



Pesticide Reregistration Progress Report



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I. INTRODUCTION

This is the fourth report produced by the Special Review and Reregistration Division (SRRD), Office of Pesticide Programs (OPP), U.S. Environmental Protection Agency (EPA), on the progress towards pesticide reregistration as mandated under the 1988 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). A/

This report will show the status of reregistration through the first quarter of the 1992 fiscal year. B/ Further information on the reregistration process and descriptions of technical terms have been provided in the Technical Appendix at the end of this document. Please refer to the corresponding reference letters as indicated in the document. These letters are printed in boldface type, followed by a slash mark.

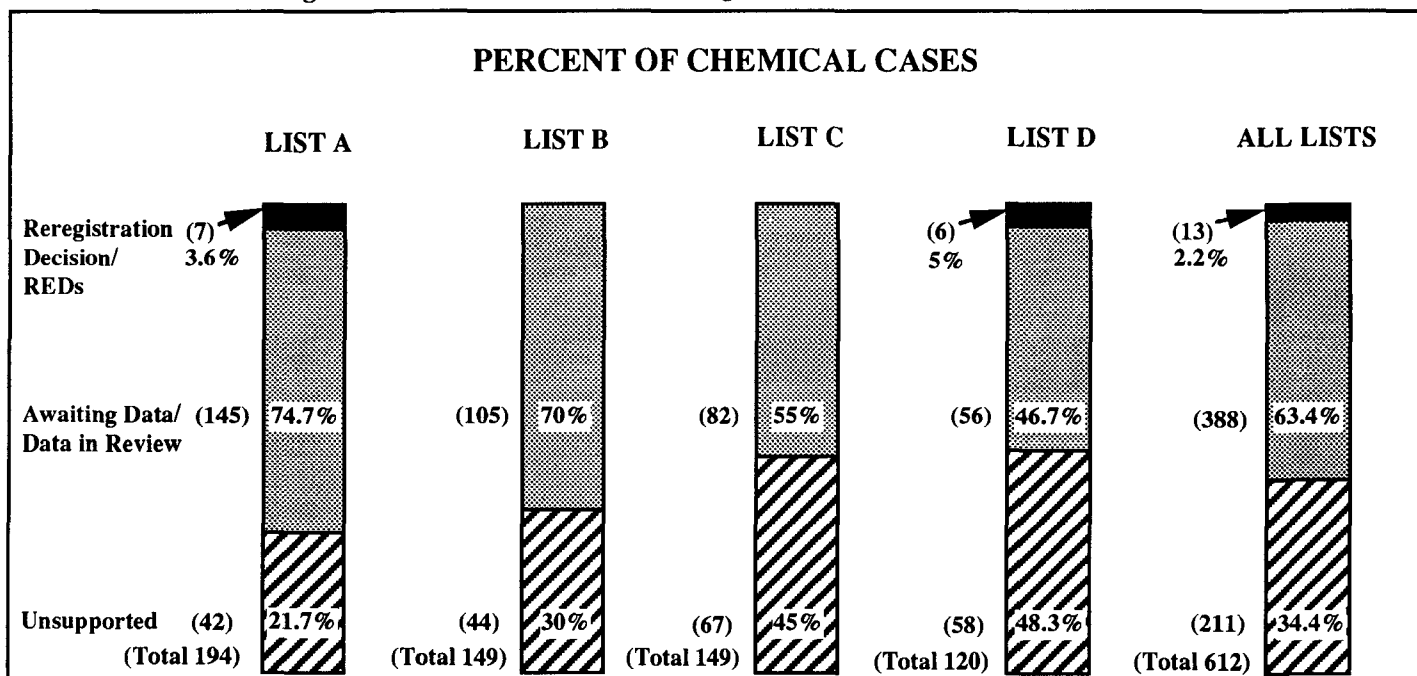
A. Current Status of Reregistration

Figure 1 shows the status of the chemical cases in Lists A, B, C, D, and all lists combined through the first quarter fiscal year 1992. Each column shows the total number of chemical cases currently on the list, as well as the percentage of cases in each stage of the process. The five-phase process described in the Technical Appendix has been compressed in Figure 1 into three general stages: Unsupported, Awaiting Data/Data in Review, and Reregistration Decision . C/ While the process for List A chemical cases is

less formal than that for Lists B, C, and D, it involves a similar sequence of events. List A cases are subject only to Phases 1 and 5. List B, C, and D cases must pass through each of the five phases.

No new reregistration decisions were made since the last quarterly report. This report will examine other measures of progress, significant regulatory decisions, and reregistration decisions to date. A list of all reregistration decisions can be found in Further Information.

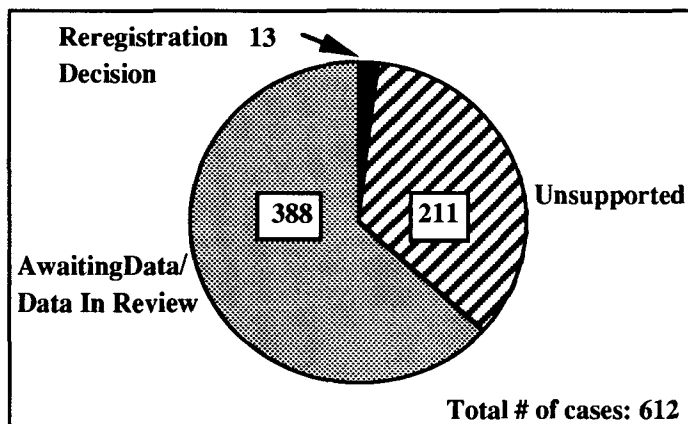
Figure 1
Current Status of Reregistration - Chemical Cases - First Quarter FY 92



Note: These numbers change frequently as the reregistration process continues. Percentage discrepancies may result from rounding.

Figure 2 shows the status of the total number of chemical cases by the end of the first quarter fiscal year 1992.

Figure 2
Total Chemical Cases - First Quarter FY 92



The following is a brief description of the terms used in Figures 1 and 2. D/

Unsupported

A chemical case is considered unsupported and is proposed to be canceled if the registrant (pesticide producer registering the chemical with EPA) fails to submit data in response to EPA's "Data Call-In" (DCI) request. DCI is a term which refers to EPA's request for studies on a chemical case. The implementation of mandatory Maintenance Fees in 1991 resulted in the cancellation of 1,277 registrations for

non-payment. The Cancellation Notice for these registrations was published in the Federal Register on October 17, 1991.

EPA also announced a 90-day deferral of cancellation for ten other registrations. This period will provide an opportunity for affected users to persuade the registrants to continue support for the registrations.

Awaiting Data/Data in Review

The Awaiting Data/Data In Review category is used in this report to represent the entire review process for cases in all lists. For List A chemical cases, this stage involves reviewing data submitted in response to the Registration Standards and requiring new data where appropriate.

Lists B, C, and D are subject to a five-phase formal process. For the purpose of simplification, phases 2 to 4 have been compressed into the Awaiting Data/Data in Review category of Figures 1 and 2. Chemical cases in these lists do not have Registration Standards.

Reregistration Decision

Once all of the data are evaluated and all the requirements are met for a chemical case, EPA makes a reregistration decision in the form of a Reregistration Eligibility Document (RED). This report measures progress in terms of issuing REDs or reregistration eligibility decisions.

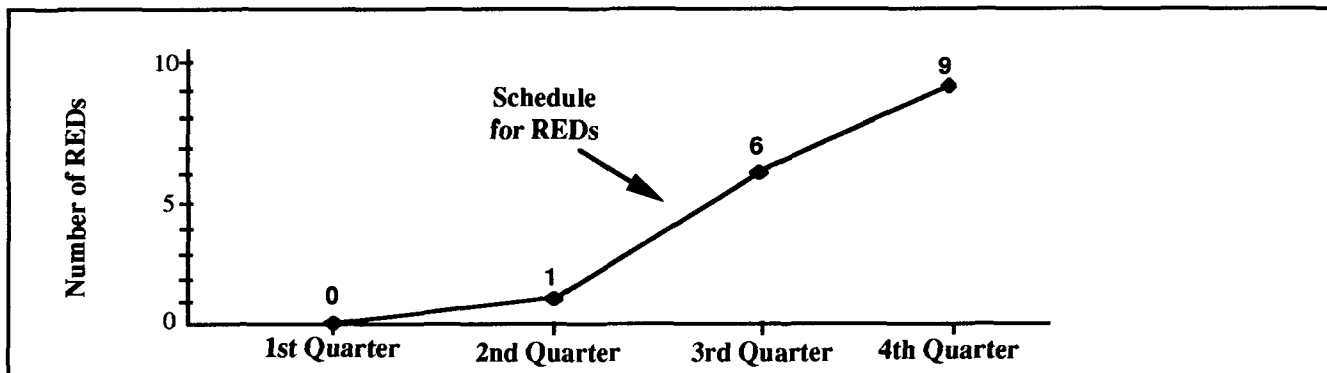
II. REREGISTRATION PROGRESS

A. REDs Schedule

Figure 3 shows the REDs scheduled by quarter for fiscal year 1992. As of the end of fiscal year 1991, a total of 13 REDs had

been completed. No new REDs were completed in the first quarter fiscal year 1992.

Figure 3
REDs Scheduled - First Quarter FY 92



B. Chemical Cases with REDs

Table 1 shows the cumulative number of cases with REDs completed by list and the resulting risk reduction measures with regard to dietary exposure, non-dietary exposure, and environmental fate and ecological effects. E/ The numbers in the boxes represent the chemical cases that required change to date

for each category. For each list, chemical cases can fall into multiple categories. For example, a chemical case may have a protective clothing requirement and a label modification requirement. The first column is the total number of REDs completed to date. All REDs completed so far have been from List A and List D.

Table 1
Results of Reregistration (Cumulative Summary) - First Quarter FY 1992

LISTS	Total Cases with REDs	Dietary Exposure			Non- Dietary Exposure				Environmental Fate and Ecological Effects		
		Tolerance Reduction	Pre Harvest Interval Adjustment	Other	Re-entry	Protective Clothing	Restricted Use	Other	Restricted Use	Label Modification	Other
List A	7			4	1	3		2		6	
List B											
List C											
List D	6				1	3				5	
Total	13			4	2	6		2		11	

Source: Reregistration Eligibility Documents (REDs)

C. Minor Uses

An early notification network was jointly established by the U.S. Department of Agriculture (USDA), EPA, and the National Agricultural Chemicals Association (NACA). This network communicates registrant actions that would impact on pesticide usage to those affected, particularly the pesticide users. This notification is intended to afford end users of pesticides sufficient time to try to influence

decisions. EPA can be contacted for further information on minor uses, reregistration, and growers' minor use pesticide needs. The EPA telephone lines are (703) 308-8068 and (703) 308-5310.

Table 2 lists the chemicals and products that are proposed to be canceled and the uses that would be affected by these cancellations.

Table 2
Proposed Cancellations Affecting Minor Uses - First Quarter FY 92

Chemical	Products	Affected Uses
Terbacil	Sinbar	Citrus, Strawberries
Trifluralin	Treflan	Spearmint, Peppermint
Triphenyltin Hydroxide	TPTH	Carrots
Ethoprop	Mocap	Soybeans
Fluvalinate	Spur 22EW	Tobacco seed
Methyl Parathion	Methyl Parathion	Almonds, Apples, Apricots, Cherries, Cucumbers, Gooseberries, Grapes, Hops, Peaches, Pears, Peppers, Plums, Prunes, Tobacco, Tomatoes, Sunflower, and Strawberries
Mevinphos	Phosdrin	Greenhouse Uses
Asulam	Asulox	Ditchbanks
Chloropyrilos	Lorsban	Dill, Okra Note: A special local needs use on clover in Oregon was approved.

D. Reregistered Products

EPA reregistered its first products in January 1992. The two products are shown in Table 3. Products are reregistered in the Registration Division of OPP upon completion of applicable product-specific data and compliance with the terms and conditions specified in the REDs.

Table 3
Reregistered Products - January 1992

Chemical with RED	Products
Aliette	Aliette fungicide, Fosetyl-Al Technical

III. OTHER MEASURES OF PROGRESS

A. Rejection Rate Study

EPA is currently researching the reasons that most frequently cause guideline studies required for reregistration to be rejected. In the spring of 1991, a FIFRA Reregistration recosting analysis was conducted to determine the resources needed to complete reregistration. This analysis indicated that rejected studies posed the most significant potential for delays in the production of REDs. Reregistration decisions require that reasonable risk assessments be performed for all relevant human health and ecological end points for each chemical. Performing such risk assessments requires a "substantially complete" data base. To achieve such a "substantially complete" data base, the registrants must submit acceptable quality studies to EPA. A significant reduction in study rejection rates is necessary for OPP to be able to meet its production schedule for REDs.

The Rejection Rate Study is divided into the five scientific disciplines including Residue Chemistry, Environmental Fate, Ecological Effects, Non-Dietary Exposure, and Toxicology (CORT) and Toxicology (Non-CORT). The first chapter, on Residue Chemistry, is expected to be completed in the second quarter fiscal year 1992. The following are brief descriptions of the disciplines:

Residue Chemistry - These studies measure the amount of the pesticide remaining on a crop or

commodity and how the pesticide is broken down within the crop or domestic animal.

Environmental Fate - Also referred to as "Environmental Chemistry," these studies measure how the chemicals are broken down and released into the environment.

Ecological Effects - These studies measure the toxicity to wildlife and aquatic organisms.

Non-Dietary Exposure - Also referred to as "Occupational and Residential Exposure," these studies measure human contact with pesticides either at work or in a domestic setting other than being exposed to the chemical via the diet.

Toxicology (CORT/Non-CORT) - CORT studies monitor Chronic feeding, Carcinogenicity (Oncogenicity), Reproduction, and Developmental Toxicity (Teratology). Essentially, these studies measure exposure to a pesticide over an extended period of time. Non-CORT studies measure toxicity of pesticides in other than CORT studies. Generally, this category includes studies which measure the effects of acute or limited exposure to the pesticide.

IV. SIGNIFICANT REGULATORY DECISIONS

Another area that relates to reregistration is the Special Review process for chemicals which have met or exceeded the risk criteria of unreasonable adverse effects as set forth in 40 CFR 154. This section gives a summary of significant regulatory decisions on Special Review chemicals made in the first quarter fiscal year 1992 and early January 1992. For further information on Special Review chemicals, call (703) 308-8010.

Sodium Arsenite - EPA is proposing to revoke all tolerances for sodium arsenite, (expressed as

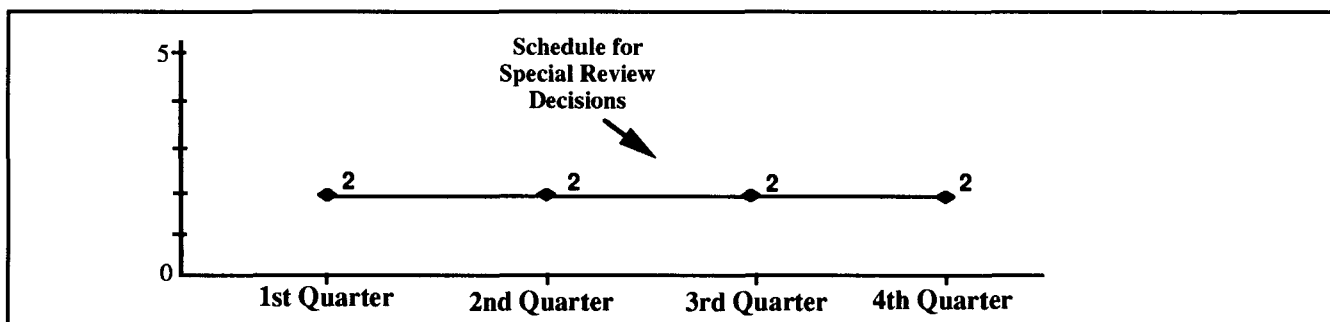
arsenic trioxide (As_2O_3)). Sodium arsenite, an inorganic arsenical, is classified by EPA as a known human carcinogen. EPA is proposing to revoke tolerances set for residues of sodium arsenite in liver, kidney, fat, meat, and meat by-products of cattle and horses (40 CFR 180.330), resulting from the insecticidal use of sodium arsenite, upon publication of the final rule. EPA is proposing to revoke the interim tolerance of sodium arsenite on grapes (40 CFR 180.319), resulting from the fungicidal use of sodium arsenite, as of June 30, 1994.

This proposed action is being taken because EPA canceled the insecticidal use of sodium arsenite in 1988, and Agtrol Chemical Products, the sole registrant of the fungicidal use, has requested voluntary cancellation of its two registrations of products containing sodium arsenite (EPA registration numbers 55146-35 and 55146-25). EPA has published a final order canceling these two registrations of sodium arsenite.

Special Review decisions represent major EPA actions which may ultimately cancel,

deny, or reclassify the registration of pesticide products, because uses of the product may cause unreasonable adverse effects on human health or the environment. In addition, Special Review decisions may include other major documents that establish policy or guidelines on which other environmental decisions relating to pesticide registrations are based. Figure 4 shows the Special Review decisions scheduled by quarter for fiscal year 1992. The two Special Review decisions that were scheduled for the first quarter will be made up in subsequent quarters.

Figure 4
Special Review Decisions Scheduled - First Quarter FY 92



V. CALENDAR OF EVENTS (FY 92)

3rd Quarter 1992	4th Quarter 1992
<ol style="list-style-type: none"> 1. The second public Reregistration Workshop is planned. 2. The Rejection Rate Study is scheduled for completion. 3. The revised Rainbow Report is scheduled for completion. F/ 	<ol style="list-style-type: none"> 1. A total of 16 REDs will be completed by the end of the fiscal year. 2. A total of 8 Special Review decisions will be completed by the end of the fiscal year. 3. A total of 77 List C DCIs will be completed by the end of the fiscal year.

Announcement: Reregistration Workshop

The EPA is sponsoring a Reregistration Workshop, scheduled for the end of April 1992. This is the second Reregistration Workshop; the first was held in September 1990. The purpose of the workshop is to provide a forum for discussion and input for parties interested in reregistration. For further information contact: (703) 684-5588 or (703) 308-8080.

VI. FURTHER INFORMATION

For further information on reregistration issues related to this progress report, please contact the following sources:

Pesticide Reregistration pamphlet, April 1991

Available from SRRD/OPP, U.S. EPA,
or from EPA's Public Information Center (PIC)
401 M Street, SW (PM-2118)
Washington, DC 20460
(202) 260-7751

National Pesticide Telecommunications Network (NPTN)

For information about pesticide poisoning symptoms and general information:
Tel: 1-800-858-7378; Fax: 806-743-3094

Federal Register Publication of Lists A, B, C, and D

List A: FR 2/22/89, pages 7740-7750
List B: FR 5/25/89, pages 22706-22714
List C: FR 7/24/89, pages 30846-30855
List D: FR 10/24/89, pages 43388-43396
U.S. Government Printing Office
732 North Capitol Street, NW
Washington, DC 20401

Minor Uses

For information contact: (703) 305-5310
EPA Tel: (703) 308-8068

Rainbow Report

For information contact: (703) 308-8000

Rejection Rate Study

For information contact: (703) 308-8000

Reregistration Workshop

For information contact: (703) 684-5588
or (703) 308-8080

Reregistration Eligibility Documents (REDs) and RED Fact Sheets - As of January 1992

OPP has completed REDs and summary fact sheets for the following pesticides. Copies of these documents may be obtained from the Public Response and Program Resources Branch, Field Operations Division (H-7506C), Office of Pesticide Programs, U.S. Environmental Protection Agency, Washington, DC 20460 Tel: (703) 305-2805.

- | | | | |
|-------------------------------|----------------|--|----------------|
| 1. Fosetyl-Al (Aliette) | January 1991 | 8. Dried Blood | September 1991 |
| 2. Heliothis zea NPV..... | January 1991 | 9. Inorganic Nitrate/Nitrite | |
| 3. Methoprene | May 1991 | (Sodium and Potassium Nitrates)... | September 1991 |
| 4. Sulfur | May 1991 | 10. Carbon and Carbon Dioxide | |
| 5. Potassium Bromide | June 1991 | (See 2 separate fact sheets)..... | September 1991 |
| 6. Warfarin | June 1991 | 11. Silicon Dioxide and Silica Gel.... | September 1991 |
| 7. Sodium and Calcium | | 12. Propionic Acid..... | September 1991 |
| Hypochlorite Salts..... | September 1991 | 13. Sodium Diacetate..... | September 1991 |

Comments

EPA welcomes your comments on this progress report or on activities related to reregistration. Please address your comments to:

Attention: Pesticide Reregistration Progress Report
Special Review and Reregistration Division (H7508W)
United States Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

TECHNICAL APPENDIX

- (A) FIFRA is the statute under which EPA regulates the marketing and use of pesticides in the United States.
- (B) This report describes the progress of reregistration in terms of "chemical cases," which are groups of structurally similar chemicals or active ingredients.
- (C) **Formal Pesticide Reregistration Process:**
- Phase 1: EPA publishes lists of pesticides.
- Phase 2: Registrants decide to support chemicals by agreeing to conduct the required studies and by paying maintenance fees.
- Phase 3: Registrants summarize and reformat existing studies and certify access to raw data. The registrants flag potential adverse effects data and pay an additional fee to keep chemicals registered.
- Phase 4: EPA reviews Phase 2 and 3 submissions and identifies additional data needs. EPA publishes lists of missing studies and notifies registrants of required studies.
- Phase 5: All chemical studies must be submitted before this phase. Product-specific studies are required. Once these studies are reviewed and deemed acceptable, products will be reregistered.
- (D) When a chemical is unsupported, it is proposed for cancellation and may ultimately be canceled by EPA. The number of unsupported chemical cases is constantly changing. Chemical cases can drop out of the reregistration process if a registrant decides it is not cost effective to produce the necessary data. However, it is possible for another registrant to support a chemical case by submitting the appropriate data and fees to EPA. This is considered a "revived case."
- The formal review process is different for List A chemical cases than for Lists B, C, and D. List A chemical cases had Registration Standards completed prior to the 1988 FIFRA amendments.

Registration Standards were comprehensive reviews of the data available, decisions on label amendments, and requests for new data to be submitted. By the end of 1988, these had been issued on most of the important food-use chemicals.

REDs are produced once the data on a chemical case have been reviewed and no significant issues remain concerning the use of the pesticide chemical. REDs summarize the findings of the review process and reflect EPA's decision to impose any new conditions on the use of a chemical (e.g., reduction of tolerances), to call in product specific data, or to take other regulatory action. Once a chemical case has a completed RED, EPA essentially has determined that the active ingredient does not pose any unreasonable risk when used under its established terms and conditions. The reregistration process makes a determination that products which contain a particular active ingredient are eligible for reregistration. Products are reregistered by the Registration Division upon completion of applicable product-specific data and compliance with the terms and conditions specified by RED.

(E) **Definitions of Risk Reduction Measures**

I. Dietary Exposure

- A. **Tolerance Reduction:** This measure indicates where EPA has reduced the maximum acceptable residue level on food/feed products below the previously existing level.
- B. **Pre-Harvest Interval Adjustment:** This measure refers to the amount of time since the last pesticide application before a crop can be harvested. Adjustment usually would result in the establishment of a longer period of time to avoid worker and consumer exposure to unacceptable levels of pesticide on a crop.
- C. **Other:** This measure primarily tracks label modifications or other tolerance changes.

TECHNICAL APPENDIX, continued

II. Non-dietary Exposure

- A. Re-entry: This measure may result from requiring workers to delay entering a field where crops have been treated with pesticides.
- B. Protective Clothing: This measure is intended to reduce pesticide exposure to mixers, loaders, applicators, and field workers.
- C. Restricted Use: This classification generally limits sale and use of a pesticide to certified applicators or persons under their direct supervision.

III. Environmental Fate and Ecological Effects

- A. Label Modification: This measure refers to changes required in a pesticide label.

(F) Rainbow Report

This annual report will list and describe the status of each pesticide in the reregistration process and under Special Review.