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Environmental Protection
Agency

Pesticides And
Toxic Substances
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EPA

Pesticide Reregistration Progress Report

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I. INTRODUCTION

The purpose of this report is to show the status of reregistration, as mandated by Congress under the 1988 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). 1/ The 1988 amendments to FIFRA were intended to speed up the process of reassessing and reregistering old pesticides in the U.S. by the Environmental Protection Agency (EPA).

This report will briefly cover the progress of accelerated reregistration from its initiation in 1988 up to now. This report is not intended to be an exhaustive review of reregistration, nor will it give specific chemical information, other than providing information on chemical cases that have completed the review process and have had reregistration decisions made within the last quarter.

For a detailed description of the reregistration process, a Pesticide Reregistration pamphlet is available on request from the Special Review and Reregistration Division (SRRD), Office of Pesticide Programs (OPP). 2/ Other information related to reregistration that will be made available to the public will include:

- Chemical-specific fact sheets summarizing the reregistration decision for each chemical.
- Data tables showing the status of each chemical in the reregistration program.

This report will describe the progress of reregistration in terms of "chemical cases", which are groups of structurally similar chemicals or active ingredients.

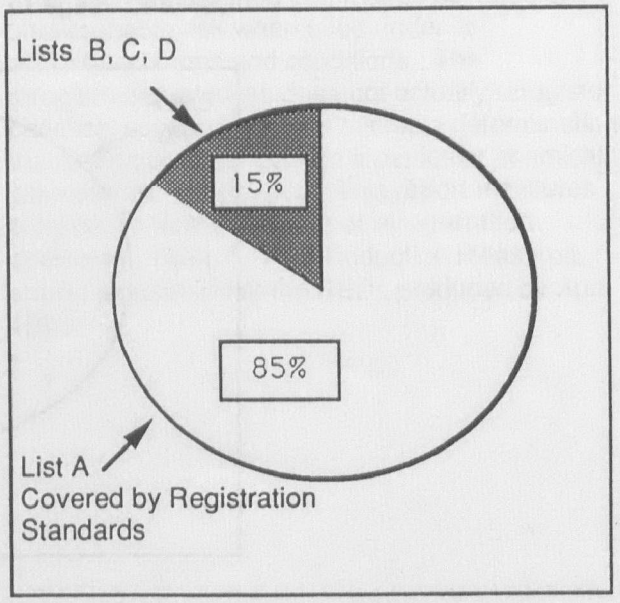
A. FIFRA '88 Reregistration

Prior to the FIFRA '88 amendments, the Registration Standards program was used to conduct a thorough scientific review of the chemical database. This program gave review priority to high-volume and food-use chemicals. By 1988, 194 Registration Standards had been issued on most of the important food-use pesticides and other high exposure pesticides. In 1988, these chemicals represented approximately 85% of the total volume of conventional pesticides manufactured and used in the U.S. annually. 3/ Under FIFRA '88, all chemicals subject to reregistration were divided into four lists. As shown in Figure 1, chemicals covered under the Registration Standards program became List A and the remaining chemicals became Lists B, C, and D. The next two sections of this report describe the current pesticide usage in the U.S. and the status of each list in reregistration.

In October 1988, the President signed into law the amendments to FIFRA which accelerated the reregistration process. EPA was directed to acquire sufficient resources to carry out the task. During the past two years, OPP made a major effort in hiring personnel and acquiring computer systems and office space to enable it to carry out the ambitious reregistration schedule laid out in the FIFRA '88 amendments.

The initiation of the reregistration process resulted in the immediate loss of pesticide products that had little or no recent production. The number of registered pesticide products was reduced from approximately 44,000 to about 23,000 and chemical cases subject to reregistration have decreased from 611 to 417.

Figure 1
1988 Pesticide Usage in the U.S for Conventional Chemicals Subject to Reregistration



B. Current Pesticide Usage in the U.S.

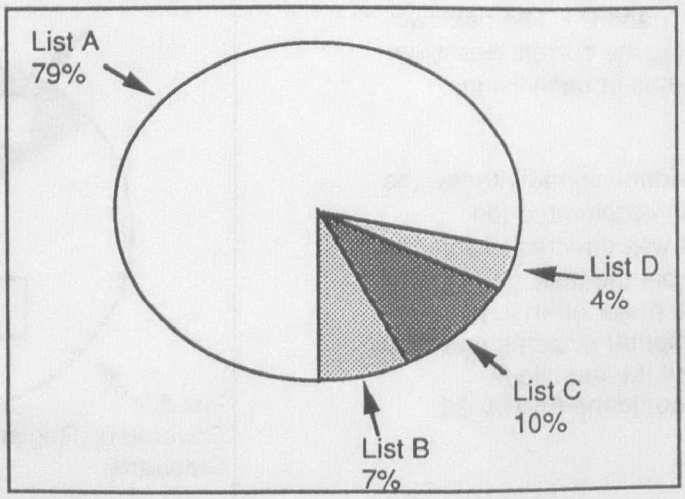
Table 1 shows a breakdown of the current pesticide usage in the U.S. for chemicals still being supported in reregistration. The five general categories include food-use chemicals, chlorine, wood preservatives, bleach, and other uses. This breakdown includes chlorine and wood preservatives which were not included in the 1988 assessment of "conventional" pesticides shown in Figure 1.

Table 1
Pesticide Usage in the U.S. for All Currently Supported Chemicals Subject to Reregistration - March 1991

	Usage Millions of lbs.	% of Use	Number of Cases
Food-Use Chemicals	1,111	17%	232
Chlorine	3,746	58%	1
Wood Preservatives	746	12%	3
Bleach	409	6%	1
Other Uses (including antimicrobials, disinfectants, other indoor and outdoor non-food uses)	431	7%	180
Total	6,443	100%	417

Figure 2 shows a further breakdown by list of the food-use chemicals. While these chemicals make up approximately 17% of total pesticide use, they are represented in 232 chemical cases and are used in the amount of approximately 1,111 million pounds each year in the U.S.

Figure 2
Food Use Chemicals Subject to Reregistration - Current Usage in the U.S.



C. Current Status Of Reregistration

Figure 3 shows the chemical cases in Lists A, B, C, D, and all lists combined as of March 1991. Each column shows the total number of chemical cases with the percentage of cases in each stage of the process. The five phase process described in the Pesticide Reregistration pamphlet has been compressed in Figure 3 into three general stages including Unsupported, Awaiting Data/Data in Review, and Reregistration Decision. While the formal process for List A chemical cases is different than that for Lists B, C, and D, chemical cases go through a similar sequence of events. Figure 4 shows the total number of chemical cases as of March 1991.

The following is a description of each category in Lists A, B, C, and D:

Unsupported:
A chemical case is considered unsupported if the registrant (pesticide producer registering the chemical with EPA) fails to submit the information required by FIFRA '88, or fails to pay the fees to maintain the chemical case. 4/ When a chemical is unsupported, it is slated to 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. Even after a chemical case is initially unsupported, it is possible under certain circumstances for a registrant to support a chemical case by submitting the appropriate data and fees to EPA.

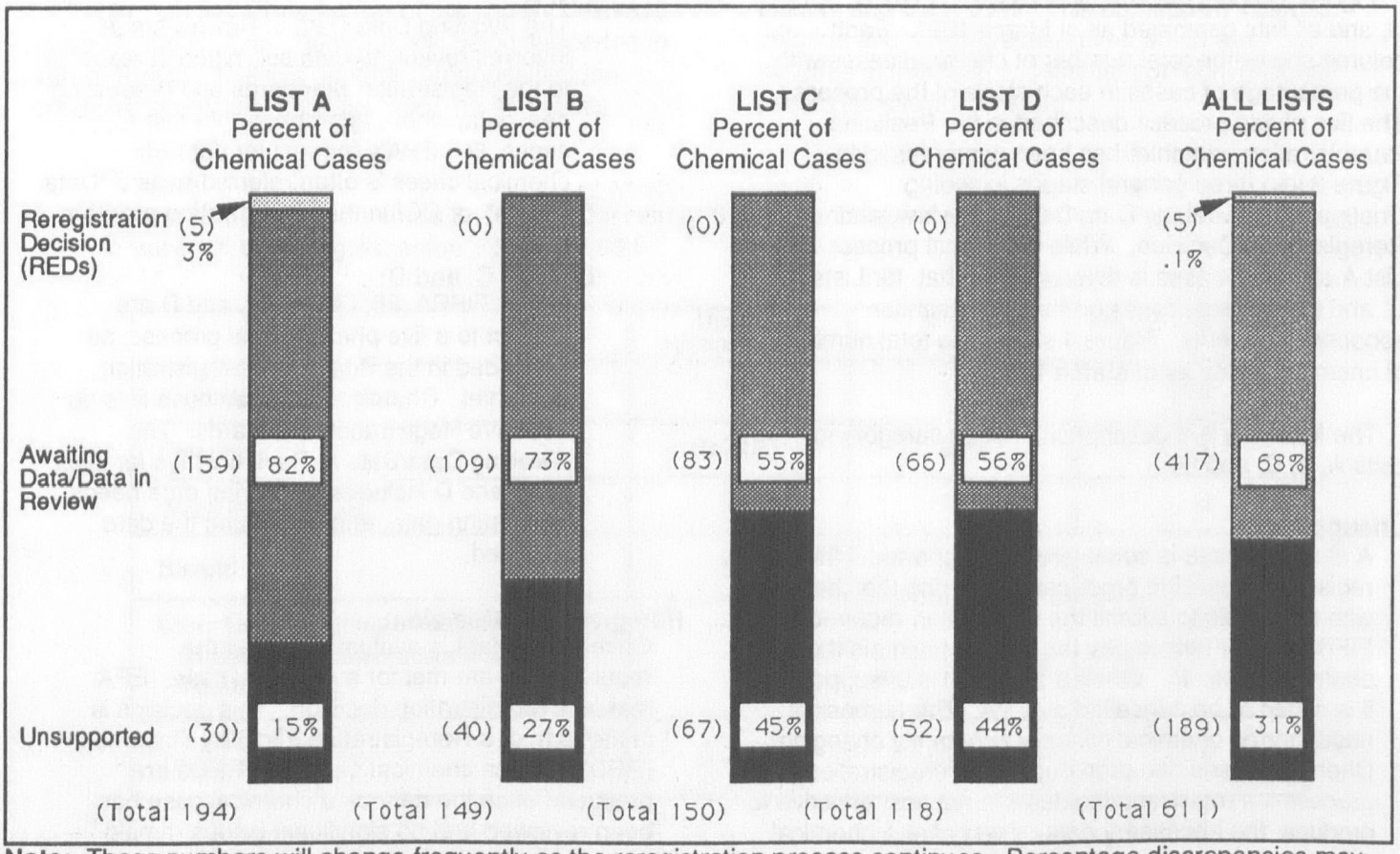
Awaiting Data/Data In Review:
The Awaiting Data/Data In Review category encompasses the entire review process for cases in all lists. As mentioned above, the formal review process is different for List A chemical cases than for Lists B, C, and D. List A chemical cases represent cases that had Registration Standards done prior to the 1988 FIFRA amendments. The Awaiting Data/Data In Review stage for List A and for Lists B, C, and D are briefly described below.

List A:
The Awaiting Data/Data in Review stage involves reviewing data submitted in response to the Registration Standards and requesting new data, where appropriate, for List A cases. 5/ EPA's request for data on chemical cases is often referred to as a "Data Call-In" or DCI in the reregistration program.

Lists B, C, and D:
Under FIFRA '88, Lists B, C, and D are subject to a five phase formal process, as described in the Pesticide Reregistration pamphlet. Chemical cases in these lists do not have Registration Standards. The Awaiting Data/Data in Review stage for Lists B, C, and D includes identifying data needs, requesting data, and evaluating the data received.

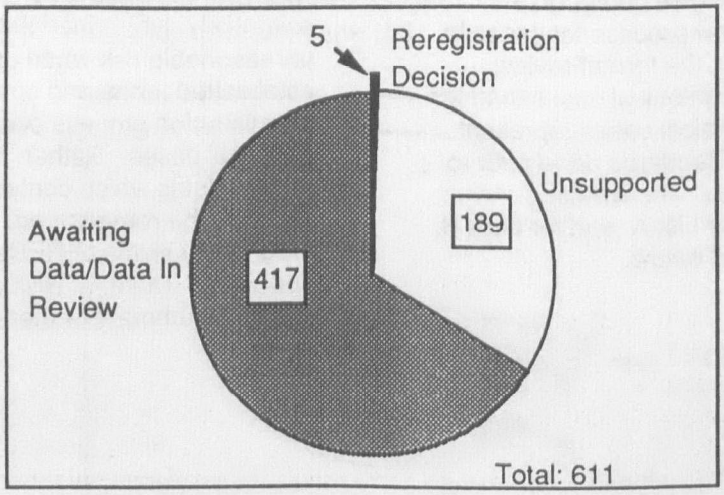
Reregistration Decision:
Once all the data is evaluated and all the requirements are met for a chemical case, EPA makes a reregistration decision. This decision is in the form of a Reregistration Eligibility Document (RED) on each chemical case. 6/ REDs are produced once the data on a chemical case has 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 (i.e. reduction of tolerances), to call in product specific data, or to take other regulatory action. Once a chemical case has a completed RED, EPA has essentially determined that it does not pose any unreasonable risk when used under its established terms and conditions. The reregistration process does not actually reregister chemical cases. Rather, it makes a determination that products which contain a particular chemical case can be reregistered. This report measures progress in terms of REDs or reregistration decisions. Table 4, Risk Reduction Measures, shows a summary of the REDs produced by April 1991.

Figure 3
Current Status of Reregistration - Chemical Cases (March 1991)



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

Figure 4
Total Chemical Cases (March 1991)



D. Data Requirements To Support Reregistration

In order to reregister a pesticide product, FIFRA '88 requires that EPA make a finding that a pesticide and its uses will not cause unreasonable adverse effects on human health or the environment. To make such a finding, EPA establishes data requirements for each pesticide based on its registered uses. EPA is required to specify the types and minimum amount of data and information it needs in order to make regulatory judgements about the risks and benefits of various kinds of pesticide products. The data required by EPA to reregister chemical cases covers five major scientific disciplines which include residue chemistry, environmental fate and groundwater, toxicology, worker and residential, and ecological effects.

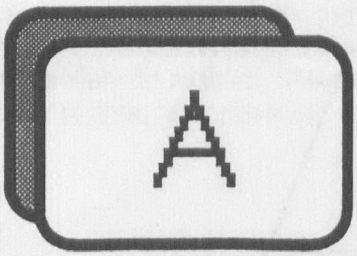
As of January 1991, OPP had received approximately 53,000 studies in response to the FIFRA '88 requirements. Table 2 shows the total number of studies by discipline that EPA collected from 1987 to 1990.

Table 2
Total Number of Studies Collected by OPP

Discipline	Number of Studies
Residue Chemistry	14,159
Environmental Fate	2,832
Ecological Effects	3,215
Toxicology	12,512
Worker and Residential Effects	216

Note: The total number of studies in Table 2 is less than 53,000 as some studies did not meet the specific guidelines, and therefore, are not included in the table.

II. REREGISTRATION PROGRESS



A. List A

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 that were listed in the Federal Register on February 22, 1989. These active ingredients are primarily food-use chemicals. Because a great deal of work had already been done in the List A Registration Standards prior to FIFRA '88, EPA conducted an inventory on List A to identify further actions needed to reregister List A chemical cases. 7/

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

EPA is now identifying List A chemicals which are ready for reregistration review. Reregistration eligibility decisions have been made on five chemical cases.

B, C, D

B. Lists B, C, and D

Lists B, C, and D include the remaining chemical cases subject to reregistration. These chemicals were first registered before November 1984 and did not fall under the Registration Standards program. These chemicals make up 417 chemical cases, including 803 active ingredients, that appear on the three lists. 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 are generally 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.

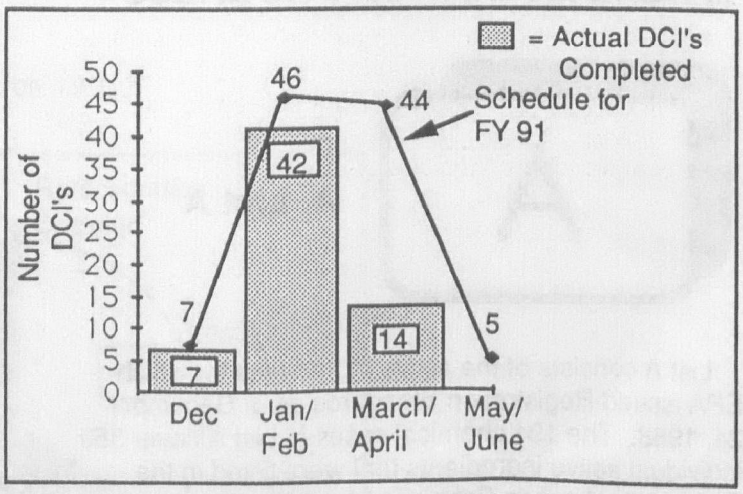
Registrants of products containing Lists B, C, and D chemical cases have submitted their Phase 2 responses indicating the intention to reregister products. These responses identify data requirements, including adequate and inadequate studies of the chemicals, and represent a commitment to fill the data gaps. The submissions for Lists B and C were received by July and October 1989, and those for List D were received by January 1990.

Because Lists B, C, and D did not have Registration Standards, the data needs for these chemicals were significant. A major accomplishment in reregistration has been the collection and management of data from registrants. The request and collection of data is measured in terms of DCIs. The List B DCIs are scheduled to be completed by the end of June 1991. Figure 5 shows the proposed schedule and the actual number of List B DCIs completed by the beginning of April 1991. The schedule is indicated by the line graph. A total of 63 DCIs were completed by the beginning of April 1991, as indicated by the bar graph.

Associated with the data collection was the need to respond to specific concerns and questions of registrants. EPA provided technical guidance instructions and addressed an estimated 17,000 specific comments, questions, and petitions from registrants, as they filed the Phase 2 requirements. Some concerns were related to data waivers, inapplicability of data requirements, and protocols. EPA sent approximately 750 responses addressing comments and concerns of registrants.

One result of the early communication with the registrants was commitments to begin conducting new studies now, rather than wait until the Phase 4 deadline, then approximately two years away.

Figure 5
List B DCI Completion Status (Schedule vs. Actual)



Note: The number of DCIs presented for March/April represent those completed by the first week of April only.

C. Reregistration Eligibility Decisions

C1. Chemical Cases with REDs Scheduled

Since FIFRA '88 was enacted, the reregistration program has experienced a reduction of about 200 supported chemical cases. The number of supported chemical cases is constantly changing as chemical cases become unsupported or have REDs completed. Table 3 shows five chemical cases that had REDs completed by the beginning of April 1991. The five chemical cases are listed, with the number of chemicals (active ingredients) within each case that are eligible for reregistration, and the total number of products that contain the chemical.

Table 3
REDs Completed by April 1991

CASE	Chemicals Completed	Total Products
Sulfur	1	332
Warfarin	2	250
Heliothis NPV	1	1
Methoprene	1	63
Aliette	1	2

Source: Reregistration Eligibility Documents (REDs)

Table 4 shows the risk reduction measures that would result from reregistering the chemical cases according to the REDs. The key below indicates the measures of 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 if a chemical was required to change from unrestricted use to restricted use. 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.

Within Dietary Exposure, the Tolerance Reduction measures required in the REDs indicate where EPA has reduced the maximum acceptable residue level on food products below the existing level (raw agricultural commodities and/or processed food and feed items). The Pre-Harvest Interval Adjustment refers to the amount of time, after pesticide application, that workers can harvest the crop. The adjustment would require a longer period of time to avoid consumer exposure to a concentrated amount of a pesticide on the crop.

Under Non-Dietary Exposure, the three categories of risk reduction measures include Re-entry, Protective Clothing, and Restricted Use. Under Re-entry, a risk reduction measure would result from requiring workers to delay entering a field where crops have been treated with pesticides. Protective Clothing will reduce the risk of exposure to harmful chemicals. Restricted Use requires that the pesticide is applied by a certified applicator or that the use of a pesticide is supported by a certified applicator. Under Environmental Fate and Ecological Effects, Label Modification refers to changes required in a pesticide label.

Table 4
Risk Reduction Measures

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
Sulfur					▨				▨	
Warfarin										
Heliothis NPV			▨ *						▨	
Methoprene			▨ **						▨	
Aliette				▨	▨				▨	

Source: Reregistration Eligibility Documents (REDs)

* Proposed amended language for the current tolerance exemption

** Proposed revocation of tolerance exemptions for mosquito vector control uses

Key: Based on risk assessment

□ — No changes/Not applicable

▨ — Minor changes

▤ — Major changes

Table 5 shows the number of cases with REDs completed by list and the cumulative risk reduction measures required. The numbers in the boxes represent the number of chemical cases that required change. For each list, chemical cases can fall into multiple categories (categories are the same as Table 4). The numbers do not indicate the level of Risk Reduction per chemical case as displayed in Table 4. The first column is the total number of REDs completed to date. All REDs so far have been in List A.

Table 5
Results of Reregistration (Cumulative Summary)

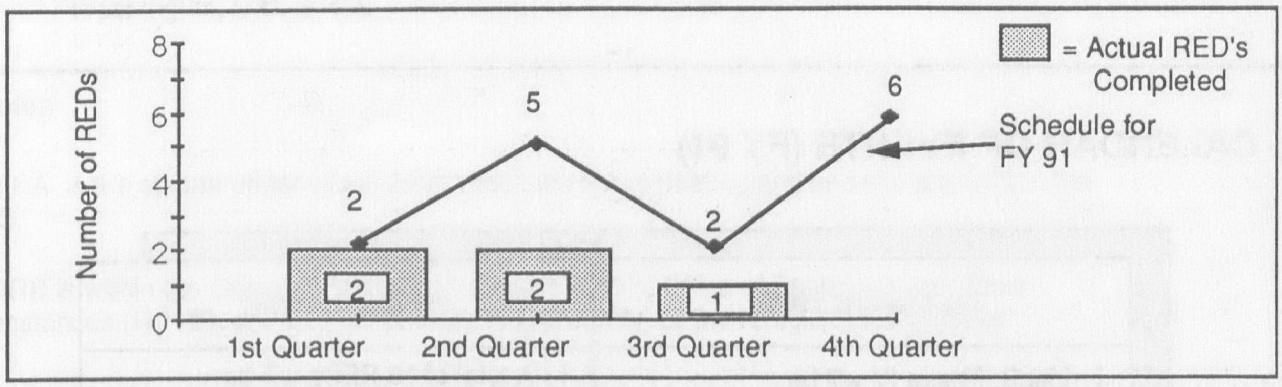
LISTS		Dietary Exposure			Non- Dietary Exposure				Environmental Fate and Ecological Effects		
	Total Cases with RED's	Tolerance Reduction	Pre Harvest Interval Adjustment	Other	Re-entry	Protective Clothing	Restricted Use	Other	Restricted Use	Label Modification	Other
List A	5			2	1	2				4	
List B				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

Source: Reregistration Eligibility Documents (REDs)

C2. Reregistration Eligibility Documents (REDs) Schedule

Fifteen REDs are scheduled for completion by the end of FY 91. Figure 6 shows the REDs scheduled by quarter, and the actual number of REDs completed each quarter. By April 1991, five REDs had been completed.

Figure 6
REDs Scheduled and Completed (FY 91)



Note: Third quarter figure represents submissions only to the beginning of April 1991.

D. Minor Uses

An unfortunate result of reregistration is the potential loss of minor uses. Minor uses include a variety of crops such as daily foods (fruits, vegetables, nuts) and specialty items (flowers, hops, herbs, trees, etc.). Minor use crops collectively account for approximately 35 billion dollars of sales at the farm gate, or one-fifth of the total value of sales by all U.S. producers.

A minor use is generally considered a pesticide use with limited market potential, which does not generate sufficient economic return to the registrant to offset the data development costs for registration or reregistration. Thus, a registrant may choose to delete minor uses from the label rather than provide data to support reregistration.

EPA recognized the minor use reregistration problem and is cooperating with the Interregional Research Project No. 4 (IR-4) program for pesticide minor uses. This program is supported by the U.S. Department of Agriculture (USDA) and is currently identifying and developing data to support minor uses that would otherwise be unsupported.

IR-4 has committed to develop residue chemistry data on about 20 pesticides to support approximately 100 minor uses. They are currently investigating making other commitments on minor uses as the need justifies. In addition, USDA, EPA, IR-4, and the National Agricultural Chemicals Associations (NACA) are working to provide early notification to grower groups of the potential loss of minor uses. Through this network, grower groups will be advised as soon as a registrant decides not to support a pesticide product or use through the reregistration process.

The Minor Uses section of this report will track minor use crops that are supported by the IR-4 project. In March 1991, the early notification network informed grower groups about three chemical cases that were being cancelled. The cancelled cases are shown in Table 6. For further information about these cancelled cases please refer to the following list of contacts.
(**Source**: IR-4 Pesticide Reregistration Alert)

Table 6
Cancelled Cases Affecting Minor Uses

Malathion Ethyl Parathion Methidathion

Contacts

1. Malathion: Malathion Reregistration Task Force: William Steller (609) 799-6315
2. Ethyl Parathion: Kurt Halling (202) 338-3377
3. Methidathion: USDA National Pesticide Impact Assessment Program (202) 447-4751

III. CALENDAR OF EVENTS (FY 91)

3rd Quarter 1991	4th Quarter 1991
1. List B, Phase IV will be completed by EPA by the end of June 1991.	1. A total of 15 REDs will be completed by the end of FY 91.

IV. FURTHER INFORMATION

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

National Technical Information Service (NTIS)
Attention: Order Desk, 5385 Port Royal Road, Springfield, Va. 22161. Tel: (703) 487-4650

IR-4 Pesticide Reregistration Alert
Interregional Research Project No. 4 (IR-4)
McLean Research Laboratory
P.O. Box 231, Cook College, Rutgers University
New Brunswick, NJ. 08903-0231

Pesticide Reregistration pamphlet, April, 1991
Available at NTIS or SRRD

Reregistration Eligibility Documents (REDs)
Sulfur, Warfarin, Heliothis NPV, Methoprene, Aliette. Published REDs are available at NTIS

Federal Register Publications 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,
Washington, D.C. 20402

National Pesticide Telecommunications Network (NPTN)
Phone: 1-800-858-7378; Fax 806-743-3094

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 S.W.
Washington, D.C. 20460

Footnotes

1/ FIFRA is the statute under which EPA regulates the marketing and use of pesticides in the U.S.

2/ SRRD is within the Office of Pesticide Programs (OPP), Office of Pesticides and Toxic Substances (OPTS), and has the primary responsibility for the reregistration process.

3/ Conventional pesticides do not include chlorine or wood preservatives.

4/ There are two types of fees levied on the registrants; maintenance fees and reregistration fees. For a detailed description of these types of fees, refer to the Pesticide Reregistration pamphlet.

5/ The term "data" refers to all studies and summaries of studies pertaining to a chemical case that are required for reregistration. The Data Requirements section of this report lists the types of studies required.

6/ Reregistration Eligibility Documents (REDs) are available at National Technical Information Service (NTIS). See section on Further Information for more details.

7/ The inventory project grouped List A chemicals into one of three categories: no longer subject to reregistration, reregistration queue, and data call-in (DCI).