



Pesticide Reregistration Progress Report



Contents

I. INTRODUCTION	1
A. Current Status of Reregistration	1
II. REREGISTRATION PROGRESS	3
A. List A	3
B. Lists B, C, and D	5
C. Reregistration Eligibility Decisions	7
C-1. REDs Schedule	7
C-2. Chemical Cases with REDs Scheduled	7
D. Minor Uses	9
III. SIGNIFICANT REGULATORY DECISIONS	9
IV. CALENDAR OF EVENTS (FY 92)	10
V. FURTHER INFORMATION	10
Comments	10
TECHNICAL APPENDIX	TA-1

I. INTRODUCTION

This is the third in a series of periodic reports 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 fourth quarter of the 1991 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.

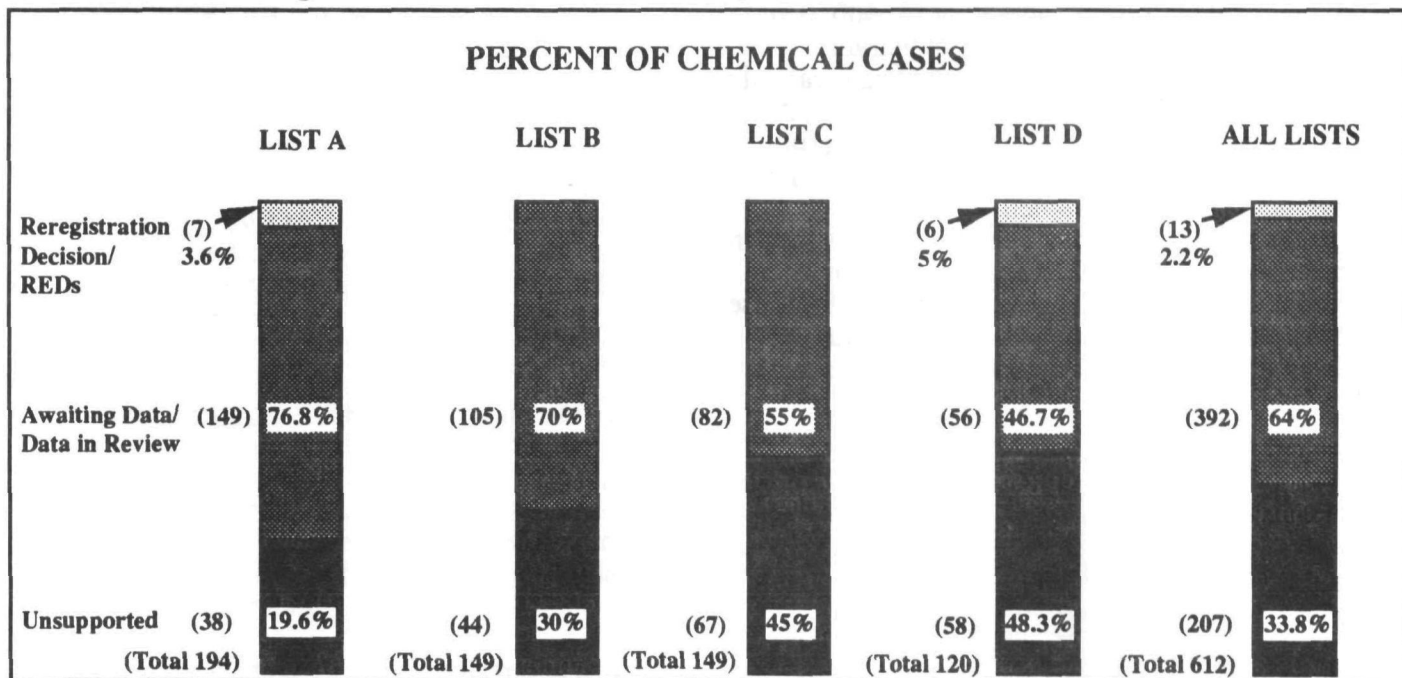
A. Current Status Of Reregistration

Figure 1 shows the status of the chemical cases in Lists A, B, C, D, and all lists combined through the fourth quarter fiscal year 1991. 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.

Figure 1

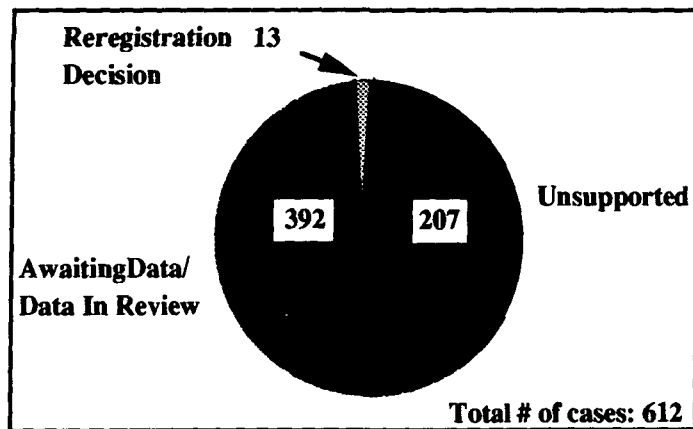
Current Status of Reregistration - Chemical Cases - Fourth Quarter FY 91



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 fourth quarter fiscal year 1991.

Figure 2
Total Chemical Cases - Fourth Quarter FY 91



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 cancelled 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

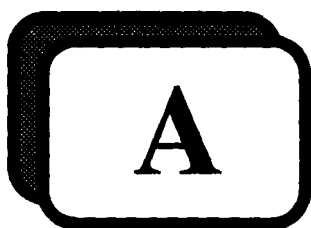
The Awaiting Data/Data In Review category is used in this report to represent the entire review process for cases in all lists. For List A chemical cases, this stage involves reviewing data submitted in response to the Registration Standards and requiring new data where appropriate.

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. Table 2 on page 8, Risk Reduction Measures, shows a summary of the REDs produced by the end of the fourth quarter fiscal year 1991.

II. REREGISTRATION PROGRESS



A. List A

Figure 3 shows a further breakdown of the categories described on the List A column of Figure 1. E/ EPA made a total of seven reregistration eligibility decisions for List A cases by the end of September 1991. The Special Issues category includes chemical cases that are in litigation or have data requirements that are under review (e.g., changes in use patterns/sites).

Figure 4 provides an overview of studies EPA has received in response to DCIs. These studies are broken down into the seven major scientific disciplines, which include TOX (CORT), TOX (Non-CORT), Ecological Effects, Environmental Fate, Non-Dietary Exposure, Residue Chemistry, and Special Studies.

TOX (CORT) - These 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.

TOX (Non-CORT) - These 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.

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

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

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.

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.

Special Studies - These studies include additional data not required unless specifically requested by EPA.

Figure 3
Status of List A - Fourth Quarter FY 91

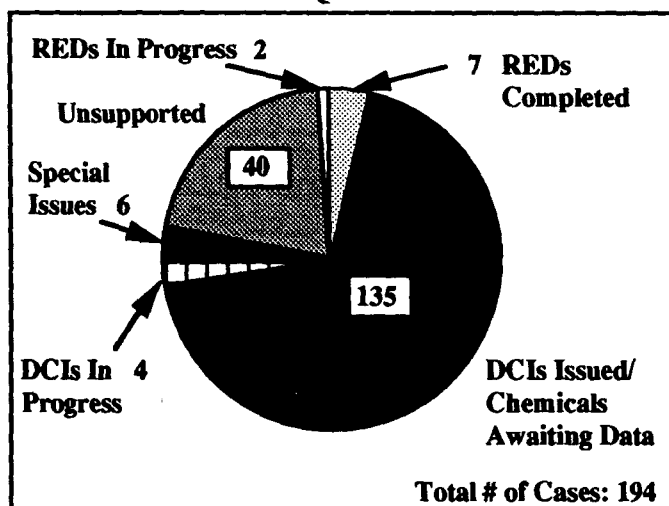


Figure 4 - List A Studies Received - by Discipline
Fourth Quarter FY 91

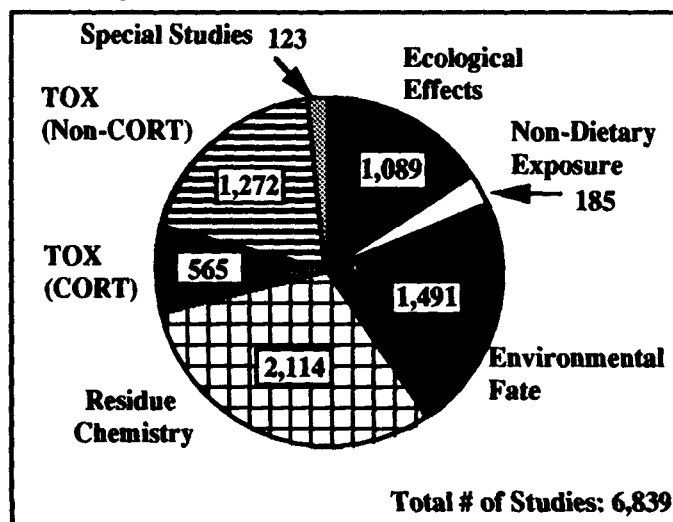


Figure 5 shows the total number of studies by discipline that have been reviewed and the total number that are awaiting review.

Of the studies that have been reviewed, Figure 6 shows by discipline those that were

considered acceptable, upgradable, or unacceptable to EPA.

Due to the high rate of rejected studies, EPA has begun a project to analyze the factors that cause a study to be rejected. This project is due to be completed by early 1992.

Figure 5

List A Review Status of Received Studies by Discipline - Fourth Quarter FY 91

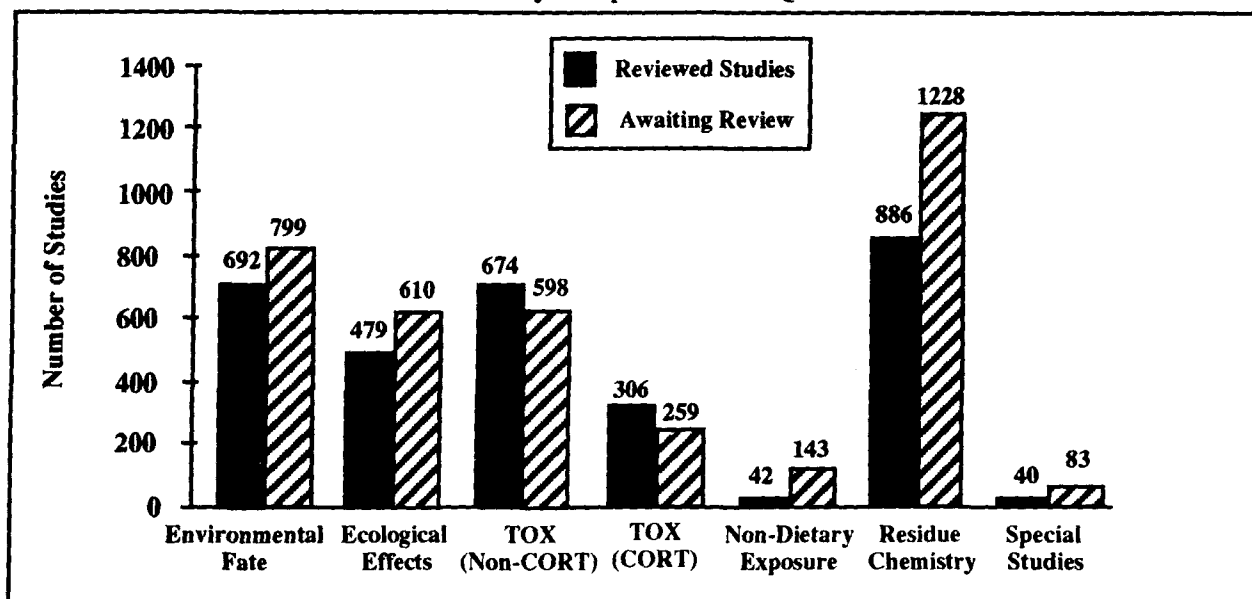
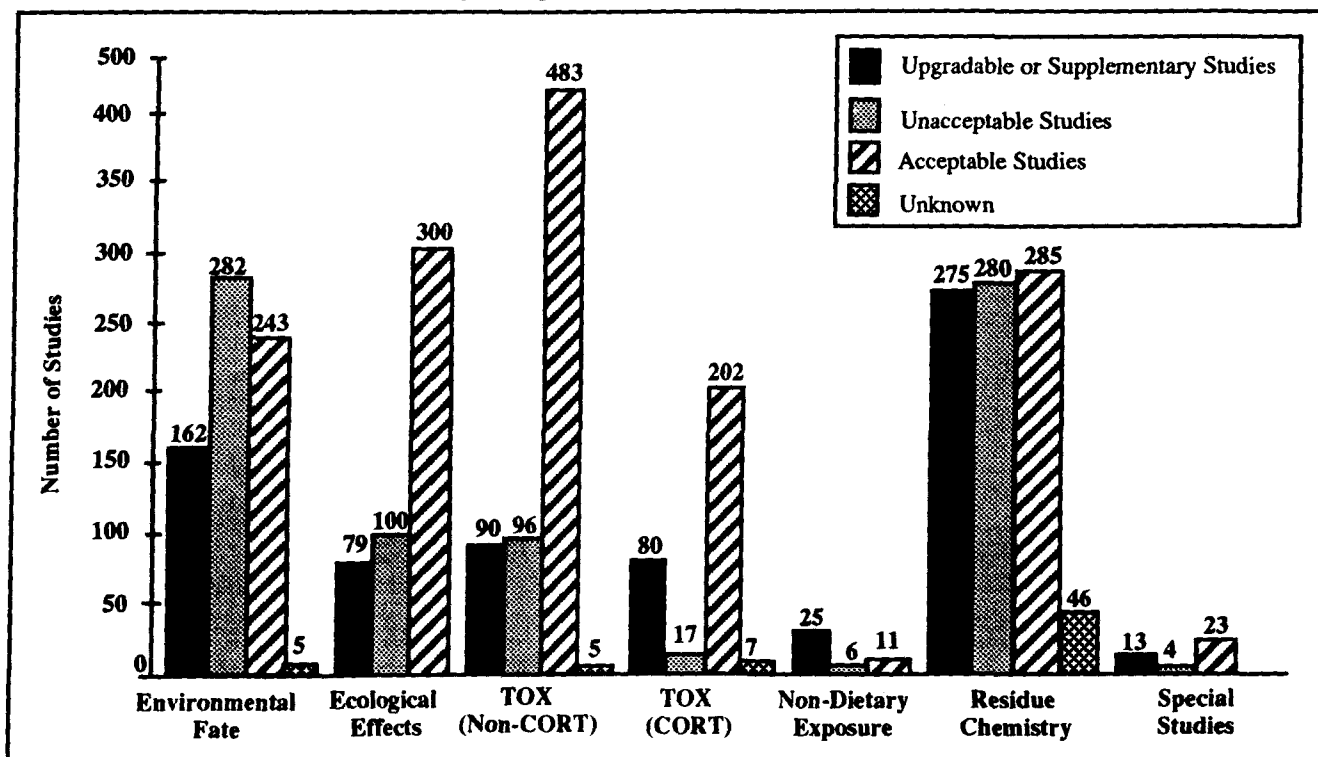


Figure 6

List A Results of Reviewed Studies by Discipline - Fourth Quarter FY 91



B, C, D

B. Lists B, C, and D

As shown in Figure 7, the Phase 4 review of List B is complete. Figure 8 shows a breakdown of the categories described in the List B column of Figure 1. F/

Figure 9 provides an overview of studies EPA has received in response to DCIs for List B. These studies are broken down into the six major scientific disciplines as discussed on Page 3.

Figure 10 shows the total number of studies by discipline that have been reviewed and the total number that are awaiting review.

Of the studies that have been reviewed, Figure 11 shows by discipline those that were considered acceptable, upgradable, or unacceptable to EPA.

Figure 8
Current Status of List B - Fourth Quarter FY 91

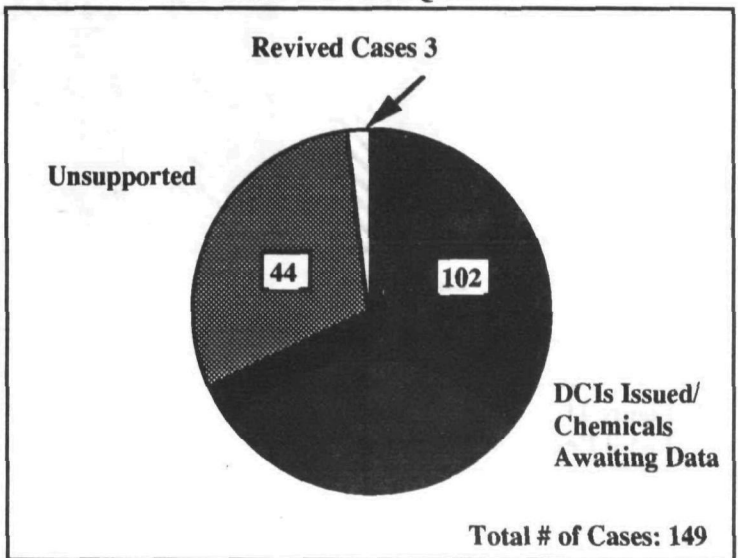


Figure 7
FY 91 List B DCI Completion Status
(Schedule vs. Actual) - Fourth Quarter FY 91

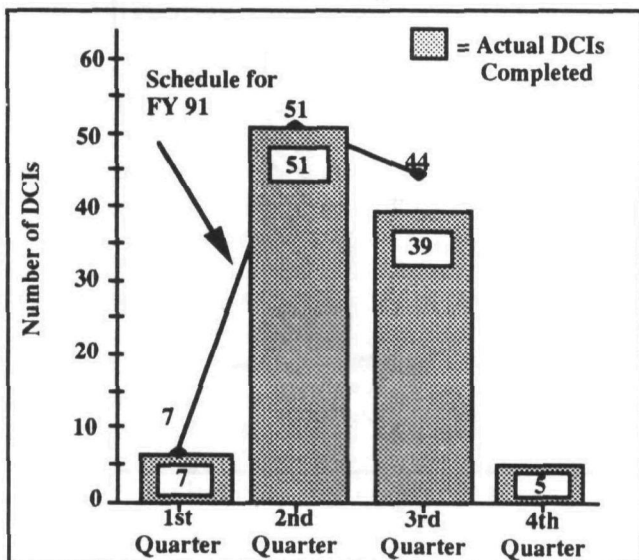


Figure 9
List B Studies Received in Response to FIFRA 88
by Discipline - Fourth Quarter FY 91

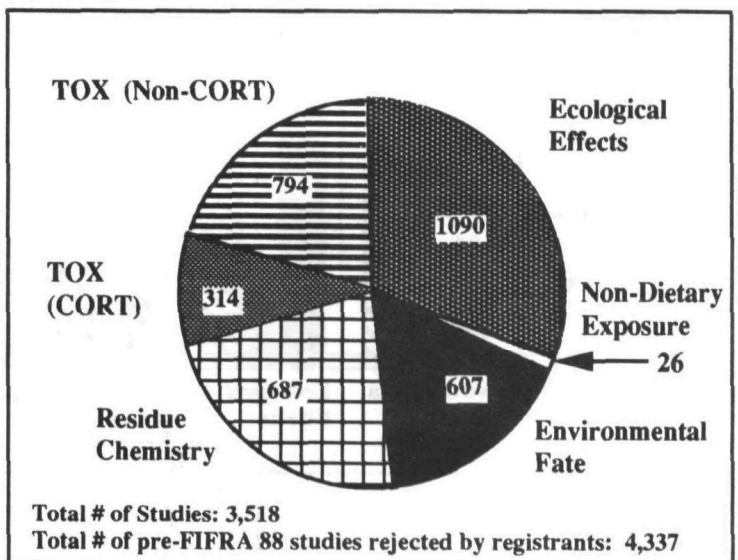


Figure 10

List B Review Status of Received Studies by Discipline - Fourth Quarter FY 91

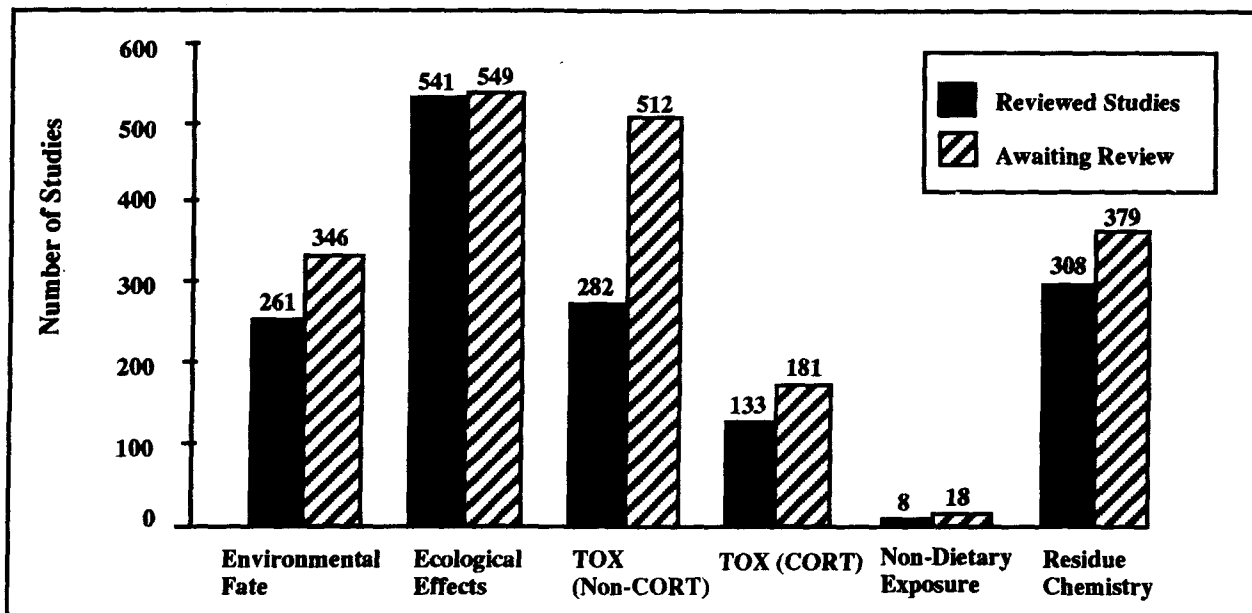
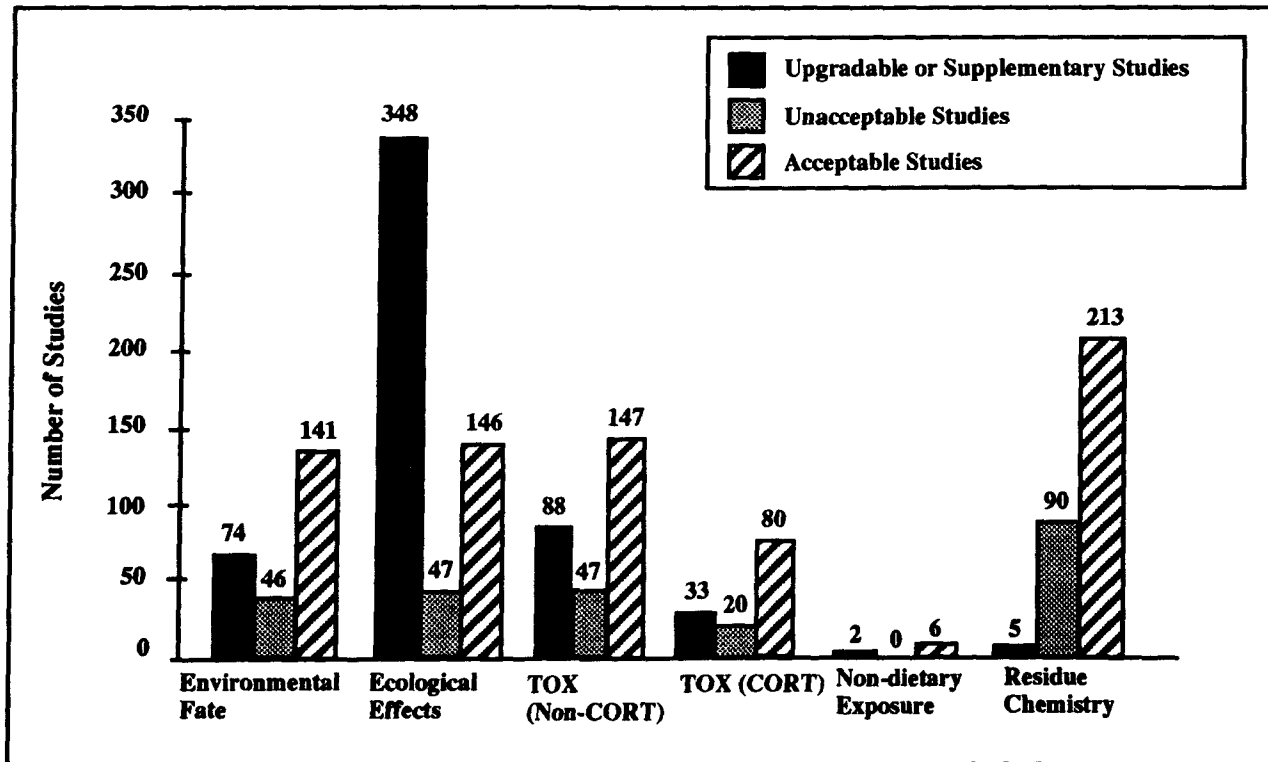


Figure 11

List B Results of Reviewed Studies by Discipline - Fourth Quarter FY 91



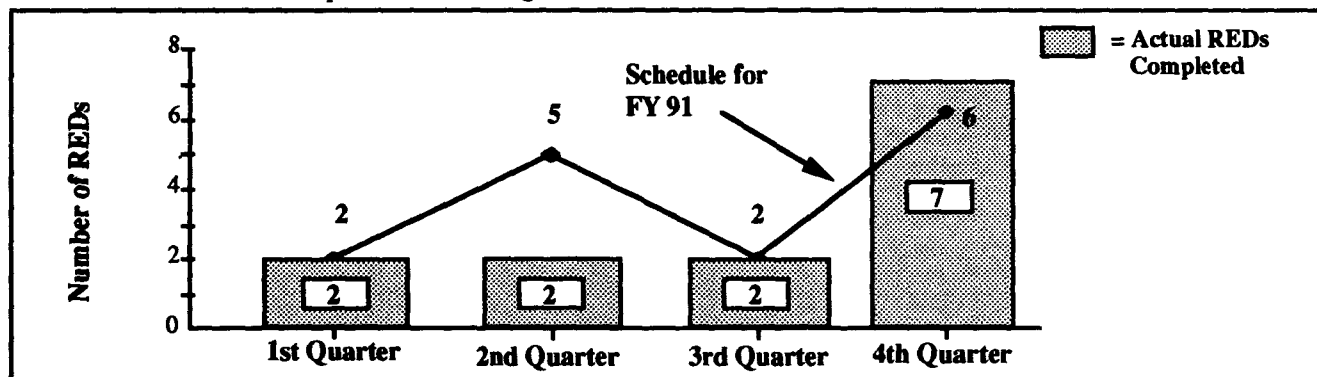
C. Reregistration Eligibility Decisions

C-1. REDs Schedule

Figure 12 shows the REDs scheduled by quarter and the actual number of REDs completed each quarter.

By the end of the fourth quarter fiscal year 1991, a total of 13 REDs had been completed.

Figure 12
REDs Scheduled and Completed - Fourth Quarter FY 91



C-2. Chemical Cases with REDs Scheduled

Since FIFRA '88 was enacted, the number of supported chemical cases has been reduced by about 200 cases to approximately 400. The number of supported chemical cases is still changing as some chemical cases become unsupported.

Table 1 shows seven chemical cases that had REDs completed in the fourth quarter fiscal year 1991. The seven chemical cases are listed with the number of chemicals (active ingredients) within each case that are eligible for reregistration. Also listed are the total number of products that contain the chemical and the number of tolerances or food uses associated with each chemical case. The Total Tolerances/Food Uses category does not capture exemptions. EPA grants tolerance exemptions if the toxicology database or other studies do not indicate any toxic effects.

Table 1
REDs Completed - Fourth Quarter FY 91

CASE	Chemicals Completed	Total Products	Total Tolerances/Food Uses
Carbon/CO2	2	9	0
Nitrates/Nitrites	2	6	0
Propionic Acid	1	4	0
Sodium Diacetate	1	2	0
Silica Gel & Silicon Dioxide	2	75	0
Dried Blood	1	3	0
Hypo-chlorites	2	770	0

Source: Reregistration Eligibility Documents (REDs)

Table 2 shows the risk reduction measures that would result from reregistering the products in accordance with the requirements specified in the REDs. The key below indicates the measures brought about by actions required in the REDs. These actions range from No Changes/Not Applicable to Major Changes. The No Changes/Not Applicable measure indicates the absence of

an existing standard or that the existing standard was not changed. An example of a Major Change is the imposition of a restricted use classification when uses were previously unclassified. Refer to the key for the amount of change. The table summarizes the risk reduction measures with regard to dietary exposure, non-dietary exposure, and environmental fate and ecological effects. G/

Table 2
Risk Reduction Measures Brought About by the REDs Completed - Fourth Quarter FY 1991

CASE	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
Carbon/C02										
Nitrates/Nitrites										
Propionic Acid										
Sodium Diacetate										
Silica Gel & Silicon Dioxide										
Dried Blood										
Hypochlorites										

Source: Reregistration Eligibility Documents (REDs)

Key: Based on risk assessment

- ☐ — No changes/Not applicable
- ☒ — Major changes
- ☒ — Minor changes

* Deletion of use in sugar syrup and raw sugar since an appropriate FDA food additive regulation has not been sought or established. Proposal to remove sodium hypochlorite from 180.2 GRAS list and establish either an exemption or finite tolerances.

** Require standard aquatic invertebrate toxicity statement. Require statement of practical treatment on front panel of label.

While Table 2 shows individual cases for the fourth quarter fiscal year 1991, Table 3 shows the cumulative number of cases with REDs completed by list and the resulting risk reduction measures. 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 3
Results of Reregistration (Cumulative Summary) - Fourth Quarter FY 1991

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)

D. Minor Uses

The early notification network, jointly established by the U.S. Department of Agriculture (USDA), EPA, and the National Agricultural Chemicals Association (NACA), 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 affect decisions.

USDA and EPA have two free telephone lines to provide further information on minor uses and reregistration and to learn of growers' minor use pesticide needs. The USDA line is 1-800-262-0216, and the EPA line is 1-800-552-8879.

Table 4 lists the chemicals and products that are proposed to be cancelled and the uses that would be affected by these cancellations.

Table 4
Proposed Cancellations Affecting Minor Uses - Fourth Quarter FY 91

Chemical	Products	Affected Uses
Triallate	FAR-GO	Canary Grass
Methomyl	All products	Watercress
Sethoxydim	POAST	Ginseng, Plantago, Ovata
Fluvalinate	Mavrik 2E	All uses
Diclofop	Hoelon 3EC	Lentils, dry peas (field peas), Austrian winter peas and flax
Linuron	All products	Cotton
Triadimefon	BAYLETON	Almonds
DCNA	BOTRAN 75W, 75WDC	All uses
Benomyl	BENLATE WP	All ornamental uses
	TERSAN WP	All dip, drench, container, and green house uses

III. 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 within the fourth quarter fiscal year 1991. For further information on Special Review chemicals call (703) 308-8010.

Parathion - EPA reached a settlement agreement with the registrants of the pesticide parathion (ethyl

parathion) in September 1991, whereby most uses of this product were voluntarily cancelled. Action was taken on parathion after it was determined to be one of the most acutely toxic chemicals registered with EPA, causing an unacceptable number of poisonings of agricultural workers. Parathion is an organophosphate pesticide which had been used as an insecticide and miticide. EPA has also pronounced its intent to cancel the remaining uses of parathion in the near future. Of the approximately 90 crops for which parathion use has been registered to control insects, the September agreement eliminates all but nine uses.

IV. CALENDAR OF EVENTS (FY 92)

1st Quarter 1992	2nd Quarter 1992
1. The revised Rainbow Report is scheduled for completion. H/	1. The second public Reregistration Workshop is planned. 2. Rejection Rate Study will be completed.

V. 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) 475-7751

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

Reregistration Eligibility Documents (REDs) and
RED Fact Sheets

Carbon/CO₂, Nitrates/Nitrites, Propionic
Acid, Sodium Diacetate, Silica Gel/Silicon
Dioxide, Dried Blood, Hypochlorites.
Published REDs and RED fact sheets are
available from the Docket, FOD/OPP (H7506C)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460
(703) 557-2805

National Pesticide Telecommunications Network
(NPTN)

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

USDA/EPA/NACA Early Notification Network

For information about minor uses and
reregistration:
USDA Tel: 1-800-262-0216
EPA Tel: 1-800-552-8875

Rejection Rate Study

For information contact Peter Caulkins,
Deputy Director, SRRD
(703) 308-8000

Rainbow Report

For information contact:
(703) 308-8000

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 cancelled 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. End-use 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) List A consists of the active ingredients for which EPA issued Registration Standards as of December 24, 1988. The 194 chemical cases in List A cover 350 individual active ingredients as listed in the Federal Register on February 22, 1989. These active ingredients are primarily food-use chemicals. EPA conducted an inventory on List A in 1989-90 to identify further actions needed to reregister List A chemical cases.

For List A chemicals, payment of reregistration fees has been the principal indicator of registrant support for reregistration. Failure to pay the fees results in cancellation of all products containing the active ingredient.

Technical Appendix, cont.

- (F) Lists B, C, and D include the remaining chemical cases subject to reregistration. These chemicals were registered for the first time before November 1984, but did not have reviews completed under the Registration Standards program. Chemicals appearing on the three lists currently make up 418 chemical cases, including 802 active ingredients. Each successive list represents chemicals with use patterns that generally have less human and environmental exposure. Thus, chemical List D represents chemicals of least exposure.

List B chemicals generally are characterized as the less significant food-use pesticides, outdoor non-food crop, and indoor use pesticides. List C chemical cases are predominantly antimicrobial, which includes disinfectants and wood preservatives among other things. List D chemical cases are a mixture of other outdoor and indoor use pesticides and antimicrobial pesticides. List D also includes many biochemical and microbial pesticides.

(G) 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 may track label modifications or other tolerance changes.

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

(H) Rainbow Report

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

This report is called the Rainbow Report because it was traditionally printed on multi-colored paper.