence;
alse or misleading comparison with devices;
statement directly or indirectly im- that the device is recommended or ed by any agency of the Federal Gov- nt;
e statement used in such a way as to false or misleading impression to the aser;
el disclaimers which negate or detract labeling statements required under the ed regulations; or
-numerical and/or comparative state- s on the safety of the product.

Section 7, Registration of Establish- s (7 U.S.C. 136e). On November 6, regulations (40 CFR Part 167) for mplementation of section 7, Regis- n of Establishments, were published e FEDERAL REGISTER (38 F.R. 30557). scope of the requirements is set forth 167.2(a): "All establishments, as de- in this part, which produce any cide or device subject to the provi- of this section, must be registered ant to the requirements of these lations * * *" At § 167.1(k) the term ice" is defined as "* * * any device ass of devices as defined by the Act det- ined by the Administrator pursuant to section 25(c) to be subject to the provisions of section 7 of the Act."

Section 7 imposes three basic requirements: (1) Registration of device-producing establishments, (2) labeling which reflects the EPA establishment number assigned to the establishment in which the device was produced, and (3) submission of annual production reports.

All establishments in which devices subject to the Act are produced must be registered with the Environmental Protection Agency as producing establishments. This includes foreign establishments in which devices shipped to the United States are produced, as well as establishments located in the United States which produce devices for export.

To register establishments, producers should obtain from an EPA regional office the Application for Registration of Pesticide-Producing Establishments (EPA Form 3540-3). The applications require such information as the name and address of the company headquarters and the names and addresses of all device-producing establishments owned and operated by the company. This application must be submitted to the regional office on or before January 18, 1976. Upon receipt of a completed application, the regional office shall register each establishment listed and shall assign each establishment an EPA establishment number. This EPA establishment number must be displayed on all devices released for shipment by the establishment after 90 days after the producer is notified of the assigned number.

The production reports (EPA Form 3540-16) must be submitted to the regional office within thirty days after notification of registration and by February 1 each year thereafter.

C. *Section 8, Books and Records (7 U.S.C. 136f)*. On September 18, 1974, regulations (40 CFR Part 169) for the implementation of section 8, Books and Records, were published in the FEDERAL REGISTER (39 F.R. 33512). Pursuant to the authority of section 8(a) of the Act, these regulations (at 40 CFR 162.2) specify those records pertaining to development, testing, production, holding, and distribution, which all producers of devices declared subject to the Act are required to maintain and submit to inspection. These requirements apply to domestic and foreign persons producing devices for sale and distribution in the United States and to domestic producers who export devices.

Specifically, producers of devices subject to the Act are required to maintain the following records:

169.2(b): Records showing the brand names and quantities of devices produced. These records shall be retained for two years.

169.2(c): Records showing the following information regarding the receipt of devices: (1) Brand name of device, (2) Name and address of shipper, (3) Name of delivering carrier, (4) Date received, and (5) Quantities received.

These records shall be retained for two years.

169.2(d): Records showing the following information regarding the shipment of devices: (1) Brand name of device, (2) Name and address of the consignee, (3) Name of originating carrier, (4) Date shipped or delivered for shipment, and (5) Quantities shipped or delivered for shipment.

These records shall be retained for two years.

169.2(e): Inventory records with respect to the types and amounts of devices in stock which he has produced. These records may be disposed of when a more current inventory record is prepared.

169.2(h): In the case of devices intended solely for export to any foreign country, copies of the specifications or directions of the foreign purchaser for the production of the devices. These records shall be retained for two years after expiration of the contract.

Pursuant to the authority of section 8(b) of the Act, 40 CFR 169.3(b) requires that distributors, carriers, dealers or other persons who sell or deliver (or offer to sell or deliver) devices declared subject to the Act, allow inspection of the records they have pertaining to the following:

(1) The delivery or holding of the device and quantity held; (2) Date of shipment and receipt; (3) Name and address of consignee and consignor; and (4) Any guarantees received pursuant to section 12(b)(1).

D. *Section 17, Imports and Exports (7 U.S.C. 136o)*. On August 1, 1975, regulations (19 CFR Part 12.1) for the implementation of section 17, Imports and Exports, were published in the FEDERAL REGISTER (40 FR 32321). These regulations require that devices produced by foreign manufacturers and imported into the United States comply with all requirements applicable to domestic producers. In addition, the regulations require an importer to submit to EPA a Notice of Arrival of Pesticides and Devices (EPA Form 3540-1, available at any EPA office) for review and determination as to whether the shipment should be sampled and/or permitted entry into the United States. The Act also provides that samples may be collected and examined and that shipments may be permitted entry, detained until brought into compliance, destroyed, or re-exported.

With respect to devices produced in this country for export, section 17(a) of the FIFRA as amended requires that such devices must be prepared or packed in accordance with the specifications or directions of the foreign purchaser and that producers of such devices must maintain books and records pursuant to section 8(a).

VI. ENFORCEMENT AUTHORITIES

Section 9(a) (7 U.S.C. 136(g)(a)) of the Act authorizes officers of the Agency to inspect any establishment or other place where a device is held for distribution or sale in order to obtain a sample of the device as packaged, labeled and released for shipment, and samples of any containers or labeling for the device. Officers of the Agency are also authorized

to inspect books and records required to be maintained under section 8(a) and copies of records which are available under section 8(b).

Pursuant to section 12(a)(2)(B) of the Act, it is unlawful for any person to refuse to keep or to permit inspection of books and records, or to refuse to permit inspection of an establishment. Pursuant to section 12(a)(1)(F) of the Act, it is unlawful to sell or distribute any device which is misbranded. Finally, pursuant to section 12(a)(2)(L) of the Act, it is unlawful to violate any provision of section 7.

Upon a finding of any unlawful act, the Administrator may assess a civil penalty pursuant to section 14(a) of the Act or initiate criminal proceedings pursuant to section 14(b) of the Act. If, upon inspection or tests, a device is believed to be in violation of the Act, or if it is believed that a device is intended to be distributed or sold in violation of the Act, a Stop Sale, Use or Removal Order may be issued pursuant to section 13(a). Additionally, section 13(b) authorizes in rem seizure proceedings in a federal district court against any device which is misbranded or which, when used in accordance with the requirements imposed under the Act causes unreasonable adverse effects upon the environment. Finally, the Administrator may seek injunctive relief pursuant to section 16(c) to prevent and restrain violations of the Act.

VII. Public Comment

The Administrative Procedure Act (5 U.S.C. 533(b)) provides that the solicitation of comments is not required of Federal agencies for "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice." EPA has determined that this Notice falls within this exemption from the requirement to solicit public comment. Nonetheless, interested persons may submit written comments regarding the policy set forth in this Notice to the Pesticides and Toxic Substances Enforcement Division (EN-342), Office of Enforcement, U.S. Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460. Three copies of these comments should be submitted to facilitate the work of the EPA and others interested in inspecting such documents.

Dated: November 8, 1976.

STANLEY W. LEGRO,
Assistant Administrator
for Enforcement.

[FR Doc.76-34119 Filed 11-18-76;8:45 am]

NOTICES 52573

[FRL 646-5]

PEST CONTROL DEVICES PROCEDURES

Consolidation and Clarification of Requirements

Correction

In FR Doc. 76-34119 appearing on page 51065 in the issue for Friday, November 19, 1976, on page 51066, middle column, third full paragraph, in the 12th line, "January 18, 1976" should have read "January 18, 1977".

Publicity and Outreach

Environmental News Release

Letter to Manufacturers and Professional Associations

EPA Environmental News

DRAFT

Sibbison (202) 755-0344

EPA WILL INVESTIGATE WATER PURIFIERS

The Environmental Protection Agency said today it is initiating a program to test the ability of non-chemical water purification devices to purify water.

EPA said it will take enforcement action against the manufacturer of any product which fails in the tests to remove microorganisms that could cause disease.

A non-chemical water purification device is a product which uses a physical means to eliminate microorganisms, such as bacteria and viruses, from previously untreated water. These physical means include ultraviolet radiation, filtration, reverse osmosis, distillation, and ozone or chlorine generation.

Water purification devices are most often used in areas where municipally treated water is not available and the individual is dependent on water from a well, lake, or stream. Often the quality of this water is of questionable safety because it may be contaminated with disease causing microorganisms.

If a water purification device fails to eliminate these microorganisms, there is a risk of causing such diseases as hepatitis, dysentery, and infection of the stomach and intestines.

EPA will have about 50 water purification devices tested by the State of New York Department of Health, Division of Laboratories and Research, Environmental Health Center, in Albany.

A.E. Conroy II, of EPA's Office of Enforcement, said the Agency has received complaints from consumers indicating that some of the devices do not work properly. In addition, he said, a 1979 study published by the Canadian Environmental Health Directorate concerning three types of purifiers using ultraviolet light showed that two of them effectively removed bacteria but a third device did not.

(more)

"We have reason to believe that users of some of these purifiers sold in the United States may be exposed to dangerous levels of microorganisms," Conroy said.

Under Section 7 of the Federal Insectiicde, Fungicide, and Rodenticide Act, all manufacturers of water purification devices are required to register with the Environmental Protection Agency and submit annual production reports on their devices. This information is crucial, Conroy said, to the Agency's ability to successfully carry out this monitoring program and protect the public health.

Once a manufacturer has been registered, he or she will receive an EPA establishment registration number which must appear on the device's label. If a consumer should find a water purification device that does not bear an EPA establishment registration number on its label, he or she should write to A.E. Conroy II, U.S. EPA, EN-342, 401 M Street, S.W., Washington, D.C. 20460, Attention: Water Purification Devices.

# # #

Letter to Manufacturers and Professional Associations

DRAFT

To Whom It May Concern:

The Environmental Protection Agency (EPA) has recently become aware of the fact that many manufacturers of water purification devices do not realize they are required to register their establishments with the Agency.

We have learned that your firm may be a manufacturer of water purification devices and therefore subject, along with the device, to the Federal Insecticide, Fungicide, and Rodenticide Act as Amended (FIFRA). A device is defined in FIFRA as "any instrument or contrivance...which is intended for trapping, destroying, repelling, or mitigating any pest...." Bacteria, viruses and other microorganisms are considered pests under FIFRA section 2(t) and 40 CFR 162.14 (b)(4) and (5).

Any product which claims to purify water must make previously untreated water suitable for human consumption (i.e., eliminate all pathogenic microorganisms). This definition of a water purifier comes from a 1964 ruling in Federal Trade Commission v. Sibco and has recently been reiterated in a 1978 EPA decision In re Contact Industries Inc.

There are basically two broad categories of water purifiers, those which use a chemical means to destroy the microorganisms and those which use a physical means. Purifiers which use a chemical means are considered pesticides and subject to registration requirements in section 3 and section 7 of the Act (product and establishment registration). Those which use a physical means are considered devices and subject only to those registration requirements in section 7 (establishment registration). Examples of such devices include but are not limited to: Ultraviolet light systems, submicron filters, reverse osmosis units, distillers, chlorine generators, and ozone generators.

All manufacturers of water purification devices are required to register their establishments with the Agency and submit annual production and distribution data on their devices. Enclosed you will find a copy of FIFRA, two Federal Register Notices, and 40 CFR 162.15 clarifying the Agency's authority and requirements of the Act.

Also enclosed is EPA form 3540-8, Application for Registration of Pesticide Producing Establishment. If you manufacture water purification devices, please complete EPA form 3540-8 if you have not already done so.

Once an EPA establishment number has been assigned, EPA form 3540-16, Pesticides Report for Pesticide-Producing Establishments, will be sent to you for completion. Include either the words "point-of-use" or "small system" in parentheses after the product name, depending on the intended use of the product. Point-of-use purifiers are those intended for use in a single family household, camper, boat, etc. Small systems would be used for industrial or commercial purposes or to supply water for twenty-five people or more.

If you do not manufacture water purification devices, we would greatly appreciate it if you would inform us at the address given below so that we may remove your name from our list.

If you have any questions concerning your product and whether it is subject to FIFRA, please contact Josephine Huang, Toxicologist, U.S. EPA, EN-342, 401 M Street S.W., Washington, D.C. 20460, (202) 472-3701.

Sincerely yours,

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

Enclosures

Support Documents

- Protocol for Product Testing
  (draft available from headquarters)

- Criteria for Review Team Analysis

  (under development)

- List of Products

  (under development)

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

OCT 17 1980

OFFICE OF ENFORCEMENT

MEMORANDUM

SUBJECT: Routine Use of SEC "10-K" Statements in TSCA and FIFRA Civil Penalty Actions

TO: Regional Enforcement Division Directors

Introduction

The Office of Enforcement is interested in the financial status of companies charged with TSCA or FIFRA violations for two reasons: (1) to establish appropriate civil penalties and (2) to challenge corporate claims that severe economic consequences will result from civil penalty assessments.

At present, the Regions utilize Dun and Bradstreet publications to determine the general financial condition of a business enterprise. However, the general level of detail provided by the Dun and Bradstreet publications, if used as the only source of information, may provide an incomplete and potentially misleading picture of a company's financial condition.

In exploring various alternative sources of financial information, PTSED has discovered a potentially excellent tool for determining financial status: the "10-K" statements filed by companies with the Securities and Exchange Commission (SEC). The purpose of this memo is to explain what 10-K statements are and how they can be used in the TSCA/FIFRA enforcement program to improve our ability to determine financial status.

The 10-K Statement

Purpose of 10-K Statement

A basic purpose of the federal securities laws is to provide disclosure of financial and other information on companies seeking to raise capital through the public offering of their securities and companies whose securities are already publicly held. The goal is to enable investors to evaluate the securities of these companies on an informed and realistic basis.

The Securities Exchange Act of 1934 deals in large part with securities already outstanding and requires the registration of securities listed on a national securities exchange as well as over the counter securities in which there is a substantial public interest. Companies which issue registered securities must file annual and other periodic reports designed to provide a public file of current material information. Currently over 11,000 companies file disclosure statements with the SEC (July 1980 estimate).

Contents of 10-K Statement

The 10-K statement is the official annual business and financial report which must be filed by most companies. The financial section (Part I) must be filed within 90 days of a company's fiscal year end. Supporting data (Part II) of the 10-K contains the information normally required in a proxy statement. Schedules to financial statements may be filed by amendment within the 120-day limit. No other source of corporate information provides more comprehensive or current information about a company than this report with its schedules, exhibits and amendments. The following is a description of the items contained in parts I and II of the 10-K statement that pertain to a company's financial status.

Form 10-K

Business. Identifies principal products and services of the company, principal markets and methods of distribution and, if "material", competitive factors; backlog and expectation of fulfillment; availability of raw materials; importance of patents, licenses, and franchises; estimated cost of research; number of employees; and effects of compliance with ecological laws.

Summary of Operations. Summary of operations for each of the last five fiscal years and any additional years required to keep the summary from being misleading (Per-share earnings and dividends are included). Includes explanatory material describing reasons for changes in revenues, earnings, etc.

Properties. Location and character of principal plants, mines, and other important properties and if held in fee or leased.

Parents and Subsidiaries. List or diagram of all parents and subsidiaries and for each named, the percentage of voting securities owned or other basis of control.

Legal Proceedings. Brief description of material legal proceedings pending. When civil rights or ecological status are involved, proceedings must be disclosed.

Executive Officers of the Registrant. List of all executive officers, nature of positions and offices held.

Enforcement Use of 10-K Statements

Civil Penalty Assessment

A 10-K statement will greatly assist the Regions in applying the adjustment factors as required by the TSCA civil penalty process. Section 16 of TSCA provides for civil penalty amounts which range up to $25,000 per violation. A number of factors must be considered in assessing a civil penalty:

"In determining the amount of a civil penalty, the Administrator shall take into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and other such matters as justice may require" (Section 16, TSCA).

The gravity based penalty in the Civil Penalty System (Federal Register, September 10, 1980) developed to implement this Section reflects the seriousness of the violation's threat to health and environment. The 10-K statement is not applicable to this part of the Agency penalty assessment. However TSCA also requires the Agency to consider certain adjustment factors related to the violator. The following is a discussion of the ways EPA can use 10-K statements during its deliberations concerning the applicability of the adjustment factors to a particular company.

1. Violation History

The TSCA Gravity Based Penalty is designed to apply to "first offenders." Where a violator has demonstrated a similar history of violations, the Act requires the penalty to be adjusted upward. Generally, companies with multiple establishments are considered as one when determining violation history. Thus, if one establishment of a company commits a TSCA violation, it counts as history when another establishment of the same company, anywhere in the country, commits another TSCA violation. The same policy applies where a parent corporation in the substantially similar line of business as that of its subsidiary, commits a violation. Because many large companies are comprised of smaller corporate entities with different names than their

parent company, it is sometimes difficult to identify past violations.

The 10-K statement should be requested whenever there is any question about the corporate holdings of a violator during civil penalty assessment. This is particularly true where a large corporation is involved since there is an increased likelihood of subsidiary companies. This information can then be used to determine if any part of the company has committed TSCA violations in the past.

2. Ability to Pay and Ability to Continue in Business

Section 16 of TSCA lists "ability to pay" and "ability to continue in business" as two adjustment factors. The TSCA penalty policy states that "the distinctions between the two are so narrow and artificial that they are treated as one." Consequently "ability to pay" will henceforth be used to include "ability to continue in business." Measuring a firm's ability to pay a cash penalty without ceasing to be operable can be extremely complex.

The current formula in the TSCA penalty policy determines ability to pay by reference to the company's yearly net income as determined by a fixed percentage of total sales. This formula may not yield a complete and accurate picture of the company's ability to pay.

Since the 10-K statement provides a more comprehensive summary of financial status, it is suggested that the Regions take the following steps in reviewing 10-K statements to determine ability to pay.

1. Look at the assets of the company for the most current two year period. The factors in this category include cash on hand, marketable securities, receivables, inventories, current assets, property, plant and equipment, and depreciation. All of these factors should be summed and to obtain the total assets of the firm.

2. Look at the liabilities of the company for the most current two year period. The factors in this category include accounts payable, notes payable, taxes due, total current liabilities, long term debt, and shareholders equity.

3. Look at the income statement of the company for the most current two year period. The factors in this category include net revenue, cost of goods, gross profit, general and administrative expenses, income before tax, extraordinary items, and net income.

The income section of the 10-K statement is the most useful for assessing a company's ability to pay a civil penalty (item 3 above). In particular, the gross profit of a company provides a good picture of the stability of a company. Gross profit is the income that the company derives after the deduction of the cost of goods. It does not reflect the general and administrative expenses associated with running the business.

The gross income should be compared with the net income of the company. Net income reflects the "bottom line" on a company's profitability. A negative net income may indicate that the company cannot afford to stay in business if a civil penalty is assessed. However this may not be true in view of the company's gross income. For instance non-recurring "extraordinary" items may have caused a temporary loss. If so, the company can probably afford to pay a civil penalty. Additionally, the Region should remember that a company can liquidate assets to meet penalty amounts and still remain in business.

In complex cases, the Region may need to rely on a management division economist or an accountant to analyze the firm's ability to pay and, on a case by case basis, to evaluate the proposed penalty. The usual case can be satisfactorily evaluated by an analysis of the gross and net income figures on the 10-K statement.

Obtaining 10-K Statements

The Regions should obtain 10-K statements before assessing civil penalties in enforcement actions. A 10-K statement may be obtained in various ways. EPA regional offices in San Francisco, Chicago, and New York may contact the local SEC office to obtain 10-K statements for companies with headquarters located in the Region. In addition, the SEC Headquarters in Washington will mail out 10-K statements upon request. Inquiries should be mailed to the SEC, 500 N. Capital Street, Washington, D.C. 20549. Regions must specify the name of the company and the years for which the 10-K is requested. A nominal fee is charged for this service; twenty-four hour response is possible upon request.

I hope that the Regions will begin using this important tool immediately. Please contact Russell B. Selman of my staff if any questions arise at 755-9404.

A. E. Conroy II

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

Sample Extracted Filings

COMPANY PROFILE

0592799 PROFILE LAST FILED: 79/07/31 CO NO: G321300000
GENESCO INC
GENESCO PARK
NASHVILLE TN 37202
INCORPORATED IN: TN
EXCHANGE: NYS TICKER SYMBOL: GCO
SEC FILE NO: 1-3083 IRS NO: 62-0211340 CUSIP: 3715323
SIC CODES: 2311 2331 3143 3144 5661
DESCRIPTION OF BUSINESS: MANUFACTURES AND RETAILS CLOTHING. OPERATIONS ARE DIVIDED INTO FOUR SEGMENTS: FOOTWEAR, MEN'S APPAREL, SPECIALTY RETAILING AND VARIETY RETAILING. OPERATES 61 MANUFACTURING PLANTS AND WAREHOUSES AND APPROXIMATELY 1,400 RETAIL STORES AND LEASE DEPARTMENTS THROUGHOUT THE U.S. AND CANADA.
FISCAL YEAR END: 07/31
10-K 79/07/31
ARS 79/07/31
10-Q 79/04/30
8-K 79/04/12
PRSPCT 79/02/13
REGST S08 78/05/01

10-K EXTRACT

0592791 10-K DATE: 79/07/31 CO NO: G321300000
GENESCO INC
SHARES OF COMMON STOCK: 12,620,920
NUMBER OF SHAREHOLDERS: 32,403
NUMBER OF EMPLOYEES: 26,500
PARENTS:
N/A
SUBSIDIARIES:
BBC, INC.;
COLLEGE GROVE TRUCK COMPANY;
FLAGG BROS. OF PUERTO RICO, INC.;
GENERAL RETAIL CORPORATION;
GENESCO APPAREL AND FOOTWEAR (FAR EAST) LIMITED;
GENLEATHER INCORPORATED;
S. H. KRESS OF LOUISIANA, INC.;
GENESCO ITALIA S.P.A.;
TENNESSEE RAVENWOOD PROPERTIES, INC.;
GCO PROPERTIES, INC.;
GENESCO GROUP INC.;
UNIVERSAL SHOE AND APPAREL EXPORT, INC.;
HENRI BENDEL, INC.;
I. MILLER & SONS, INC.;
S. H. KRESS AND COMPANY;
V. J. ELMORE AND COMPANY;
[illegible]ESCO MERGER COMPANY, INC.;
[illegible] SHOPS INCORPORATED;
[illegible]EN RESTAURANT CORPORATION;
[illegible]ESCO APPAREL LIMITED;
AGNEW-SURPASS SHOE STORES, LIMITED;

10-K Extract cont.

	LIABILITIES	
ACCOUNTS PAYABLE	75,347,000	87,035,000
NOTES PAYABLE	27,365,000	78,365,000
TAXES DUE	N/A	N/A
TOTAL CURRENT LIAB.	117,174,000	187,078,000
LONG TERM DEBT	129,928,000	126,662,000
SHAREHOLDERS EQUITY	90,698,000	84,104,000
	INCOME STATEMENT	
NET REVENUE	992,925,000	1,048,351,000
COST OF GOODS	672,812,000	705,740,000
GROSS PROFIT	320,113,000	342,611,000
SELL, GEN. & ADMIN. EXP.	292,157,000	302,960,000
INCOME BEFORE TAX	(1,045,000)	19,364,000
EXTRAORDINARY ITEM	N/A	N/A
NET INCOME	6,332,000	14,936,000

COMMENTS:
EXTRAORDINARY ITEM IS OPERATING LOSS CARRYFORWARD
FOOTNOTES:
ACCOUNTING PRINCIPLES: ACCOUNTING CHANGE FOR COMPUTING THE U.S. TAX PROVISION
MERGER AND/OR ACQUISITION: PURCHASE, TENNESSEE RAVENWOOD PROPERTIES, INC., PAYMENT IN CASH
PRINCIPLES OF CONSOLIDATION: GENESCO FINANCIAL CORP. CARRIED ON EQUITY METHOD
DEPRECIATION: SUM OF DIGITS; DOUBLE DECLINING BALANCE; PRINCIPAL METHOD IS STRAIGHT LINE
INVENTORIES: FIFO; RETAIL METHOD USED FOR RETAIL COMPANIES
SHORT TERM DEBT: LINE OF CREDIT: COMPENSATING BALANCE: RESTRICTING
LONG TERM DEBT: COLLATERALIZED; CONVERTIBLE; RESTRICTING; AMENDED; SUBORDINATED NOTE, SENIOR SINKING FUND NOTE, SUBORDINATED DEBENTURES, FIRST MORTGAGE NOTES
TAXES: NET OPERATING LOSS CARRYFORWARD, $66,433,000, EXPIRES IN 1985
STOCK OPTION: UNQUALIFIED; KEY EMPLOYEES STOCK OPTION PLAN, EMPLOYEE INCENTIVE PLANS A & B
FOREIGN OPERATIONS: TRANSLATION GAINS OR LOSSES
LEASES: CAPITALIZED: EXPENSED: FASB 13; SUBLEASES.
PENSION PLANS: FUNDED; COST ACCRUED; VESTED BENEFITS EXCEEDED ASSETS
COMMITMENTS/CONTINGENCIES: LEASES; LITIGATIONS
SUBSEQUENT EVENTS: N/A
OTHER FOOTNOTES: REPLACEMENT COSTS; QUARTERLY FINANCIAL DATA; SEGMENT INFORMATION; COMMON STOCK; SUPPLEMENTARY INCOME STATEMENT INFORMATION; CAPITAL STOCK, PREFERRED STOCK; RECEIVABLES; CURRENT ASSETS OF OPERATIONS BEING DIVESTED; INVESTMENTS AND LONG TERM RECEIVABLES; FIXED ASSETS OF OPERATIONS BEING DIVESTED; SUBORDINATED COMMITMENT TO FOREIGN FINANCE SUBSIDIARY; PROVISION FOR OPERATIONS BEING DIVESTED AND RETAIL STORE CLOSINGS

The cost for retrieval and display of the above information (all 3 reports) is in the approximate range of $6.00 to $12.00 depending on search complexity and system vendor used.

10-K Extract cont.

DISCO SHOES LIMITED;
GENESCO OF CANADA CO. LTD.;
CONTINENTAL SHOE SALES CORPORATION LTD.;
SHOE VILLA LIMITED;
J. A. JOHNSTON COMPANY OF CANADA LIMITED;
REWARD SHOE STORES OF CANADA LIMITED;
DEXTER SHOES, LIMITED;
GENESCO WORLD APPAREL, LTD.;
PINEBROOK REALTY CORP.;
GENESCO INTERNATIONAL CORP.;
FULTON PROCESS & CHEMICAL CORPORATION

LEGAL PROCEEDINGS:
VIOLATION OF SECURITIES, IMPROPER SUSPENSION OF EXCHANGE RIGHTS OF HOLDERS OF SERIES C STOCK AND SERIES B STOCK, CLASS ACTION, DENCO AND MICHAEL W. CRAMER V. GENESCO, INC., DISPOSITION ADVERSE, APPEAL PENDING;
VIOLATION OF SECURITIES, IMPROPER SUSPENSION OF THE RIGHT TO EXCHANGE SERIES B STOCK, FALSE AND MISLEADING STATEMENTS, ERWIN CAMP, ET AL. V. GENESCO, INC., DISPOSITION ADVERSE SUMMARY JUDGEMENT, OTHER ISSUES PENDING;
VIOLATION OF SECURITIES, WRONGFUL REFUSAL TO MAKE DEPOSITS TO SINKING FUND, GEORGE THOMAS, ET AL. V. GENESCO, INC., DISPOSITION PENDING;
VIOLATION OF ANTITRUST, RETAIL PRICE FIXING, VARIOUS CLASSES OF CHARGE ACCOUNT CUSTOMERS V. GENESCO, INC. AND CERTAIN RETAILERS, DEFENDANTS IN SEVERAL ACTIONS, DISPOSITION PENDING;
VIOLATION OF SECURITIES, FALSE AND MISLEADING STATEMENTS, INFLATING OF COMMON STOCK PRICES, CLASS ACTION, LILA ZIPKIN V. GENESCO, INC., DISPOSITION PENDING;
VIOLATION OF SECURITIES, CLASS ACTION, GENESCO, INC., GENESCO FINANCIAL CORP., LEEDS SHOES, INC. ET AL. DEFENDANTS, DISPOSITION PENDING;
VIOLATION OF SECURITIES, FALSE AND MISLEADING STATEMENTS, INFLATING COMMON STOCK PRICES, FORMER OWNERS OF AN ACQUIRED CORPORATION V. GENESCO, INC., DISPOSITION PENDING

DIRECTORS AND OFFICERS:
HANIGAN, JOHN L.; CHAIRMAN, PRESIDENT AND CHIEF EXECUTIVE OFFICER
BOWLES, RALPH M.; EXECUTIVE VICE PRESIDENT, GENERAL MANAGER OF RETAILING
LANGSTAFF, GEORGE Q.; EXECUTIVE VICE PRESIDENT, GENERAL MANAGER OF FOOTWEAR
SHELTON, LARRY B.; EXECUTIVE VICE PRESIDENT, GENERAL MANAGER OF MEN'S APPAREL
WIRE, WILLIAM S. II; VICE PRESIDENT - FINANCE AND TREASURER, CHIEF FINANCIAL OFFICER
CLARK, THOMAS B.; VICE PRESIDENT, GENERAL COUNSEL
O'CONNOR, WILLIAM C.; SECRETARY, ASSISTANT GENERAL COUNSEL
WHITE, JIMMIE D.; VICE PRESIDENT, CHIEF ACCOUNTING OFFICER

EXHIBITS: COMPUTATION EARNINGS PER SHARE; REVOLVING CREDIT AGREEMENT, 3/13/79, GROUP OF 14 BANKS AND GENESCO FINANCIAL CORPORATION; EMPLOYMENT AGREEMENT, AMENDED, 9/25/79, GENESCO AND JOHN L. HANIGAN; STOCKHOLDERS' PROPOSAL, FUTURE STOCK OPTION PLANS, ANNUAL MEETING 12/4/78; GENESCO RETIREMENT SAVINGS PLAN, 1/1/79; HIGHLIGHTS OF THE GENESCO RETIREMENT SAVINGS PLAN; GENESCO RETIREMENT PLAN, 1/1/79, SUMMARY PLAN DESCRIPTION

AUDITOR: PRICE WATERHOUSE & CO.

AUDITOR'S REPORT: UNQUALIFIED

FISCAL YEAR OF REPORT	1979		1978
	$	ASSETS	$
CASH	12,371,000		20,576,000
MARKETABLE SECURITIES	N/A		N/A
RECEIVABLES	24,537,000		27,574,000
INVENTORIES	197,687,000		213,471,000
CURRENT ASSETS	242,226,000		294,419,000
PROP, PLANT AND EQUIP.	98,350,000		102,451,000
DEPRECIATION	N/A		N/A
TOTAL ASSETS	360,127,000		426,953,000

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

Trial Program

DEC 17 1980

OFFICE OF ENFORCEMENT

MEMORANDUM

SUBJECT: Regulation of Public Health Related Disinfectant Products

TO: Enforcement Division Directors
Pesticide Branch Chiefs

In a memorandum dated July 31, 1980, we requested a temporary stop to the collection of sample requests intended for testing at the Chemical and Biological Investigations Branch, Beltsville, MD. This action was requested to facilitate an on-going review of the Agency's Disinfectant Monitoring Program.

We have at this time completed our evaluation of the disinfectant program. Based on this review we have developed a new program plan for monitoring claims of selected disinfectant products. The major program changes are as follows:

- Testing of medical related disinfectant products only
- A new testing procedure for determining efficacy failures
- Beltsville will perform both chemical analysis and biological efficacy testing
- Failure of a product to destroy Ps. aeruginosa will be considered equal to failure of a product to destroy S. choleraeuis or S. aureus

We are in the process of selecting disinfectant products to be tested under this program and will be forwarding sample requests to Regions beginning February 1, 1981. Appropriate measures should taken to facilitate the collection of these requests. We have attached for your review several documents which explain the details of this program.

We look forward to your help and cooperation on this program. Please address any questions or comments by January 12, 1981, to Josephine Huang, Toxiologist, U.S. EPA, EN-342, 401 M Street S.W., Washington D.C. 20460.

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

Attachments

cc: W. Bontoyan

Table of Attachments

Attachment A : Program Development Strategy
(To be placed in the Case Proceedings Manual and Inspectors Manual)

Attachment B : Summary of Data Collection and Data Flow
(To be placed in the Case Proceedings Manual and Inspectors Manual)

Attachment C : Laboratory Procedures/Enforcement Actions
(To be placed in the Case Proceedings Manual)

Attachment D : Test Level I
(To be placed in the Case Proceedings Manual)

Attachment E : Test Level II
(To be placed in the Case Proceedings Manual)

Attachment F : Request to Stop Collection of Sample Requests for Testing at Beltsville.

PROGRAM DEVELOPMENT STRATEGY

A. Criteria of Selection:

- o Sample requests will include only those disinfectant products with public health related claims, such as those used on clinic or hospital premises.

- o Selection of products to be tested will focus on:

  - disinfectant products for which there is reason to believe that a violation has occured; this will be determined by consumer or competitor complaints and scientific judgment based on the study of product formulation

  - disinfectant products widely used on hospital or clinic premises

  - disinfectant products produced and distributed in large volumes

B. Data Collection and Data Flow:

- o Samples to be tested will be selected by:

  - Headquarters/Pesticides and Toxic Substances Enforcement Division - Compliance Monitoring Branch (PTSED-CMB)

- o PTSED-CMB will send the sample requests to the Regions for collection on a quarterly basis (approximately 40 sample requests on a national level every three months).

- o The Regions will set-up an I.D. jacket for each sample requested.

- When the requested sample has been collected, the PRD Acknowledgment copy will be forwarded to the Compliance Monitoring Branch with the "Sample Identification" Section of the request form completed. This will inform Headquarters that an inspector has been assigned and the sample collected.

- The regional (or state) inspector will obtain and/or complete all information necessary for sample collection (see the Pesticide Inspector's Manual for instructions).

  - All information obtained by the inspector will be placed in the I.D. jacket and forwarded to Beltsville along with the requested sample.

  - This information will include a copy of the product label in addition to the label attached to the sample container. This copy is intended for the sample's I.D. jacket.

- Beltsville will perform the chemical analysis and biological efficacy tests for sample requests originating from Headquarters.

  - These samples will be retained at the Beltsville laboratory for a two year period.

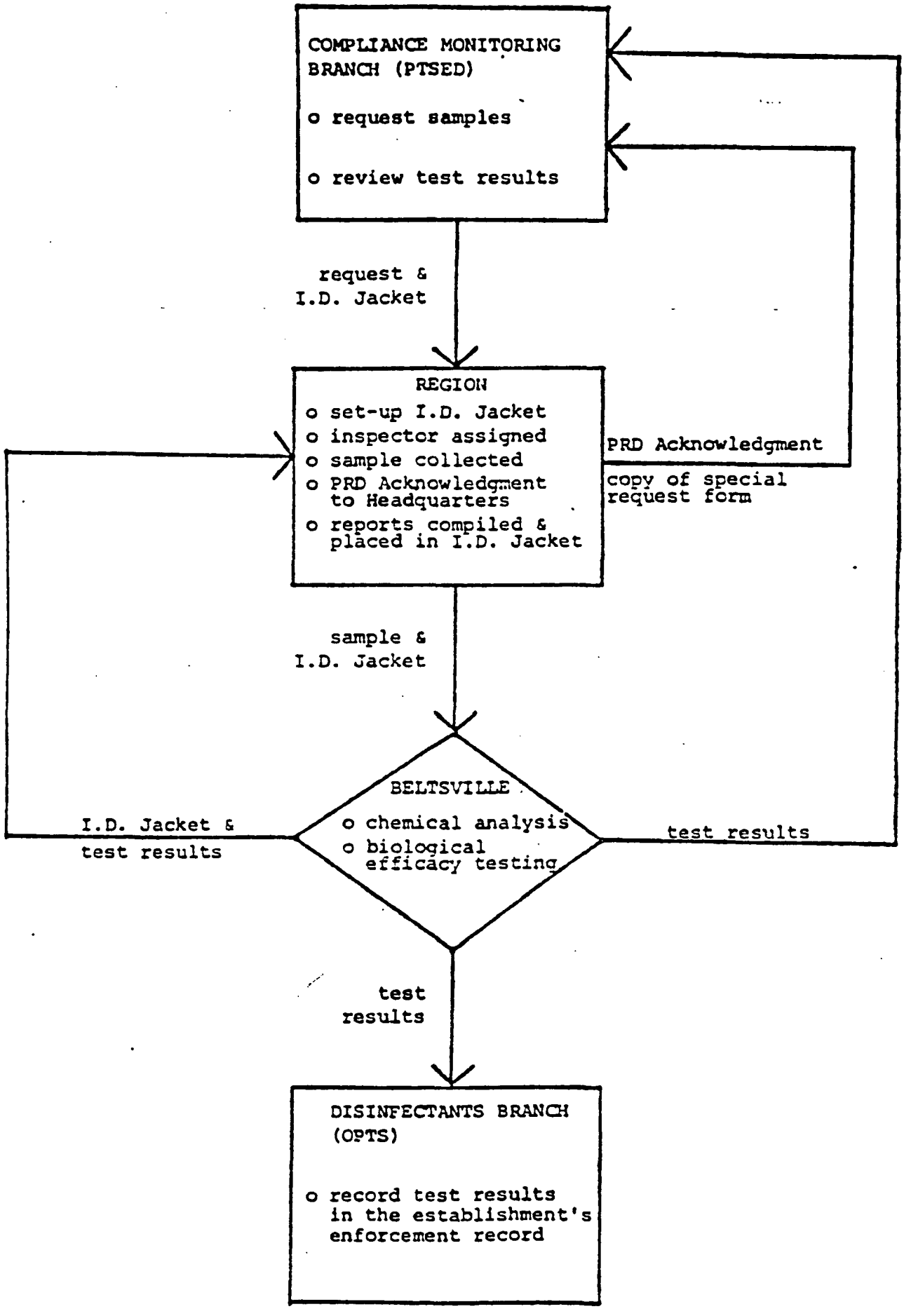
- Once testing has been completed:

  - All test results will be placed in the sample's I.D. jacket and sent to the Regions.

- The Beltsville laboratory will forward a copy of the test results to:

  - Headquarters/Compliance Monitoring Branch (PTSED)

  - Headquarters/Disinfectant Branch (OPTS)


COMPLIANCE MONITORING BRANCH (PTSED)
o request samples
o review test results
request & I.D. Jacket
REGION
o set-up I.D. Jacket
o inspector assigned
o sample collected
o PRD Acknowledgment to Headquarters
o reports compiled & placed in I.D. Jacket
PRD Acknowledgment
copy of special request form
sample & I.D. Jacket
BELTSVILLE
o chemical analysis
o biological efficacy testing
I.D. Jacket & test results
test results
test results
DISINFECTANTS BRANCH (OPTS)
o record test results in the establishment's enforcement record

- All I.D. jackets will be retained on file at the appropriate Region.

    - In some instances the Regions may be requested to forward a copy of information retained in the I.D. jacket to Headquarters for review.

C. Monitoring Failures for Enforcement Action:

- Test failures are of two types:

    - Formulation violations/chemical defects - product does not comply with accepted labeling

    - Biological efficacy - product does not effectively eliminate certain organisms as claimed by the manufacturer

- The Regions will initiate all enforcement actions.

Testing Scheme (Beltsville):

- All samples requested under this program will undergo chemical analysis prior to efficacy testing.
- The A.O.A.C. "Use Dilution Method" (modified for soil load 1-step cleaner disinfectants) will be used to test the efficacy of disinfectants products with claims against the following organisms:
  - -Salmonella choleraesuis
  - -Staphylococcus aureus
  - -Pseudomonas aeruginosa
- 60 carriers will be tested for each of the above organisms.

II. Definition of Failures/Enforcement Procedures:

A. Test Level I:

- 3 samples representing different batches will be tested at this level.
- Each sample will be tested against each of the above mentioned organisms.
- The definition of failure at Level I will be based on the performance standards required by OPTS for registration of disinfectant products (a sample which fails in 2 or more of the 60 carriers in any test is determined to have failed efficacy testing).
- A product will be determined to have failed efficacy testing at Level I if the product fails to destroy any organism in 2 or more of the 3 samples.
  - -For each batch which fails efficacy testing at Level I, the manufacturer will be issued a stop sale, use or removal order against the batches from which the samples were collected.

- If the product fails at Level I:

  - The manufacturer will be informed of the product's failure and that 5 additional samples (each representing a different batch) will be collected for testing at Level II.

  - A civil complaint will be issued for violations at Level I according to the Penalty Matrix.

- If only 1 sample out of the three batches tested fails to effectively eliminate the test organism, then the product will be determined to have successfully passed efficacy testing.

B. Test Level II:

- If a product is determined to have failed Level I testing, 5 additional samples representing different batches will be collected for testing at Level II.

- Each sample will be tested against the organism(s) the product fails to destroy in Level I.

- 60 carriers will be tested for each organism.

- At Level II, 2 or more failures out of the 60 carriers tested for each organism in each sample constitutes failure of the batch to meet efficacy requirements.

- The definition of product failure at Level II will be based on the upper bound of the 95% Confidence Interval for 2 failures out of 60 carriers. The 95% Confidence Level = 5 failures out of 60 carries.

- A product will be determined to have failed efficacy testing at Level II if the product fails to destroy any organism in 3 or more of the five samples.

- OPTS will initiate action to cancel product registration for efficacy failure at Level II based on the 95% Confidence Interval.

- Representatives from PTSED agreed that failure to effectively eliminate the test organism (based on the minimum of 2 failures out of 60 carriers) in any of the samples tested will result in:

    - a stop sale, use or removal order issued against the batch from which the samples failing efficacy testing were collected

    - a civil complaint issued according to the Penalty Matrix

TEST LEVEL I

Definition of Failure/Enforcement Action:

Definition of Failure:

1) Sample Failure = failure to destroy the test organism in 2 or more out of the 60 carriers

Enforcement Action: a stop sale, use or removal order will be issued on the batch from which the sample was collected

a civil penalty will be issued for failure of the batch to meet efficacy requirements

2) Product Failure = failure to destroy any test organism in 2 or more out of the 3 samples

Enforcement Action: initiate Level II testing

EXAMPLE

Product X with claims against Ps. aeruginosa; S. choleraesuis; S. aureus

Failure out of 60 carriers

Sample #	Ps. aeruginosa	S. cholaraesuis	S. aureus	Enforcement Action
1	*4/60	1/60	0/60	*stop sale, use or removal order and civil penalty
2	*7/60	0/60	1/60	*stop sale, use or removal order and civil penalty
3	*3/60	1/60	0/60	*stop sale, use or removal order and civil penalty

The product fails to destroy Ps. aeruginosa in Samples #1, #2 and #3 thus Level II testing is to be initiated.

At Level II only those organisms the product failed to destroy at Level are to be tested.

Definition of Failure/Enforcement Action:

Definition of Failure:

1) Sample Failure = failure to destroy the test organism in 2 or more of the 60 carriers

Enforcement Action: a stop sale, use or removal order will be issued on the batch from which the sample was collected

a civil penalty will be issued for failure of the batch to meet efficacy requirements

2) Product Failure = failure to destroy any test organism in 3 or more of the five samples based on the 95% Confidence Interval for 2 failures out of 60 carriers; Confidence Inteval = 5 or more failures out of the 60 carriers (see example below, Possibility B)

Enforcement Action: procedures will be initiated to cancel product registration

3) A product is determined to have failed efficacy testing if 3 or more of the five samples fail testing. For those products which fail in only 1 or 2 samples enforcement actions will be taken against the batches from which the samples failing efficacy tests were collected.

Enforcement Action: a stop sale, use or removal order will be issued on the batch from which the sample was collected

a civil penalty will be issued for failure of the batch to meet efficacy requirements

EXAMPLE

Product X with claims against Ps. aeruginosa; S. choleraesuis; S. aureus. At Level I Product X successfully destroyed S. cholaraesuis and S. aureus but failed to destroy Ps. aeruginosa

Possibility A

Sample #	Failure out of 60 carriers Ps. aeruginosa	Enforcement Action
1	*4/60	* a stop sale, use or removal order will be issued against the product batch from which the sample failing efficacy test was collected; a civil penalty will also be issued against these batches
2	*4/60	
3	*5/60	
4	*6/60	
5	*3/60	

Possibility B

Sample #	Failure out of 60 carriers Ps. aeruginosa	Enforcement Action
1	*7/60	* a stop sale, use or removal order will be issued against the product batch from which the sample failing efficacy test was collected; a civil penalty will also be issued against these batches
2	*10/60	
3	*4/60	
4	*6/60	
5	*7/60	

Since product X fails to destroy the test organism in 3 or more of the samples tested based on the 95% Confidence Interval for 2 failures out of 60 carriers (product failed in samples #1, #3, #4, & #5), procedures will be initiated to cancel product registration.

JUL 31 1980

MEMORANDUM

SUBJECT: Request to Stop Collection of Sample Requests for Testing at Beltsville

TO: Enforcement Division Directors
Pesticide Branch Chiefs

We are in the process of evaluating the Agency's Disinfectant Monitoring Program. The objective of our review is to establish an effective monitoring system for the purpose of improving test procedures and data flow between Headquarters, the Regions, and Beltsville.

Until further notice, appropriate measures should be taken to stop collection of all outstanding sample requests intended for testing at the Chemical and Biological Investigations Branch, Beltsville, Md.

Your cooperation in this matter is appreciated.

/S/

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

Tuesday
March 3, 1981

Part III

Environmental Protection Agency

Pesticide Registration, Reregistration, and Classification Procedures; Clarification of Policies on Special Packaging

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 162

[PP-TSL 1744-1; OPP 250011B]

Pesticide Registration, Reregistration, and Classification Procedure; Clarification of Policy Issues on Special Packaging

AGENCY: Environmental Protection Agency (EPA).

ACTION: Rule related notice.

SUMMARY: This interpretation of the child-resistant packaging regulation (40 CFR 162.16) provides clarification on several aspects of the regulation. This interpretation became necessary because the pesticide industry had raised a number of questions which the agency feels can best be resolved by this publication. It is intended that through these clarifications the affected pesticide registrants will be in a better position to comply with the regulation by March 9, 1981, when it becomes effective.

FOR FURTHER INFORMATION CONTACT: Rosalind L. Gross, Registration Division (TS-767C), Office of Pesticide Programs, Environmental Protection Agency, Rm. 707, CM#2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703-557-7851).

SUPPLEMENTARY INFORMATION: On March 9, 1979, the Environmental Protection Agency (EPA) issued final regulations which require certain toxic pesticides to be in special, i.e., child-resistant, packaging after March 9, 1981. The regulations are now contained in 40 CFR 162.16. Because so many registrants have had questions about the implementation of these regulations, EPA has decided to publish this Notice, to answer those questions and to clarify the regulations in areas where they might be unclear. These clarifications can be used immediately in order to amend registrations with respect to child-resistant packaging. Where EPA proposes to amend the regulations, those amendments will of course become effective after full notice and comment rulemaking.

A. Eye and Skin Irriation Criteria

Many questions were received concerning the conduct and interpretation of eye and skin irritation studies. As indicated in the preamble to the final regulations (44 FR 13021), testing for a pesticide's eye and skin irritation effects should be done in accordance with the National Academy of Science/National Research Council Publication 1138 protocols.

B. "Inherently Child-Resistant" Products

A number of registrants have questioned whether their products need to be tested for child-resistant effectiveness, contending that they are "inherently" child-resistant. These products fall into two main categories: (1) those where it is claimed that the package is intrinsically unopenable by children, and therefore "inherently" child-resistant, and (2) those where it is admitted that the product is toxic and accessible to children, but where it is contended that it would not be possible for a child to consume or be exposed to a sufficiently large amount of the toxic pesticide to cause him harm.

It is the agency's position that neither of these classes of products is "inherently child-resistant." In the first case, where product design is the basis for the "inherently child-resistant" claim, it will be necessary for that package to be tested, like all other pesticide packages, in accordance with the Consumer Product Safety Commission protocols, as discussed in the regulations and clarified below. In the second case, it is open to the registrant to attempt to show that its product falls within the exemption category of 40 CFR 162.16(c)(3), on the ground that despite the pesticide's meeting of one or more of the toxicity criteria, it is not hazardous to man. The registrant must show that a child could not be exposed to a toxic or harmful amount of the pesticide. The fact that a pesticide has not been implicated in a large number of accidents involving children is not in itself sufficient grounds for exemption. Product specific test data and an appropriate scientific rationale must be submitted in support of an exemption request.

C. Distinction Between "Exempt From Special Packaging" and "Not Being Subject to Special Packaging"

Many registrants are requesting exemptions for products, when in actuality they are asking if their product is subject to the regulation. An exempt is only appropriate for a product which is subject to the regulation.

A product whose label does not allow for residential use, is classified for restricted use, or does not meet the toxicity criteria, is generally not subject to the special packaging regulations. A product "allows for residential use" if its label either directly recommends residential use or reasonably can be interpreted to permit residential use.

Determining the potential for residential use from the label directions may be difficult. Many ornamental plants and garden vegetables, for example, are grown by the individual homeowner and, therefore, a label which lists them can be interpreted as permitting residential use. Residential use thus may not be automatically excluded for a relatively large number of products. In fact, the same formulation may be used, for example, by the commercial vegetable grower as well as the home gardener raising the same crop. The registrant of a product is best aware of the actual use area/user group of the pesticide. The registrant is therefore in a position to either choose proper labeling (see I below) for those products not intended to be used by the homeowner or to choose child-resistant packaging for those products used and stored in residential areas. For those products which will not enter the residential area even by use of a serviceperson (see I below) the agency will continue to follow its customary distinction between pesticides products entering the home market and those which are intended for commercial production of food crops and ornamental plants. This distinction has over the years been accomplished by a number of means, for example, use directions and size limitations. On a case-by-case basis, and in case of uncertainties, the agency has also allowed or requested label language such as "for agricultural use only" or "not for use in or around the home."

The regulations provide for exemptions under two circumstances: (1) technical infeasibility or (2) where a product's meeting of the toxicity criteria is not indicative of a genuine hazard to man.

Technically feasible means that the technology exists to produce special packaging for a particular pesticide. The agency is not required to find either that the packing is readily available or that it will lend itself conveniently to the existing packages or packaging equipment of the registrant. EPA considers practicability and appropriateness to be components of technical feasibility. In EPA's view, packaging is practicable if it is susceptible to modern mass production and assembly line techniques and appropriate if it is chemically compatible with the pesticide contained in the package.[1]

[1] This definition is consistent with that of the Consumer Product Safety Commission (CPSC), published in the Federal Register of February 16, 1972 (37 FR 3427).

D. "Dormant" Pesticide Registrations

A pesticide whose registration is "dormant" is one which is validly registered with EPA but is not currently in production. Obviously, the registrant of a "dormant" product subject to the child-resistant packaging regulations must comply with those regulations when it either begins or renews production after March 9, 1981.

E. Voluntary Child-Resistant Packaging

A number of registrants whose products are not required to be in child-resistant packaging have asked whether they may nonetheless use it. The anwer is yes. However, once a registrant chooses to use child-resistant packaging, the registrant must comply in all respects with the child-resistant packaging regulations. It would be misleading to the public to have two types of child-resistant packaging—voluntary and compulsory—which were not of equal safety or effectiveness.

F. Product Toxicity and Child-Resistant Packaging

A pesticide product's toxicity places it in one of three categories in regard to child-resistant packaging. These are:

1. Those products which clearly meet or exceed the toxicity criteria in 40 CFR 162.16(c)(2). These products must be in child-resistant packaging unless the registrant can demonstrate grounds for an exemption under 40 CFR 162.16(c)(3).

2. Those products for which the existing toxicity data are not precise enough to indicate whether the product meets or exceeds the toxicity criteria of 40 CFR 162.16(c)(2). The registrants of these products may either do further testing to determine the precise toxicity of their products, or they may concede that their products are sufficiently toxic to be in child-resistant packaging, and comply with the child-resistant packaging regulations. This second situation does not constitute voluntary child-resistant packaging. There are three notable situations where this may occur:

(i) For purposes of precautionary labeling the agency may have considered oral toxicity data sufficient to show that the product was in toxicity category III (LD_{50} of from 500 through 5,000 mg/kg), but not specific enough to determine whether the product has an LD_{50} of 1.5 g/kg or less.

(ii) Eye irritation studies may have been submitted which showed corneal effects past day 7, and the study may have been terminated without determining whether the effects were reversible in 21 days. Such a study was sufficient for purposes of precautionary labeling (category I) but is no longer adequate to determine whether or not child-resistant packaging (CRP) is needed.

(iii) The third situation applies to skin irritation studies using an exposure period of 24 hours. These studies would not necessarily allow a conclusion as to whether the criteria for CRP have been exceeded.

3. Those products which clearly do not meet the toxicity criteria in 40 CFR 162.16(c)(2). These products are not required to be in child-resistant packaging, although a registrant may choose to use child-resistant packaging voluntarily, in accordance with E above.

G. Released for Shipment

The phrase "released for shipment" is defined as follows: "A product is released for shipment by a producing establishment when it is the intent of the producer to introduce the product into commerce." Products at the distributor and retail levels are considered to have been previously released for shipment by the producing establishment.

H. Testing Procedure for Child-Resistant Packaging Which Requires a Tool for Opening

As the regulations indicate, the protocol testing procedures of the Consumer Product Safety Commission (CPSC) 16 CFR 1700.20) are to be followed in testing the child-resistant packaging of pesticides. The CPSC policy for testing child-resistant packaging which requires a tool to open the packaging, published in the Federal Register of October 13, 1972 (37 FR 21632), will also be followed. The test policy is that:

1. children need not be given the tool during the test unless the tool and product are marketed together, and

2. adults will be given the tool for testing.

I. Limited Exception for Products Sold to, and Used by, Servicepersons

EPA has determined, based on comments submitted by various industry groups, that pesticides which are used in residential areas by janitors, professional pest control applicators, exterminators, swimming pool operators, lawncare and landscaping personnel, and other similar people need not be in child-resistant packaging. This is because the storage and usage patterns generally employed by these people are such that a significant hazard to young children is not apparent.

Therefore, EPA plans to propose to amend the present child-resistant packaging regulations to provide that pesticides applied and used by servicepersons, as defined below, will not be within the scope of the regulations. EPA's proposed amendments to the regulations will be published shortly, and will be subject to public comment. In the meantime, EPA will exercise its prosecutional discretion not to enforce the child-resistant packaging regulations against those manufacturers who comply with these restrictive measures enumerated below.

EPA now plans to propose amendments which are substantially as follows:

1. Serviceperson. As used in the child-resistant packaging regulations, a serviceperson is defined as one who provides a service of controlling pests without delivering any unapplied pesticide to any person so served. The term "serviceperson" includes, but is no limited to, a janitor, pest control operator, maintenance person, lawncare and landscaping personnel. "Serviceperson" does not include a household servant, such as maid, housekeeper, or private gardener.

2. A pesticide which meets the criteria for child-resistant packaging and is distributed only to servicepersons may be marketed without child-resistant packaging if the registrant labels its product (either by conventional or sticker label), "Only for Sale to, Use, and Storage by Servicepersons." This statement must be in type at least as large as the child hazard warning statement. Sale or other distribution of a pesticide labeled in this way to a person other than a serviceperson will violate FIFRA section 12(a)(2)(F), once the restriction is imposed by regulation. Use of a pesticide labeled in this way by anyone other than a serviceperson will be a violation of FIFRA section 12(a)(2)(G).

J. Testing Each Size of a Design

The regulations provide that, "Standards for special packaging shall be evaluated for each size of a design used pursuant to the Consumer Product Safety Commission protocols specified in 16 CFR 1700.20 * * *" 40 CFR 162.16(d)(3). In explaining the necessity for testing each size of a design, the Preamble to the final regulations stated that:

> Tests do not have to be run on each pesticide product, only on each special packaging design * * *. However, in § 162.16(d)(3) a requirement has been added to test each size of a closure design used. In discussions with the Consumer Product Safety Commission, EPA was advised that changing the size of a design often reduces the child-resistant effectiveness. Requiring each closure size to be tested will eliminate

the possibility of an ineffective package being marketed (44 FR 15020).

EPA recognizes that this preamble language is somewhat ambiguous, because it refers both to the testing of the entire special packaging design and testing of the closure size alone. While it was the intent of the drafters of the regulations to require that the entire special package be tested for its child-resistant effectiveness,[2] the preamble language apparently prompted some registrants to test only the closure size which they intended to use on their pesticide product.

In view of the closeness of the March 9, 1981, deadline for compliance with the special packaging regulations, EPA is now prepared to resolve this possible ambiguity by permitting pesticide registrants to certify that their pesticides packages are in compliance with the regulations based solely on the testing of each closure size. EPA will then propose amended regulations, to be open for public comment, which will make it clear that the phrase "each size of a design" means the entire package. The entire package will be defined to consist of the following elements: belonging to a specific ASTM (American Society for Testing and Materials) classification of packages; being made by a particular packaging manufacturer; having a specific trade name; being a specific model/style number; having a particular shape; having a particular size (capacity) container/package; having a particular size closure (if applicable); having a specific liner (if applicable); and having the container/closure or package being constructed of a particular material.

EPA recognizes that the time and expense necessary to test each specific package of each product requiring registration would be considerable. Accordingly, to lessen the impact which would occur if such testing were required, EPA will offer manufacturers an alternative method by which the packaging of products can be certified.[3] It is believed that this scheme provides a reasonable degree of assurance that a package not tested will still meet the effectiveness specifications for special packaging.

[2] As early as the 1977 proposed regulations, EPA stated that "[U]nder this regulation it is intended that the entire package be tested. Containers which, for example, use safety closures which are not compatible with the container body are not acceptable" (42 FR 55225).

[3] However, should a pesticide package be tested and found not to comply with the child-resistant effectiveness standards of 16 CFR 1700.20, it will not be a defense that the similar product on which the registrant relied did meet those standards. Ultimately, each special package must be evaluated on its own merits.

EPA's proposal is set forth below, in the hope that some manufacturers will voluntarily comply with it before it becomes effective.

Proposed Testing Scheme

If a registrant uses a package other than the exact package system for which the protocol test data are available, EPA will accept certification if the package used meets the following criteria:

(1) Package shape: The package for which protocol data are available must be a conventional shape, e.g., cylindrical, rectangular, square, and the package for which certification is sought, even if different from the shape of the package tested, must also be conventional in shape. If an "F" style metal can or a conical metal can are involved, the shape used must be the same as the shape tested. All nonconventional package shapes, e.g., hourglass configuration, triangular packages, must be tested individually.

(2) Container/package material: The material of the package/container for which certification is sought must be generically equivalent and have the same physical/chemical properties (e.g., bursting strength, tear strength, etc.) as the material of the package for which protocol data are available. Different materials include polypropylene, low density polyethylene (LDPE), high density polyethylene (HDPE), glass, tin plate (steel), aluminum, etc. If data are available for a glass package and an LDPE package is used, it must be tested.

(3) Volume of the package: For certification on the basis of data involving a package other than the exact one used by the registrant, the protocol test data must demonstrate that the package tested has a child-resistant effectiveness of 88 percent of more after demonstration. The size of the package used must fall within the limits set forth below. The 88 percent figure was chosen, based on statistical analysis, to ensure that a package similar but not identical to the one tested would meet the 80 percent and 85 percent effectiveness testing requirements of the CPSC protocols. See 16 CFR 1700.20. If a registrant wants to certify that its package is child-resistant on the basis of testing the package actually used, a minimum of 80 percent child-resistant effectiveness after a demonstration is proper.

1. To use test data from a package which contains 0 to 8 fl. oz.,[4] the registrant's package must be the exact size of the package tested.

2. To use test data from a package which contains 8–64 fl. oz.,[4] the registrant's package can be equal to or as much as twice the size of the package test. For example, if an 8 fl. oz. package has been tested, its data (assuming that all other factors were equal) could be used for a package from 8 to 16 fl. oz.

3. To use data from a package which is larger than 64 fl. oz.,[4] the registrant's package can be equal to or as much as 1.5 times the volume of the package tested.

4. Closure/package: The closure/package used must be the same ASTM classification, the same model/style, the same model/style number, manufacturer, and trade name as the package tested.

5. Closure size: For certification on the basis of data involving a closure other than the exact one used by the registrant, the protocol test data must demonstrate that the closure tested has a child-resistant effectiveness of 88 percent or more after demonstration (see (3) above). The size of the closure used must fall within the limits set forth below:

a. To use data from a closure with a diameter less than 20 mm or greater than 45 mm, the registrant's closure must be the exact size of the closure tested.

b. If the registrant wishes to rely on data from one other closure, which is between 20 and 45 mm in diameter, inclusive, he may do so, provided that the diameter of the registrant's closure is in the size range between 20 and 45 mm inclusive and is between 1 and 1.15 times that of the closure tested. (Numbers should be rounded to the next highest whole number). For example, a registrant with a 28 mm closure could rely on test data for a 24 mm closure.

c. If the registrant wishes to rely on test data for two closures, which are between 20 and 45 mm in diameter, inclusive, and within 10 mm of each other, he may rely on that data for any closure which falls between the two tested. For example, if a 24 mm and a 33 mm closure of the same design were tested, the registrant could certify to the child-resistant effectiveness of its similar closures which were 26, 28, and 30 mm in diameter.

6. Closure material: The material of the closure used must be generically equivalent and have the same physical/chemical properties, i.e., bursting strength, tear strength, etc., as the closure material for which protocol data are available.

[4] Volumes measured in cubic inches can be converted to fluid ounces using the rule that 1 fl. oz. = 1.8 cu. in. Numbers should be rounded to the next highest whole number.

7. Liners: The materials of the registrant's liner and the liner on whose test data the registrant wishes to rely must be identical. This is because, in the experience of the Consumer Product Safety Commission, the closure liner is an integral part of the child-resistant package, and changing the liner may impair or eliminate the child-resistant effectiveness of a closure or packaging design.[1] In the situation where test data exist for a closure-liner system that differs from the closure-liner system used only in terms of closure diameter (>20 mm and <45 mm) certification is permissible if:

a. closure diameter used is greater than the diameter tested but is within the permissible range (size used is equal to or greater than the size tested and equal to or less than 1.15 times the size tested), then the closure to be used need not be tested if scientific data exist to demonstrate that the mechanical properties of the closure-liner system used are comparable to that tested. An example is if a 24 mm closure with a PVC liner is tested, then its data may be used for certification of a 28 mm version of the same closure with a PVC liner, provided there is scientific evidence that the 28 mm closure-liner system has mechanical properties similar to the 24 mm closure-liner system or

b. test data exist for two closure sizes with a difference equal to or less than 10 mm, the liner used in the two closure sizes for which data exist must be the same as the liner in the size used, then the closure to be used need not be tested. An example would be the test data for a 24 mm and 33 mm closure, both with a vinyl pulp backed liner. These data can be used for the certification of a 28 mm closure with a vinyl pulp backed liner.

The agency acknowledges that only a limited amount of data are available on large size packages. Consequently, exceptions will be considered in those cases where a registrant has submitted appropriate scientific and technical data.

K. Label Language

The particular wording of the label giving directions for child-resistant packaging opening and closing instructions is at the discretion of the registrant, so long as it clearly explains to the adult user how to use the package.

[1] This is why even an apparently minor modification in the liner, such as adding an insert for promotional purposes, may require retesting to ensure that the child-resistant effectiveness of the closure or package has not been impaired.

L. Certification of Child-Resistant Effectiveness

According to 40 CFR 162.16(e), the amendments for child-resistant packaging shall include a certification by the registrant that the package meets the standards of § 162.16(d).

The registrant is furthermore required to maintain records concerning the package (§ 162.16(f)) which include a complete copy of the data resulting from the tests conducted in accordance with § 162.16(d). As indicated under J, above, the agency realizes that it was not made entirely clear whether certification as to the child-resistant effectiveness of a particular package should be based on protocol tests carried out on the entire package or merely the closure. Therefore, by March 9, 1981, the agency is allowing two types of certifications, both of which will equally serve to comply with the regulation. After the agency has formally proposed and published a final regulation concerning the testing of package designs (see J, above) certain packages may have to be retested and recertified.

(a) Certification of effectiveness based on testing scheme listed under J above. If the protocol test data in the registrant's files show that either the exact package or a package meeting the criteria enumerated under J, above, has been tested, the registrant shall certify that the package meets the effectiveness criteria for child-resistance. The certification statement must include the registration number of the product, the registered product name, the registrant's name and address, date, the name, title, and signature of the company official. The certification, which should be submitted in triplicate, should include at a minimum the following statement:

I hereby certify that the special packaging for this product and all applicable supplementally registered distributor products have been tested and found to meet the requirements of 40 CFR 162.16(d), Standards of Special Packaging.

I understand that I am required to retain the records described in 40 CFR 162.16(f)(1), (2), and (3) for as long as the registration is valid. These records shall be available upon request, for inspection or copying purposes or for submission to EPA. Furthermore, I certify that should the special packaging for this product be changed, I will update this certification statement.

Additionally, if the product is sold in several sizes of packages all the sizes which this certification applies must be listed.

(b) Certification of effectiveness based on testing the package closure only. If the protocol test data in the registrant's files show that the closure used has been tested for effectiveness but it was actually tested on a container (package) other than the one used or outside the limitations of the scheme listed under J, above, he shall certify the effectiveness on the basis of the exact size closure. The certification statement, which should be submitted in triplicate, shall include the information listed under (a) above and shall include at a minimum the following statement:

I hereby certify that the exact closure used on the package of this product and all applicable supplementally registered distributor products have been tested and found to meet the requirements of 40 CFR 162.16(d), Standards for Special Packaging.

I understand that I am required to retain the records described in 40 CFR 162.16(f)(1), (2), and (3) 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. Furthermore, I certify that should the special packaging for this product be changed, I will update this certification statement.

If a product is sold in a line of several size packages, some of these packages may be certifiable under method (a) and some under (b). In this case two certification statements are required, one for those packages meeting the specifications of (a) and one for those which meet the specifications of (b).

(c) Information concerning the package/closure used. The child-resistant packaging regulation does not require the registrant to submit information concerning the type and make of child-resistant packaging used, although this information is part of those records which must be kept, and which must be available for inspection and submission upon request by EPA. The agency at this time, however, requests the cooperation of registrants to supply this information voluntarily as an addendum to the certification statement. This request is made for purposes of gathering information on the variety of packages and/or closures which have undergone extensive testing to allow certification by (a) above, for example. The agency feels that this information will be extremely helpful in providing data which may permit it to propose a more liberal testing scheme than the one listed under J. The information requested is as follows: Product sizes; name of special packaging manufacturer; name of special packaging and model/style; (ASTM classification); closure sizes, and liners used.

M. Amended Product Registrations for Child-Resistant Packaging (CRP)

There are basically three types of amended registration applications that may be submitted in conjunction with

...e Special Packaging Regulations. An ...mendment may be filed to indicate the ...se of special packaging and to submit ...e associated certification statement: ...n amendment may be filed to revise ...ing to remove a package from the ... of the special packaging ...ations: or an amendment may be ...ed to change the product formulation ...r submit new toxicity data to remove a ...esticide from the scope of the special ...ackaging regulations. The registrant ...ust indicate the use of special ...ackaging on Form 8570–11 and must ...esignate CR Package in Box 6 under ...ype of amendment."

1. Amendments for child-resistant ackaging certification: The registrant ...ust submit the required certification ...tatement (original and two copies) ...long with the amended application. If ...hild-resistant packaging instructions ...r opening and resecuring such ackaging appear on the product label ...r on an accompanying circular, then ...e label or circular must be submitted. ...f the instructions are on the container ...r closure, only a copy of the ...nstructions should be submitted.

2. Labeling amendments: Registrants ...ust file an amended application to ...evise their labeling to indicate specific ...onresidential use areas, or restricted ...se, i.e., the elected restriction of ...urchase, storage, and use only by a ...erviceperson; see section I. Registrants ... ...ish to amend their registrations to ... ...ifferent labels for the same ...oduct may do so. The same product ...ay be packaged in child-resistant ...ackaging and non-child-resistant ...ackaging in accordance with sections ... through L of this Notice. The revised ...abeling must be submitted to and ...eviewed by EPA to determine if it ...omplies with the special packaging ...egulations. If sticker labels are used on ...n interim basis the sticker must be ...ubmitted with the amendment.

3. Revisions to registrations to submit ...ew toxicity data and/or to change ...ormulations: A product may be less ...oxic than is currently indicated by its ...egistration and precautionary labeling. ...ome registrants may subject their ...roduct to additional testing to ...etermine its precise toxicity, or they ...ay reformulate their products so that ...hey do not meet the toxicity criteria ...nder 40 CFR 162.16(c)(2) (see F. 2 ...bove). If a product is reformulated an ...pplication for amended or new ...egistration must be filed as for any ...ther formulation change. If the ...egistrant's retesting indicates that the ...roduct is more toxic than previously ...ndicated, the registrant must submit ... ...ew test data to EPA, pursuant to FIFRA section 6(a)(2). If this toxicity testing also indicates that the registrant's product should be placed in a new (either higher or lower) toxicity category for labeling pruposes under 40 CFR 162.10(h)(1), the registrant must file an application for amended registration. If the new toxicity testing indicates that the registrant's product is less toxic than previously known, so that child-resistant packaging is not required but does not require that the product be placed into a different category, the registrant is not required to bring this information to EPA's attention. However, it would be helpful for him to do so, in order to avoid unnecessary enforcement actions in regard to the child-resistant packaging regulations.

N. Child-Resistant Packaging Certification for Registration of a New Pesticide Product Which Meets the Criteria

1. *Forms.* An applicant for the registration of a new pesticide product must indicate the use of special packaging on Form 8570–01 but a sample of the packaging need not be submitted. The applicant must submit the required certification statement (original and two copies).

2. *When certification is required.* Applicants may initiate registration procedures for new products before they obtain the child-resistant packaging data for certification. However, the child-resistant effectiveness certification must be submitted before any new product registration is issued after March 9, 1981.

3. *Labeling.* Instructions for opening and resecuring child-resistant packaging may appear on either the product label, accompanying labeling or circular, the container itself, or the closure. Instructions for special packaging on the label or circular will normally be submitted, as labeling is required for a new registration. If such instructions appear on the container or closure, then a copy of the instructions should be submitted. The container or closure should not be submitted.

O. Requesting Exemptions

The Special Packaging Regulations allow for exemption from child-resistant packaging of those products which meet the criteria for required special packaging only on the basis of technical infeasibility or on the basis that the hazards indicated by the toxicity criteria are not indicative of hazard to man.

An exemption should be mailed or delivered to Ms. D. Jean Jenkins, Special Packaging Coordinator, Registration Division (TS–767), Office of Pesticide Programs, Environmental Protection Agency, Rm. E–317, 401 M St. SW., Washington, D.C. 20460, (202–755–8930).

The regulation states that in order for an exemption to be granted it must be based on sufficient data which accompany the request, to support the decision. Additionally, it provides that any such decision shall be published in the Federal Register and shall be applicable to any product with identical or substantially similar composition and intended uses.

Initially, the procedures and data necessary to consider an exemption request will be determined on an individual basis. However, this document recommends certain procedures and data to help the agency in its consideration of requests for exemption. The agency requests but does not require that an exemption:

1. Be written in the English language.

2. Contain the name, address, and telephone number of the registrant.

3. Contain the Pesticide Registration Number and name of the Pesticide Product Manager.

4. Contain an explicit request for exemption from special packaging requirements.

5. Identify the particular product for which the exemption is sought.

6. Describe the package size of the product for which the exemption is sought.

7. Be typewritten.

8. Be accompanied by at least two copies of the request.

9. Explain the reason for the exemption based on one or more of the following grounds:

a. If the justification is based on the hazard indicated by the toxicity criteria in 40 CFR 162.16(c)(2) not being indicative of the risk to man, the justification shall state how the lack of human exposure, certain pharmocological mechanisms, or other human experience evidence [6] for the product clearly support granting of the exemption.

b. If the exemption is requested because special packaging is not technologically feasible (which includes compatible, practicable, or appropriate for the product), the justification shall explain why.

c. Where the exemption request is based upon an allegation that special packaging is incompatible with the particular product or would seriously and adversely compromise the utility or stability of a product, the registrant shall

[6] Human experience data, indicating the lack of accidents, are considered helpful but not primary evidence for an exemption.

submit adequate evidence to support the allegation.

d. If the allegation of incompatibility is based upon the fact that the shelf-life of the product limits package choice, the exemption shall outline the particular limitation and shall include a time schedule for the registrant to reestablish shelf-life data.

Granting exemptions: Where the agency determines that reasonable grounds for an exemption are presented, the agency shall publish that decision in the Federal Register, and it shall be applicable to any product with identical or substantially similar composition and intended uses.

"Reasonable grounds" for granting an exemption are information and data sufficient to support the conclusion that:

(a) The hazard indicated by the toxicity criteria in 40 CFR 162.16(c)(2) are not indicative of the risk to man.

(b) Special packaging is not technically feasible, which includes compatible, practicable, or appropriate for the product.

Denying exemptions: Where the agency determines that reasonable grounds for an exemption are not presented, the exemption shall be denied, and the registrant notified in writing of the denial, including a brief statement of the reasons therefor.

Effect of filing an exemption: The filing of an exemption shall not have the effect of staying the regulation from which the exemption is sought. Therefore, products subject to special packaging shall be considered to be in violation of the law unless packaged in special packaging during the agency's consideration of the exemption request after March 9, 1981.P.

Data Compensation

In accordance with the data compensation regulations contained in 40 CFR 162.9–1, and particularly paragraph (b)(17) thereof, all amendments to registration which are made solely to achieve compliance with the special packaging regulations and which do not require EPA to review scientific data before deciding whether to permit the amended registration, will not be subject to the data compensation provisions of FIFRA sections 3(c)(1)(D) and 3(c)(2)(B).

(Sec. 25(c)(3) as amended (Pub. L. 92-516, 86 Stat. 963; Pub. L. 94–140, 89 Stat. 755; Pub. L. 95–396, 92 Stat. 819; 7 U.S.C. 136 et seq.))

Dated: January 26, 1981.

Edwin L. Johnson,

Deputy Assistant Administrator for Pesticide Programs.

[FR Doc. 81-6718 Filed 3-2-81; 8:45 am]

BILLING CODE 6560-32-M

JUN 8 1981

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

OVERVIEW

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- 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

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.

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

4 JAN 1979

OFFICE OF ENFORCEMENT

SUBJECT: Primary Use Enforcement Responsibility

TO: Pesticide Branch Chiefs
Enforcement Division Directors

The Federal Pesticide Act of 1978 (P. L. 95-396) which amended the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA) was signed into law by President Jimmy Carter on September 30, 1978. This law contains two new sections, §26 State Primary Enforcement Responsibility and §27 - Failure by the State to Assure Enforcement of State Pesticide Use Regulations, which substantially affect the manner by which EPA will be dealing with the use and misuse of pesticides. I have included as Appendix A these two new sections of FIFRA.

In many respects these new sections to FIFRA contain directives which approximate current procedures found in the guidance for cooperative enforcement grants. For example, one major aspect of successful cooperative agreements is the establishment of on-going working relationships with State enforcement officials. A part of this working relationship should include a mechanism for the orderly flow of information concerning pesticide enforcement activities, including information and complaints about alleged pesticide use violations and subsequent State action. Such a scheme is also contemplated in these new FIFRA sections dealing with primary use enforcement. Where such relationships have not been established, Congress intends, through the primary use enforcement mechanism, that EPA immediately establish such work relationships.

This memorandum provides an interim policy under which EPA and States can operate until regulations formalizing this relationship are in place. EPA and States need a means by which either can recognize who has primary use enforcement responsibility at any instant moment. In addition, until a formal mechanism for referring complaints or information about alleged violations of the use provisions of FIFRA is in place, the procedures outlined in this memorandum will govern.

A. Primary Enforcement Responsibility

1. What is it?

When a government entity, be it EPA or State, has primary enforcement responsibility, it has the first (or primary) option for investigating and taking appropriate enforcement action against pesticide use violations.

2. How does a State get it?

In brief, there are three ways by which a State shall have primary responsibility for pesticide use enforcement:

a. A State will have the primary responsibility for pesticide use enforcement if, upon request by the State, EPA has determined that 1) the State has adequate pesticide use laws and regulations, 2) the State has adequate procedures for implementing these laws and regulations, and 3) the State will keep records and make reports showing compliance with 1) and 2) above.

b. Notwithstanding this, any State with a cooperative agreement with EPA to cooperate in the enforcement of FIFRA, pursuant to Section 23, shall immediately upon implementation of that agreement, have primary responsibility for pesticide use enforcement within its borders.

c. A State may also receive primary responsibility for use enforcement if EPA determines that the State has an approved plan under section 4 for certifying applicators and the plan meets the criteria of a. above.

If at anytime after September 30, 1978, a State asks for and receives a determination that it meets the test of adequate laws, regulations, and procedures under a. above, implements a cooperative enforcement agreement with EPA or, upon final approval of its section 4 Plan, receives a determination that the plan meets the criteria of a. above, that State shall have primary enforcement responsibility for use violations within that State.

If a State with a cooperative enforcement agreement chooses to withdraw from that agreement, the State will lose their primary enforcement responsibility upon the date of termination of the cooperative agreement. Should that same State have an approved State

Plan under section 4, EPA will review that plan for enforcement adequacy as soon as practical to determine whether the State can regain use enforcement primacy.

3. Who has it?

The following States, as of the date of this memorandum, have primary enforcement responsibility for pesticide use violations:

Region I	Region IV	Region VIII
Connecticut	Kentucky	Montana
New Hampshire	Mississippi	North Dakota
Vermont	North Carolina	South Dakota
	Tennessee	
Region II	**Region V**	**Region IX**
		1/
New Jersey	Indiana	Arizona
New York	Michigan	California
Puerto Rico	Minnesota	Guam
Virgin Islands		Hawaii
Region III	**Region VI**	**Region X**
D. C.	Arkansas	Idaho
Delaware	Louisiana	Oregon
Maryland	New Mexico	Washington
Pennsylvania	Oklahoma	
Virginia	Texas	
West Virginia		
	Region VII	
	Iowa	
	Kansas	

1/ Arizona divides responsibility for use enforcement between the structural Pest Control Board and the Arizona Board of Pesticide Control (Agriculture). EPA has a cooperative enforcement agreement with the former, not the latter. Therefore, Arizona has primary use enforcement responsibility for pesticide use violations that come within the jurisdiction of the Structural Pest Control Board; EPA has responsibility for all other use enforcement activities. If there are other instances of very distinguishable separation of use enforcement authority within a State and EPA has a cooperative enforcement agreement with only one of the authorities, the region should bring this to the attention of PTSED.

4. Who does not have it?

The following States, as of the date of this memorandum, do not have primary enforcement responsibility for pesticide use violations; EPA continues to have primary responsibility.

Region I	Region VII	Region X
Maine*	Missouri*	Alaska*
Massachusetts	Nebraska	
Rhode Island*		
Region IV	**Region VIII**	
Alabama*	Colorado*	
Florida*	Utah*	
Georgia	Wyoming*	
South Carolina*		
Region V	**Region IX**	
Illinois*	Trust Territories	
Ohio*	Samoa	
Wisconsin*		

* EPA will be conducting a rapid evaluation (to be completed within 6 months of the date of enactment of this law) of these State's §4 Plans in order to determine the enforcement adequacy of the State's pesticide use laws, regulations, and procedures.

5. What is EPA's role in pesticide use enforcement?

In States that do not have primary use enforcement responsibility, EPA will have the primary responsibility. In those States where EPA has the primary responsibility for pesticide use enforcement, Congress has affirmatively provided that the Agency may inspect the books and records and work establishments of commercial applicators and "for hire" applicators. Also, samples may be taken of pesticides or use dilutions of pesticides held by those applicators. "For hire" applicators are those applicators that are in the business of applying pesticides. Examples of "for hire" applicators, for whom controlling pests is all or part of their occupation, are structural pest control operators, aerial applicators, arborists, lawn maintenance workers, and janitorial service workers. Nothing in this Act precludes the Agency from

continuing routine use surveillance, (i.e. use observations where there is no prior evidence of misuse) whether or not that surveillance takes place in a State that has primary use enforcement responsibility. However, in those States having primary use enforcement responsibility, the Agency may not include within that routine surveillance visits to commercial or "for hire" applicator establishments for purposes of sampling or reviewing books and records. In those States, routine use surveillance shall be confined to application sites where entry has been gained by consent of the owner. Any information or evidence that points to a significant violation of FIFRA (i.e. one which we would deem worthy of further investigation) shall be referred to the State if that State State has primary enforcement responsibility.

6. How will the referral of complaints or information indicating use violations of FIFRA work?

Section 27(a) of the amended FIFRA requires that EPA refer any complaints or other information alleging or indicating a significant violation of the pesticide use provisions of FIFRA to the appropriate State officials for their investigation. Of course, such referral need only be made when the State has primary use enforcement responsibility. Further, if the State does not commence appropriate enforcement action within thirty days, EPA may act upon the complaint or information.

If any information or complaint, indicating or alleging a significant violation of FIFRA, is received after September 30, 1978, and the alleged violation took place in a State with primary use enforcement responsibility, such information or complaint shall immediately be referred to the appropriate official in that State. Any such information or complaint received in EPA headquarters shall be referred to the State via the appropriate regional office. Regions will be responsible for immediately establishing working relationships with States for the orderly flow of information on enforcement activities and for determining who the appropriate State officials for handling such information are. The State will have thirty days to initiate appropriate enforcement action upon making a determination that a possible violation of either FIFRA or the State pesticide law has occurred. It is expected that appropriate enforcement action will be t·.en by the State under that State's pesticide law in cases where the evidence indicates either a violation of only the State law or both the State law and FIFRA.

At the conclusion of the thirty day time period, the regional office shall request information on the status of the particular investigation. Obviously, in some cases States may be unable to investigate and commence appropriate enforcement action, particularly in complicated cases, within the thirty day time frame referred to in the amended FIFRA. Regions should use their discretion when determining whether to extend the time period for a State to commence appropriate enforcement action or to request return of the case file. It is expected that States will forward all evidence obtained in an investigation to the EPA regional office: 1) where no enforcement proceedings have been initiated within thirty days of a determination of a possible violation of State law and FIFRA, 2) where the investigation determines that a possible violation of only FIFRA occurred, (not State law), or 3) where EPA determines that the enforcement action taken by the State is not appropriate to the alleged violation. Until regulations are in place for rescinding primary enforcement responsibility for failure by the State to assure enforcement of State pesticide use regulations, a region shall request concurrence from their PTSED regional coordinator before overriding any State enforcement action.

Complete and thorough documentation must be kept of all referrals to States of complaints or information on alleged use violations and subsequent follow-up actions by States. A draft complaint referral form is attached for use by those regions without any current referral form (Appendix B). Two copies of this form, with additional attached information, where appropriate, shall be completed and forwarded to the appropriate State official immediately upon receipt of any complaint or information about a use violation. Within thirty days (or longer, if extended), the State should be instructed to return one copy of the State form with a brief description of the disposition of the case, i.e. either a notation of the kind of enforcement action taken (e.g. 2 month suspension of applicator's license) or an explanation as to why no enforcement action was taken (e.g. not a violation of State law). If no report on the disposition of a case is received within a suitable period of time, the region shall follow-up with either a written or telephonic request for such information. Such records will be necessary for future determinations as to whether States are properly discharging their enforcement responsibilities in the pesticide use area.

7. How should emergencies arising out of the use of pesticides be handled?

When the region becomes aware of emergency conditions arising out of the use of pesticides, they should immediately inform the appropriate State officials. State officials are to be requested to respond to the emergency; the region should offer whatever assistance they can. If State officials indicate that they are unwilling or unable to adequately respond to the emergency, the region should respond to the fullest extent possible.

Should you have any questions concerning this interim policy, please contact your PTSED regional coordinator or Jack Neylan (755-0997).

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

Attachments

"SEC. 26. STATE PRIMARY ENFORCEMENT RESPONSIBILITY.

"(a) For the purposes of this Act, a State shall have primary enforcement responsibility for pesticide use violations during any period for which the Administrator determines that such State—

"(1) has adopted adequate pesticide use laws and regulations: Provided, That the Administrator may not require a State to have pesticide use laws that are more stringent than this Act;

"(2) has adopted and is implementing adequate procedures for the enforcement of such State laws and regulations; and

"(3) will keep such records and make such reports showing compliance with paragraphs (1) and (2) of this subsection as the Administrator may require by regulation.

"(b) Notwithstanding the provisions of subsection (a) of this section, any State that enters into a cooperative agreement with the Administrator under section 23 of this Act for the enforcement of pesticide use restrictions shall have the primary enforcement responsibility for pesticide use violations. Any State that has a plan approved by the Administrator in accordance with the requirements of section 4 of this Act that the Administrator determines meets the criteria set out in subsection (a) of this section shall have the primary enforcement responsibility for pesticide use violations. The Administrator shall make such determinations with respect to State plans under section 4 of this Act in effect on the date of enactment of the Federal Pesticide Act of 1978 not later than six months after that date.

"(c) The Administrator shall have primary enforcement responsibility for those States that do not have primary enforcement responsibility under this Act. Notwithstanding the provisions of section 2(e)(1) of this Act, during any period when the Administrator has such enforcement responsibility, section 8(b) of this Act shall apply to the books and records of commercial applicators and to any applicator who holds or applies pesticides, or use dilutions of pesticides, only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served, and section 9(a) of this Act shall apply to the establishment or other place where pesticides or devices are held for application by such persons with respect to pesticides or devices held for such application.

"SEC. 27. FAILURE BY THE STATE TO ASSURE ENFORCEMENT OF STATE PESTICIDE USE REGULATIONS.

"(a) Upon receipt of any complaint or other information alleging or indicating a significant violation of the pesticide use provisions of this Act, the Administrator shall refer the matter to the appropriate State officials for their investigation of the matter consistent with the requirements of this Act. If, within thirty days, the State has not commenced appropriate enforcement action, the Administrator may act upon the complaint or information to the extent authorized under this Act.

"(b) Whenever the Administrator determines that a State having primary enforcement responsibility for pesticide use violations is not carrying out (or cannot carry out due to the lack of adequate legal authority) such responsibility, the Administrator shall notify the State. Such notice shall specify those aspects of the administration of the State program that are determined to be inadequate. The State shall have ninety days after receipt of the notice to correct any deficiencies. If after that time the Administrator determines that the State program remains inadequate, the Administrator may rescind, in whole or in part, the State's primary enforcement responsibility for pesticide use violations.

"(c) Neither section 26 of this Act nor this section shall limit the authority of the Administrator to enforce this Act, where the Administrator determines that emergency conditions exist that require immediate action on the part of the Administrator and the State authority is unwilling or unable adequately to respond to the emergency.

REFERRAL FORM

Date Rec'd

Description of Alleged Complaint or Information

Disposition

Referred to:	Referred by:	Date referred
	For further information, contact	Date response du

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

MAR 14 1979

OFFICE OF ENFORCEMENT

MEMORANDUM

SUBJECT: Review of State Certification Plans Pursuant to FIFRA Section 26

TO: Regional Enforcement Directors
Regional Branch Chiefs

The new section 26 of the amended FIFRA automatically grants to States who have Cooperative Enforcement Agreements (CEAs) with EPA the primary enforcement responsiblity for pesticide use violations. States without CEAs, but who have section 4 (applicator certification) plans approved by the Administrator, should have their pesticide laws and regulations reviewed by EPA by March 29, 1979, to determine whether they are adequate for EPA to also grant them primary use enforcement responsiblity. At present there are thirteen (13) States which fall into this latter category (see ATTACHMENT A).

In light of the fact that EPA was given a short deadline for the completion of this review and in the absence of any delegation of authority from the Administrator for the implementation of this new FIFRA provision, PTSED plans to carry-out this congressionally mandated review of the thirteen approved State plans at a meeting to be held on March 23rd at EPA Headquarters in Washington, D. C. (see ATTACHMENT B). I have designated Mr. John C. Ulfelder, Head of the Legal Support Section, as Chairperson for this meeting. PTSED will also be represented by Jack Neylan, David Stangel and Joseph Virgilio of the Policy and Guidance Branch, as well as John Martin, William Danson and David Hanneman of the Program Operations Branch. In addition, OPP has agreed to allow Ralph Colleli, formerly with the Operations Division, to assist us with our review of the thirteen State plans.

Basically the State plans will be measured against the standards set forth in sections 26(a)(1) and (2) of the amended FIFRA. They require that the State:

> (1) has adopted adequate pesticide use laws and regulations; Provided, that the Administrator may not require a State to have pesticide use laws that are more stringent than this Act; [and]
>
> (2) has adopted and is implementing adequate procedures for the enforcement of such State laws and regulations;...

While there is a presumption that States with approved applicator certification plans have adopted adequate laws for violations involving restricted use pesticides, it will still be necessary to make certain that their laws and regulations are also adequate for violations involving general use pesticides. It is clear, however, that the focus of the review will be on the question whether each State has, in fact, established adequate procedures for enforcing against use violations and whether they are implementing those procedures adequately. Some of the procedural aspects that will be examined include: 1. Are sufficient State resources committed to the investigation and actual enforcement of use violations; 2. Are complaints of pesticide misuse followed-up promptly and concluded in a timely manner; 3. Are State personnel properly trained to handle investigations and enforcement actions involving allegations of pesticide misuse; 4. Do substantive complaints of misuse actually result in State enforcement action; and 5. Is the State enforcement action appropriate in light of the violation and the enforcement options open to the State enforcement Agency?

Since EPA regional representatives are the most knowledgable about the status of pesticide enforcement in the States in their regions, it will be essential to the success of the review of each State's plan and operating procedures to have strong regional participation on March 23rd. Although the Regions' views can either be presented in writing in advance of the meeting or in person on March 23rd (or both), if a Region is of the opinion that a particular State should not be granted primary use enforcement responsibility, it should plan to send a representative to the March meeting to discuss that position with the Headquarters personnel. For States where the regional office thinks there is little question about the appropriateness of granting State primary use enforcement, it would be sufficient to submit such a recommendation in writing before March 23rd. Once a decision has been made about the status of each of the thirteen States, letters will be prepared for Mr. Costle's

signature notifying the various State lead agencies about EPA's decision. In addition, each State being granted primary use enforcement responsibility in accordance with the new section 26 will be asked to meet certain minimal reporting requirements concerning pesticide use enforcement until final regulations implementing sections 26 and 27 are implemented.

I would appreciate it if each of the seven Regions that have State plans to be reviewed at the March meeting would notify Mr. Ulfelder whether or not they plan to be represented at that meeting. If you have any questions about the review of the thirteen State plans, please direc your questions to Mr. Ulfelder at 472-3701.

A. E. Conroy II, Direct
Pesticides and Toxic Substa...
Enforcement Division

Attachments

ATTACHMENT A

List of States With Approved Section 4 Plans, But Without CEAS

REGION I:	Maine
REGION IV:	Alabama
	Florida
	Georgia
	South Carolina
REGION V:	Illinois
	Ohio
	Wisconsin
REGION VII:	Missouri
REGION VIII:	Utah
	Wyoming
REGION IX:	Arizona (Agricultural Use Only)
REGION X:	Alaska

ATTACHMENT B

Friday, March 23, 1979

Location: EPA Headquarters
Washington, D.C.
3rd Floor Conf. Rm., East Tower
Room No. 344

I. 9:00 a.m. - 12:00 noon

The following States will be reviewed:

Region I:	Maine
Region IV:	Alabama Florida Georgia South Carolina
Region V:	Illinois Ohio Wisconsin

II. 1:30 p.m. - 4:30 p.m.

The following States will be reviewed:

Region VII:	Missouri
Region VIII:	Utah Wyoming
Region IX:	Arizona
Region X:	Alaska

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

MAR 4 1980

OFFICE OF ENFORCEMENT

MEMORANDUM

SUBJECT: Clarification of Primary Use Enforcement Responsibility Guidance

TO: Regional Pesticide Branch Chiefs
Regional Enforcement Division Directors

On January 4 of last year, the Pesticides and Toxic Substances Enforcement Division (PTSED) sent out an interim policy statement describing procedures for EPA/State cooperation in the area of primary responsibility for enforcing pesticide use violations. This memorandum supplements the January 4 guidance by expanding upon the proper Agency response to receipt of a State file which indicates a pesticide use violations.

Since the amended FIFRA, per sections 26 and 27, directs the Agency to allow the States to have first option for bringing enforcement actions against violators of pesticide use requirements, EPA should take no action except in emergencies as described under section 27(c), based on any State file until the appropriate Region consults with the State on the investigatory or enforcement status of the case. After the State has been allowed time to conduct its inquiry, the Region should request a statement indicating the proposed enforcement action chosen by the State. If the State's action is not "appropriate" (see section 27(a)) in light of the gravity of the alleged violation, the Region should after obtaining concurrence from the Office of Enforcement's Pesticides and Toxic Substances Enforcement Division, send a notice to the State (1) communicating its disagreement with the selected action, (2) recommending the type of State action which the Agency would consider to be "appropriate", and (3) notifying the State that it has 30 days to commence an appropriate action.

- As a general operating principle, the Regions should avoid using already-scarce Federal resources merely to reinforce state enforcement actions taken in response to minor violations of the pesticide laws. Rather the Regional Offices, in accordance with stated Agency goals of protecting public health and safety and preserving sensitive ecosystems, should be careful to focus their efforts and resources on those situations which significantly endanger public health or the environment and which are not otherwise appropriately addressed by state actions.

Richard D. Wilson
Deputy Assistant Administrator
for General Enforcement

DEC 18 1980

MEMORANDUM

SUBJECT: Appropriate Documents to be Presented by State Inspectors Conducting Pesticide Use Inspections in States Having Primacy

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

At present most State inspectors conducting pesticide use inspections present credentials headed: "United States Environmental Protection Agency". The credential later identifies the inspector as "an employee of the State of _____." This credential has been supplied by the Agency as a convenience to States which have cooperative enforcement agreements with EPA. (EPA Form 3540-28 (Rev. 4-78))

These credentials were designed before primacy when States conducted use inspections for violations of FIFRA under the auspices of a cooperative agreement. Pursuant to Section 26, most States now exercise primary enforcement responsibility for all use violations. Use inspections are, therefore, primarily a State activity. Consequently, use inspections in States with primacy are undertaken under the authority of State law, (this is true even where the use inspections are Federally funded).

Therefore, during use inspections, it is appropriate for State inspectors to present credentials which indicate that the inspectors are acting under authority of State law. The existing Federally supplied credentials are misleading since they are headed "United States Environmental Protection Agency." In the future, State inspectors conducting pesticide use inspections ~~should~~ must present credentials that are issued by their State employers. If State credentials do not already exist, the State is responsible for designing and providing such credentials to their inspectors.

It is additionally necessary for States to cease using the Federally supplied "Notice of Inspection" form, (EPA Form 3540-2 (Rev. 3-75)). The present form erroneously identifies use inspections as being authorized under the authority of the "U.S. Environmental Protection Agency". The States are responsible for drafting new Notice of Inspection forms. The States must design their Notice of Inspection form in a manner which parallels the EPA form. A consistent format will greatly aid the indexing of the information in the Agency computer. The State Notice of Inspection form should indicate the relevant State statutes which authorize the inspection. While States await the printing of the new forms, they may use the Federally supplied forms if all indicia of Federal authority are obscured.

It should also be noted that State inspectors conducting use inspections cannot rely upon FIFRA for authority to take affidavits. Consequently the Agency affidavit form (EPA Form 3540-11 (Rev. 9-75)) may not be used by States during use inspections. If State law grants this power, of course, the inspector may take an affidavit according to State procedures.

I hope that the Regions will implement these guidelines during the next 60 days. Please contact John Martin of my staff at 755-1075 if you have any questions.

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

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 173

[OPP 00159; PH-FRL 2215-3]

Federal Insecticide, Fungicide, and Rodenticide Act, State Primary Enforcement Responsibilities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final interpretive rule.

SUMMARY: This rule states EPA's interpretation of several of the key provisions in sections 26 and 27 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), but does not impose substantive requirements on the States. Sections 26 and 27 established a standard and procedure for according States the primary enforcement responsibility for pesticide use violations (primacy). The rule also provides operational substance to the criteria used by EPA for primacy related decisionmaking, and ensures that such decisionmaking is consistent throughout the regions.

EFFECTIVE DATE: This rule will not take effect before the end of 60 calendar days of continuous session of Congress after

the date of publication. EPA will publish a notice of the actual effective date of this rule. See **SUPPLEMENTARY INFORMATION** for further details.

FOR FURTHER INFORMATION CONTACT: Laura Campbell, Pesticides and Toxic Substances Enforcement Division (EN-342), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. M-2624E, 401 M St., SW., Washington, D.C. 20460, (202-382-5566).

SUPPLEMENTARY INFORMATION:

Background

In 1978, Congress enacted Pub. L. 95-396 which contained numerous revisions to the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*). One of the changes added two new sections to FIFRA, sections 26 and 27, U.S.C. 136w-1 and 136w-2, which together established a standard and procedure for according States the primary enforcement responsibility for pesticide use violations (primacy).

Section 26 provides three methods by which a State can obtain primacy. Section 26(a) requires a State to be accorded primacy if the Administrator finds that the State has (1) adopted adequate use laws, (2) adopted adequate procedures for implementing those laws, and (3) agreed to keep such records and make such reports as the Administrator may require by regulation. Section 26(b) allows a State to obtain primacy if the State has an approved section 4 certification plan that meets the criteria set forth in section 26(a), or if a State enters into a cooperative agreement for the enforcement of pesticide use restrictions under section 23.

Section 27 authorizes the Administrator to override or rescind a grant of primacy in certain situations. Section 27(a) requires the Administrator to refer significant allegations of pesticide use violations to the States. If a State does not commence appropriate enforcement action within 30 days of such referral, EPA may bring its own enforcement action.

Section 27(b) authorizes the Administrator to rescind the primary enforcement responsibility of a State if she finds that the State is not carrying out such responsibility. The Administrator initiates a rescission proceeding by notifying the State of those aspects of the State's pesticide use enforcement program which the Administrator has found to be inadequate. If the State does not correct the deficiencies in its program within 90 days, the Administrator may rescind the States's primary enforcement responsibility in whole or in part. EPA has promulgated procedures which govern the conduct of a proceeding to rescind State primacy. These procedures were published in the Federal Register of May 11, 1981 (46 FR 26058). (40 CFR Part 171).

Section 27(c) authorizes the Administrator to take immediate action to abate an emergency situation where the State is unable or unwilling to respond to the crisis.

As is evident from the above description, several of the operative terms in sections 26 and 27 require further definition. This rule clarifies the meaning of such words as "adequate" and "appropriate" which FIFRA sets forth as the criteria for most of the decisions which will be made under these two sections. The rule also sets guidelines to be used by EPA in making primacy-related decisions, and ensures that such decisionmaking is consistent by limiting, although not eliminating, Agency discretion in the primacy area.

Specifically, this rule addresses the following issues:

1. Procedures EPA will follow when referring allegations of pesticide use violations to the State and tracking State responses to these referrals (see Unit I, Subdivision A below).

2. The meaning of "appropriate enforcement action" (see Unit I, Subdivision B).

3. Clarification of when a State will be deemed to have (1) adopted adequate pesticide use laws and regulations, and (2) implemented adequate procedures for the enforcement of such laws and regulations (see Unit II).

4. The criteria the Administrator will use to determine whether a State is adequately carrying out its primary enforcement responsibility for pesticide use violations (see Unit III).

5. The factors which constitute an emergency situation, and the circumstances which require EPA to defer to the State for a response to the crisis (see Unit IV).

Comments Received

Four comments were received in response to the proposal of the Interpretive Rule. (47 FR 16799, April 20, 1982).

In the proposed rule, a determination of the gravity of violation was based on two factors: (1) risk associated with the violative action, and (2) risk associated with the pesticide. Some of the comments stated that EPA should determine the gravity of each violation based on whether actual harm occurred as a result of the violation. If the Agency were to determine the seriousness of a violation based on the actual harm which occurred in a particular case, pesticide users would be encouraged to take the risk of misusing a pesticide, with the hope that no actual harm would result from their unlawful act. Congress charged EPA with regulating pesticide use in a manner which will prevent unreasonable risk of pesticide exposure to man or the environment. Congressional intent would not be carried out if EPA encouraged pesticide users to engage in unsafe activities by not charging violations in cases where no actual harm occurred. For this reason, the final rule retains the language of the proposed rule.

Two comments concerning the imposition of criminal penalties for pesticide misuse were received. One comment stated that Congress intended criminal sanctions to be applied only in cases involving unlawful manufacture of pesticides. Nothing in FIFRA or its legislative history so limits the use of criminal penalties. The only criterion in the statute for the imposition of criminal penalties is that a violation is "knowing". The language referring to criminal penalties in the proposed rule has been largely retained in the final rule.

Another comment expressed the concern that imposing more stringent sanctions where violations are found to be "knowing" penalizes persons who are informed about the law. Section 14 of FIFRA states that "knowing" violations are subject to criminal penalties. Knowledge of the violator is a valid criterion to use in determining gravity because of a "knowing" violation shows a disregard for the law.

One comment stated that no State with more stringent pesticide use laws than the Federal law should be granted primacy. Although EPA cannot require a State to enact a pesticide use law that is more stringent than FIFRA, there is no prohibition against granting primacy to a State whose pesticide use law is more stringent.

One comment suggested a change in the requirement that State laboratories conducting sample analysis participate in EPA's check sample program. The comment stated that the National Enforcement Investigation Center (NEIC) check sample program should be coordinated with the American Association of Pest Control Officials (AAPCO). The NEIC check sample program is currently coordinated with the AAPCO check sample program. The rule has been changed to reflect this comment.

Further Information on Effective Date of This Rule

On December 17, 1980, the Federal Insecticide, Fungicide, and Rodenticide Act extension bill (Pub. L. 96-539) became law. This bill amended several sections of FIFRA, including section 25 ... rulemaking. Section 4 of the Extension Act adds a new paragraph, section 25(e), to FIFRA which requires EPA to submit final regulations to Congress for review before the regulations become effective. Copies of this rule have been transmitted to appropriate offices in both Houses of Congress.

Under section 4 of the 1980 FIFRA Extension Act, this rule will not take effect before the end of 60 calendar days of continuous session of Congress after the date of publication of this rule. Since the actual length of this waiting period may be affected by Congressional action, it is not possible, at this time, to specify a date on which this regulation will become effective. Therefore, at the appropriate time EPA will publish a notice announcing the end of the legislative review period and notifying the public of the actual effective date of this regulation.

Compliance With the Regulatory Flexibility Act

I hereby certify that this rule will not have a significant economic impact on small entities. The rule affects only ... pesticide control agencies, which ... of small entities under the ...latory Flexibility Act, 5 U.S.C. 601 *et seq.*

Compliance With Executive Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is "Major" and therefore subject to the requirement of a Regulatory Impact Analysis. This regulation is not Major since it is interpretive in nature and does not contain new substantive requirements. The regulation:

1. Does not have an annual effect on the economy of $100 million or more.

2. Will not substantially increase costs to consumers, industry, or government.

3. Will not have a significant adverse effect on competition, employment, investment, productivity, or innovation.

This regulation was submitted to the Office of Management and Budget for review as required by Executive Order 12291. (Sec. 25(a)(1) (7 U.S.C. 136w)). [Note: This rule will not appear in the Code of Federal Regulations.]

I. Appropriate Enforcement Action

A. *Procedures Governing Referrals.* 1. *General.* Section 27(a) requires EPA to refer to the States any information it receives indicating a significant violation of pesticide use laws. If a State has not commenced appropriate enforcement action within 30 days, EPA may act on the information.

Given current resource limitations, EPA is not in a position to monitor State responses to every allegation of pesticide misuse referred by the Agency. Rather, the Agency will focus its oversight activities on evaluating the overall success of State pesticide enforcement programs, and will track, on a case-by-case basis, only those allegations involving particularly serious violations. Such "significant" allegations will be formally referred to the States and tracked by EPA, while other less serious complaints will be forwarded to the States for information purposes only.

2. *Criteria for significant cases.* To determine which alleged violations are sufficiently significant to warrant formal referral and tracking, the regions will go through a two step process. First, the regions, in consultation with each State, will identify priority areas for referral. These priority areas will consist of those pesticide activities in the State which present the greatest potential for harm to health or the environment (e.g. the application of a pesticide by a certain method to a particular crop, such as ground application of endrin to apple trees). The selection of these priority areas will depend primarily on the results of pesticide enforcement program evaluations conducted by the States and the regions. The priority areas will be revised on an annual basis based upon the effectiveness of the program in reducing the harm associated with pesticide use.

Thereafter EPA will determine on a case-by-case basis which allegations in these priority areas involve sufficiently "significant" violations to be formally referred to the State and tracked. If a complaint received by EPA alleges a minor infraction which clearly presents little or no danger to health or the environment, or if the information contains patently spurious allegations, such as those from sources which have repeatedly proved unreliable, the matter will be forwarded to the State for information purposes only.

3. *The 30-day time period.* The Agency interprets the term "commence appropriate enforcement action" in section 27(a) to require States to initiate a judicial or administrative action in the nature of an enforcement proceeding, if one is warranted. Starting an investigation of the matter would not be sufficient. If the State does not commence an appropriate administrative, civil, or criminal enforcement response, EPA would then be permitted, although not required, to bring its own enforcement action.

Although section 27(a) permits EPA to act if the State has not commenced an enforcement action within 30 days, the Agency recognizes that States may not be able to complete their investigation of many formal referrals in so short a time. The time needed to investigate a possible use violation will vary widely, depending upon the nature of the referral. A referral which simply conveys an unsubstantiated allegation will usually require more investigation than a referral which partially or fully documents a pesticide use violation. Consequently, the Agency wishes to develop a flexible approach towards the tracking of referrals.

To accomplish this objective, EPA is adopting a system in which the referral process is broken down into two stages, investigation and prosecution.

4. *The investigation stage.* Following the formal written referral of an allegation of a significant pesticide use violation, the appropriate regional pesticide official will contact the State to learn the results of the investigation and the State's intended enforcement response to the violation. If the State has not conducted an adequate investigation of the alleged violation, the region may choose to pursue its own investigation or enforcement action after notice to the State. As a general rule, however, the regional office will attempt to correct any deficiencies in the investigation through informal communication with the State.

An investigation will be considered adequate if the State has (1) followed proper sampling and other evidence-gathering techniques, (2) responded expeditiously to the referral, so that evidence is preserved to the extent possible, and (3) documented all inculpatory or exculpatory events or information.

5. *The prosecution stage.* After completion of the investigation, the State will have 30 days, the prosecution stage, to commence the enforcement action, if one is warranted. An appropriate enforcement response may consist of required training in proper pesticide use, issuance of a warning letter, assessment of an administrative civil penalty, referral of the case to a pesticide control board or State's Attorney for action, or other similar enforcement remedy available under State law. The 30-day period may be extended when necessitated by the procedural characteristics of a State's regulatory structure (see Unit V.A. Hypothetical 1).

If, after consultation with the State, EPA determines that the State's intended enforcement response to the violation is inappropriate (see subdivision B), EPA may bring its own action after notice to the State. Regional attorneys will not, however, initiate an enforcement proceeding sooner than 30 days after the matter was referred to the State.

At times, a State may find that the particular enforcement remedy it views as the appropriate response to a use violation is not available under the State's pesticide control laws. Therefore the State may, at any time, request EPA to act upon a violation utilizing remedies available under FIFRA. In these instances, of course, EPA will immediately pursue its own action, if one is warranted.

To illustrate better the proposed referral system, two hypothetical situations are described in Unit V. A.

B. *Appropriate Enforcement Action.* 1. *General:* After the Agency learns of the enforcement action, if any, the State proposes to bring against the violator, the EPA regional pesticide office will consider, in consultation with the State, whether the proposed action is "appropriate", relative to the remedies available to the State under its pesticide control legislation. EPA interprets the modifier "appropriate" in section 27(a) of FIFRA to require that the severity of the proposed enforcement action correlate to the gravity of the violation.

It is not possible in this Interpretive Rule to prescribe the specific enforcement action which will constitute an appropriate response to a particular violation. There are too many variables which will influence the treatment of a use violation, including the disparity between the types of enforcement remedies available under the various State pesticide control statutes. This document can, however, establish criteria to be employed in evaluating the appropriateness of a proposed State enforcement action. More detailed guidance on evaluating relative gravity is contained in EPA's "Guidelines for the Assessment of Civil Penalties under Section 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended", published in the Federal Register of July 31, 1974 (39 FR 27711). The Guidelines establish dollar amounts to be applied under the Federal statute to use violations in civil penalty proceedings. Regional personnel can use these figures as a guide in evaluating the gravity of a particular violation. The Agency will not require that a State response to a violation have a monetary impact equivalent to that of a civil penalty which EPA would impose under the Guidelines. Rather, the dollar amounts contained in the penalty matrices can be used by regional personnel to define the relative gravity of a violation by comparing the figures applicable to different violations.

2. *Gravity of the violation.* The Agency believes that the gravity of a pesticide use violation is dependent upon the risk the violation poses to human health and the environment. The factors which determine the degree of risk presented by a use violation can be divided into two categories: factors related to the particular action which constituted the violation and factors related to the pesticide involved in the incident.

a. *Risk associated with the violative action.* The circumstances surrounding the violative action partially determine the risk the violation presents to human health or the environment. To assess the degree of such risk, State and regional personnel should ask such questions as:

i. Did the violation occur in a highly populated area, or near residences, schools, churches, shopping centers, public parks or public roads, so that health was endangered?

ii. Did the violation occur near an environmentally sensitive area, such as a lake or stream which provides drinking water to the surrounding community, a wildlife sanctuary, a commercial fishery, or other natural areas?

iii. Did a structural application threaten to contaminate food or food service equipment?

iv. Did the violation have the potential to affect a large or a small area?

v. What was the actual harm which resulted from the violation?

vi. Was the nature of the violation such that serious consequences were likely to result?

This last question is designed to take into account the variation in the inherent risk associated with different categories of use violations. For example, a drift violation resulting from improper aerial application generally presents a greater risk of harm than a storage violation, since the latter infraction does not necessarily involve the improper exposure of the pesticide to the environment.

b. *Risk associated with the pesticide.* The factors which will be crucial in evaluating the risk associated with the pesticide itself include:

i. The acute toxicity of the pesticide or pesticides involved in the incident. The toxicity of a pesticide will be indicated by the "human hazard signal word" on the labels (see 40 CFR 162.10). "Danger" or "Poison" are indicators of a highly toxic pesticide while "Warning" and "Caution" signify successively less toxic substances.

ii. The chronic effects associated with the pesticide, if known.

iii. The amount of the pesticide involved in the incident, relative to the manner of application (e.g., aerial versus structural).

iv. Other data concerning the harm a pesticide may cause to human health or the environment, such as data concerning persistence or residue capability.

An analysis of the interrelationship between these two categories of risk factors should yield a notion of the relative gravity of the violation and the severity of the action which should be taken in response.

3. *Category of applicator, size of business, and history of prior violation.* Gravity is not the only factor which EPA will take into account in evaluating the propriety of an enforcement action. Section 14 of FIFRA requires that distinctions in the severity of an enforcement response be made between the categories of persons who commit use violations. The intent of Congress, as expressed in section 14, is that commercial pesticide applicators who violate use requirements will be subject to more stringent penalties that other persons who violate use restrictions. Congress also envisioned that the size of the violator's business will be a factor in determining the severity of the penalty. In addition, section 14 distinguishes between violators who have committed previous infractions and those who are first offenders. Thus, the issuance of a warning letter by a State to a person or firm who has been repeatedly warned in the past about a certain violation would not generally be considered an appropriate response to the violation.

4. *Knowing violations: criminal penalties.* The state of mind of the violator is another important consideration. In extreme circumstances where the civil penalty remedy is inappropriate, it is the Agency's policy to pursue a criminal action against persons who knowingly violate a provision of FIFRA. EPA will be particularly interested in pursuing criminal prosecution for those violations which involve a death or serious bodily injury or in which the violator has demonstrated a reckless or wanton disregard for human safety, environmental values or the terms of the statute. To be appropriate, a State's response to a knowing violation under the circumstances indicated above must be similarly severe.

5. *Deterrence.* It should be noted that the appropriateness of an enforcement

action is a dynamic, rather than a static, concept. Because it is dynamic, penalties must be periodically evaluated. If a certain violation is occurring more frequently, the leniency of the remedies which have been applied to this infraction in the past should be questioned. Consequently, what is appropriate in one year may be viewed as an inadequate response in the next.

The factors described above, together with the aforementioned Guidelines, should help to clarify the Agency's definition of "appropriate enforcement action." To understand better how the criteria described above can be used to evaluate whether a proposed State enforcement action is appropriate, the reader is referred to the hypothetical fact situations in Appendix B.

II. Criteria Governing Grants of Primacy

Section 26 of FIFRA sets forth the general criteria which apply to EPA's decision whether to grant primacy to a State:

"(a) For the purposes of this Act, a State shall have primary enforcement responsibility for pesticide use violations during any period for which the Administrator determines that such State—

"(1) has adopted adequate pesticide use laws and regulations; *Provided*, That the Administrator may not require a State to have pesticide use laws that are more stringent than this Act;

"(2) has adopted and is implementing adequate procedures for the enforcement of such State laws and regulations; and

"(3) will keep such records and make such reports showing compliance with paragraphs (1) and (2) of this subsection as the Administrator may require by regulation.

"(b) Notwithstanding the provisions of subsection (a) of this section, any State that enters into a cooperative agreement with the Administrator under section 23 of this Act for the enforcement of pesticide use restrictions shall have the primary enforcement responsibility for pesticide use violations. Any State that has a plan approved by the Administrator in accordance with the requirements of section 4 of this Act that the Administrator determines meets the criteria set out in subsection (a) of this section shall have the primary enforcement responsibility for pesticide use violations. The Administrator shall make such determinations with respect to State plans under Section 4 of this Act in effect on September 30, 1978 not later than March 31, 1979.

Thus, a State may obtain primacy in two ways: (1) by demonstrating that the elements of its use enforcement program, or of its approved certification program, satisfy the two main criteria in section 26(a), (adequate laws and adequate procedures implementing those laws), or (2) by entering into a cooperative agreement for the enforcement of use restrictions, provided the terms of the agreement do not specify otherwise. The Agency will also evaluate the adequacy of a State's use enforcement program before conferring primacy by this latter method.

A. *Adequate Laws and Regulations.* To be considered adequate, a State's pesticide control legislation must address at least the following areas:

1. *Use restrictions.* State pesticide control legislation will be considered adequate for purposes of assuming full primacy if State law prohibits those acts which are proscribed under FIFRA and which relate to pesticide use. The activities presently proscribed under FIFRA include:

a. Use of a registered pesticide in a manner inconsistent with its label (FIFRA section 12(a)(2)(G)).

b. Use of a pesticide which is under an experimental use permit contrary to the provisions of the permit (section 12(a)(2)(H)).

c. Use of a pesticide in tests on humans contrary to the provisions of section 12(a)(2)(P).

d. Violation of the provision in section 3(d)(1)(c) requiring pesticides to be applied for any restricted use only by or under the direct supervision of a certified applicator. Violations of suspension or cancellation orders are not considered use violations for purposes of the primacy program.

States may be granted partial primacy if they regulate less than all categories of use violations. For example, EPA may in the future decide to issue "other regulatory restrictions" on use under section 3(d)(1)(C)(ii), (such as a requirement to notify area residents before pesticide spraying). If such a restriction were issued, (and not reflected on pesticide product labels), each State would automatically have partial primacy extending to all of the categories listed above which are proscribed by State law, unless the State already has authority to enforce such restrictions. A State with partial primacy would obtain full primacy by enacting a prohibition tracking the section 3(d)(1)(C)(ii) restriction.

2. *Authority to enter.* To carry out effectively their use enforcement responsibilities, State officials should be able to enter, through consent, warrant, or other authority, premises or facilities where pesticide use violations may occur. States should also have concomitant authority to take pesticide samples as part of the use inspection process.

3. *Flexible remedies.* Finally, State legislation must provide for a sufficiently diverse and flexible array of enforcement remedies. The State should be able to select from among the available alternatives an enforcement remedy that is particularly suited to the gravity of the violation. Without such flexibility, a State may frequently be forced to underpenalize violators, and thereby fail significantly to deter future use violations. Thus, in order to satisfy the "adequate laws" criterion, States should demonstrate that they are able to:

a. Issue Warning Letters or Notices of Noncompliance;

b. Pursue administrative or civil actions resulting in an adverse economic impact upon the violator, e.g., license or certification suspensions or civil penalty assessments; and

c. Pursue criminal sanctions for knowing violations.

B. *Adequate Procedures for Enforcing the Laws.* In order to obtain primacy, States must not only demonstrate adequate regulatory authority, but must also show that they have adopted procedures to implement the authority. These procedures must facilitate the quick and effective prevention, discovery, and prosecution of pesticide use violations.

1. *Training.* One step towards this objective is the training of enforcement personnel. At a minimum, States, in cooperation with EPA, should implement procedures to train inspection personnel in such areas as violation discovery, obtaining consent, preservation of evidence, and sampling procedures. Enforcement personnel should be adequately versed in case development procedures and the maintenance of proper case files.

Instruction in these techniques should take the form of both on-the-job training and the use of prepared training materials. The Agency also considers a continuing education program to be a crucial training procedure, so that enforcement personnel can be kept abreast of legal developments and technological advances.

2. *Sampling techniques and laboratory capability.* Requests for primacy should also show that the State is technologically capable of conducting a use enforcement program. States must have ready access to the equipment necessary to perform sampling and laboratory analysis, and should implement a quality assurance program to train laboratory personnel and protect the integrity of analytical data. Laboratories conducting sample analyses must also agree to participate in EPA (NEIC) Check Sample programs which are designed to ensure minimum standards of analytical capability. (Such a program is already operational for formulation samples, and a residue sample program is also under consideration). The EPA Check Sample program is coordinated with the Association of American Pesticide Control Officials (AAPCO) to reduce unnecessary duplication of effort. The EPA will be guided in evaluating the adequacy of State analytical procedures by official compilations of approved analytical methods, such as the Food and Drug Administration's (FDA) Pesticide Analytical Manual, the CIPAC (Collaborative International Pesticides Analytical Council) Handbook, the EPA Manual of Chemical Methods for Pesticides, and Official Analytical Chemists Analytical Procedures. For additional guidance on adequate sampling techniques, States should consult EPA's FIFRA Inspectors Manual or contact the appropriate regional office.

3. *Processing complaints.* Since a significant portion of pesticide use violations are identified through reports from outside EPA or the State lead agency, the State must implement a system for quickly processing and reacting to complaints or other information indicating a violation. An adequate referral system should contain:

a. A method for funneling complaints to a central organizational unit for review.

b. A logging system to record the receipt of the complaint and to track the stages of the follow-up investigation.

c. A mechanism for referring the complaint to the appropriate investigative personnel.

d. A system for allowing a rapid determination of the status of the case.

e. A procedure for notifying citizens of the ultimate disposition of their complaints.

4. *Compliance monitoring and enforcement.* Along with the above described enforcement procedures, States must provide assurance that sufficient manpower and financial resources are available to conduct a compliance monitoring program, i.e., either planned or responsive use inspections. In addition, States must implement procedures to pursue enforcement actions expeditiously against violators identified through compliance monitoring activities.

The Agency also believes that program planning and the establishment of enforcement priorities is an integral part of an adequate enforcement program. Such planning, taking into account the national program priorities as manifested through the grant negotiation process, as well as the priorities specific to the individual State, will help assure that compliance monitoring and enforcement resources are properly allocated.

5. *Education.* States should implement a program to inform their constituencies of applicable pesticide use restrictions and responsibilities. Examples of education methods include disseminating compliance information through cooperative extension services, seminars, publications similar to the Federal Register, newspapers, and public assistance offices where persons can call to ask questions or report violations. Such an educational program will promote voluntary compliance and is essential to effective enforcement. States should also develop procedures for soliciting input from the public regarding the administration of the pesticide use enforcement program.

III. Criteria Governing Rescission of Primacy Under Section 27(b)

Section 27(b) authorizes the Administrator to rescind primacy from a State in certain situations:

> "(b) Whenever the Administrator determines that a State having primary enforcement responsibility for pesticide use violations is not carrying out (or cannot carry out due to the lack of adequate legal authority) such responsibility, the Administrator shall notify the State. Such notice shall specify those aspects of the administration of the State program that are determined to be inadequate. The State shall have ninety days after receipt of the notice to correct any deficiencies. If after that time the Administrator determines that the State program remains inadequate, the Administrator may rescind, in whole or in part, the State's primary enforcement responsibility for pesticide use violations.

In deciding whether a State is not carrying out, or cannot carry out, its use enforcement responsibilities, the Administrator will apply the criteria for an adequate program set forth in Unit II to the performance of the State during the time the State had primacy.

A. *Adequate Laws.* The legal authority can conduct an adequate use enforcement program is a criterion which affects both the decision to grant primacy and the decision to rescind it. Within the context of rescission, the Administrator will assess the impact of any amendments or supplements to the State's pesticide use laws and regulations. If legislative changes have adversely affected the State's ability to collect information or bring enforcement actions, the State may be subject to a rescission action on grounds of inadequate laws.

B. *Adequate Procedures.* In determining whether a State which has adequate legal tools is carrying out its use enforcement obligations, the Agency will examine the efficacy of the procedures adopted by the State to implement its pesticide laws. The Agency will be particularly interested in the remedies the State has actually applied to the various use violations. The lack of sufficient correlation between the gravity of a use violation and the severity of the enforcement response would be evidence that the State's arsenal of remedies is not being applied in a flexible manner.

In addition, EPA will evaluate each program element listed in Unit II.B., in light of the performance of the State during the period the State had primary use enforcement responsibility.

1. *Training.* The Administrator will note whether any difficulties encountered by the State in enforcing pesticide use restrictions have resulted from a lack of adequate training of State enforcement personnel.

2. *Sampling techniques and laboratory capability.* The Administrator will consider whether the State's sampling techniques and

analytical capabilities are enhancing or hindering the State's ability to unearth and prosecute successfully persons who misuse pesticides. Another important consideration will be the degree to which State laboratory and sampling procedures have kept pace with developments in analytical technology.

3. *Processing complaints.* The Administrator will examine whether complaints have been processed quickly and efficiently. The degree to which citizens alleging a use violation seek redress from EPA after first directing their complaint to the State will be considered. In addition, the Administrator will take into account the performance of the State in responding to allegations referred to the State by EPA under section 27(a) of FIFRA.

4. *Compliance monitoring and enforcement.* Under this element, the Administrator will compare the State's level of compliance monitoring activities with that of other comparable States. The EPA will review State case files to determine whether the State has aggressively investigated a case before deciding on the disposition of the matter. The EPA will also investigate whether a State's Attorney General's office or other prosecutorial authorities have demonstrated a willingness to pursue cases referred by the State's pesticide control lead agency.

The Agency will examine whether State enforcement resources have been directed towards the more significant enforcement problem areas, and whether enforcement priorities have been reevaluated as the demands of an adequate program change over time.

5. *Education.* The Administrator will evaluate whether the State's education program is encouraging voluntary compliance with pesticide use restrictions. As part of this process, the Administrator will note those use violations which are at least partially attributable to the violator's lack of familiarity with applicable laws and regulations. The Administrator will also review State procedures for facilitating public participation in the enforcement program.

These criteria are indices of the adequacy of a State's use enforcement program, but they do not conclusively determine whether a State is discharging its primacy responsibilities. Since the Agency's goal is to protect the public from the risks associated with pesticides, one of EPA's central inquiries will be whether the State's primacy program assures compliance with pesticide use restrictions. EPA, in evaluating State program adequacy, will consider both the deficiencies of the program and the success of the program in achieving compliance.

IV. Emergency Response

Notwithstanding other provisions of sections 26 and 27, the Administrator may, after notification to the State, take immediate action to abate emergency situations if the State is "unwilling or unable adequately to respond to the emergency."

FIFRA does not define "emergency conditions." Other EPA-administered statutes, however, characterize emergencies in fairly consistent terms. The consensus of these statutes is that an emergency presents a risk of harm to human health or the environment that is both serious and imminent, and that requires immediate abatement action.

Examples of use-related emergency situations are:

1. Contamination of a building by a highly toxic pesticide.

2. Hospitalizations, deaths, or other severe health effects resulting from use of a pesticide.

3. A geographically specific pattern of use or misuse which presents unreasonable risk of adverse effects to health or sensitive natural areas. This situation may occur, for example, if a hazardous pesticide is consistently misused in a particular area so that the net effect is the creation of substantial endangerment to the environment, such as runoff into a water supply.

A. *"Unwilling".* When EPA learns of an emergency situation, Agency representatives must notify the affected State. These representatives will try to obtain a commitment from the State as to (a) what the State is capable of doing in response to the situation, and (b) when the State intends to respond to the crisis.

Emergencies, by nature, require the quickest possible response. In most cases, due to proximity, the State will have the opportunity to be first on the scene. If the State manifests an unwillingness to respond rapidly to the situation, or if the State cannot give assurances that it will respond more quickly than EPA could respond, Agency emergency response teams will be activated.

B. *"Unable".* The EPA will immediately take action to abate an emergency if the State is unable to do so. The Agency interprets "unable" to mean that either the State does not have the authority to adequately respond or that the State is incapable of solving the problem due to the lack of technology or resources.

1. *Authority.* The EPA can utilize its authority in section 16(c) of FIFRA to seek, in conjunction with the Department of Justice, a district court order preventing or restraining misuse of a pesticide. States should also be able to address a use-related emergency in this manner or by the rapid issuance of an enforceable stop-use order or other similar means. If the State lacks this authority and the emergency conditions warrant a legal response in the nature of specific enforcement or equitable relief, EPA may initiate its own action after notice to the State.

2. *Technical capability.* Some emergency situations may present problems which the States are technologically incapable of solving. In these instances, if EPA possesses the requisite technology or equipment, the Agency will immediately respond to the crisis. For example, where a dissolved organic pesticide has contaminated a surface water system, EPA would activate its portable advanced waste treatment unit, a resource that is not generally available to the States.

The EPA will also take action if the State cannot rapidly commit the necessary manpower to the emergency situation. In most cases EPA will not, however, initiate a response on this basis if the State has developed an emergency response plan detailing the procedures to be followed in counteracting a pesticide emergency.

V. Hypothetical Situations

In reading the hypotheticals in Units A and B, assume that the cases discussed fall under priority referral areas discussed in Unit I.A.2.

A. *Action by Citizen. Hypothetical 1.* EPA refers to the State a citizen's allegation that an aerial applicator has allowed pesticides to drift over his property. After 25 days, the EPA Region obtains the results of State's investigation and learns that the State plans to issue a warning letter to the applicator. The EPA advocates a more firm response and, after discussion, the State agrees to suspend the applicator's certification. The State certification board does not meet, however, until two months later. In this instance, the Region may decide to extend the normal 30 day prosecution stage to accommodate the schedule of the board.

Hypothetical 2. A citizen calls EPA with information concerning a fish kill which occurred in a stream near his residence. The citizen claims that he reported his information to the State, but State officials have not responded to his complaint. The EPA's Regional official calls the State, and learns that the State did indeed know of the problem, but has not yet had the opportunity to investigate the allegation. The Regional

official, believing the allegation to be significant, formally refers the complaint to the State, and the State agrees that the matter should be investigated within 30 days. After 20 days, the Region learns that the State has not yet begun its investigation. In this case, the Region may begin its own inquiry into the matter, and may commence its own enforcement action, after notice to the State, provided that 30 days have elapsed from the date of the referral.

B. *Action by State.* In both of these hypotheticals, assume that the State has chosen a Warning Letter as the appropriate enforcement response.

Hypothetical 1. Mr. Smith operates a one-man crop dusting company. Smith is hired to spray Herbicide A over a power company's lengthy right-of-way. The right-of-way is bounded on one side by residential development and on the other by a wooded area. Smith performs the aerial application amidst high swirling winds in contravention of the instructions on the herbicide's label. A significant portion of the herbicide drifts into the wooded area. Herbicide A, which contains the hazard word "danger" on its label, is a highly toxic and persistent restricted use pesticide. Smith has no record of prior pesticide-related violations with government pesticide control offices.

The Agency would consider the issuance of a warning letter to be an inappropriate response to this violation.

a. *Risk associated with the violative action.* Fortunately in this instance, the violation did not result in damage to humans or sensitive environmental areas. But at the time the violation was committed, the risk that harm would result from the misuse was quite significant, given the high swirling winds and the proximity of a residential neighborhood. Only chance prevented the herbicide from drifting into an inhabited area. The risk of harm was also increased by the fact that a great deal of land was subject to drift given the length of the target area.

b. *Risk associated with the pesticide.* Herbicide A is labelled "danger" and is therefore an acutely toxic Category I pesticide under 40 CFR 162.10. The harm that would result from exposure to this persistent substance is substantial, regardless of whether chronic effects or residue properties have been ascribed to it. In addition, a large amount of Herbicide A was involved in the violation.

c. *Other factors.* Smith is a commercial applicator under FIFRA and could be subject to the maximum penalty. As a mitigating factor, however, Smith could point to the absence of prior FIFRA violations.

In summary, since Smith's actions were highly likely to result in serious harm to human health, his drift violation warrants a severe enforcement response, such as assessing a fine or suspending his certification. Despite Smith's clean record, a warning letter would not be deemed "appropriate enforcement action."

Hypothetical 2. A small food processing firm which markets frozen TV dinners utilizes company maintenance personnel to accomplish its pest control needs. No particular training is provided for such employees but they are instructed to read and follow the label directions. They are provided all appropriate application equipment and protective clothing. A company employee applied a non-persistent general-use (Category IV) pesticide which was registered for structural pest control to combat a particularly serious cockroach infestation. Despite label instructions requiring the user to avoid contaminating food, food containers, or cooking utensils, the employee applied the pesticide directly upon and below counter tops and related surfaces in the room where food cooking racks are stored. The application took place late Friday afternoon. The cooking racks were not utilized again until Monday morning. An inspection took place on Monday morning. This was the third pesticide use inspection which the State had conducted at the firm in the last four years. None of the prior inspections had revealed a pesticide-related violation. Residue samples taken Monday morning revealed no trace residue of the pesticide on the treated surfaces.

Since the violation constitutes a first offense by an "other person" under section 14(a)(2) of FIFRA, the maximum federal enforcement response would be a Notice of Warning. Accordingly, the Warning Letter issued by the State would constitute an appropriate enforcement action.

a. *Risk associated with the violative action.* The direct application of any pesticide to a cooking rack in a food processing establishment poses some risk of exposure to humans. Although the pesticide used in this case was not applied in great amounts or over large areas, the inherent risk associated with the violation is relatively high, since violation results in the introduction of the pesticide into non-target surfaces with the likelihood of human exposure.

b. *Risk associated with the pesticide.* In this instance, the risk associated with the pesticide itself is relatively small. This Category IV pesticide is not acutely toxic or persistent, and is not known to cause any chronic effects. Sample analysis revealed no trace of the product at the time the exposed cooking racks were to be used.

c. *Other factors.* Under FIFRA, the issuance of a Notice of Warning is the maximum enforcement response to a use violation committed by a private applicator with no history of prior violations. Thus, the Agency would, of course, view the proposed State enforcement action as appropriate. If the violation were repeated, a more stringent enforcement action would be warranted.

Dated: December 22, 1982.

John W. Hernandez, Jr.,

Acting Administrator.

[FR Doc. 83-0 Filed 1-4-83; 8:45 am]

BILLING CODE 6560-50-M

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

APR 21 1983

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

EMORANDUM

SUBJECT: Final FY84 Cooperative Agreement Program Guidance

TO: Air and Waste Management Division Directors
Environmental Service Division Directors
Pesticide Branch Chiefs

Attached is the final guidance for the FY84 FIFRA cooperative agreement program. This document combines guidance for both the pesticides enforcement and the applicator certification and training programs. For your convenience, the sections entitled FY 1984 FIFRA Cooperative Agreement Program Guidance and FIFRA Cooperative Agreement Program Guidance are included in their entirety. These sections replace the FY 1983 Cooperative Agreement Program Guidance and the FIFRA Cooperative Agreement Program Guidance sections in the FY83 guidance. Also, many of the Appendices in the FY83 guidance have either been amended, revised or replaced and five new appendices have been added.

This final guidance has been modified in response to most comments on the earlier draft. Specifically, the following areas have been changed:

- o Base Allotment
- o Product/Facility Related Priority Setting Model (Appendix I, addendum)
- o Nonfunded Priority Program
- o §26 and §27 Interpretive Rule Procedures
- o LIP and CRP Inspection Strategies

For FY84, the enforcement cooperative agreement base funding level has been increased from $45,000 to $60,000. The weighted factors used to distribute the funds remaining after each State's base allotments were subtracted from the total program allotment have also been revised to reflect new data on the numbers of private and commercial applicators reported for FY82.

Commentors asked if a State could conduct, as part of its first quarter outputs, the product/facility priority setting. States who are unable to complete their product/facility priority setting prior to the awarding of their FY84 cooperative agreement may include that portion of their priority setting as part of their first quarter outputs. Part III, Award Conditions of the EPA Notification of Assistance Award Action for such States must include a condition requiring States to conduct product/facility priority setting by no later than the end of the first quarter.

The section on nonfunded priority problems has been clarified. Some States' current pesticide programs may already address pesticide problems identified through priority setting. In such cases, States are requested to provide this information as a supplement to their cooperative agreement applications so that EPA will have a complete picture of how a State is addressing all its pesticide problems. This information will aid the Regions in evaluating the State's cooperative agreement application.

All States must update their previous years use priority setting and include it in their FY84 cooperative agreement applications.

The final guidance document summarizes and expands the procedures to be followed by the Regions in reviewing State investigations and enforcement actions under the Interpretive Rule for FIFRA §§26 and 27. The Regional offices and the States will annually define significant cases to be tracked by EPA after referral to the State. The guidance outlines the procedures which the Regions must follow 1) in reviewing the adequacy of State investigations or enforcement actions and 2) before conducting a Federal investigation or taking Federal enforcement action.

Finally, inspection strategies for the LIP and CRP programs are included in Appendix XI and Appendix XII. The Office of Pesticide Programs, Registration Division will provide the required data as outlined in the inspection strategies.

If you have any questions, please contact John Martin, of my staff, at (202) 382-5572.

A. E. Conroy II, Director
Compliance Monitoring Staff
Office of Pesticides and Toxic Substances

Attachment

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FY 1984 FIFRA COOPERATIVE AGREEMENT PROGRAM GUIDANCE

This annual guidance outlines Regional funding allotments and discusses national priorities to be followed by the Regions in implementing FY84 cooperative agreements for pesticides enforcement and applicator certification and training. The Compliance Monitoring Staff (CMS) of the Office of Pesticides and Toxic Substances Compliance Monitoring Staff (OPTS) expects to receive $6,918,400 to fund State and Indian Tribe cooperative enforcement programs and has received $2,000,000 for funding cooperative applicator certification and training programs.

ENFORCEMENT

Allotment of Funds

The President's annual budget submission to the Congress requests an overall program appropriation for pesticides enforcement cooperative agreements. Individual State allotments for financial assistance are initially determined by application of a two step formula. States are to use these initial allotments to develop, with their respective Regional offices, work programs that meet both State and Agency needs.[40 CFR Part 35.115(h)] Final allotments will be based on the States' initial allotments and a redistribution of surplus funds.

Initial Allotment

Because of a proposed reduction in the amount of pesticides enforcement cooperative agreement funds available for FY84, EPA Headquarters' initial financial assistance allotments will consider only those States, Territories and Indian Tribes presently participating in the pesticides cooperative agreement program. Any non-participating State (Ohio, Nebraska, Colorado, Wyoming, and Alaska) or Indian Tribe which wishes to be included in the final allotment, must send EPA a written commitment to submit an application and participate in the program prior June 15, 1983.

For FY84, EPA Headquarters will first determine the initial Regional allotments for pesticides enforcement cooperative agreements by adding the following: $60,000 for each participating State, Puerto Rico and the District of Columbia (47); $25,000 for the Virgin Islands; and $10,000 for each participating Territory (4) which comprise a base level of funding. The initial Regional allotment also includes 10% of the available funds (1% per Region) as pesticides enforcement incentive funds; and $200,000 for cooperative agreements with Indian Tribes (7).

Then, Headquarters will distribute the funds remaining after the base funds, pesticides enforcement incentive funds and Indian Tribe funds are subtracted from the proposed budget appropriation according to the following factors and weightings:

1981	July 1, 1981, Provisional Estimates of Population, U.S. Bureau of the Census - April 1982.	20%
1982	Number of Pesticide Producing Establishments per State - FIFRA and TSCA Enforcement System (FATES) printout, December 23, 1982, CMS. (Numbers do not include Custom Blenders).	20%
1982	Number of Certified Private Applicators per State, September 30, 1982, CMS.	10%
1982	Number of Certified Commercial Applicators per State, September 30, 1982, CMS. (Individual categories were counted separately).	20%
1982	Estimated Number of Farms Per State - Crop Reporting Board, (SRS) U.S. Department of Agriculture (USDA) Farm Numbers, August 1982.	20%
1982	Estimated Farm Acreage Per State - Crop Reporting Board, SRS, USDA Farm Numbers, August 1982.	10%

Each Region's initial allotment is obtained by adding the appropriate base amount for each of its States, Territories or Indian Tribes, the proportioned amount determined by the above factors and weightings and the pesticides enforcement incentive funds.

Each State's initial allotment is obtained by adding the appropriate base amount and the proportioned amount determined by the above factors and weightings. The pesticides enforcement incentive funds will be used by the Regional Administrator to reward innovative or exceptional pesticides enforcement programs. (Regional and State allotments are attached.)

Adjustments to Initial Allotment

Regions should not award funds based solely on a State's initial allotment but rather based on the negotiated need of the State. The Regional Administrator may modify any State allotment as necessary as long as total funding for all States does not exceed the Regional allotment. 40 CFR Part 35.115(d) states that the Administrator or the Regional Administrator may use funds not awarded or committed to an applicant to supplement awards to other applicants for pesticides enforcement.

Allotment

ne Regional office must furnish the following information in riting to Headquarters no later than July 1, 1983:

1. The names of States and Indian Tribes that will be participating in Fiscal Year 1984.

2. The anticipated financial assistance funding level for each participating State and Indian Tribe.

ne EPA Headquarters will make the final allotment of cooperative greement funds and notify the Regional offices in writing by uly 15, 1983. This final allotment will include a reallotment f funds from Regions whose States do not need their entire nitial allotments to Regions whose States demonstrate a need or additional funding. The final Regional allotment consists f the sum of each participating State's final allotment and esticide enforcement incentive funds and will be included in ach Region's FY84 operating budget.

ne Regions will base the distribution of cooperative agree- ent funds on both the allotment schedule and the thoroughness f the State's own priority setting process. The States should dentify priority enforcement problem areas by a method similar at outlined in the Priority Setting section of the State . ication Standards and Evaluation Procedures, Appendix I and ts addendum, so that resource allotment decisions will be ased on objective measures. The Region will base final State nding allotment decisions for State applications on the initial llotment, the demonstrated pesticide enforcement priorities f the State and the exceptional nature of a program justifying ward of a portion of the pesticide enforcement incentive funds.

ternative Funding

ne Regional Administrator may use current year funds remaining fter the initial State awards to 1) supplement existing awards 2) award new partially funded cooperative agreements for ne next year. A partially funded cooperative agreement is a ew agreement that would begin immediately after the current ooperative agreement had ended and is funded, partially, with rrent year funds.

rtially funded cooperative agreements offer States a method f maintaining program continuity during EPA's transition om fiscal year to fiscal year. All funds must be obligated n accordance with the legislative restrictions that limit ne amount of funds that can be obligated in the fourth quarter. ese funds shall not be used to extend budget or project ds of existing cooperative agreements.

National Priorities

Each year, Headquarters formulates national pesticide enforcement priorities based on major recurring areas of concern identified by the States through their priority setting systems and on related information from other sources.

Based on the available data and priorities established by States that conducted priority setting in their FY83 cooperative agreement applications, Headquarters has identified the following general areas of concern as National Priorities for FY84.

1) Drift from pesticide application;

2) Misuse by pest control operators during structural applications;

3) Disposal of pesticides and pesticide containers; and

4) Pesticide use problems associated with major spray programs, i.e. gypsy moth, forest service (conifer release), and mosquito control.

5) Worker exposure to pesticides before, during and after application.

The EPA has designated these areas of concern as national priorities to guide the States in their priority setting process. Although these areas may not be of apparent concern in all States, the States should consider these areas as they develop data for use in setting their individual priorities. After considering pertinent data, a State may find that some or all of these areas are not priority problems in the State. In that case, the State should, of course, direct its enforcement resources to those areas which do present major pesticide problems.

APPLICATOR CERTIFICATION AND TRAINING

Allotment of Funds

The President's annual budget submission to the Congress requests an overall financial assistance program appropriation for pesticide applicator certification and training cooperative agreements. Individual State allotments for financial assistance are initally determined by application of a two step formula including certain factors and weightings described below. States are to use these initial allotments to develop, with their respective Regional offices, work programs that meet both State and Agency needs. [40 CFR Part 35.115(i)]

Initial Allotment

In FY84 financial assistance funds for the pesticides applicator certification programs with States will be alloted from FY83 funds.[1]

For FY84, EPA Headquarters will first determine the initial Regional allotment for pesticide applicator certification and training cooperative agreements by adding $10,000 for each participating State which comprises a base level of funding. Each Regional allotment will also include an amount for cooperative agreements with Indian Tribes that are approved and operating before the issuance of this guidance document.

Then, Headquarters will distribute the funds remaining after the base funds and Indian Tribe funds are subtracted from the proposed budget appropriation according to the following factors and weightings:

1982 Estimated Number of Farms Per State - Crop Reporting Board, SRS, U.S. Department of Agriculture (USDA) Farm Numbers, August 1982.	25%
1982 Number of Certified Private Applicators per State, September 30, 1982, CMS. (Adjusted for recertification period).	30%
1982 Number of Certified Commercial Applicators by Category per State, September 30, 1982, CMS. (Adjusted for recertification period).	35%

[1] In FY83 the $2,000,000 for the Pesticide Applicator Certification and Training Program will be distributed as follows: $174,000 for the Federal pesticide applicator certification and training programs in Colorado and Nebraska and Indian Tribes for FY83; $913,000 to USDA for training of pesticide applicators in participating States for FY83; $913,000 or the remainder will be proportioned between the States through cooperative agreements for FY84.

Regional discretionary allotment for pesticide applicator certification and training programs.	10%

Each Region's initial allotment is obtained by adding for each of its States the base funding amount, the proportioned amount determined by the above factors and weightings and the Regional discretionary allotment for pesticide applicator certification and training.

Each State's initial allotment is obtained by adding the base funding amount and the proportioned amount determined by the above factors and weightings. The Regional discretionary allotment for pesticide applicator certification and training programs will be used by the Regional Administrator to reward exceptional programs. (Regional and State initial allotments attached).

Final Allotment

The initial allotment will become the State's final allotment. However, if a State cannot use its entire initial allotment the unused funds will be redistributed by the Regional Administrator to other States within the Region requiring additional assistance. Prior to awarding unused funds to another State the Regions must inform CMS where these unused funds will be used.

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

April 11, 1983

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

TO: Addressees

SUBJECT: Revised State and Regional Initial Allotments for Pesticide Enforcement Cooperative Agreements

Attached is a copy of the revised State and Regional Initial Allotments for Pesticides Enforcement Cooperative Agreements for FY84 and the supporting allotment formula data. This allotment schedule incorporates two major changes:

- Utilizes the numbers of private and commercial certified applicators on September 30, 1982, instead of the 1981 numbers. The 1982 numbers were unavailable when the previous allocation was made on January 11, 1983.

- Base funding level was increased from $45,000 to $60,000 per state. This change was recommended by the Association of American Pesticide Control Officials and the State-FIFRA Issues Research and Evaluation Group.

This allotment schedule is based on the President's FY84 budget request of $6,918,400 for pesticide enforcement cooperative agreements. These allotments should be used in planning the FY84 pesticide enforcement program with the States in your Region. As indicated in the Draft FY84 Cooperative Agreement Program Guidance the Initial Allotment Schedule may be revised to provide funding for any non-participating State (Ohio, Nebraska, Colorado, Wyoming and Alaska) making a written commitment, prior to June 15, 1983, to apply for a grant. The final allotment schedule will be issued by July 15, 1983.

A. E. Conroy II

A. E. Conroy II, Director
Compliance Monitoring Staff
Office of Pesticides and Toxic Substances

Attachment

State and Regional Initial Allotments for Pesticide Enforcement Cooperative Agreements for FY84

Reg. I	Formula Funding Percent	Formula Funding Amounts	Base Funding	Total Funding
CT	.627	19,708	60,000	79,708
ME	.383	12,038	60,000	72,038
MA	1.155	36,303	60,000	96,303
NH	.214	6,726	60,000	66,726
RI	.226	7,104	60,000	67,104
VT	.232	7,292	60,000	67,292
Regional Incentive			69,000	69,000
Regional Totals	2.837	89,171	429,000	518,171
Reg. II				
NJ	2.275	71,507	60,000	131,507
NY	4.912	154,392	60,000	214,392
PR	1.243	39,069	60,000	99,069
VI	-	-	25,000	25,000
Regional Incentive			69,000	69,000
Regional Totals	8.430	264,968	274,000	538,968
Reg. III				
DC	.112	3,520	60,000	63,520
DE	.227	7,135	60,000	67,135
MD	1.010	31,746	60,000	91,746
PA	2.981	93,697	60,000	153,697
VA	1.779	55,917	60,000	115,917
W VA	.677	21,279	60,000	81,279
Regional Incentive			69,000	69,000
Regional Totals	6.786	213,294	429,000	642,294

	Formula Funding Percent	Formula Funding Amount	Base Funding	Total Funding
Reg. IV				
AL	1.665	52,333	60,000	112,333
FL	4.376	137,544	60,000	197,544
GA	3.154	99,135	60,000	159,135
KY	3.060	96,180	60,000	156,180
MS	1.369	43,030	60,000	103,030
NC	3.103	97,532	60,000	157,532
SC	1.189	37,372	60,000	97,372
TN	2.910	91,466	60,000	151,466
Regional Incentive			69,000	69,000
Regional Totals	20.826	654,592	549,000	1,203,592
Reg. V				
IL	4.686	147,288	60,000	207,288
IN	2.517	79,113	60,000	139,113
MI	2.533	79,616	60,000	139,616
MN	2.661	83,639	60,000	143,639
OH	-	-	-	-
WI	2.731	85,840	60,000	145,840
Regional Incentive			69,000	69,000
Regional Totals	15.128	475,496	369,000	844,496
Reg. VI				
AR	1.487	46,739	60,000	106,739
LA	1.862	58,525	60,000	118,525
NM	.921	28,948	60,000	88,948
OK	2.107	66,226	60,000	126,226
TX	10.331	324,719	60,000	384,719
Regional Incentive			69,000	69,000
Regional Totals	16.708	525,157	369,000	894,157

	Formula Funding		Base	Total
	Percent	Amount	Funding	Funding
Reg. VII				
IA	2.848	89,517	60,000	149,517
KS	2.097	65,912	60,000	125,912
MO	3.172	99,700	60,000	159,700
NB	-	-	-	-
Regional Incentive			69,000	69,000
Regional Totals	8.117	255,129	249,000	504,129
Reg. VIII				
CO	-	-	-	-
MT	1.201	37,749	60,000	97,749
ND	1.422	44,696	60,000	104,696
SD	1.310	41,175	60,000	101,175
T	.615	19,330	60,000	79,330
WY	-	-	-	-
Indian Tribes(6)	-	-	100,000	100,000
Regional Incentive			69,000	69,000
Regional Totals	4.548	142,950	409,000	551,950
Reg. IX				
AZ	1.481	46,550	60,000	106,550
CA	9.322	293,005	60,000	353,005
HI	.369	11,598	60,000	71,598
NV	.427	13,421	60,000	73,421
Am Samoa	-	-	10,000	10,000
Guam	-	-	10,000	10,000
Mariana Is.	-	-	10,000	10,000
Trust Terr.	-	-	10,000	10,000
Indian Tribes(2)	-	-	100,000	100,000
Regional Incentive			69,000	69,000
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

	Formula Funding		Base Funding	Total Funding
	Percent	Amount		
Reg. X				
AK	-	-	-	-
ID	1.254	39,415	60,000	99,415
OR	1.656	52,051	60,000	112,051
WA	2.119	66,603	60,000	126,603
Regional Incentive			69,000	69,000
Regional Totals	5.029	158,069	249,000	407,069
Total to Regions	100.008	3,143,400	3,775,000	6,918,400

FY84 FIFRA ENFORCEMENT GRANT
Allotment Formula Data

March 21, 1983

The attached table shows the statisical data used in developing the formula for the allotment of the FY84 Pesticides Enforcement Grants. Only data from the 45 states participating in the program plus Puerto Rico and the District of Columbia are included. The other territories and the Indian Tribes do not receive any formula funds. The statistics used in the formula were amended to include the 1982 certified applicator numbers and include the following:

Population

July 1, 1981 Provisional Estimates of the Population - Bureau of Census, April 1982.

Farm Numbers and Acreage

1982 Preliminary estimates - Crop Reporting Board, SRS, USDA, August 1982.

Producer Establishments

FATES Data System - December 23, 1982 printout. Numbers used do not include Custom Blenders.

Private Applicators

Number of Private Applicators certified on September 30, 1982.

Commercial Applicators

Number of Commercial Applicators certified on September 30, 1982. Individual categories were counted separably.

	Population		Farms		Farm Acreage		Pest. Producers		Private Applic.		Comm Applic.		Formula Fun
	State (1000)	%	State	%	State (1000)	%	State	%	State	%	State	%	
Reg. I													
CT	3,134	.290	4,300	.038	490	.005	52	.150	2,074	.021	2,005	.123	.627
ME	1,133	.105	7,900	.071	1,560	.017	19	.055	2,975	.031	1,698	.104	.383
MA	5,773	.534	5,300	.047	630	.007	113	.327	1,879	.019	3,622	.221	1.155
NH	936	.087	3,200	.029	540	.006	14	.040	803	.008	725	.044	.214
RI	953	.088	750	.007	80	.001	23	.066	338	.004	981	.060	.226
VT	516	.048	7,500	.067	1,700	.019	5	.014	2,565	.027	928	.057	.232
Reg. Total	12,445	1.152	28,950	.259	5,000	.055	266	.652	10,634	.110	9,959	.609	2.837
Reg. II													
NJ	7,404	.685	9,500	.085	1,030	.011	271	.783	3,270	.034	11,073	.677	2.275
NY	17,602	1.628	50,000	.446	9,500	.105	280	.809	15,507	.160	28,846	1.764	4.912
PR	3,186	.295	31,837	.284	1,750	.019	53	.153	16,260	.168	5,296	.324	1.243
Reg. Total	28,192	2.608	91,337	.815	12,280	.135	604	1.745	35,037	.362	45,215	2.765	8.430
Reg. III													
DC	631	.058	0	0	0	0	6	.017	0	0	601	.037	.112
DE	598	.055	3,400	.030	660	.007	16	.046	2,260	.023	1,089	.066	.227
MD	4,263	.394	18,000	.161	2,750	.030	78	.225	8,288	.086	1,865	.114	1.010
PA	11,871	1.098	60,000	.536	8,800	.097	233	.673	32,780	.338	3,903	.239	2.981
VA	5,430	.502	60,000	.536	9,800	.108	66	.191	15,687	.162	4,577	.280	1.779
W VA	1,952	.181	20,600	.184	4,300	.048	22	.064	14,129	.146	.880	.054	.677
Reg. Total	24,745	2.288	162,000	1.447	26,310	.290	421	1.216	73,144	.755	12,915	.790	6.786

	Population		Farms		Farm Acreage		Pest. Producers		Private Applic.		Comm Applic.		Total % Formula Funds
	State (1000)	%	State	%	State (1000)	%	State	%	State	%	State	%	
Reg. IV													
AL	3,917	.362	57,000	.522	12,300	.136	129	.373	9,977	.103	2,757	.169	1.665
FL	10,183	.942	41,000	.366	13,000	.144	864	2.497	17,308	.179	4,059	.248	4.376
GA	5,574	.515	58,000	.518	15,200	.168	281	.812	34,865	.360	12,771	.781	3.154
KY	3,662	.339	101,000	.902	14,500	.160	89	.257	86,257	.890	8,376	.512	3.060
MS	2,531	.234	53,000	.473	14,500	.160	64	.185	8,632	.089	3,733	.228	1.369
NC	5,953	.551	88,000	.786	11,100	.123	182	.526	52,292	.540	9,432	.577	3.103
SC	3,167	.293	33,000	.295	6,100	.067	79	.228	12,391	.128	2,914	.178	1.189
TN	4,612	.427	95,000	.848	13,400	.148	140	.405	79,441	.820	4,292	.262	2.910
Reg. Total	39,599	3.663	526,000	4.710	100,100	1.106	1,828	5.283	301,163	3.109	48,334	2.955	20.826
Reg. V													
IL	11,462	1.060	104,000	.928	28,700	.317	418	1.208	53,808	.556	10,087	.617	4.686
IN	5,468	.506	89,000	.794	17,000	.188	166	.480	15,000	.155	6,443	.394	2.517
MI	9,204	.851	65,000	.580	11,500	.127	184	.532	6,041	.062	6,226	.381	2.533
MN	4,094	.379	103,000	.919	30,400	.336	152	.439	20,000	.206	6,247	.382	2.661
OH	-	0	-	0	-	0	-	0	-	0	-	0	.000
WI	4,742	.439	92,000	.821	18,500	.205	152	.439	28,737	.297	8,677	.530	2.731
Reg. Total	34,970	3.235	453,000	4.042	106,100	1.173	1,072	3.098	123,586	1.276	37,680	2.304	15.128

	Population		Farms		Farm Acr.		Pest. Producers		Private Applic.		Comm Applic.		% ula Funds
	State (1000)	%	State	%	State (1000)	%	State	%	State	%	State	%	
Reg. VI													
AR	2,296	.212	57,000	.509	16,400	.181	52	.150	20,807	.215	3,596	.220	1.487
LA	4,308	.398	37,500	.335	10,200	.113	146	.422	38,316	.396	3,237	.198	1.862
NM	1,328	.123	13,500	.121	47,400	.524	19	.055	3,004	.031	1,104	.067	.921
OK	3,100	.287	71,000	.634	34,300	.379	58	.168	26,856	.277	5,929	.362	2.107
TX	14,766	1.366	185,000	1.651	138,400	1.531	508	1.468	118,493	1.223	50,567	3.092	10.331
Reg. Total	25,798	2.386	364,000	3.250	246,700	2.728	783	2.263	207,476	2.142	64,433	3.939	16.708
Reg. VII													
IA	2,899	.268	117,000	1.044	33,800	.374	220	.636	19,609	.202	5,305	.324	2.848
KS	2,383	.220	76,000	.678	48,500	.536	100	.289	16,054	.166	3,397	.208	2.097
MO	4,941	.457	117,000	1.044	31,400	.347	204	.590	52,886	.546	3,079	.188	3.172
NB	-	0	-	0	-	0	-	0	-	0	-	0	.000
Reg. Total	10,223	.945	310,000	2.766	113,700	1.257	524	1.515	88,549	.914	11,781	.720	8.117
Reg.VIII													
CO	-	0	-	0	-	0	-	0	-	0	-	0	.000
MT	793	.073	24,000	.214	62,100	.687	25	.072	7,828	.081	1,214	.074	1.201
ND	658	.061	38,000	.339	41,700	.461	38	.110	17,527	.181	4.426	.270	1.422
SD	686	.063	37,000	.330	44,500	.492	56	.162	14,930	.154	1,782	.109	1.310
UT	1,518	.140	12,900	.115	12,300	.136	22	.064	5,562	.057	1,679	.103	.615
WY	-	0	-	0	-	0	-	0	-	0	-	0	.000
Reg. Total	3,655	.337	111,900	.998	160,600	1.776	141	.408	45,847	.473	9,101	.556	4.548

	Population		Farms		Farm Acre		Pest. Producers		Private Applic.		Comm Applic.		al %
	State (1000)	%	State	%	State (1000)		State	%	State	%	State		Formula Funds
eg. IX													
AZ	2,794	.258	7,200	.064	39,000	.431	94	.272	992	.010	7,286	.446	1.481
CA	24,196	2.238	80,000	.714	33,700	.373	886	2.560	40,000	.413	49,466	3.024	9.322
HI	981	.091	4,300	.038	1,960	.022	37	.107	4,640	.048	1,032	.063	.369
NV	845	.078	2,900	.026	8,900	.098	29	.084	773	.008	2,179	.133	.427
Reg. Total	28,816	2.665	94,400	.842	83,560	.924	1,046	3.023	46,405	.479	59,963	3.666	11.599
eg. X													
AK	-	0	-	0	-	0	-	0	-	0	-	0	.000
ID	959	.089	24,000	.214	15,100	.167	45	.130	9,572	.099	9,077	.555	1.254
OR	2,651	.245	36,000	.321	18,300	.202	92	.266	11,467	.118	8,245	.504	1.656
WA	4,217	.390	39,000	.348	16,300	.180	139	.402	15,677	.162	10,426	.637	2.119
Reg. Total	7,827	.724	99,000	.883	49,700	.549	276	.798	36,716	.379	27,748	1.696	5.029
National Totals	216,266	20.003	2,240,587	20.012	904,050	9.993	6,921	20.001	968,557	9.999	372,129	20.000	100.008

(45 States
plus DC & PR)

FEB 24 1983

FY 83 State Certification Breakout - $ in Thousands
(Funds to support activities in FY 84)

Region I	
Regional	3.3
Connecticut	11.5
Maine	11.8
Massachusetts	12.4
New Hampshire	10.6
Rhode Island	10.6
Vermont	11.1
TOTAL	71.3

Region II	
Regional	3.5
New Jersey	16.7
New York	29.0
Puerto Rico	17.3
Virgin Islands	10.2
TOTAL	76.7

Region III	
Regional	4.6
Delaware	10.8
District of Columbia	10.5
Maryland	16.7
Pennsylvania	22.6
Virginia	19.8
West Virginia	14.5

Region IV	
Regional	8.0
Alabama	16.9
Florida	22.3
Georgia	23.5
Kentucky	29.2
Mississippi	16.6
North Carolina	18.9
South Carolina	11.5
Tennessee	26.0
TOTAL	172.9

Region V	
Regional	6.7
Illinois	26.9
Indiana	19.1
Michigan	19.1
Minnesota	22.4
Ohio	29.5
Wisconsin	22.1
TOTAL	145.8

Region VI	
Regional	4.1
Arkansas	13.3
Louisiana	22.1
New Mexico	11.5
Oklahoma	19.5
Texas	18.2
TOTAL	88.7

Region VII	
Regional	3.1
Iowa	22.2
Kansas	18.2
Missouri	24.2
Nebraska (Fed. Program)	
TOTAL	67.7

Region VIII	
Regional	2.8
Colorado (Fed. Program)	
Montana	13.1
North Dakota	17.7
South Dakota	15.0
Utah	12.1
Wyoming (no fed. $ requested)	
TOTAL	60.7

Region IX	
Regional	3.5
Arizona	14.3
California	37.4
Hawaii	11.3
Nevada (No fed. $ requested)	
Guam	10.4
TOTAL	76.9

Region X	
Regional	2.4
Alaska	10.3
Idaho	11.1
Oregon	17.3
Washington	11.7
TOTAL	52.8

TOTAL TOTAL 913

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Introduction

Section 23 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizes the U.S. Environmental Protection Agency to enter into cooperative agreements with the States and Indian Tribes for pesticides enforcement and for applicator certification and training. Regulations governing financial assistance to participants in the cooperative pesticides enforcement and applicator certification and training programs are found at 40 CFR Part 35.001 to 35.605. This guidance document, developed by the Compliance Monitoring Staff (CMS) of the Office of Pesticides and Toxic Substances (OPTS), supplements those regulations by setting forth in detail the required elements of cooperative agreement applications, the process of awarding financial assistance and requirements for program management.

Financial assistance in the form of cooperative agreements for the pesticides enforcement program is designed to support (a) improved coordination of a cooperative Federal/State pesticides enforcement program, (b) more efficient allocation of resources through improved planning and management, and (c) program review and evaluation. The program which a State conducts under the cooperative agreement should provide for pesticides enforcement that satisfies both State and Federal pesticide laws. Areas of mutual pesticides enforcement include use/misuse investigations, producer establishment inspections, experimental use permit inspections, marketplace inspections, restricted use pesticide surveillance, and applicator certification enforcement inspections.

Financial assistance in the form of cooperative agreements for the pesticide applicator certification and training program is designed to support (a) the pesticide applicator certification and training program, (b) more efficient allocation of resources through improved program planning and management and (c) improved program review and evaluation. The program conducted by the State should provide pesticide applicator certification and training to all persons who wish to use restricted use pesticides. State work programs conducted under the cooperative agreement will include an estimate of the number of applicators to be certified or recertified by the State, the number of training sessions to be monitored and the number or frequency of the certification testing sessions.

In FY84 States are encouraged to consolidate their pesticides enforcement and applicator certification and training cooperative agreement applications. The consolidated cooperative agreement process is voluntary. A State which chooses to follow this process may develop a single application for separate financial assistance programs that are administered by the same agency within the State. Consolidating cooperative agreement applications does not alter existing statutory requirements governing eligibility, matching funds or maintainence of effort. Consolidating cooperative agreement applications does eliminate duplicating similar procedures in each individual assistance application. The single consolidated application will reduce excessive paperwork and administrative costs.

REQUIRED APPLICATION ELEMENTS

The formal application for assistance will consist of an "Application for Federal Assistance", EPA Form No. 5700-33, and shall include all elements outlined in this section. This form contains a section entitled "Part IV Narrative Statement" which the new 40 CFR Part 35.130 simplifies and replaces.

In addition to meeting the requirements contained in 40 CFR Part 30, a complete assistance application must contain the following elements:

- o Ability to Implement the Program including certifying statements that the State program is consistent with EPA-approved strategies and there are no impediments to the State's ability to carry out the program; designation of a lead agency; and a discussion of the State's performance to date under the existing award.

- o State Program Management Plan detailing a list of program objectives and priorities; and a description of the process through which the State identifies priorities.

- o Work Program specifying the work years and amount and source of funding estimated to be needed for each program element including any outputs required; a schedule for accomplishment of outputs; and an identification of the agency responsible for each of the elements and outputs.

- o Conditions of the Cooperative Agreement containing a statement that the State agrees to follow the quality assurance, and case preparation and enforcement or certification and training requirements.

Ability to Implement the Program

State Certifying Statements

Each applicant must certify that there are no impediments to the State's ability to carry out its proposed program or programs. Applicants with continuing cooperative agreement programs are not required to annually certify their ability to carry out the proposed programs unless one or more of the areas described below has changed. The applicant should address the areas described below as well as any others which might pose problems.

Authority to Conduct the Proposed Program

A State must have enacted legislation which empowers it to:

- o Enter into a cooperative agreement with EPA, and
- o Conduct specific activities proposed under the cooperative agreement or consolidated agreement.

Authority to Accept Federal Funds

A State which can only implement a program under a cooperative agreement with prior authorization by its legislature to spend Federal funds must include a statement indicating the date on which such authorization will be obtained. Commitment of EPA funds will be contingent upon such authorization by the State legislature.

Designation of Lead Agency

Although several State agencies may be responsible for regulating various aspects of pesticide manufacture, handling, and use, EPA will enter into only one cooperative agreement with a State for pesticide enforcement and only one cooperative agreement for pesticide applicator certification and training.

The Governor of the State, through a letter to the Regional office, should designate a separate lead agency which will be responsible for each of the cooperative agreement programs or a single lead Agency responsible for both programs under a consolidated agreement. The designated lead agency(ies) must have the authority to enter into contracts or interagency agreements with other agencies for the performance of all necessary activities.

Discussion of Performance

Each State is required to provide a discussion of progress under its current cooperative agreement. In this discussion, the State shall examine the appropriateness of its established priorities as well as the quality and effectiveness of its compliance monitoring and enforcement activities. For the applicator certification and training program, the State shall disucss the number of training programs in which the State participated; the number of training sessions monitored; the number of individuals examined for certification, for recertification; the number of certification sessions conducted, recertification sessions conducted; and any changes made to training materials.

Enforcement Management Plan Development

Defining State Program Objectives

Each State should define objectives which support the achievement of the national priorities, adjusted for the particular needs of the State. Identification of specific State pesticide problem areas is central to the task of developing the State objectives (see Priority Setting, below).

State objectives may include management oriented objectives such as improving planning of the enforcement program, achieving greater compliance through increased compliance monitoring in certain areas or improving the quality or availability of compliance information.

Priority Setting

To attain its objectives, the State should establish enforcement priorities that permit the most efficient use of resources and personnel. The priority setting process will enable a State to concentrate its training, compliance monitoring, and enforcement programs on specific pesticide manufacturing, distribution, and use activities which pose a risk to health or the environment.

Use or Product Related Priorities

As part of the process of setting general objectives for its pesticides enforcement program, the State should identify specific problem areas related to pesticide use, production, distribution and disposal. To identify priority pesticide problems, the State should develop a mechanism which analyzes information from a variety of sources. The result of the State's analysis should be a list of specific pesticide problems in the State. Following is a discussion of basic elements which should be involved in the priority setting process.

Review of Information Sources

In establishing priorities, the States should consult as many information sources as are reasonably accessible. The most accessible information source is likely to be a State's enforcement and complaint files. These records should indicate trends in certain use and non-use violations, and recurrence of violations involving specific pesticide producing or distribution establishments, pesticides or practices, as well as potential associations between a pesticide or application practice and health or environmental incidents.

Information related to potential areas of priority concern would be found in State records on local pesticide production and distribution establishments, or pesticides and pesticide practices commonly used in the State. The State may wish to consider information concerning chemicals which pose more serious health and environmental risks such as restricted use pesticides, emergency or experimental use pesticides, and special local use registrations as well as application methods most likely to result in harm if improperly carried out.

Finally, the State should identify and consider the concerns of persons in the State who may be exposed to pesticides or otherwise affected by the pesticides enforcement program. The EPA considers a State effort to gain public participation in the planning process to be an important element of the program. Each State may use a variety of means to identify the concerns of the public and involve them in the State planning process. The States, in formulating their policy, may wish to use EPA's Public Participation Policy, January 19, 1981, 46 Fed. Reg. 5736, as a guide.

Establishing Priority Setting Criteria

Since States may have a large body of information to review and analyze, each State should develop a set of criteria for use in ranking problem areas. For use-related problems, these criteria may reflect such factors as the degree of actual or potential harm to health or the environment and the degree of public concern. For product/facility related problems, violation history and frequency of past establishment inspections may be pertinent criteria.

Ranking of Specific Problems

Once the information has been reviewed and criteria have been established for setting priorities, each State should develop its list of priority problems. Using the selected criteria, the State can develop a hierarchy of areas of priority concern. The level of priority will provide a basis for the allocation of resources in the State's Action Plan.

The above mentioned elements are general guidelines to be followed by the States in developing priorities. The Compliance Monitoring Staff (CMS) of the Office of Pesticides and Toxic Substances (OPTS) has also developed documents outlining a step by step approach for setting use and product/facility related priorities. (See Appendix I and addendum) Each State is free to follow these models, to modify them, or to establish its own similarly objective priority setting methodology.

In any case, however, the State should include in its application not only a listing of its general program objectives and specific areas of priority concern, but also a discussion of the methodology used to develop and rank its priorities. All State priorities should be as specific as possible, but must either be placed into one of the following (fixed) broad types of pesticides problem areas under each activity for use-related priorities (See also Appendix I p.29) or one of the 5 broad types of pesticide problems areas under each activity for product/facility-related priorities (See also Addendum to Appendix I).

Use-related Priorities

Home/Yard Incidents
- Involving PCO's
- Involving homeowner's personal use of pesticides

Other Urban Incidents
Agricultural Incidents
- Involving Aerial Application
- Involving Ground Application
- Not Involving Application

Non-Urban, Right-of-Way Incidents
- Involving Aerial Application
- Involving Ground Application

Woodland Incidents
Incidents at Other Sites

Product/Facility-related Priorities

Violators within the State
Establishments not visited within the State
Inspected Establishments with no violations detected
Others (from Action Plan activity categories)
Educational Activity

Enforcement Work Program

The Work Program must specify the workyears and the source of funding for each program element, including any outputs and an identification of the agency responsible for each of the elements and outputs. (40 CFR Part 35.130)

Action Plan

Once the State has developed its list of priorities for both use-related and product/facility-related priorities, it should describe its plan for carrying out a balanced program that addresses each of these areas during the agreement period. Outputs the State proposes to accomplish during the agreement period must be aimed primarily at solving and dealing with pesticide problems identified by the priority setting process. However, the plan may also include any other activities not identified by priority setting such as responding to non-priority complaints provided these activities relate to violations of FIFRA.

A pesticides enforcement program that consists of elements from both State pesticide statutes and FIFRA should contain outputs for the activity categories which are defined as follows:

Use/Misuse Inspection is a FIFRA or State inspection. FIFRA use/misuse inspections are conducted to discover violations described in FIFRA Sections 12(a)(2)(F,& G). State use/misuse inspections would be conducted under State statutes. A State or Federal use inspection is an inspection identified under a neutral or routine inspection scheme to monitor or observe the use of pesticides. A State of Federal misuse inspection is an inspection identified as a "for cause" inspection such as a follow-up to a complaint, referral or tip.

Monitoring the Certification Program is a FIFRA or State 1) inspection at pesticide dealers to determine if Restricted Use Pesticides are being sold in violation of FIFRA Section 12(a)(2)(F) or State statute; 2) inspection of applicators to determine if they are properly licensed and maintaining records.

Producer Establishment Inspection is a FIFRA inspection of an establishment where pesticides or devices are held for distribution or sale for the purpose of inspecting and obtaining samples. While conducting pesticide producer establishment inspections States should review product labels for compliance with the Label Improvement Program (LIP). The Office of Pesticide Programs (OPP) has issued guidelines for the upgrading of pesticide product labels for several classes of pesticides as well as replacing or modifying certain labeling requirements. (See Appendix XI) The States should also inspect pesticide products that are subject to the Child Resistant Packaging (CRP)

regulations issued by OPP.[1] CRP inspections should be conducted in accordance with enforcement strategy (See Appendix XII) and the inspection guidelines previously issued by CMS.[2]

Marketplace Inspection is a FIFRA or State inspection at the retail sale, distribution or wholesale level for determination of product registration, labeling violations, or product decomposition. Marketplace inspection samples must be samples of unregistered products, products with violative labeling, products subject to decomposition, or products unavailable at producer establishment inspections. States should give marketplace inspections a low level of priority unless product violation rates and compliance ratios show that such inspections will prevent significant harm.

Other Inspection is a FIFRA or State inspection. Under FIFRA this would include custom blender and import inspections, section 18 and 24(c) inspections etc. Under the State program, this might include bulk tank sampling at repackaging establishments, inspection of the calibration of application equipment, etc.

Experimental Use Inspection is a FIFRA or State inspection to monitor experimental use permits. Samples should only be collected if a violation is suspected. Inspections must be conducted on site; telephone inspections or monitorings will not be credited under the cooperative agreement.

Educational Activity is a State outreach or related activity directed towards educating or providing additional information to consumers of pesticides or pesticide services designed to increase compliance with State pesticide laws and FIFRA.

Nonfunded Priority Program

The Agency is aware that not all States' pesticide priority problems are addressed in the Federal cooperative agreement. Some States' current pesticide programs may already address pesticide problems identified through priority setting. In such cases, States are requested to provide this information as a supplement to their cooperative agreement applications so that EPA will have a complete picture of how a State is addressing all its pesticide problems. This will aid the Regions in evaluating the State's application.

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1 40 CFR Part 162.16 Final Rule for Child Resistant Packaging, March 19, 1979, FR Notice pages 13019 through 13024.

2 CRP Inspection Guidelines issued by A. E. Conroy II, dated March 29, 1982.

Proposed Budget

Each application must contain the State's proposed budget for the program. Expenditures for personnel, fringe benefits, travel, equipment, and supplies must be supported by itemized statements or fact sheets detailing their necessity.

When funding activities under this agreement, EPA will give priority to ongoing operating expenses that are directly related to the enforcement of pesticide law, e.g., inspections, investigations, sample analyses, and travel.

EPA's share of the "total project cost" should not exceed 85% of the total award. The State's share may be paid in direct or allowable indirect or in-kind contributions.

The application must also contain a summary of work hours or work years devoted to each of the following activity categories: Administration, Supervisory, Inspectional (non-priority and priority, broken down by specific use-related and product/facility-related activities as identified under priority setting for the State), Analytical, Analytical Support, Clerical and Legal.

Enforcement Conditions of the Cooperative Agreement

Pesticides enforcement cooperative agreement awards are subject to the regulations found at 40 CFR Part 35.001 through 35.605, entitled "State and Local Assistance", as well as the "EPA General Grant Regulations and Procedures" (40 CFR Part 30). In addition, the applicant must agree to the conditions described below before obtaining an award.

Quality Assurance & Procedures

Quality Assurance Plan

For FY84 States are required by the EPA Grants Administration Division (GAD) to include quality assurance plans for analytical laboratories under the cooperative agreement. All analytical laboratories involved in environmental monitoring must have submitted a quality assurance plan within 90 days of award of the FY84 cooperative agreements. To assist States in complying with this requirement, CMS has developed model quality assurance guidelines. The States may use these guidelines or develop their own. Each Region has an individual assigned as quality assurance officer and that person will be available to assist the State in development of a quality assurance program. (see Appendix XIII)

FIFRA Forms and Procedures. During all inspections and sample collections performed under the authority of FIFRA, inspectors shall use standard forms and procedures as outlined in the EPA Pesticides Inspection Manual. To assure sample integrity, EPA chain-of-custody procedures shall be adopted during sampling, handling, shipping, storage, and analysis of pesticides collected under Federal law.

State Forms and Procedures. During all inspections, observations, and sample collections performed under authority of State law, State procedures and forms should be used. During sampling, handling, shipping, storage and analysis of pesticides collected under State law, State chain-of-custody procedures should be followed.

Referral and Inspection Procedures under FIFRA §26. Under the Final Interpretive Rule governing FIFRA Sections 26 and 27 (40 CFR Part 173), EPA and each State will annually define significant cases to be tracked by EPA after referral to the State. (FIFRA State Primary Enforcement Responsibilities, Final Interpretive Rule, January 5, 1983, 48 FR Notice pages 404-411)

After EPA formally refers a significant case to a State, the Agency will contact the State to learn the results of the investigation. The Region should determine whether the State has conducted an adequate investigation. An investigation should be considered adequate if the State has 1) followed proper sampling and other evidence gathering techniques, 2)responded expeditiously to the

referral, and 3)documented all inculpatory or exculpatory events or information. If the Region cannot negotiate an adequate investigation with the State, the Region may pursue its own investigation after notice to the State. That notice should summarize the facts relating to the State investigation, discuss the reasons for EPA's determination that the action is inadequate, and state that the EPA will initiate its own investigation.

Analytical Methods. Pesticide samples collected shall be analyzed by the State laboratory, or other laboratories specified in the agreement, using the EPA Manual of Chemical Methods for Pesticides, Association Of Analytical Chemists (AOAC), The State laboratory may use the Collaborative International Pesticides Analytical Council Limited (CIPAC) Handbook, the FDA Pesticide Analytical Manual (PAM), or other approved analytical methods for sample analysis. All violative samples shall be verified by a check analysis performed by a second chemist.

Cross Contamination Screening. States shall establish a cross contamination screening program in accordance with EPA Cross Contamination Guidelines. (See revised Appendix III.)

Check Sample. The State shall participate in the EPA (NEIC) Check Sample Program. Under this program, EPA submits known pesticide samples to State laboratories for analysis and cross contamination screening. The States will submit a report indicating the methodology used and results of the analysis to EPA. EPA will review the report and inform the States regarding the accuracy of their analysis and the methodology selected. If a State failed to obtain the correct results, EPA will assess the problem and provide assistance to the State laboratory, if requested. This program also assists in determining if the States are screening pesticides for cross contamination, since the check sample may be contaminated with another pesticide.

Check Analysis Procedure. The State shall participate in the Sample Check Analysis Procedure. A check analysis is a second analysis of a sample originally analyzed by a State laboratory. It is usually done when:

- o A State which is unsure of the results of an analysis requests an impartial or second analysis before initiating an enforcement action.

- o A State requests that EPA take the enforcement action and EPA desires to check the State's analysis.

Samples in these instances would be sent to either another State laboratory or EPA for a check analysis.

Training of Analytical Chemists. EPA will provide knowledgeable personnel for the training of analytical chemists. The States should avail themselves of EPA courses offering training to chemists on proper analytical procedures, instrumentation, and methodology. Personnel from EPA are available, if requested, to review State laboratories and discuss areas of improvement.

States are also encouraged to participate on their own in professional association meetings such as those held by AOAC, as well as other professional training courses.

Provision of Analysis Results. The State shall send a copy of the results of any sample analysis made under the authority of FIFRA to the person from whom the sample was collected.

Submission/Retention of Reports. Copies of all inspectional and analytical reports shall be retained by the State for examination by EPA or forwarded to the Regional office.

Training of Case Preparation Officers and Inspectors. EPA will provide for the training of State case preparation officers, attorneys and inspectors.

Special Projects. The EPA/National Environmental Investigation Center (NEIC) will provide, on a limited basis, investigation and laboratory support for special State pesticide problems such as:

- o Affirmative compliance monitoring of major pesticide spray programs; and
- o Response to pesticide incidents for which States did not include resources in the cooperative agreement application.[3]

Case Preparation and Enforcement

The State shall review the quality and adequacy of evidence gathered in the course of all investigatory activities performed under the cooperative agreement. For misuse cases, the States could establish a committee to review inspectors' findings and determine if any violations of State or Federal law exist. This committee would provide the States with an objective enforcement framework for all misuse cases.

State Cases

The State must review the quality and sufficiency of evidence gathered in the course of all investigative activities performed under the cooperative agreement.

If the evidence reveals a violation of only the State's pesticide laws, the State shall pursue an appropriate remedy provided by State law.

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[3] All special projects assistance requests shall be submitted to the appropriate Regional Office as soon as the State determines a need for such assistance. EPA Headquarters in conjunction with the Regions will evaluate each request based on the seriousness of the problem and the amount of EPA resources available.

If evidence reveals a violation of both State and Federal law, the state may bring appropriate enforcement action under State law or refer the case to EPA for action under FIFRA. In the event that a case is referred to EPA for action, the Agency case preparation officer should review the case file to ensure that the State inspection procedures adhere to basic constitutional guarantees. If the State evidence gathered by State inspectors was legally obtained and is within the scope of admissible evidence, EPA should proceed with the case.

Since States with cooperative agreements have primary enforcement responsibility for pesticide use violations, the Regions and States should follow the Final Interpretive Rule governing Sections 26 and 27.(48FR pages 404-411, January 5, 1983)

Under the Final Interpretive Rule [governing FIFRA Sections 26 and 27 (40 CFR Part 173)], EPA and each State will annually define significant cases to be tracked by EPA after referral to the State.

The State must commence appropriate enforcement action for cases tracked under the Interpretive Rule within 30 days after completion of the investigation. The Region may, after negotiation with the State, extend this period if required by the procedural characteristics of the State's regulatory structure.

If the Region determines that the State's intended enforcement response to the violation is inappropriate, EPA should first attempt to negotiate an appropriate State enforcement response. If a State is unwilling or unable to alter its original enforcement response, EPA may bring its own action after notice to the State. That notice should summarize the facts relating to the State's enforcement response, discuss reasons for EPA's determination that the enforcement action is inadequate and state that EPA will initiate its own enforcement action. (See the Final Interpretive Rule governing Sections 26 and 27, 48FR pages 404-411, January 5, 1983, Section 5B for criteria) Regional attorneys should not, however, initiate an enforcement action sooner than 30 days after the matter was referred to the State.

For all pesticide cases, if a State feels that the most appropriate enforcement action is not available under State law, it may refer the case to EPA for enforcement under FIFRA.

Federal Cases

Where evidence reveals a possible violation of Federal law only, the State shall immediately forward the information to the EPA Regional office and prepare testimony and provide witnesses as necessary.

State Records and Reports

Semi-Annual Reports

The State should submit semi-annual reports to the Regional Office within 15 working days after the end of the second and fourth quarters. Each report should compare actual accomplishments with the projections as specified in the cooperative agreement.

Records of Enforcement Actions

The State should maintain records regarding enforcement actions. These records should include the type of violation, who was involved (e.g. applicator, producer, homeowner), certification status of the applicator, name of the pesticide, application site and method, compliance history of the violator, and the type of enforcement action taken. This information will be used in developing the State's future enforcement priorities.

EPA Report of Enforcement Actions

EPA shall furnish the State with copies of all enforcement actions taken as a result of inspections conducted by the State and referred to EPA for action. This information will be useful to the State in future priority setting.

Applicator Certification and Training Management Plan Development

Defining State Program Objectives

The States should define objectives which support the achievement of the national goal of training applicators in the safe handling and use of pesticides, especially restricted use pesticides. State objectives may include management oriented objectives such as: 1) improving planning of the certification program; and 2) recommending areas of additional training because of use problems encountered through the pesticides enforcement cooperative agreement or to provide applicators with information regarding the impact of other Federal statutes on applicators.

Applicator Certification and Training Work Program

The work program must specify the work years and amount and source of funding estimated to be needed for each program element including any outputs required, a schedule for accomplishment of outputs and an identification of the agency responsible for each of the elements and outputs (40 CFR Part 35.130).

Action Plan

Once the State has identified its program objectives, it must describe its plan for carrying out a balanced program that addresses each of the program objectives under the agreement.

A pesticide applicator certification and training program that meets the requirements of both State pesticide statutes and FIFRA should contain at least the following elements/outputs.

- Number of training sessions in which the State will participate.[4]
- Number of training sessions which the State will monitor.
- Number of individuals to be examined for certification.
- Number of applicators to be examined for recertification.
- Number of certification sessions the State will conduct.
- Number of recertification sessions the State will conduct.
- Any changes the State will make to training materials.

[4] EPA Region VII has developed a training slide and tape presentation on how disposal of pesticide wastes and used pesticide containers by applicators is regulated under the Resource Conservation and Recovery Act (RCRA). This presentation can be obtained for State training sessions by contacting Roger Gold, Ph.d., University of Nebraska, Institute of Agriculture and Natural Resources, 101 Former Vet Science Building, East Campus, Lincoln, Nebraska 68583.

Additional training slide and tape presentations can be obtained for State training sessions by contacting Dr. James Parochetti, Program Leader -- Pesticides, Applicator Training and Weed Science, U. S. Department of Agriculture, Extension Service, Washington, D. C. 20250

These outputs should be listed separately for private applicators and for commercial applicators. For commercial applicators, the outputs should be broken down by certification category as well.

Proposed Budget

Each application must contain the State's proposed budget for the program. Expenditures for personnel, fringe benefits, travel, equipment, and supplies must be supported by itemized statements or fact sheets detailing their necessity.

The EPA's share of the "total project cost" shall not exceed 50% of the total award. The State's share may be paid in direct or allowable indirect or in-kind contributions.

Applicator Certification and Training Conditions of the Cooperative Agreement

Pesticide applicator certification and training cooperative agreement awards are subject to the regulations found at 40 CFR Part 35.001 through 35.605, entitled State and Local Assistance, as will as the EPA General Grant Regulations and Procedures (40 CFR Part 30). In addition the applicant must agree to the conditions described below before obtaining an award.

State Reports

The States will submit a semi-annual report corresponding to the project and budget period of the cooperative agreement. This semi-annual report must be submitted within 30 days after the end of the second and fourth quarters of the Cooperative Agreement outputs and will include:

1. The total number of applicators, private and commercial, by category, currently certified.
2. The number of applicators, private and commercial, by category, certified during the last reporting period.
3. The number of applicators, private and commercial, by category, recertified during the last reporting period.

The States are required to submit an annual report corresponding to the project and budget period of the cooperative agreement. This annual report for both the State plan and Cooperative Agreement outputs will include:

1. The total number of applicators, private and commercial, by category, currently certified.
2. The number of applicators, private and commercial, by category, certified during the last reporting period.
3. The number of applicators, private and commercial, by category, recertified during the last reporting period.
4. Any changes in commercial applicator subcategories.

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[2] Certification and Training Program Directive #81-2 issued by A. E. Conroy II, dated 9-10-81.

5. A summary of enforcement activities related to use of restricted use pesticides during the last reporting period.
6. Any significant proposed changes in required standards of competency.
7. Proposed changes in plans and procedures for enforcement activities related to use of restricted use pesticides for the next reporting period.
8. Any other proposed changes from the State plan that would significantly affect the State certification program.[2]

The States may combine the Annual FIFRA §4 State Plan report and the final report of outputs accomplished under the cooperative agreement, since the first three reported items under the State Plan annual report are identical to the outputs reported under the cooperative agreement.

EPA APPLICATION AND AWARD PROCEDURES

Summary of EPA Role

EPA Headquarters has the primary responsibility for:

- o Developing national priorities and strategies for the pesticides enforcement program and applicator certification and training program;
- o Preparing guidance for implementing and managing the programs;
- o Making funds available to the Regions for disbursement to the States;
- o Providing a special review of applications upon written request from the Regional offices; and
- o Developing laboratory support for State personnel.

EPA Regional Offices have primary responsibility for:

- o Providing applicants with annual guidance and application criteria to be used in awarding cooperative agreements;
- o Notifying eligible State agencies of the availability of funds;
- o Working closely with the States to develop a complementary Federal/State program which considers State as well as EPA priorities and resources;
- o Negotiating outputs with applicants;
- o Reviewing and approving applications;
- o Developing training for State personnel; and
- o Conducting Mid-year and End-of-year program evaluations.

Each participating Region should establish a cooperative agreement Review Panel to review and evaluate all pesticides enforcement and applicator certification and training cooperative agreement applications. This panel should consist of at least one member from each of the following offices:

- o Regional Air and Waste Management Division/or Waste Management Division
- o Regional Grants Administration Office, and
- o CMS (Grants and Evaluation Group).

Application Submission

To apply for a cooperative agreement under FIFRA, a State must submit an "Application for Federal Assistance", EPA Form No. 5700-33 complete with all elements required by the guidance. (See Appendix V)

Applications must be submitted at least 60 days prior to the beginning of the budget period. (40 CFR Part 35.140)

Application Review

The Regional Administrator will review each completed cooperative agreement application and should approve, conditionally approve, or disapprove the application within 60 days of receipt. (40 CFR Part 35.141)

The Agency will allocate funding for cooperative agreements on the basis of the appropriateness of the State's program plan when compared to the criteria set forth in the Required Application Elements section of this guidance and the State and Local Assistance regulations. (40 CFR Part 35.001 through 35.605)

Each application will be subject to two reviews:

- o Technical and Program Review; and
- o Administrative Review.

Technical and Program Review

A technical and program review will be made by the Cooperative Agreement Review Panel to determine the merit of the proposed outputs in view of the objectives and priorities of the cooperative pesticides enforcement program and applicator certification and training program. For the pesticides enforcement cooperative agreement applications, CMS has developed a form for use by the review panel in determining answers to basic evaluation questions. (See Appendix VI.)

CMS has also developed Output Time Factors for use in evaluating pesticides enforcement cooperative agreement applications for financial assistance. The following time factors were obtained by averaging figures submitted to CMS by the States:

Activity	Work Hours to Complete Activity
Agricultural Use Inspection	20
Non-agricultural Use Inspection	20
Experimental Use Inspection	15
Producer Establishment Inspection	15
Marketplace Inspection	5

Activity	Work Hours to Complete Activity
Import Inspection	10
Dealer Record Inspection	5
Applicator License and Record Inspection	5
Sample Collection and Preparation	5
Sample Analysis (Formulation and Residue)	11

These figures take into account all inspectional or analytical time spent to complete an activity, including supervisory time, travel time, document preparation, sample shipment, etc. The work hours given also include the prorated time for administrative activities of inspectors and chemists. Additional time for administrative, case preparation, legal, clerical, and program planning activities time may be charged if the State can show that such activities are prerequisites to conducting the program.

The Regional office should compare each State's proposed outputs and the personnel requested in the pesticides enforcement cooperative agreement application with the work years computed by using the output time factors amounts shown above. The purpose of these computations is to determine if the State's requested work hour levels (or work years) for inspectional and analytical outputs are consistent with the work hours computed for each activity using the above output time factors. An Output Time Factors Computations Worksheet has been developed to assist the Regions in this comparison. (See Appendix VII.)

The Regions should use these time factors as a guide in negotiating and evaluating pesticides enforcement cooperative agreement applications. The number of inspections, samples, and analyses multiplied by the appropriate time factors should equal the approximate number of work hours which each State requested to complete the projected outputs under the cooperative agreement. To ensure equal treatment of all States, CMS has identified a normal work year as consisting of 1800 hours after allowing for leave and holidays.

Deviations from these time factors can be expected due to differences in travel time, local procedures, etc. However, the Regions should not permit work hours grossly in excess of these computed levels. Significant differences between the amount requested and the amount computed must be justified, e.g., the need for extensive travel time. If an applicant's commitments are in excess of those indicated by the computations, the Regional Office must assure itself that the quality of work is not suffering at the expense of the quantity of outputs.

The Review Panel will evaluate both pesticides enforcement and applicator certification and training cooperative agreement applications to determine whether:

- o The application contains all elements outlined in the Required Application Elements section of this guidance;
- o The applicant's priority-setting process is adequate; (for pesticides enforcement agreements only)
- o The outputs are appropriate based on the priorities or objectives set by the State;
- o The applicant's objectives and expected results are consistent and compatible with EPA priorities and policies; and
- o It is feasibile to achieve such objectives in view of the State's existing problems, program authority, and resources.

Administrative Review

The Regional Grants Administration Office will perform an administrative evaluation to determine whether the application meets the requirements of the EPA General Grant Regulations (40 CFR Part 30) and regulations for State and Local Assistance (40 CFR Part 35.001 through 35.605 Appendix VIII). At each stage of the evaluation, the State may be required to provide further information or to amend the application to satisfy the concerns of the Agency.

PROGRAM MANAGEMENT AND ACCOUNTABILITY

After award of the cooperative agreements, both States and the Regions will have program management responsibilities in the areas of accountability, training, reporting, evaluation and agreement modification.

Accountability under the Cooperative Agreement

States must maintain accounting records for funds awarded under each agreement (including receipts, State matching contributions, and expenditures) in accordance with all applicable EPA grant regulations and with generally accepted accounting principles. Headquarters suggests that the Regional Grants Administration Office review State accounting practices and procedures prior to award of funding to assure the State's ability to maintain appropriate records.

State expenditures under the agreement must follow cost categories (i.e., budget line item or program elements) established in the original agreement. Deviations may be made by the State from the proposed budget as long as they are in accordance with the general grant regulations or approved by the EPA Regional project officer.

Training

Training under the pesticides enforcement program will be conducted by the EPA Regional Office with support from EPA Headquarters. Training will consist of instruction in inspectional and sample collection techniques, sample analysis, and case preparation, in both classroom and on-the-job form. The cooperative agreement should contain a schedule for conducting training activities agreed upon by EPA Regions, Headquarters or NEIC and the State.

Regional Reporting

The Regions must forward copies of all agreement applications and all mid-year, and/or annual reports to CMS for review. CMS should also be kept informed of any problem areas or serious deficiencies that develop within a State program.

The Regions must also enter into the FIFRA And TSCA Enforcement System (FATES) all State enforcement and certification and training projections from the completed cooperative agreement applications, as well as mid-year, if appropriate, and end-of-year accomplishments. The Regions must enter this data into FATES within 30 working days after the award of the cooperative agreement

and within 30 working days of the end of the second and fourth quarters. For certification and training cooperative agreements data must be entered within 30 working days after the award of the agreement and within 30 working days of the end of the forth quarter. (See attachment X)

The Regions are responsible for reporting to the Administrator data from the State applications and reports for the following: (See attachment XIV)

- o Indicators for Environmental Results
- o Administrators Accountability System
- o Environmental Management Report

Program Evaluation

Program evaluation by EPA is an essential ingredient of the management of the cooperative agreement program. Regional personnel must meet with appropriate State officials on a semi-annual basis to conduct mid-year and end-of-year evaluations of the cooperative programs. Mid-year and end-of-year evaluations must be conducted within 30 days following the end of the quarter.

The Compliance Monitoring Staff (CMS) of the Office of Pesticides and Toxic Substances (OPTS) developed an evaluation protocol for use by the Regions in evaluating State programs. CMS developed the protocol to standardize the Regional evaluation reports of State programs. The Regions shall use the evaluation protocol for all State FIFRA enforcement and pesticide applicator certification and training cooperative agreement end-of-year evaluations.(See Appendix IX.)

Mid-year Evaluations

At mid-year, the Regions shall conduct a general review of each State's outputs and accounting procedures. During the general review, evaluators should, where appropriate:

- o Compare actual accomplishments with output commitments;
- o Review selected sample collection documents, inspection reports, investigation reports, and results of sample analyses for accuracy and quality, and review appropriateness of enforcement actions;
- o Review, with State accounting personnel, the following accounting information:
    - a. Employee time and attendance reports;
    - b. Records for one-time non-expendable property expenditures;

c. Estimate, (excluding one-time non-expendable property expenditures), of the amount of funds expected to be remaining at the end of budget period.

If the review indicates areas for improvement or change, the Region is expected to offer the State suggestions and guidance in those areas.

End-of-year Evaluations

The scope of the program evaluation conducted by the Region at the end of the year will differ from that of the mid-year evaluation. The end-of-year evaluation will be an in-depth qualitative review of the Federal/State cooperative enforcement program and the pesticide applicator certification training program.

The Regions shall use the evaluation protocol, found in Appendix IX, to conduct all cooperative agreement program end-of-year evaluations.

When conducting an evaluation using the protocol, the Regions shall answer all questions. The Regions can fill out certain parts of the protocol in advance from the application and quarterly reports; other parts must be completed during the on-site visit in the State. The Regions should plan on a minimum of three days to conduct the on-site evaluation in the State.

Evaluation Reports

The Regional office shall prepare a written report of each evaluation and send a copy to the State within 20 working days of completion of the on-site evaluation. If the evaluation protocol is completed properly, it could serve as the basis of the evalution report. The report should include a discussion of suggested program improvements. The State shall be allowed 15 working days from the date of receipt of the report to comment on the findings contained in the evaluation report. The Regions shall send a copy of the Regional evaluation report and the State's response to Headquarters.

Evaluations of both the pesticides enforcement and the applicator certification and training agreements are especially important in FY84 because State applications for continuing assistance must contain a discussion of their performance under the existing award. (40 CFR Part 35.140) Funding levels for the next cooperative agreement project period could be affected if a State's performance is less than satisfactory.

Modification, Suspension, or Termination of the Agreement

The provisions and funding of the agreement must be modified by EPA and the State if it is found that actual accomplishments differ significantly from the planned accomplishments. These

changes may include, but are not limited to, changes in the outputs, changes in the date of performance for specific outputs, or changes in the budget for the period of the agreement. Changes in the agreement are effective only upon the execution of a written amendment. If performance by the State does not improve after modification of the agreement, steps may be taken by EPA to suspend or terminate the agreement.

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APPENDICES

Appendix I — Ranking Procedure to Establish Pesticide Enforcement Priorities And Allocate Enforcement Resources (revised 1/83)

Appendix II — Deleted

Appendix III — Contaminant Screening Guidelines (revised /)

Appendix IV — Deleted

Appendix V — EPA Application for Federal Assistance - EPA Form 5700-33 (Revised 1/83 to include examples for completing form to apply for a consolidated cooperative agreement.)

Appendix VI — Pesticides Enforcement Cooperative Agreement Application Technical Review Form

Appendix VII — Output Time Factors Computations Worksheet (Revised 1/83)

Appendix VIII — Revised 40 CFR Part 35.001 - 35.605 Subpart A, EPA regulations governing State and Local Assistance (Replaces 40 CFR Part 35.750 - 35.786)

Appendix IX — Evaluation Protocol

Appendix X — Pesticides Enforcement Cooperative Agreement and Applicator Certification and Training Output Projections and Accomplishments Forms for input into FATES (Revised 1/83)

Appendix XI — Label Improvement Program (LIP):
- Dec. 4, 1980 letter from H. Harrison re: LIP with attachments: PR Notice 80-1, Storage and Disposal Statements and Sample Label.
- PR Notice 80-2 re. deletion of Salt Water Emesis
- Termiticides Label Improvement Program
- Anti-fouling Paints Label Improvement Program
- Funigants Label Improvement Program

Appendix XII — CMS Strategy for the Enforcement of CRP from A. E. Conroy II dated June 8, 1981 and the OPP listing of product types subject to CRP from Reto Engler, Chief Disinfectants Branch dated 2-26-81.

Appendix XIII — Model Quality Assurance Project Plan for State Pesticide Laboratories from A.E. Conroy II, dated 12/14/82.

Appendix XIV — Developing Indicators for Environmental Results memorandum from T.E. Hunt dated 9/28/82.

Appendix XV — Final Interpretive Rule governing FIFRA §26 & 27 (48 FEDERAL REGISTER, Pages 404-411, Jan. 5, 1983)

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, 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:

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

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.

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:

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

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WASHINGTON, D.C. 20460

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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:

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Product Manager (15)
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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 41393) 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

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 exhaused. 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:

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*/ 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

A. E. Conroy II/07

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								
SYMBOL	A-132	A-132						
SURNAME								
DATE	9/29/76	10/5	10/8					

EPA FORM 1320-1 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 chloroane 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)

CSMA
FOUNDED 1914

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 after 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 voluntary 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
Executive Director

RE:kas
cc: A.E. Conroy

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 26, 1976, the Administrator granted registrants' petition for reconsideration of the 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 quanitity is reached) will become "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 Order (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 Febraury 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 effective date. 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 registrations 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 fulfill certain substantive requirements to be afforded a stay of the effective date 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, pink patch, or fusarium patch), Typhula incarna, Typhula ishikariensis, and Sclerotinia borealis.

3/ As part of the settlement agreement, Mallinckrodt has agreed to amend the subject products' labeling to include the caution "Do not apply within twenty-five (25) feet of any body of water where fish are taken for human consumption" and the direction that the product may be used "... only by or under the direct supervision of golf course superintendents." These label additions will also be made to the O. M. Scott and W. A. Cleary products 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 immediate 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.

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/MT

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

sons Seed Saver Dust; EPA Reg. No. 1969-91

arsons Seed Saver Dust was included in the settlement greement, but a search of EPA records has revealed that t was never registered. It carries the file symbol). 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

cc: Coleburn T. Cleveland

OFFICIAL FILE COPY

ENVIRONMENTAL PROTECTION AGENCY

P. E. 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

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. PSTSED 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

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 26, 1976, the Administrator granted registrants' petition for reconsideration of the 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 become "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 Febraury 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 effectiv[illegible]. 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 forms

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"
1969-53	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 registrations 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 fi 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" include: if Fusarium nivale (pink snow mold, pink patch, or fusarium patch), Typhula incarna, Typhula ishikariensis, and Sclerotinia borealis.

3/ As part of the settlement agreement, Mallinckrodt has agreed to amend the subject products' labeling to include the caution "Do not apply within twenty-five (25) feet of any body of water where fish are taken for human consumption" and the restriction that the product may be used "... only by or under the direct supervision of golf course superintendents." These label additions will also be made to the O. M. Scott and W. A. Cleary products 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 effectuate 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, 1976 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.

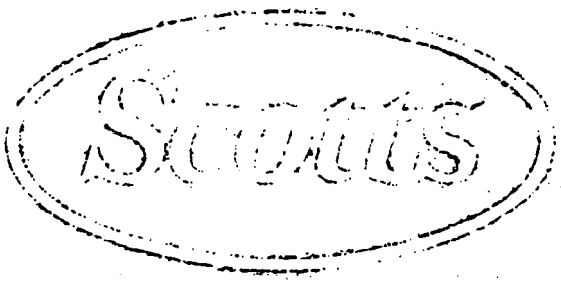
87/23

[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	94.66%
Total	100.00%

EPA EM 538 Ch 1

US Pat No 3,083,039 EPA Reg No 538-27 Product of USA

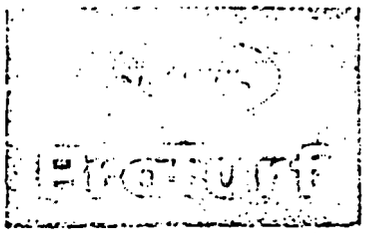
ProTurf Division, O M Scott & Sons Marysville, Ohio 43040

ACCEPTED

DEC 1 1976

[illegible] Insecticide, [illegible] Act, [illegible]

[illegible] No. 538-27



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 45 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: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 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)

California fertilizer plus fungicide

Scotts

ProTurf

22-5-5

California fertilizer plus fungicide

FOR USE ON WINTER TURF DISEASES

California fertilizer plus fungicide

8503

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.

8503

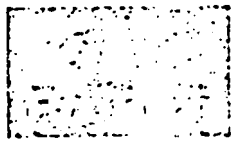
ACCEPTED

DEC 1 1976

Under the Federal Insecticide, Fungicide, and Rodenticide Act, for the pesticide

Reg. No. 538-54

8503



22-5-3

Golfer's 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.

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)

Scott's

ProTurf

22-5-5

California fertilizer plus fungicide

FOR USE ON SUMMER TURF DISEASES

California fertilizer plus fungicide

California fertilizer plus fungicide

8503

8503

CAUTION: KEEP OUT OF REACH OF CHILDREN

[illegible]

Toxic to fish and wildlife. Keep out of any body of water.

Active ingredients: Phenylmercuric acetate			0.4[illegible]%
Thiram (Tetramethylthiuram disulfide)			2.9[illegible]%
Inert ingredients			96.6[illegible]%
EPA Reg No 538		Total	100.00%
Net weight 45 lbs	California fertilizer plus fungicide	22-5-5	guaranteed analysis
Total nitrogen (N)			22%
1.0% ammoniacal from ammoniated phosphate			
13.6% water soluble from urea and methylene ureas			
7.4% water insoluble from methylene ureas			
Available phosphoric acid (P2O5) from ammoniated phosphate			5%
Soluble potash (K2O) from muriate of potash			5%

Potential acidity equivalent to 60 lbs. calcium carbonate per ton

U.S. Pat. Reg. (Cont. Ohio 1,076,699, 2,076,700)

Product of USA

ProTurf Division, O.M. Scott & Sons

Marysville, Ohio 43040

8503

ACCEPTED

OCT 4 1976

Under the Federal Insecticide, Fungicide and Rodenticide Act, [illegible] under [illegible] No. 538-150

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 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.

87/23

broad spectrum fungicide

NET WEIGHT 26 LBS (11.8 Kg)

Scotts

ProTurf

broad spectrum fungicide

FOR USE ON
SUMMER TURF DISEASES

ACCEPTED

OCT 1 1976

Under the Federal Insecticide, Fungicide, and Rodenticide Act, [illegible] for the pesticide registered under EPA Reg. No. 538-149

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	4.65%
Inert ingredients	94.66%
Total	100.00%

US Pat. No. [illegible] EPA Reg. No. 538-149 Product [illegible]
Marysville, Ohio 43040

Proturf

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

3545

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: Phenylmercurio acetate	0.80%
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 (*1)	24%
1.1% ammoniacal nitrogen from ammoniated phosphate	
14.9% soluble nitrogen from urea and methylene urea	
8.0% insoluble nitrogen from methylene urea	
Available phosphoric acid (P2O5) from ammoniated phosphate	5%
Soluble potassium (K2O) from potassium sulfate	3%

Potential acidity equivalent to 1000 lbs calcium carbonate per ton

US Process Pat Nos 3,231,365 3,705,734 Other Pat Pend Product of USA

ProTurf Division of M Scott & Sons Marysville, Ohio 43040

*In Michigan and Canada reads "minimum guaranteed analysis"

ACCEPTED

DEC 1 1976

[illegible] Insecticide, [illegible] Fungicide Act, [illegible]

[illegible] No. 538-36

ProTurf

24-5-3

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.

46⅔ LBS (21.1 Kg) TREATS 22,000 SQ FT (½ ACRE/2044 SQ M) AT NORMAL RATE
46⅔ LBS (21.1 Kg) TREATS 11,000 SQ FT (¼ ACRE/1022 SQ M) AT DOUBLE RATE
46⅔ 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	over/on wheels	4½	6	3½
Scotts Rotary	3 mph	6 feet	D	G	B
Lely-WTR & WHR Models	4.5 mph	16 feet	2½ TC	3½ TC	1½ TC
Lely-HR (PTO Model)	450 rpm G4.5 mph	16 feet	2½ TC	3½ TC	1½ TC
Gandy 8 ft 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 injection, 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.

Toxic to fish and wildlife. Keep out of any body of water.

Active ingredients: Phenylmercuric acetate	0.50%
Thiram (Tetramethylthiuramid sulfide)	5.50%
Inert ingredients	93.60%
EPA Reg No 538-[illegible] Est 530-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% soluble nitrogen from urea and methylene ureas	
8.0% [illegible]	
Available [illegible] from ammoniated phosphate	5%
Soluble [illegible]	3%

Potential [illegible] 100 lbs [illegible] carbonate per ton

US Pro[illegible] Other Pat Pend Product of USA

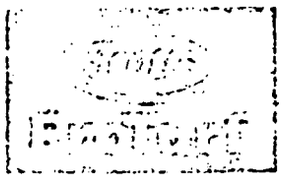
ProTurf Division, O M Scott & Sons Marysville, Ohio 43040

*In Michigan and Canada reads "minimum guaranteed analysis"

ACCEPTED

[illegible] 1976

Under the [illegible] Insecticide, Fungicide, and Rodenticide Act, [illegible] registered under EPA Reg. No. 538-148



24-5-3

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	6
Lely-W/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 9 h.4 Series	4.5 mph	overlap wheels	13½	17½	10½
Model 42 model	2.5 mph	overlap wheels	24	30	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 SIGNAL 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
FR FORM 9-253
ARS:PR:EEW:cls
10-10-68

Parsons

SEED SAVER®

SLURRY CONCENTRATE

"60"

FOR SLURRY SEED TREATERS ONLY

Parsons SEED SAVER SEED TREATMENT

WHEAT OATS

This Will Dye Seed Grain Red

A MERCURIAL FUNGICIDE

DANGER — 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 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	SEE GAT
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 b amounts are used.

WARNING

ANTIDOTE — If swallowed, give milk or white of egg beaten tablespoonful of salt in a glass of warm water, and repeat until Repeat milk or white of egg beaten with water. 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. a warranty, expressed or implied, concerning the use of this pro dicated on the label. Buyer assumes all risk of use and/or handli when such use and/or handling is contrary to label instructions.

DIRECTIONS FOR USE

ned and well cure I before treating. LIQUID SEED SAVER ATE "60" must be diluted with water before use. The folper dilution for use of SEED SAVER "60" in a Slurry Seed

D "60" on	WATER Gallon	SLURRY BUCKET	SEED GATE	RATE PER BUSHEL
(1)	20	23 cc.	15	¼ fl. oz.
(1)	12	23 cc.	20	¼ fl. oz.

added if desired.
l 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.

ce Delayed Chemical Burns. Do not breathe spray mist. considered poisonous and handled with care. Allow adee operator. If spilled on skin, immediately wash thoroughly May be fatal if swallowed. Do not get in eyes, on skin or into eyes, flush with water for at least 15 minutes and get product contains a strong concentration of dye, therefore h will dye hands or articles that come into contact with it an gest wearing gloves and old clothing.

Keep container closed. Keep liquid away from open flame, ent, or heated surfaces. Do not reuse empty container. ng or crushing. Bury or discard in a safe place.

SER -- Parsons Chemical Works Inc. and Seller mak implied, concerning the use of this product other tha yer assumes all risk of use and/or handling of this materia andling 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. Suggest tripping gate 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:

"INFECTED SEED — POISONOUS TO ANIMAL AND MAN.
DO NOT USE FOR FOOD, FEED OR OIL."

USDA REG. NO. 1999-57

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 REGISTERED UNDER NO. 1999-57

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. 1969-98
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

Parsons

LIQUID SEED SAVER

For Liquid Seed Treating Machines

Parsons SEED SAVER BRANDS SEED TREATMENT

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 anything else. The following table shows proper amou[illegible]

SEED	Mist-O-Matic	Adaptors or Conversion Kits	Pan[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
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
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
FLAX	1½ fl. oz. per bu. 5 cc. cup to 6⅔ pounds pan load. 9 dumps per bu.	1½ fl. oz. per bu.	1½ f[illegible] per

*See machine manual for cup size and panload.

WARNING

ANTIDOTES — If swallowed. Give milk or white [illegible] beaten w[illegible] glass of warm water, and repeat until vomit fluid [illegible]. Repeat. Call a Physician immediately! If on skin. Wash immediately with with water for at least 15 minutes, and get medical attention.

Warning: May Produce Delayed Chemical Burn. Do not breath[illegible] or on clothing. Wash thoroughly after handling.

Store [illegible] cool place. Keep container closed. Do not get in [illegible] Keep liquid away from open flame, spark-producing equipment, or strong concentration of dye, therefore handle with care because it contact with it and it is hard to wash off. Suggest [illegible] gloves.

NOTICE TO PURCHASER — Parsons Chemical Wks, Inc., [illegible] concerning the use of this product other than [illegible] handling of this material when such use and or [illegible]

DIRECTIONS FOR USE

...d and well cured before treating. Not to be diluted with ... table shows proper amounts:

...ic	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
...u. ...½ ...ad. ...	¾ fl. oz. per bu.	¾ fl. oz. per bu.	½ fl. oz. per bu. 23 cc. cup to 8.5 pounds use 1½ pt. per gal. water Seed Gate 20
...u. ...½ ...ad. ...bu.	¾ fl. oz. per bu.	¾ fl. oz. per bu.	½ fl. oz. per bu. 23 cc. cup to 10 pounds use 1¼ pt. per gal. water Seed Gate 18
...bu. ...⅔ ...ad. ...u.	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

...ve milk or white of egg beaten with water, then a tablespoonful of salt in a ...until 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.

...al Chemical Burns. Do not breathe spray mist. Do not get in eyes, on skin ...after handling.

...ontainer closed. Do not get in eyes, on skin or clothing. Wash thoroughly, ... spark-producing equipment, or heated surfaces. This product contains a ...re handle with care because it will dye hands or articles that come into ...ch oil. 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

16 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:RPB:je 4-14-72

U.S. DEPARTMENT OF AGRICULTURE
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)

CAUTION: READ INSTRUCTIONS ON REVERSE

1. DATE OF APPLICATION: April 7, 1970

2. NAME OF ECONOMIC POISON *(Must be same product name as on label-do not list active ingredients)*: Seed Saver Dust Drill Box Treatment

3. TYPE OF PESTICIDE *(Check each category that describes product)*: 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 [ ] 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 [ ] GLASS [ ] PLASTIC [ ] PAPER [X] 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)*:

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 specific name and percentage of each active and each inert ingredient. *(This information is treated confidentially.)*

12. RECEIVED BY USDA – PESTICIDES REGULATION DIVISION, WASHINGTON, D. C.

IN ANY CORRESPONDENCE ON THIS PRODUCT, REFER TO THIS FILE SYMBOL NO.:

14. SIGNATURE OF AUTHORIZED FIRM REPRESENTATIVE: [signature] 4/7/70 - [illegible]

TITLE: Technical Dept.

16. DATE SIGNED: 4-7-70

PR FORM 9-199
MAY 1969

EXISTING STOCK OF PR FORM 9-199 (JULY 1968) WILL BE USED UNTIL EXHAUSTED

PARSONS CHEMICAL WORKS
Manufacturing Chemists Since 1916
P. O. BOX 156—GRAND LEDGE, MICHIGAN

April 7, 1970

Mr. Harold G. Alford
Assistant Director for Registration
U. S. Dept. of Agriculture
Agricultural Research Service
Pesticides Regulation Division
Washington D. C. 20250

Dear Mr. Alford:

We are enclosing five (5)corrected SEED SAVER DUST (Drill Box Seed Treatment) labels. Also enclosed is five (5) copies of the formula for your information.

We trust that this product will now be in line for registration.

Yours truly,

PARSONS CHEMICAL WORKS, Inc.

A. R. Fox, Technical Dept.

ARF/pr
enc.

Parsons

SEED SAVER DUST

[illegible]

MERCURIAL FUNGICIDE

WHEAT OATS
RYE BARLEY

Parsons SEED SAVER GRAINS SEED TREATMENT

ACTIVE INGREDIENTS
PHENYL MERCURIC AMMONIUM ACETATE ... 1.0500%
INERT INGREDIENTS ... 98.3575%
[illegible] ... .0025%
[illegible] ... 0.9500%

POISON

Antidote:

If swallowed. Give milk or white of egg beaten with water, then a tablespoonful of salt in a glass of warm water, [illegible] until vomit fluid is clear. Repeat milk or white of egg beaten with water. Call a Physician Immediately!

DANGER

KEEP OUT OF REACH OF CHILDREN

See Other Panels for Additional Cautions

NET WEIGHT 2 POUNDS

TREATS 16 BUSHELS

[illegible]

Parsons

THE EASY MODERN METHOD TO TREAT SEED GRAIN

WARNING:

May Produce Delayed Chemical Burns! Do not breathe dust. Do not get in eyes, on skin or on clothing. Wash thoroughly after handling.

USDA NO.
196[illegible]

SEEDS	Usually Controls Diseases	Suggested Amount To Use Per Bu.
WHEAT	Stinky Smut or Bunt	2 Oz.
BARLEY	Covered Smut Black Loose Smut—Stripe	2 Oz.
OATS	Smuts	2 Oz.
RYE	Stem Smuts Covered Smuts	2 Oz.

Or use one pound to 8 bushels of seed grain.

DIRECTIONS

Be sure seed grain is well cured and thoroughly clean before treating with DUST. Do not treat weak or Poor Germination test seeds or seeds that are real dark with Smut Dust. For better stands and yields always plant high Germination test seeds. Shake the can to loosen up material.

Apply PARSONS SEED SAVER DUST directly to dry seeds in planter or drill box until seed is thoroughly coated.

NOTICE TO PURCHASER

Our recommendations for use of this product are based upon tests believed to be reliable. The use of this product being beyond our control no guarantee, expressed or implied, is made as to the effects of such of the results to be obtained if not used in accordance with directions or established safe practice. The buyer must assume all responsibility, including injury or damage, resulting from its misuse as such, or in combination with other materials.

CAUTION

Provide adequate ventilation. Avoid prolonged breathing of dust. Advisable to wear a mask or wet handkerchief over the nose and mouth while working with the dust. Do not get dust on skin, and especially when perspiring. Do not use seed treated with DUST for any food purpose. Not to be swallowed.

Do not reuse empty container. Destroy it by perforating or crushing. Bury or discard in a safe place.

REGISTERED IN U.S. PATENT OFFICE NO. 370,564

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."

Manufacturing Chemists Since 1916

PARSONS CHEMICAL WORKS
Laboratories—Grand Rapids, Mich.

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 28, 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

OFFICE OF ENFORCEMENT

APR 05 1979

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 federally 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 28, 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

SUSPENDED USES

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
	Golf courses
Rights-of-way: highways, pipelines, powerlines, utilities, roadsides, roadways, etc.	Home use, lawns, grass, ornamental turf, patios, sidewalks, driveways, farmyards
Pasture	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
	Fence rows, hedgerows, fences (not otherwise included in suspended uses, e.g., rights-of-way, pasture, home and garden)
Lumberyards	
Refineries	
Nonfood crops	Nonfood crop areas
Storage areas	Noncrop areas
Noncrop areas	Storage areas
Wastelands (not otherwise included in suspended uses, e.g., forestry)	Waste areas
Vacant lots	Vacant lots, parking areas, etc.
Industrial sites and areas (not otherwise included in suspended uses, e.g., rights-of-way)	Industrial sites or buildings (not otherwise included in suspended uses, e.g., rights-of-way, commercial/ornamental turf)

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.

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

2 JUL 1982

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

TO: Air and Waste Management Division Directors
Pesticide Branch Chiefs

SUBJECT: General Compliance Strategy for Products Suspended Under §3(C)(2)(B) of FIFRA

Attached is the final General Compliance Strategy for products suspended under §3(c)(2)(B) of FIFRA. The final strategy incorporates comments received on the May 10, 1982, draft. Also attached is a complete list of suspension actions initiated or accomplished under section 3(c)(2)(B) of FIFRA by OPP. This list will be updated as needed by OPP.

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

Attachments

GENERAL COMPLIANCE STRATEGY FOR PRODUCTS SUSPENDED UNDER §3(c)(2)(B) OF FIFRA

Overview

Section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes the Administrator to request additional data on registered products in order to allow EPA to further evaluate the product's active ingredient. Registrants who fail to produce the data requested face suspension of their product. A Notice of Intent to Suspend (NOIS) is issued by the Office of Pesticide Programs (OPP) for specific products produced by a registrant if the registrant fails to take steps to produce the data requested. The NOIS is sent by certified mail to the affected registrants. Effective suspension of a product is accomplished through the issuance of a Stop Sale, Use or Removal Order (SSURO) and timely coordination between Headquarters, Regions and States.

Regulated Industry

Requests for additional data made pursuant to Section 3(c)(2)(B) are directed to all registrants who produce a product containing the specific active ingredient.

Requirements of The Rule

Section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA):

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

- Requires registrants to take appropriate steps to secure the additional data within 90 days or face suspension.
- Grants EPA the authority to issue a Notice of Intent to Suspend if a registrant fails to take steps to secure the required data.
- Allows a registrant and other parties to request a hearing within 30 days of receipt of the NOIS 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 disposition of existing stocks is consistent with the Act. The effective date of the suspension is affected by the registrant's request for a hearing.

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

1) develop the required data himself or jointly with other registrants;
2) certify that the product is exempt because it is an end-use product formulated from a registered, non-suspended manufacturing use or technical grade product purchased from another producer;
3) request and receive a waiver of some or all of the data requirements; or
4) voluntarily request cancellation.

Failure to exercise any of these options within certain specified time periods results in the suspension of the registrant's product.

Enforcement Objectives

The aim of the compliance strategy is to stop the manufacture, and possibly the distribution, of products subject to the suspension. This can be accomplished through the issuance of a SSURO to the registrant at the point of manufacture. Because suspensions initiated pursuant to §3(c)(2)(B) are based on a failure to submit data rather than on product deficiencies, it is not necessary to recall suspended products from the marketplace.

The sale and use of existing stocks[1] of suspended products which are already in the marketplace is allowed to continue for a period deemed appropriate by the Administrator. Production is commonly permitted for 120 days after receipt of the NOIS by the registrant.

Types of Violations

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

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[1] Existing stocks are those packaged, labeled and released for shipment at the time production is suspended.

Administrative Considerations

Program Management

Upon final suspension, PTSED will send the regions:

1) A copy of the NOIS issued by OPP including,

   a) a list of companies and specific products affected
   b) the Agency's decision on the disposition of existing stocks;

   c) dates when production must cease; and

2) Any pertinent supporting documents.

The NOIS will allow the registrant a period of time, determined by OPP, after the effective date of the suspension notice to stop production of the suspended product(s). Additionally, registrants will, generally, be allowed a period of time to dispose of existing stocks of the suspended product(s).

Prior to the date when all production must stop, the region will send any affected registrants a copy of the NOIS and a SSURO, effective the day after the production termination date. The cover letter which accompanies the NOIS and SSURO should include a discussion of the options available to the registrant to remove the suspension. OPP shall be contacted by the Region to discuss what options are available to the registrant of the suspended product. States should be notified by the region of the suspension action upon the region's receipt of the PTSED transmittal and should be provided with copies of all the information the region has received from PTSED.

The Regions should also work with the States in which the affected registrants are headquartered to schedule inspections of the affected registrants. Production facilities of affected registrants should be visited by the State after termination of the time period allowed by the NOIS for production. Normally, only one inspection should be necessary for each registrant. States should determine that production of the suspended product has been halted and that the registrant understands the options available to lift the suspension, should the registrant so desire. States should explain that the EPA will allow existing stocks of the suspended products to be sold for the period of time authorized by the Administrator. States should also determine the amount of existing stocks of suspended products in the control of the registrant and report this information to EPA. Dealers, possessing products produced prior to the production termination date, will not be affected by any time limit for the sale of existing stocks.

Intrastate products included in a §3(c)(2)(B) action are to be treated as federally registered products.[2] States may take action against these products and are encouraged to do so. Regions are expected to assist in any State effort to suspend or restrict the sale and distribution of suspended intrastate products.

Allocation of Responsibilities

1) Headquarters Responsibility.

a) Provide Regions with strategy for §3(c)(2)(B) suspensions.

b) Provide Regions with copies of all pertinent correspondence in this suspension action.

c) Effective dates of suspension actions.

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2 PEPS No. 3, 40 CFR 162.17

2) Regional Responsibility

a) Send copies of Notice of Intent to Suspend and the SSURO by certified mail to all registrants of suspended products.

b) Provide guidance for State enforcement efforts.

c) Encourage States to suspend intrastate registrations.

3) State Responsibility

a) Conduct follow-up inspections to ensure compliance with the SSURO.

b) Suspend intrastate registrations if possible.

Penalties

Violation of the SSURO is a violation of Section 12(a)(2)(I) and subject to the penalties found under section 14(a)(1) and 14(b)(1).

Active Ingredient	Effective Date	Stocks Packaged by	May be Sold by Registrant Until	Products Affected	Company #
Maleic hydrazide	11/9/82	12/9/82	forever	MH30 00400-00091	Uniroyal
				Sle-Gro 00400-00663	"
				Grow-Slo 00400-00077	"
				Maleic Hydrazide 30 00456-00097	Chemical Formulators
				Baird S Maleic Hydrazide 00551-00190	Baird and McGuire
				Agsco Chip 'N Store 00554-00110	Agsco
				E-Z Flo Maleic Hydrazide 00635-00632	Grower Service Corp.
				Gro-Yard 01765-00195	National Chemsearch
				Maleic Hydrazide 30 01812-03076	Griffin
				Sucker Control 02749-00040	Aceto Agricultural Chemicals
				Sprout Stop 02749-00049	" " "
				Stunt-Man 02749-00098	" " "
				Liquid Lawnmower 02749-01245	" " "
				De-Sprout 10337-00001	Fairmount
				De-Cott 10337-00002	"
				Sucker Stuff 19713-00014	Drexel
				Retard 19713-00015	"
				Sprout-Stop 19713-00016	"
Chloronated Isocyanurates	10/26/80			See memo of 12/31/80 and list attached.	List attached.

SUSPENSION ACTIONS INITIATED OR ACCOMPLISHED UNDER FIFRA SECTION 3 BY THE SPECIAL PESTICIDE REVIEW DIVISION, OPP

Active Ingredient	Effective Date	Stocks Packaged by	May Be Sold by Registrant Until	Products Affected	Company Name
Carbophenothion	10/25/81	1/25/82	9/25/82	Carbophenothion 8EC 002749-00203	Aceto Agricultural Chemicals
Disulfoton	10/25/81	1/25/82	1/25/82	Disulfoton 15G Systemic Insecticide 002749-00233	" " "
				Disulfoton Liquid Concentrate Insecticide 002749-00290	" " "
Ethion	4/24/82	7/24/82	7/24/82	Ethion 25WP Insecticide 002749-00211	" " "
				Ethion 67 Oil 002749-00220	" " "
				Ethion 8EC Insecticide 002749-00223	" " "
				Ethion 4 Miscible Miticide Insecticide 002749-00261	" " "
				Ethion Technical Insecticide 002749-00293	
TEPP	7/29/82	4/29/82	12/29/82	Killmite 40 000072-89	Miller Chemical & Fertilizer
Tetradifon	5/15/82	8/13/82	4/15/83	Tetradifon Technical 013001-00002	Intrachem S.A.
				Tetradifon 50W 002749-00225	Aceto Agricultural Chemicals
				Tetradifon Technical Miticide 002749-00285	" " "
				Tetradifon Technical Miticide 033660-00009	I PI Ci
TCBC	5/20/82	8/18/82	4/20/83	Actoc Granular Selective Weed Killer 002749-00254	Aceto Agricultural Chemicals Corp.
Monocrotophos	5/20/82	8/18/82	8/18/82	Azodrin 5 Water Miscible Insecticide 002749-00178	" " "

Active Ingredient	Effective Date	Stocks Packaged by	May be Sold by Registrant Until	Products Affected	Company Name
Demeton	action pending			Demox Spray Conc. Systemic Insecticide 002749-00115 Demox 6 lbs/gal Concentrate Systemic Insecticide 002749-00192 Demox 2 lbs./gal 002749-00200	Aceto Agricultural Chemicals • • •
Dinitramine	action pending			Cobex Herbicide 001624-00104 Cobex 001624-00107 Dinitramine 001624-00107 Cobex Eptam 001624-09843 Cobex Eptam 001624-09844	United States Borax and Chemical Company • • • • •

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 918 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 §6 of FIFRA. Such a hearing will consider only whether the registrant has initiated and pursued appropriate action to comply with the order within the time provided or whether the Administrator's decision regarding the disposition of existing stocks is consistent 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.

5/10/82

FIFRA COMPLIANCE PROGRAM POLICY COMPENDIUM

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

The Compliance Program Policies contained in this compendium and the Policy and Criteria Notices published by the Office of Pesticide Programs have been cross referenced by subject matter in a "Key Word Index" located at the end of this compendium. Copies of the Policy and Criteria Notices are not provided but a list of all current Notices is attached.

These Compliance Program Policies will supersede all existing policies.

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FIFRA COMPLIANCE PROGRAM POLICY No. 2.1

Use Recommendations

FIFRA Section: 2(ee)

Issue:

Should the Agency allow the advocacy of Section 2(ee) uses by any person without regard to his financial interest in the sale of pesticides?

Policy:

To the extent that Section 2(ee) allows a particular use, any person, regardless of his financial interest in the sale of pesticides, may legally recommend or advertise such uses provided that recommendations made under Section 2(ee) pertaining to the amount of diluent used in applying pesticides for forestry or agricultural purposes is in accordance with the Advisory Opinion issued March 3, 1981 (46 FR 14965).[1]

Discussion:

Background

Federal jurisdiction over the use of pesticides was established through the 1972 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Sections 3(d)(1); 4; 12(a)(2)(G). Acceptance of the label submitted with the registration of a pesticide product by the U.S. Environmental Protection Agency (EPA) is a central part of the pesticide registration process. The pesticide label dictates the approved uses for each registered pesticide. Any use of a registered pesticide which is inconsistent with its labeling is unlawful, (Section 12(a)(2)(G)).

In 1975, the Pesticides and Toxic Substances Enforcement Division (PTSED) initiated a series of Pesticide Enforcement Policy Statements (PEPS). The PEPS are designed to inform interested members of the public about the policies adopted by the Agency in the exercise of its prosecutorial discretion in the enforcement of FIFRA (40 FR 19526). Such exercise of prosecutorial discretion has been guided in each instance by the legislative history of the 1972 FIFRA amendments which states that it was the intent of Congress to ensure that the Agency evaluate the meaning of the term "inconsistent with the label" in a common sense manner,

1. Supersedes Federal Register Notice, (Vol. 44, No. 112, Friday, June 8, 1979, p. 33151), which limited Section 2(ee) recommendations to user/applicators. This Policy does not prospectively amend any existing pesticide labeling; all changes in a registered pesticide label must still be approved by the Agency.

(H.R. Rep. No. 92-511, 92d Cong. 1st Sess., 16 (1971)). In accord with this Congressional direction, the PTSED determined that some uses or applications which were not expressly stated on the label were, nonetheless, to be allowed. In particular, the following uses were not subject to prosecution:

1) Use of registered pesticides at less than the label dosage rate (40 FR 19529; 40 FR 42914); (PEPS #1).

2) Use of registered pesticides for the control of unnamed target pests in structural pest control (40 FR 41175); (PEPS #2).

3) Use of registered pesticides for the control of pests not named on the label in agriculture and other non-structural pest control (41 FR 41142); (PEPS #5).

4) Use of aerial application techniques where the label instruction does not specifically prohibit such use (42 FR 21496); (PEPS #7).

The PEPS permitted these limited deviations from the language of the registered pesticide label only where the label does not explicitly proscribe such uses. Thus the question of "what" nonlabel uses were permissible was addressed by the PEPS. The second issue of "who" could recommend these uses was also answered by the PEPS.

All of the deviations permitted under the PEPS were subject to the restriction that only "knowledgeable experts" could recommend them. Under the PEPS, States could designate knowledgeable experts subject to certain educational and experiential standards. For example, knowledgeable experts could include persons employed by State Cooperative Extension Services, State Land Grant Colleges, and State Agriculture Departments.

The PEPS denied the designation of "knowledgeable expert" to individuals whose primary source of personal income is directly derived from the sale or distribution of pesticides. This limitation precluded pesticide sales representatives, marketing employees, or advertising agents from advocating PEPS deviations. The PEPS justified this position by reliance on Section 12(a)(1)(B) which makes it unlawful for any person with a financial interest in pesticide marketing to make a claim which differs substantially from registered pesticide labeling.

In short, the PEPS have had two consequences. First, they made certain pesticide use deviations permissible even though the uses do not appear on the registered pesticide label. Secondly, all persons with a direct financial interest in the sale of pesticides were forbidden under Section 12(a)(1)(B) from recommending any of the pesticide uses permitted by the PEPS.

Federal Pesticide Act of 1978

FIFRA was again amended by enactment of the Federal Pesticide Act of 1978 (FPA). The FPA broadened the construction of Section 12(a)(2)(G) of FIFRA by adding Subsection 2(ee). Section 2(ee) defines the term "to use any registered pesticide in a manner inconsistent with its labeling." According to the language of this new section, it is a violation of Section 12(a)(2)(G) to use a registered pesticide "in a manner not permitted by the labeling" with the exception of four specific areas. The areas specifically excluded from enforcement are almost identical to those previously listed in the PEPS.[2] Under Section 2(ee) it is not a misuse to:

1) Apply a pesticide at any dosage, concentration, or frequency less than that specified on the labeling (PEPS #1);

2) Apply a pesticide against any target pest not specified on the labeling if the application is to the crop, animal, or site specified on the labeling (unless the label states that the pesticide may be used only against pests specified on the label) (PEPS #2,5);

3) Employ any method of application not prohibited by the labeling (PEPS #7); and

4) Mix a pesticide or pesticides with a fertilizer when such mixture is not prohibited by the labeling. (This issue was not expressly dealt with by PEPS but was covered by Policy and Criteria Notice 2000.1, Fertilizer-Pesticide Combinations.)

Thus, Section 2(ee) defines by law certain uses which will not be considered inconsistent with labeling even though these uses are not listed. The PTSED responded to Section 2(ee) by publishing a Federal Register Notice which rescinded PEPS numbers 1, 2, 5, and 7 (Vol. 44, No. 112, p. 33151). As explained in the Federal Register, the PTSED restricted the advocacy of Section 2(ee) uses to user/applicators. The PTSED has now reconsidered its earlier position and has decided to remove this restriction. Experience has demonstrated that the earlier policy prevented certain qualified individuals from recommending authorized deviations from the express terms of the label. The following examples illustrate the problem:

- In States with farm cooperatives there are individuals who both use and sell pesticides. These individuals were prevented from recommending authorized uses.

2. It should be noted that while the FPA amends existing Federal law concerning pesticide misuse, it does not purport to affect State laws.

- Likewise, pest advisors who serve as IPM consultants or farm management consultants were prevented from recommending Section 2(ee) uses solely because they may also be directly or indirectly connected to the sale of pesticides.

The new PTSED position is also supported by the statutory language of Section 2(ee). Since Section 2(ee) uses are no longer considered misuse, any recommendations made regarding these uses will not be viewed as substantially different from use directions appearing on the label. Accordingly, it is PTSED policy that Section 12(a)(1)(B) no longer prohibits financially interested persons from recommending or advertising such uses. Thus, to the extent that Section 2(ee) allows a particular use, any person may advocate that use, provided that recommendations made under Section 2(ee)(1) pertaining to the amount of diluent used in applying pesticides for forestry or agricultural purposes is made in accordance with the Advisory Opinion issued March 3, 1981 (46 FR 14965).

Civil Liability

This new policy not only implements the Congressional intent of Section 2(ee) to allow beneficial nonlabel pesticide uses but also provides for strong enforcement to ensure appropriate recommendations of such uses. The policy statement in no way relaxes the administrative or other civil liability of persons who recommend pesticide uses. The only change is that the PTSED no longer limits the advocacy of permitted uses on the basis of financial interest in the use. The Agency will, however, take enforcement action under Section 12(a)(1)(B) against any person with a financial interest who makes pesticide use recommendations which exceed the limits of Section 2(ee). Additionally, any person who recommends Section 2(ee) uses, of course, remains liable for possible civil damages arising out of his own negligence.

See Also:

FIFRA Compliance Program Policy No. 12.1 Using Registered or Experimental Use Pesticides in a Manner not Included on the Label, Policy and Criteria Notice 2000.1, Fertilizer-Pesticide Combinations.

Key Words:

Fertilizer-Pesticide Mixture, Knowledge Expert, Misuse, Target Pest, 2(ee), Use Inconsistent with the Labeling, Use Recommendations.

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Enforcement Division

MAY 10 [illegible]
Date

FIFRA COMPLIANCE PROGRAM POLICY No. 2.2

Labeling of Outer Containers

FIFRA Section: 2(q)

Issue:

When must a label be attached to a shipping container of a pesticide product?

Policy:

A label must be attached to a shipping container of a pesticide if the customary practice of the manufacturer is to retail the product to consumers without opening the outer shipping container to sell the product in individual units.

Discussion:

Section 2(q)(2)(C) of FIFRA states that a pesticide is misbranded unless a label is affixed to its container and to the outside container or wrapper of the retail package.

The regulations at 40 CFR 162.10(a)(4)(i) state in part:

> The label shall appear on or be securely attached to the immediate container of the pesticide product. . . . If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is part of the package as customarily distributed or sold. (emphasis added)

The preamble to these regulations clearly states EPA's intention to continue its policy which requires labeling on retail packages for sale but not on shipping containers. If it is customary to sell a product in its shipping container rather than in individual units, the outer container must also bear a full end use label. If a product is generally sold in individual units and only occasionally by the case, the outer container would not be required to bear labeling, since the outer container is not intended to serve as a retail unit.

The purpose of requiring labeling on the retail package, be it the shipping container or individual units, is to allow the person who uses the pesticide to read the entire label and be fully informed about the product. Failure to properly label the retail package is considered to be misbranding and is a violation of Section 12(a)(1)(E).

References:

Letter of June 16, 1976, from A. E. Conroy II, to Mr. C. M. Einhorn of USS Agri-Chemicals.

Memorandum of September 10, 1976, from A. E. Conroy II to Pesticide Branch Chiefs and Enforcement Division Directors.

Key Words:

Labeling, Outer Containers, Shipping Containers.

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Enforcement Division

MAY 10 1982
Date

FIFRA COMPLIANCE PROGRAM POLICY SECTION 3 INDEX PAGE

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FIFRA COMPLIANCE PROGRAM POLICY No. 3.1

Shipment Prior to Registration

FIFRA Section: 3

Issue:

May a pesticide product which is not sold under an Experimental Use Permit (EUP) be shipped to distributors prior to being registered with EPA?

Policy:

A pesticide product not sold under an EUP may be shipped prior to final approval of its EPA registration under certain circumstances. The registrant must apply to EPA for a temporary exemption to registration requirements; demonstrate a compelling need for the distributor to receive the product before its EPA registration is finalized; detail a plan for control of the product prior to registration; and receive EPA approval of the exemption request.

Discussion:

Section 3(a) of FIFRA states:

> . . . 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[y] (sic) or offer to deliver, to any person any pesticide which is not registered with the Administrator.

The exemptions to this requirement found in Section 3(b) do not address delivery of an unregistered pesticide to a distributor. However, the Agency will consider granting an exemption of this type as a matter of policy if certain conditions are met. When granting such exemptions, the Agency will consider: whether registration is imminent (final printed labeling waiting approval); the type of pesticide; the need for such action; and the registrant's ability to maintain control over the product to prevent its sale prior to registration.

Upon receiving EPA approval of the exemption request, the registrant must contact each EPA Region and State involved and inform them of the shipments. The registrant must provide the Regions and States with exact shipping data including the point of origin, the date of shipment, the name of the carrier, the name and address of the consignee, the name and telephone number of the responsible person at the consignee's, and the expected date of arrival. The registrant must also provide the Regions with a plan for control and handling of the product to prevent its sale or use prior to registration. If the product does not become registered as anticipated, the registrant must notify the Regions and States immediately and no further shipment or distribution of the product is allowed until it is fully registered.

Failure to fulfill the conditions of the exemption or sale of the product at the distributor level prior to registration is a violation of Section 12(a)(1)(A) of FIFRA.

See Also:

Registration.

References:

March 21, 1978 letter from A. E. Conroy II, Director, PTSED, to Ingrid K. Allen, Registration Coordinator, Agricultural Chemicals Division, Fisons, Inc.

Key Words:

Exemptions, Shipment, Unregistered Pesticides.

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MAY , 0 1982
Date

FIFRA COMPLIANCE PROGRAM POLICY No. 3.2

Distributor Registrations

FIFRA Section: 3

Issue:

May a distributor repackage a pesticide which it intends to sell under a supplemental registration?

Policy:

A distributor may repackage a pesticide it sells under a supplemental registration only if it is under contract to the basic registrant to do so.

Discussion:

Manufacturing or packaging a pesticide under contract and distributing a pesticide under a supplemental registration are two separate activities.

Section 3(b)(1) of FIFRA and the regulations at 40 CFR 162.5(b)(1) allow for the transfer of an unregistered pesticide from one registered establishment to another registered establishment operated by the same producer solely for packaging or use as a constituent part of another pesticide produced at the second establishment. The term "operated by the same producer" is defined at 40 CFR 162.3(dd) to mean another establishment owned by the registrant or an establishment operated by a person under contract to the registrant.

Under supplemental registration, a distributor of a registered pesticide product is permitted to market that pesticide product under the distributor's brand name if it adheres to the conditions described at 40 CFR 162.6(b)(4)(i). The regulations require, in part, that distributor products be manufactured and packaged by the same person who manufactures and packages the previously registered pesticide product (40 CFR Part 162.6 (b)(4)(i)(B)). Labeling is considered as part of packaging for the purposes of these regulations. These provisions preclude more than one person from producing a product.

The contract manufacturing policy may be applied to situations where a person, under contract to a manufacturer to produce or repackage a product, also wishes to distribute the product under a supplemental registration. a supplemental registrant (distributor) may repackage a pesticide, which it intends to sell under its own brand name, only if it is under contract to the basic registrant to do so. Where such a contractual arrangement exists, the supplemental registrant acts as an agent for the basic registrant and is held to the same standards of adulteration and misbranding imposed on the registrant at the time of registration.

A supplemental registrant under contract to the basic registrant may also label or repackage the product for other distributors. However, the product must bear the contractor's (supplemental registrant's) establishment number and the distributor number assigned to the firm whose brand name appears on the label.

Any supplemental registrant's (distributor's) name appearing on the label must be qualified by terms such as "packed for", "distributed by", or "sold by".

The Agency feels that this policy protects both the public and the environment for several reasons. The product produced by the contractor is fully registered with EPA by the basic registrant. In, addition the product must conform to the standards held for the basic registration and to the requirements for supplemental registrations.

Liability for any violation of Section 12 in such a contractual arrangement may rest with either or both parties to the contract depending upon the circumstances associated with the violation.

See Also:

FIFRA Compliance Program Policy No. 3.6., Contract Manufacturing

References:

40 CFR Part 162.26(b)(4)(i), (ii), (iii).

Memo of August 19, 1977, from A. E. Conroy II to Ed Johnson, OPP, titled "Contract Manufacturers".

Memo of December 13, 1976, from A. E. Conroy II, PTSED, to Regional Enforcement Division Directors and Pesticide Branch Chiefs titled "Relation Between Contract Manufacturers and Packagers and Distributors of Supplementally Registered Products".

Key Words:

Contract Manufacturing, Distributor Registrations, Repackaging, Supplemental Registrations.

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Pesticides and Toxic Substances
Enforcement Division

MAY 10 1982
Date

FIFRA COMPLIANCE PROGRAM POLICY No. 3.3

Fumigation of Truck Vans on Flatbed Rail Cars

FIFRA Section: 3

Issue:

Will EPA, in the absence of specific label directions, allow the fumigation of truck vans with pesticide products that generate phosphine gas while the vans are being transported on flatbed railroad cars?

Policy:

EPA will allow truck vans being transported on flatbed rail cars to be fumigated provided:

1) the pesticide label contains directions which allow the use of the product in sealed boxcars and hopper cars while in transit, on the commodity being carried in the truck van, and these directions are followed;

2) the truck vans are sealed and placarded during fumigation; and

3) the truck vans are fully aerated in accordance with label directions prior to removal from the flatbed rail car.

For the purposes of this policy, a truck van is defined as the container portion of any highway truck, trailer or semi-trailer having a demountable chassis.

Discussion:

The Agency finds that the use of aluminum phosphide products to fumigate truck vans while the vans are being transported on flatbed rail cars is allowable provided the conditions mentioned above are met.

This policy also applies to all other registered products which generate phosphine gas and bear directions for use in sealed boxcars and hopper cars. The Agency feels that the construction of truck vans is sufficiently similar to the construction of boxcars and hopper cars that there is no greater risk of exposure to phosphine gas during and after fumigation on rail cars provided that care is taken to properly seal, label, and aerate the truck vans. EPA feels that fumigation of truck vans while on rail cars provides the least risk of exposure when compared to other alternatives.

The Agency will not extend this interpretation to allow the fumigation of truck vans being transported over the highway because of concerns that the driver and other members of the public could be exposed to phosphine gas.

Key Words:

Aluminum Phosphide Products, Fumigation, Labeling, Phosphine Gas, Phostoxin, Rail Cars, Truck Fumigation, Truck Vans.

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

MAY 10 1982
Date

FIFRA COMPLIANCE PROGRAM POLICY No. 3.4

Custom Blenders

FIFRA Section: 3

Issue:

Are custom blenders of pesticides subject to the requirements of Section 3 of FIFRA?

Policy:

Although custom blenders of pesticides are subject to the registration requirements of Section 3, they need not meet these requirements when certain prescribed conditions are met.

Discussion:

Section 3 of FIFRA requires any person who produces a pesticide to register that pesticide with the Administrator before selling or distributing it. Custom blenders provide the service of mixing pesticides to a customer's specifications, usually a pesticide(s)-fertilizer(s) or pesticide-pesticide mixture. Custom blending is considered production under Section 3. The Agency, however, has determined that registration of certain custom blends is not necessary to fulfill the intent of FIFRA.

In order for a custom blender to avoid liability for failure to meet the requirements of Section 3, the following conditions must be met:

1) the blend is prepared to the order of the user and is not held in inventory by the blender; and

2) the pesticide(s) used in the blend bears end-use labeling* directions which do not prohibit use of the product in such a blend; and

3) the blend is prepared in a registered establishment; and

4) the blend is delivered to the user together with:

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* The term "end-use labeling" means labeling containing directions for use in pest control and otherwise meeting the requirements of 40 CFR 162.10. Labeling indicating that a product is intended only for use in manufacturing or formulating pesticides shall not be considered end-use labeling.

a) a copy of the end-use labeling of the pesticide used in the blend, and

b) a statement specifying the composition of the mixture.

The Agency feels that the public will be adequately protected without Section 3 registration of custom blends if custom blenders meet these criteria.

If a custom blend does not meet the criteria listed above, it must be registered as a pesticide in accordance with the requirements of Section 3.

The limited obligations of custom blenders under Section 3 are independent of their obligations under FIFRA Sections 7 and 8.

See Also:

Custom Blenders - FIFRA Compliance Program Policy No. 7.1, Policy and Criteria Notice 2000.1

References:

Memo to Pesticide Branch Chiefs and Enforcement Division Directors from Edwin L. Johnson and A. E. Conroy II, dated September 3, 1975, titled "Interim Regulations Regarding Registration of Custom Blends and Custom Blending Establishments."

Memo to Pesticide Branch Chiefs from A. E. Conroy II, dated September 10, 1980, titled "Custom Blender's Identification for ERSS."

PR Notice 73-1

Key Words:

Custom Blenders, Fertilizer-Pesticide Mixtures, Registration.

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Enforcement Division

MAY 10 1982
Date

FIFRA COMPLIANCE PROGRAM POLICY NO. 3.5

Production of Pesticides for Personal Use

FIFRA Sections: 3, 7

Issue:

May a person lawfully produce a pesticide for his own use without registering his product or establishment?

Policy:

Generally, a person may lawfully produce a pesticide for his own use without registering his product or establishment.

Discussion:

Section 3 of FIFRA requires a pesticide producer to register his product only if he sells or distributes the pesticide. Furthermore, the regulations (40 CFR Part 167) which address the registration of pesticide producing establishments under FIFRA Section 7 state that persons who produce pesticides solely for application by themselves are not required to register their establishments. Thus, a person who produces a pesticide solely for personal use is not required under FIFRA to register the pesticide or the producing establishment.

The Agency considers any application of an unregistered pesticide for other than personal use to be distribution of an unregistered pesticide, a violation under Section 12(a)(1)(A) of FIFRA. This includes applying an unregistered pesticide to another person's property for other than monetary consideration. Furthermore, a person applying an unregistered pesticide for hire, only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served, would be considered a distributor and, is therefore, subject to the higher penalties set forth in section 14(a)(1) and 14(b)(1) of FIFRA. (see S. Rep. No. 95-1188, 95th Cong., 2nd Sess. 44-45 (1978)).

References:

Memorandum to Roy Clark, Region IV, dated April 9, 1981 titled "Interpretation of FIFRA §162.4(c)(6).

Senate Report No. 95-1188, 95th Congress, 2nd Session 44-45 (1978).

Key Words:

Establishment Registration, Product Registration.

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Enforcement Division

MAY 10 1982
Date

FIFRA COMPLIANCE PROGRAM POLICY NO. 3.6

Contract Manufacturing

FIFRA Section: 3(b)(1)

Issue:

May an unregistered pesticide be lawfully transferred between two separately owned registered establishments?

Policy:

An unregistered pesticide may be lawfully transferred between two separately owned registered establishments if one establishment is operating under contract to the other. Under such a contractual arrangement, the establishment under contract must produce the product in question solely for the company to whom it is under contract.

Discussion:

Section 3(b) of FIFRA provides an exception to the general requirement of Section 3(a) that all pesticides moving in commerce be registered. Specifically, Section 3(b)(1) of FIFRA provides that an unregistered pesticide may be transferred if:

> . . . the transfer is from one registered establishment to another registered establishment operated by the same producer solely for packaging at the second establishment or for use as a constituent part of another pesticide produced at the second establishment . . . .

The phrase "operated by the same producer" as used in Section 3(b)(1) has been defined in 40 CFR 162.3(dd) to mean:

> . . . (1) another registered establishment owned by the registrant of the pesticide product or (2) another registered establishment operated under contract with the registrant of the pesticide either to package the pesticide product or to use the pesticide as a constituent part of another pesticide product, provided that the final pesticide product is registered by the transferor establishment.

Under such a contractual arrangement, the establishment under contract must produce the product solely for the company to whom it is under contract.

Any attempt by the establishment under contract to sell or distribute the product to another person would be considered sale or distribution of an unregistered pesticide under Section 12(a)(1)(A) of FIFRA. The basic registrant is responsible for any product produced by an establishment under contract.

The following are acceptable activities under the contract manufacturing policy:

Company A, the end use registrant may contract with Company B to manufacture an end use product or process an intermediate formulation into an end use product. Company A may also contract with company B to produce a technical substance which company A then processes into an end-use product. Company B may contract with Company C to perform some or all of its contract obligations with Company A. At no time, however, may Company B or C sell or distribute the end use product to anyone other than Company A. Company A may also contract with Companies D and E to produce the same technical substance or the same end use product or to process the same intermediate into the same end use product.

The Agency feels that this contract manufacturer policy protects both the public and the environment for several reasons. The product is fully registered with EPA by the company letting the contract, and the product must conform to the standards held for the basic registration. Both companies may be held liable for any product found in violation of FIFRA.

See Also:

FIFRA Compliance Program Policy No. 3.2, Distributor Registrations.

References:

Memo of August 19, 1977, from A. E. Conroy II, PTSED to Ed Johnson, OPP titled "Contract Manufacturers."

Key Words:

Contract Manufacturing, Distributor Registrations, Establishment Transfer, Unregistered Pesticides.

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Pesticides and Toxic Substances
Enforcement Division

MAY 10 1982
Date

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FIFRA COMPLIANCE PROGRAM POLICY No. 4.1

Written Examinations for Private Pesticide Applicators

FIFRA Section: 4(a)(1)

Issue:

May a State Certification Plan approved by EPA under FIFRA require a private pesticide applicator to pass a written examination to become certified or recertified?

Policy:

A State Certification Plan may require a private applicator to pass a written examination or other equivalent method of evaluating competency as a prerequisite to becoming certified or recertified.

Discussion:

Under FIFRA Sections 3(d) and 12(a)(2)(F), applicators must be certified before they may legally obtain and use pesticides classified for restricted use. FIFRA Section 4 establishes two different routes for certification: certification by a State pursuant to a Plan approved by the Administrator, or certification by the Administrator in cases where States have chosen not to submit a Plan. Only two States, Colorado* and Nebraska, do not have plans for certification of pesticide applicators.

FIFRA Section 4(a)(2) describes the criteria used by the Administrator in deciding whether to approve a State-submitted Certification Plan. Section 4(a)(2)(E) states that a Plan submitted by a State must contain "satisfactory assurances that State standards for the certification of applicators of pesticides conform with those standards prescribed by the Administrator" under FIFRA Section 4(a)(1). Section 4(a)(1) provides that a State Certification Plan must specify a method by which an applicator will establish his competency.

Under FIFRA, the Administrator may not require a private applicator to pass an examination to establish competency for certification or require a State Plan to contain such a provision.

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* Colorado is in the process of developing a certification plan, which will initially cover only commercial applicators.

FIFRA Section 4(a)(1) prohibits the Administrator from requiring private applicators to pass an examination to establish competency for certification in EPA-administered certification programs. Section 4(a)(1) also specifies "... That the certification standard for a private applicator shall, under a State plan submitted for approval, be deemed fulfilled by his completing a certification form ..." However, a State may wish to adopt a certification program which is more stringent than that prescribed under FIFRA Section 4 and related regulations. A State may on its own initiative choose to require a private applicator to pass an examination to establish competency for certification.

EPA's policy of accepting State Certification Plans which require private applicators to pass written examinations is supported by the lack of a statutory prohibition against such an action and the legislative history. The Senate and House conference report clearly affirmed the right of a State to require the passing of a written examination by a private applicator. The right of a State to require the passing of a written examination by a private applicator has been official EPA policy since the passage of FIFRA. Pursuant to this policy the Administrator has approved State Plans requiring the passing of a written examination by a private applicator as well as State Plans using methods other than written examinations to establish private applicator competency.

See Also:

Reference:

Letter dated August 30, 1982 from Edward C. Gray, Acting Associate General Counsel, Pesticides Division to Mr. Frank Graham, Florida Department of Agriculture, re: State - Imposed Requirement for Examination of Private Applicators.

Letter dated November 16, 1982 from Robert M. Perry, Associate Administrator for Legal and Enforcement Counsel and General Counsel to J. T. Griffiths, the Citrus Growers Association, subject: State - Imposed Requirements for Examination of Private Applicators.

Key Words:

Establish competency, written examination, private applicator certification.

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Office of Pesticides and Toxic Substances

28 JUL 1983

Date

FIFRA COMPLIANCE PROGRAM POLICY SECTION 7 INDEX PAGE

TITLE	NUMBER
Custom Blenders	7.1

FIFRA COMPLIANCE PROGRAM POLICY No. 7.1

Custom Blenders

FIFRA Section: 7

Issue:

Are custom blenders of pesticides subject to the requirements of Section 7?

Policy:

Although custom blenders of pesticides are subject to the Section 7 establishment registration requirements they are not required to meet the reporting requirements of Section 7 if they meet certain conditions.

Discussion:

Section 7 of FIFRA requires that all pesticide producers must register those establishments in which they produce pesticides. They must also submit to the Agency annual reports concerning production and distribution of the pesticides. The regulations promulgated pursuant to this section (40 CFR 167) provide that a custom blender is a producer and is thus subject to the requirements of Section 7.

Custom blenders provide the service of mixing pesticides to a customer's specifications. The custom blend is usually a pesticide(s)-fertilizer(s) mixture or a mixture of pesticides derived from an end-use formulation.

The Agency has, however, determined that subjecting custom blending establishments to all provisions of Section 7 is not necessary for effective regulation of the industry. Therefore the Agency will not require producers of those blends exempt from Section 3* to meet certain Section 7 requirements.

*To be exempt from Section 3, a custom blend must meet the following requirements:

1) the blend is prepared to the order of the user and is not held in inventory by the blender, and
2) the pesticide(s) used in the blend bear(s) end-use labeling directions which do not prohibit use of the product in such a blend, and
3) the blend is prepared in a registered establishment, and
4) the blend is delivered to the user together with:
   a) a copy of the end-use labeling of the pesticide used in the blend, and
   b) a statement specifying the composition of the mixture.

All custom blenders, whether or not their blends must meet Section 3 requirements, must register their establishments with EPA This is necessary to provide the Agency with the locations of pesticide blending operations. The Agency will use this information in scheduling Section 8 inspections and in tracing contaminated or oth pesticides in violation of the law.

Custom blenders whose blends need not meet Section 3 requirements are not required to report on amount produced at the establishment or to place their establishment number on the pesticide produced. Normally, the Agency requires the establishment number to be placed on a product in order to allow EPA to trace a shipment of pesticides which may be in violation of the Act. Since a custom blend is used within a day or two of purchase and the user knows the person who manufactured the blend, placing the establishment number on the blend has little value.

Production data is required for registered pesticides, so the Agency knows how much of a pesticide is produced and who produces it. This information is useful not only to know the total production of pesticides but to assist EPA in recall actions or other actions where knowledge of production is essential. Because EPA does not require custom blenders to meet the Section 3 requirements of FIFRA, the Agency would not be consistent in asking for production information on a blend which does not require registratic

Custom blenders remain subject to the provisions of Section [redacted] of FIFRA as well as to all requirements relating to proper use of pesticides including transport, storage and disposal.

See Also:

Custom Blenders - FIFRA Compliance Program Policy No. 3.4

References:

See references in FIFRA Compliance Program Policy No. 3.4

Key Words:

Custom Blenders, Establishment Registration, Reporting.

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Enforcement Division

MAY 10 1982
Date

FIFRA COMPLIANCE PROGRAM POLICY SECTION 10 INDEX PAGE

TITLE	NUMBER
Release of Pesticide Production Data	10.1

FIFRA COMPLIANCE PROGRAM POLICY No. 10.1

Release of Pesticide Production Data

FIFRA Section: 10

Issue:

Under what circumstances will EPA release yearly production data for particular pesticides?

Policy:

The EPA will not release an individual producer's production data for a specific pesticide. The Agency will release production data in the aggregate, without individual producer identification, at the request or order of an EPA Administrative Law Judge in a data compensation proceeding under FIFRA Section 3(c)(1)(D). In such a case, the EPA will indicate the confidential nature of the data to the Judge. When EPA responds to a Congressional request for confidential data, the Office of Legal Counsel will decide whether to release the data.

Discussion:

Production data which producers submit under FIFRA Section 7(c)(1) is confidential (Section 7(d)) and thus may not be released by EPA (Section 10(b)). In many cases, aggregate yearly data which does not identify individual producers may not be confidential. However, there is a risk, in some cases, that the requestor may ascertain the identities of individual producers when combining the aggregate data with other information in his possession.

The Freedom of Information Act (FOIA)(5 U.S.C. Section 552) does not require an Agency to create a record in response to an FOIA request. The EPA regulations state: "The Freedom of Information Act does not require the creation of new records in response to a request ... The Act establishes requirements for disclosure of existing records" (40 CFR Section 2.105(a), emphasis added). The United States Supreme Court has endorsed this reading of FOIA; NLRB v. Sears Roebuck, 421 U.S. 132, 161-162. Aggregation of pesticide production data submitted to EPA is clearly the creation of new records.

While EPA could choose to release aggregate pesticide production data even where not required by FOIA, it has decided not to do so due to the risk of unintended disclosure of confidential data.

FIFRA Section 10(b) authorizes the release of certain confidential pesticide data to other Federal agencies; however, production data is not included. Also, FIFRA does not authorize the release of production data to States. Therefore, EPA will not routinely release individual or aggregate production data to other Federal Agencies or States. Release of confidential pesticide data to Congress, including the General Accounting Office, is governed by EPA-wide policy (40 CFR Part 2). When EPA responds to a Congressional request for confidential pesticide data, the Office of Legal Counsel must be contacted, since that Office will decide whether to release the data.

Reference:

Protective Order, October 22, 1981, Union Carbide v. Thompson-Hayward, FIFRA COMP. Docket Nos. 27 & 45, 40 CFR Part 2.

Key Words:

Confidentiality, Establishment Registration, Production Data.

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MAY 10 1982
Date

FIFRA COMPLIANCE PROGRAM POLICY SECTION 12 INDEX PAGE

TITLE	NUMBER
Using Registered Or Experimental Use Permit Pesticides In A Manner Not Included On The Label Or Permit	12.1
Pesticides Closed Transfer, Mixing/Loading and Application Equipment (Closed Systems)	12.2
Authority for Use Inspections	12.3
Making Restricted Use Pesticides Available to Persons Without Pesticide Applicator Certification	12.4

FIFRA COMPLIANCE PROGRAM POLICY NO. 12.1

Using Registered Or Experimental Use Permit Pesticides In A Manner Not Included On The Label Or Permit

FIFRA Section: 12

Issue:

May a person legally use a registered or experimental use pesticide for testing purposes[1] not authorized by the label or permit?

Policy:

A person may legally use a registered or experimental use pesticide for testing purposes in a manner not authorized by the label or the permit if:

1. The purpose of the use is only to determine the pesticidal value of the substance or its toxicity or other properties, and

2. No one conducting the test expects to obtain any benefit in pest control from its use.

In addition, other specific conditions must be met for pesticide uses as described in 40 CFR Part 172.3(a)(1) for land use, Part 172.3(a)(2) for aquatic use and Part 172.3(a)(3) for animal treatments.

Discussion:

The experimental use permit (EUP) regulations provide at 40 CFR Part 172.2(a) that any person wishing to accumulate data necessary to register a substance under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) may apply for an EUP for:

- A pesticide not registered with the Agency, or

- A use of a registered pesticide not previously approved in the registration.

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[1] "For testing purposes" as defined in this policy refers to pesticide use for: a land use as described in 40 CFR Part 172.3(a)(1), an aquatic use as defined in Part 172.3(a)(2) and animal treatments as defined in Part 172.3(a)(3).

However, those regulations also provide at 40 CFR Part 172.3(a) that a person does not need an EUP to test a substance or mixture of substances where the only purpose of the test is to determine its pesticidal value, its toxicity or other properties, and where the persons conducting the test do not expect to receive any pest control benefit from the tests.

The regulations at 40 CFR Part 172.3(a)(1) state that such a purpose is presumed for land use tests if:

- o The total cumulative acreage treated does not exceed 10 acres for a particular substance or mixture of substances against a particular pest, and
- o The food or feed crops involved in, or affected by such tests shall be destroyed or consumed only by experimental animals unless a tolerance or exemption from the need for a tolerance has been established. These crops include crops subsequently grown on such land which may reasonably be expected to contain residues of such substances or mixtures of substances.

The regulations at 40 CFR Part 172.3(a)(2) state that such a purpose is presumed for aquatic use tests if:

- o The total area treated does not exceed 1 surface acre of water for a particular substance or mixture of substances against a particular pest,
- o The waters used in such tests will not be used for irrigation purposes, drinking water supplies or body contact recreational activities, and
- o No such tests may be conducted in any waters which contain, or which would affect, any fish, shellfish or other plants or animals taken for recreational or commercial purposes unless a tolerance or exemption from tolerance has been established.

The regulations at 40 CFR Part 172.3(a)(3) state such a purpose is presumed for animal treatments if:

- o The tests are conducted only on experimental animals, and
- o No animals may be tested if they may be used in food or feed unless a tolerance or an exemption from tolerance has been established.

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[2] This policy does not limit, but rather supplements the existing policy regarding uses not authorized by the label but allowed under FIFRA §2(ee).

The regulations also state at 40 CFR Part 172.3(c) that an EUP is not required if a registered pesticide is used in a test to determine its pesticidal value for a use not set forth on the label if the requirements at 40 CFR Part 173(a) are met.[2]

It is not a misuse violation of FIFRA to use a non-registered substance in tests to determine pesticidal value, toxicity or other properties under the previously-cited restrictions. Therefore, it is also not a violation to use a substance with an EUP in a manner contrary to the provisions of the permit, if the use is in tests which meet the conditions at 40 CFR Parts 172.3(a), 172.3(a)(1), 172.3(a)(2) and 172.3(a)(3) as set forth above.

See Also:

FIFRA Compliance Program Policy No. 2.2 - Use Recommendations

Key Words:

Experimental Use Permit (EUP), 2(ee), Use Recommendations.

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Enforcement Division

MAY 10 1982
Date

FIFRA Compliance Program Policy No. 12.2

Pesticides Closed Transfer, Mixing/Loading and Application Equipment (Closed Systems)

FIFRA Section:

12(a)(2)(G)

Issue:

Will the Environmental Protection Agency take an enforcement action under FIFRA Section 12(a)(2)(G) against the operator who uses a closed system to mix, load, transfer or apply pesticides without wearing the personal protective equipment required by the pesticide product label?

Policy:*

The Agency will not take an enforcement action under FIFRA Section 12(a)(2)(G) against the operator of a closed system who does not wear the personal protective equipment required by the pesticide product label, provided the conditions outlined in this policy are met.

Discussion:

The FIFRA Compliance Program Policy No. 12.2 issued May 10, 1982 said the Agency would take enforcement action under Section 12(a)(2)(G) against the operator for not wearing personal protective equipment required by the label if a closed system was used in transferring, mixing, loading or applying pesticides.

The California Department of Food and Agriculture and the Arizona Board of Pesticide Control petitioned the Agency to reconsider the May 10 policy. They stated that the pesticide label directs safety requirements at the most hazardous pesticide use situations without considering less hazardous situations. Further, the May 1982 policy may actually hinder the development of new equipment designed to safely handle pesticides.

The Agency's position is that wearing the personal protective equipment required by the pesticide label provides the greatest level of user protection. However, the Agency recognizes that technological and engineering advancements have made significant contributions in the field of pesticide use safety. One such advancement is the development of closed systems.

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*This policy replaces FIFRA Compliance Program Policy No. 12.2 issued May 10, 1982.

For purposes of this policy, a closed system is hardware designed to empty and rinse pesticide containers, mix or dilute the pesticide, and transfer the pesticide, its diluents, and the container rinsing agent to the application equipment without permitting the pesticide to escape.

Preliminary field experiences indicate that the incidents of pesticide exposure to persons operating a closed system generally arise due to one of the following conditions:

- o Pesticide leaks at seals, gaskets, hoses, or seams caused by worn or poor quality parts, or by parts eroded when the chemicals are allowed to stand in the container.
- o Pesticide leaks at the couplings caused by high internal pressures or incomplete coupling due to non-matching parts or operator carelessness.
- o Improper use of equipment due to disregard for proper mixing/loading procedures or lack of training.

There are, however, many documented instances when a closed system has been used without resulting in an exposure from its use. Therefore, the Agency will amend its May 10, 1982, policy and will not take an enforcement action if the operator can show the following:

- o Records are available for the current operating year which show that a cleaning schedule and maintenance program (which includes flushing the system so that pesticides are not allowed to stand in the system for more than one work day) has been developed and is administered.
- o Records are available which indicate that the operator has received training (when, by whom) in operating procedures as prescribed by the closed system manufacturer and has been informed of the potential hazards of closed system misuse or improper maintenance before using.
- o Written instructions for operating the system are posted on or near the closed system.
- o All personal protective equipment required by the label is available for the operator at all times during mixing and loading or transfer operations.

Notwithstanding the requirements of this policy, if all of the personal protective equipment required by the label is not worn while using a closed system and a pesticide exposure occurs, the Agency may take an enforcement action under FIFRA Section 12(a)(2)(G) against the operator of the closed system.

See Also:

FIFRA Compliance Program Policy No. 12.2 "Closed Application System" issued May 10, 1982.

The Pesticide Misuse Review Committee (PMRC) Advisory Opinion Nos. 14, 18, 125, 205, 293, and 315.

October 12, 1982 letter from Ms. Lori Johnston, Assistant Director, Pest Management, Environmental Protection and Worker Safety, Department of Food and Agriculture, State of California to Mr. Edwin Johnson, Director, Office of Pesticide Programs, EPA.

July 1, 1982 letter from Mr. R. W. Sweet, Administrator, Board of Pesticide Control, State of Arizona to Mr. Phillip C. Martinelli, Director, Division of Plant Industry, Nevada Department of Agriculture, State of Nevada.

References:

"Closed System Update" by R.W. Brazelton, N.B. Akesson, and K.T. Maddy, January 1980.

Key Words:

Closed System, Personal Protective Equipment.

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15 DEC 1983

FIFRA COMPLIANCE PROGRAM POLICY No. 12.2

Closed Application Systems

FIFRA Section: 12

Issue:

Should EPA take enforcement action if protective equipment required by the pesticide label is not worn by workers when mixing and loading pesticides into closed application systems?

Policy:

EPA will take enforcement action under Section 12(a)(2)(G) for failure to wear protective equipment required by the label.

Discussion:

The term "closed application system" means a device or combination of devices designed to empty and rinse pesticide containers, to mix and/or dilute the pesticide and to transfer the pesticide to application equipment or a holding vessel without permitting pesticides to escape into the surrounding environment.

Generally, any use of a registered pesticide inconsistent with the product's label is a violation of FIFRA Section 12(a)(2)(G). In the case of a closed mixing system with an automatic container opening feature, failure to wear protective clothing required by the product label would be a violation of this section. It is particularly important to wear protective clothing when using closed systems because these systems are usually used in conjunction with especially hazardous pesticides.

Reference:

Pesticide Misuse Review Committee Advisory Opinion # 315

Key Word Heading:

Closed Application System, Misuse

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MAY 10 1982
Date

FIFRA COMPLIANCE PROGRAM POLICY No. 12.3

Authority for Use Inspections

FIFRA Section: 12(a)(2)(G), 9(b)

Issue:

May EPA conduct routine "use inspections" where pesticides are not held for distribution or sale?

Policy:

EPA may conduct use inspections to enforce Section 12(a)(2)(G) of FIFRA with the consent of the owner or person in charge of the premises.

Discussion:

FIFRA Section 9(a) provides authority for EPA to inspect establishments or other places where pesticides are held for distribution or sale. Upon a showing that there is reason to believe that the provisions of FIFRA have been violated, EPA inspectors may obtain warrants to inspect such establishments pursuant to section 9(b).

Notwithstanding the limitation of Section 9, EPA has developed a program of pesticide use surveillance to enforce Section 12(a)(2)(G) of FIFRA. This Section makes it unlawful to use a pesticide in a manner inconsistent with its labeling. To enforce this subsection and to prevent pesticide misuse, EPA may routinely undertake "use inspections", as part of a neutral administrative inspection scheme. However, inspectors must obtain the consent of the owner or person in charge of the premises to be inspected. Well established Fourth Amendment principles require that the consent be knowing and voluntary.

Within the framework outlined above, EPA inspectors may also obtain samples of pesticides or devices, and samples of any containers or labeling for such pesticides or devices, if necessary for the use inspection. Any such samples must be obtained in accordance with the receipt procedure described in Section 9(a).

Reference:

Letter from William L. Hazeltine to Congressman Harold T. Johnson dated August 12, 1975.

Key Word Headings:

Inspections, Misuse, Use Inspections.

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MAY 10 1982
Date

FIFRA Compliance Program Policy No. 12.4

Making Restricted Use Pesticides Available to Persons Without Pesticide Applicator Certification

FIFRA Section: 12(a)(2)(F)

Issue:

In a State where the EPA Administrator conducts the pesticide applicator certification and training program, will EPA take enforcement action against pesticide dealers who make restricted use pesticides (RUP's) available for use to persons who are not certified applicators?

Policy:

In a State where the Administrator conducts the pesticide applicator certification and training program,[1] EPA will take enforcement action against any pesticide dealer who cannot document that the restricted use pesticide made available to a person who is not a certified applicator will be applied by a certified applicator.

Discussion:

Section 12(a)(2)(F) of FIFRA states:

> It shall be unlawful for any person to make available any registered pesticide classified for restricted use for some or all purposes other than in accordance with section 3(d) and any regulations thereunder; Provided, That it shall not be unlawful to sell, under regulations issued by the Administrator, a restricted use pesticide to a person who is not a certified applicator for application by a certified applicator.

[1] This policy affects only pesticide dealers making restricted use pesticides available to uncertified persons in States or on Indian reservations where the Administrator conducts the pesticide applicator certification and training program. States having approved FIFRA §4 State Plans and wishing to adopt a similar procedure of making restricted use pesticides available to uncertified persons shall submit to the Administrator a plan containing minimum standards as outlined in 40 CFR Part 171. Such a procedure should contain the requirements as outlined in this policy and in "IX. Purchase By Uncertified Persons For Use By Certified Applicators" of the document entitled "Optional Procedures for Classification of Pesticides Uses by Regulation; Pesticide Use Restrictions" published in the FEDERAL REGISTER of February 9, 1978 (43 FR page 5783).

The term "make available for use" means to distribute, sell, ship, deliver for shipment, or receive and (having so received) deliver, to any person. However, this term excludes transactions solely between persons who are pesticide producers, registrants, wholesalers, or retail sellers, acting only in those capacities.

EPA has not promulgated rules covering the sale of RUP's to uncertifed persons but plans to do so in the near future. In the meantime, EPA's policy is to ensure that RUP's are made available only to persons qualified to use them safely, without making it unduly burdensome for certified applicators to obtain RUP's.

Until promulgation of the pertinent regulations, the Agency will implement the following policy:

The Agency will not take enforcement action under FIFRA §12(a)(2)(F) against any person who can document that he made a RUP available to an uncertified person for use by an applicator certified for its use.

Adequate documentation consists of a record for each transaction either on the sales invoice or in a document accompanying the invoice, which includes the following information:

(A) The name and residence or business address of the person, whether certified or uncertified, to whom the RUP is made available.

(B) The name and residence or business address of the certified applicator who will use the restricted use pesticide, if this is different from (A).

(C) The certified applicator's certification number, the State (or other governmental unit) that issued his certification card, the expiration date of the certification, and the categories in which the applicator is certified, if appropriate.

(D) The product name, EPA registration number, and the State special local need registration number, granted under §24(c) of the FIFRA (if any) on the label of the pesticide.

(E) The quantity of the pesticide made available for use in the transaction.

(F) The date of the transaction.

At the time of <u>each</u> transaction, EPA recommends that the dealer obtain the information required in (A)-(C) above and assure himself that the RUP is made available for use by a certified applicator by examining <u>one</u> of the following sets of documents:

(1) The original of the certified applicator's certification card, and a driver's license or other State, County or Tribal identification document issued to the uncertified person to whom the restricted use pesticide is made available.

(2) A photocopy or facsimile of the certified applicator's certification card, a statement signed by the certified applicator authorizing the uncertified person to purchase the restricted use pesticide on his behalf, and a driver's license or other State, County or Tribal identification document issued to the uncertified person to whom the restricted use pesticide is made available.

(3) A photocopy or facsimile of the certified applicator's certification card, a copy of a signed contract or agreement between the uncertified person to whom the product is being made available for use and the identified certified applicator which provides for the use of the restricted use pesticide by the identified certified applicator and a driver's license or other State, County or Tribal identification document issued to the the uncertified person to whom the restricted use pesticide is made available.

The Agency will take enforcement actions for first time violations of FIFRA §12(a)(2)(F) as follows:[2]

1) If a dealer sells a RUP to a person who has never been certified and that person did not purchase the RUP for a certified applicator, a penalty should be assessed from the "adverse effects highly probable" category of the FIFRA civil penalty matrix.

2) If a dealer sells a RUP to a person, for his own use, whose certification has expired more than 12 months prior, a penalty should be assessed from the "adverse effects unknown" category of the FIFRA civil penalty matrix.

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[2] Penalties should be assessed in accordance with the FIFRA Enforcement Policy - Interim Penalty Guidelines, dated June 11, 1981 from A.E. Conroy II, Director, Pesticides and Toxic Substances Enforcement Division to Regional Enforcement Division Directors and Pesticide Branch Chiefs and the July 31, 1974, Federal Notice entitled "Guidelines for the Assessment of Civil Penalties under Section 14 of the Federal Insecticide, Fungicide and Rodenticide Act as amended"

3) If a dealer sells a RUP to a person, for his own use, and his certification has expired within the past 12 months, a penalty should be assessed from the "adverse effects not probable" category of the FIFRA civil penalty matrix.

4) If a dealer sells a RUP to an uncertified person without documentation to prove the RUP is to be used by a certified applicator, but the RUP is actually applied by a certified applicator, a notice of warning should be sent for the first violation.

5) If a dealer sells a RUP to a certified commercial applicator who is not certified in the appropriate category, a penalty should be assessed from the "adverse effects not probable category of the FIFRA civil penalty matrix.

Penalties for dealers continuing to make RUP's available for use to uncertified persons for use by certified applicators without the necessary documentation should be assessed under the "adverse effects highly probable" category of the FIFRA civil penalty matrix.[3]

See Also:

Federal Register Notice of July 31, 1974, pages 27711-22 entitled "Guidelines for the Assessment of Civil Penalties under Section 14(a) of the Federal Insecticide, Fungicide and Rodenticide Act as amended" [7 U.S.C. 136 i(a)].

FIFRA Enforcement Policy - Interim Penalty Guidelines, dated June 11, 1981, from A.E. Conroy II, Director, Pesticides and Toxic Substances Enforcement Division to Regional Enforcement Division Directors and Pesticide Branch Chiefs.

References

Memo entitled "Enforcement Policies for Products Restricted through Regulation" dated July 20, 1978, from A.E. Conroy II to the Enforcement Division Directors and Pesticide Branch Chiefs.

Key Words:

Certified Applicator, Dealer, Make Available For Use, Restricted Use Pesticide, RUP's, Uncertified Person.

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MAY 18 1983
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[3] EPA will take enforcement action under FIFRA 12(a)(2)(F) and 12(a)(2)(G) against any uncertified person who uses a RUP and is not under the supervision of a certified applicator.

FIFRA COMPLIANCE PROGRAM POLICY SECTION 17 INDEX PAGE

TITLE	NUMBER
Pesticide Processing in Foreign-Trade Zones	17.1
Waiver of Notice of Arrival Requirements	17.2

FIFRA COMPLIANCE PROGRAM POLICY - No. 17.1

Pesticide Processing in Foreign-Trade Zones

FIFRA Section: 17(c)

Issue:

Are pesticides which enter a foreign trade zone for further processing or repackaging subject to the requirements of FIFRA?

Policy:

A product which legally enters a foreign-trade zone for processing or repackaging is not subject to the requirements of FIFRA.

Discussion:

Foreign-trade zones or "freeports" are areas within the United States where products may be stored, processed, manipulated, manufactured and reshipped without being subject to the customs laws of the United States governing the entry of goods and the payment of duty.

Foreign-trade zones are established under the Foreign-Trade Zones Act and the general regulations and rules of procedure of the Foreign-Trade Zones Board contained in 15 CFR Part 400. The regulations contained in 19 CFR Part 146 govern admission of merchandise into a foreign-trade zone; manipulation, manufacturing, processing, etc. in a zone; exportation of merchandise from a zone; and transfer of merchandise from a zone into United States Customs territory.

In order to be considered exempt from the requirements of Customs and FIFRA, a pesticide product must be in full compliance with the laws regarding entry into the foreign-trade zone; be processed within the zone; and be reshipped to foreign points. Any product which enters the United States from a foreign-trade zone is subject to Customs laws and the requirements of FIFRA.

The only products legally entering a foreign-trade zone which are subject to the requirements of FIFRA are those which were produced in the United States or which entered into the United States and subsequently enter the foreign trade zone under the custody of United States Customs for processing or repackaging.

References:

19 CFR Part 146

Key Words:

Foreign Trade Zones, Freeports, Processing, Registration, Repackaging.

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Enforcement Division

MAY 10 1982
Date

FIFRA COMPLIANCE PROGRAM POLICY NO. 17.2

Waiver of Notice of Arrival Requirements

FIFRA Section: 17(c), 17(e)

Issue:

Can importers of multi-use chemicals and pesticides imported for non-pesticidal purposes obtain a waiver from "Notice of Arrival" requirements?

Policy:

Importers of multi-use chemicals and pesticides imported for non-pesticidal purposes can be granted a waiver from "Notice of Arrival" requirements.

Discussion:

Pesticides and devices imported into the United States must be in compliance with Section 17(c) of FIFRA. Section 17(c) states that pesticides or devices which are adulterated, misbranded or otherwise violate the provisions set forth in the Act or are injurious to health or the environment may be refused entry into the country. The Secretary of the Treasury is empowered by Section 17(e) of FIFRA to prescribe regulations for the enforcement of Section 17(c). 19 CFR Part 12.110 through 12.117 regulates the importation of pesticides and devices into the U.S. The regulations state in part that pesticides and pesticide products imported into the U.S. will not be released by U.S. Customs unless accompanied by a completed Notice of Arrival of Pesticides and Devices form (EPA Form 3540-1). To assist in monitoring compliance with this requirement, EPA developed a checklist of frequently encountered pesticides and distributed it to U.S. Customs commodity import specialists.

Some of the pesticide chemicals which appear on the list may be multi-use chemicals imported for non-pesticidal uses or pesticides imported for chemical analysis or other testing. As a matter of policy, the Agency will allow persons importing products for such purposes to request a waiver from the Notice of Arrival requirements. Such requests must be made in writing to EPA Headquarters and must state (1) the chemical being imported together with its EPA registration number, if registered; (2) the purpose for which the product is being imported; (3) the amount of chemical being imported; and (4) if known, the port of entry (If there is more than one, all ports of entry should be listed).

If EPA Headquarters approves the request, a copy of the request and the waiver granted will be sent to each affected Region.

To expedite future shipments, the Regions should encourage importers to file a copy of the waiver with Customs for each subsequent entry of the product.

References:

FIFRA Compliance Program Policy No. 2.4, Multi-Use Chemicals, 19 CFR Part 12.110 through 12.117.

Key Words:

Imports, Multi-Use Products, Notice of Arrival.

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MAY 10 1982

Date

FIFRA COMPLIANCE PROGRAM POLICY SECTION 24 INDEX PAGE

TITLE	NUMBER
Special Local Needs Labeling	24.1

FIFRA COMPLIANCE PROGRAM POLICY No. 24.1

Special Local Needs Labeling

FIFRA Section: 24(c)

Issue:

Will the Agency permit a registrant to print or affix Section 24(c) (Special Local Need) labeling on Federal labeling?

Policy:

The Agency will permit Section 24(c) labeling to appear on Federal labeling under certain conditions.

Discussion:

Section 24(c) of FIFRA states that a State may register additional uses of federally registered pesticides for distribution and use within that State to meet special local needs provided that no such use has been previously denied, disapproved or cancelled by EPA. The Agency has 90 days to review such a registration. If the Agency does not deny a use within this time period, the use is considered to be registered under Section 3 for distribution and use only within that State. If the use is for a food or feed crop, a tolerance or exemption must exist for that use. 40 CFR Part 162.150-162.156 sets forth the regulations governing the registration of products under Section 24(c).

Part 162.153(e) requires that labeling governing any State-registered uses of a Federally registered product be made available at the time of use. As a matter of convenience for both the registrant and the user, Section 24(c) use directions may appear on a Federal label provided the directions are clearly identified and separate from Federal labeling. Either a distinct border around the Section 24(c) uses or a sticker which does not obscure the information on the Federal label is an acceptable means of conveying Section 24(c) information. The labeling must also clearly identify the State in which the Section 24(c) use is allowed. If a specific identical use has been registered in a number of States, the registrant may list all the States which have registered the use. The registrant must use the statement "For distribution and use only within (name of State(s)" on all Section 24(c) labeling. A product bearing Section 24(c) uses on the label may only be sold in those States listed.

This policy applies only to additional State registered uses of a Federally registered product. It does not not apply to State registered products.

See Also:

Section 24(c) Registration Guidelines 40 CFR Part 162.150-162.156.

References:

Letter of June 23, 1977 from A. E. Conroy II to Mr. Arthur F. Gohlke, Cities Service Company.

Key Words:

Intrastate Use, Labeling, Special Local Need, 24(c).

A. E. Conroy II

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

MAY 10 1982
Date

FIFRA COMPLIANCE PROGRAM POLICY SECTION 25 INDEX PAGE

TITLE	NUMBER
Child Resistant Packaging	25.1

FIFRA COMPLIANCE PROGRAM POLICY NO. 25.1

Child Resistant Packaging

FIFRA Section: 25(c)(3)

Issue:

Are small packages of pesticide products which are labeled "For Agricultural Use Only" or which have directions expressed in number of pounds per acre but which are marketed for homeowner use automatically excluded from the Child Resistant Packaging (CRP) requirement?

Policy:

Labeling a pesticide "For Agricultural Use Only" or expressing the dosage rate in pounds per acre, label language usually reserved for "agricultural" products, does not automatically remove the pesticide from the Child Resistant Packaging requirements.

Discussion:

The Child Resistant Packaging Regulation, 40 CFR 162.16, requires a pesticide to be in such packaging if it meets certain criteria. One criterion is that the product is intended for use in, on or around all structures, vehicles or areas associated with the household or homelife.

Labeling a product "For Agricultural Use Only" removes a product from the CRP requirement only if the label statement is consistent with other label language and marketing practices for agricultural use. If, for example, the product is marketed in home or garden stores, or the entire net contents, if applied at the labeled dosage rate, would only cover a limited area such as a home garden, or other label language implies residential use, the product would require CRP if the other CRP criteria apply.

Expressing the use directions in terms of number of pounds per acre does not in or by itself preclude residential use. This also would not effect whether or not a product requires CRP.

Therefore, where the package size is small, the product is marketed in home and garden stores, or the entire net contents, if applied at the labeled dosage rate, would only cover a limited area, such as a home garden plot, CRP would be required if the CRP criteria are met regardless of whether the label also states "For Agricultural Use Only" or the dosage rate is expressed in agricultural terms, such as pounds per acre.

Additionally, a product may be misbranded, according to the proposed Registration Guidelines for Labeling, if the dosage rate exceeds the net contents of the product.

References:

40 CFR Part 162.16

Memorandum to Roy P. Clark, Region IV, from A. E. Conroy II, dated July 27, 1982.

Key Words:

Agricultural Use Only
Child Resistant Packaging
Labeling

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FIFRA COMPLIANCE PROGRAM POLICY SECTION 26 INDEX PAGE

TITLE	NUMBER
Transfer of Use Enforcement Primacy to the States	26.1
Referral of State Misuse Cases to EPA	26.2

FIFRA COMPLIANCE PROGRAM POLICY No. 26.1

Transfer of Use Enforcement Primacy to the States

FIFRA Section: 26

Issue:

At what point does primary enforcement responsibility for pesticide use violations (primacy) transfer from EPA to a State?

Policy:

Primacy authority is transferred to a State when the State formally accepts a written offer by the Administrator to convey such authority. Primacy is also transferred when a cooperative enforcement agreement is signed by the Administrator and the State, unless the terms of the agreement specify otherwise.

Discussion:

Section 26 of FIFRA authorizes the Administrator to grant primacy to a State if the State has adopted adequate laws and adequate procedures for implementing such laws, or if the State has an approved certification plan that meets the adequate laws and procedures criteria. In addition, States may obtain primacy by entering into a cooperative agreement for the enforcement of pesticide use restrictions under Section 23 of FIFRA.

To transfer primacy through the first two mechanisms, the Administrator will write to the Governor offering to grant primacy to the State. The Administrator's letter will request a formal response to the offer of primacy. The transfer of primary use enforcement responsibility will not be effective until the Governor or his representative posts a written response accepting primacy. With respect to the third mechanism, when a State signs a cooperative agreement which calls for the State to monitor and enforce compliance with pesticide use restrictions, such State assumes use enforcement primacy unless the terms of the agreement specify otherwise. Thus the signing of an agreement which specifically states that the assumption by a State of primacy depends upon the occurrence of an event does not transfer primacy authority until the event takes place. Cooperative enforcement agreements which do not contain such conditions will serve to convey primacy to a State upon signature of the Governor and the Administrator or their duly designated representatives.

Key Words:

Certification Plan, Cooperative Enforcement Agreement, Primacy, State Authority, Use Enforcement.

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Pesticides and Toxic Substances
Enforcement Division

MAY 10 1982
Date

FIFRA COMPLIANCE PROGRAM POLICY No. 26.2

Referral of State Misuse Cases to EPA

FIFRA Section: 26

Issue:

Is it legally permissible for the Environmental Protection Agency to prosecute Federal pesticide misuse violations which are based on evidence collected by State inspectors following State procedures?

Policy:

As long as States follow basic Constitutional evidentiary procedures, evidence collected under State authority can be used to prosecute violations of Federal pesticides laws.

Discussion:

Pursuant to Section 26 of FIFRA, most States now exercise primary enforcement responsibility for pesticide misuse violations. Although the Federal government retains concurrent authority with the States to prosecute misuse violations, this power is not ordinarily exercised.

Accordingly, States with primacy generally conduct use inspections under the authority of State law. In the usual pesticide misuse case, State law provides ample enforcement authority for the State to effectively prosecute misuse violations. Consequently, the States need not generally refer misuse cases to the EPA for prosecution under the parallel Federal authorities.

However, there are two instances where the States may choose to refer misuse cases to EPA for Federal prosecution:

1) When the misuse is prohibited by Federal law, but not by State law, or,

2) When both State and Federal law prohibit the misuse, but the State lacks adequate resources to pursue prosecution.

When either of these types of misuse cases is referred to EPA for action, the Agency will review the case file to ensure that the State inspection procedures adhere to basic Constitutional guarantees. Information collected by State inspectors is not excluded in court merely because it is gathered by State inspectors; instead it is subject to the common law rules of evidence or to the Federal Rules of

Evidence. The issue of the admissibility of evidence derived from State inspections involves the analysis of two questions: (1) was the information and evidence obtained by State inspectors legally obtained, and (2) is that evidence within the scope of admissible evidence. If both of these questions can be affirmatively answered for any given information, then that evidence may be properly introduced into a civil or criminal proceeding to enforce a violation of the FIFRA.

Accordingly, the wide variety of State inspection procedures do not affect the capacity of the Agency to accept a misuse case for prosecution. States may follow their own inspection procedures without regard to whether or not the misuse case will be referred to the Agency. The eventual referral of the case to the Agency for prosecution does not require a State inspector to change any existing State inspection procedures.

Key Words:

Evidence, Misuse, Primacy, State Authority.

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Enforcement Division

MAY 10 1982

Date

KEY WORD INDEX

FCPP = FIFRA Compliance Program Policy
PCN = Office of Pesticide Programs Policy and Criteria Notices

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