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Agency

Prevention, Pesticides, And
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Pesticide Reregistration Progress Report

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I. PESTICIDE REREGISTRATION

A. Introduction

The Pesticide Reregistration Progress Report is produced quarterly by the Special Review and Reregistration Division (SRRD), Office of Pesticide Programs (OPP), U.S. Environmental Protection Agency (EPA), to provide information on progress towards pesticide reregistration as mandated under the 1988 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Progress is reported both for the current quarter and cumulatively.

The current report provides the status of reregistration through the second quarter of the 1993 fiscal year (FY 93). The cumulative information is provided in Appendix A, entitled Cumulative Summary of Reregistration Actions.

Over the next few issues, you will notice changes in format and information reported in the Progress Report. These changes are a result of responses, provided by our readers, to our October 1992 Customer Survey. We would like to thank all those who responded to the Survey and hope you are pleased with these and the upcoming changes to the Progress Report. As always, your contributions are appreciated. As a result of the October Survey, we learned that this report is used by many diverse groups for many purposes. We will therefore be presenting a greater variety of material which we hope will be useful to more people.

In addition to a revised format, some of the major changes you will find include:

- Improved Reporting on Reregistration Progress
- Topics of the Quarter
- Appendix A, Cumulative Summary of Reregistration Actions

To provide a better understanding of the reregistration process, we have decided to include reporting by number of studies, products, and active ingredients, where possible. To make the reregistration process more manageable, in 1989, the Agency divided the active ingredients into chemical "Cases". These cases can consist of one or more related active ingredients. Each Reregistration Eligibility Decision (RED) is issued for a chemical case. Therefore, reporting on only REDs does not provide the most complete picture of the current status of reregistration. For example, the 31 REDs completed since 1991 represent a total of 47 chemicals/active ingredients (AIs), 2252 products, and 62 tolerances. It is our goal to provide more information on numbers of active ingredients, studies (total and by discipline), products, and tolerances to our audience.

It is important to note that the numbers are constantly changing. The numbers reported in each Progress Report will be reported as accurately as possible, but they are estimates which change frequently as the reregistration process continues. Please note that percentage discrepancies may result from rounding.

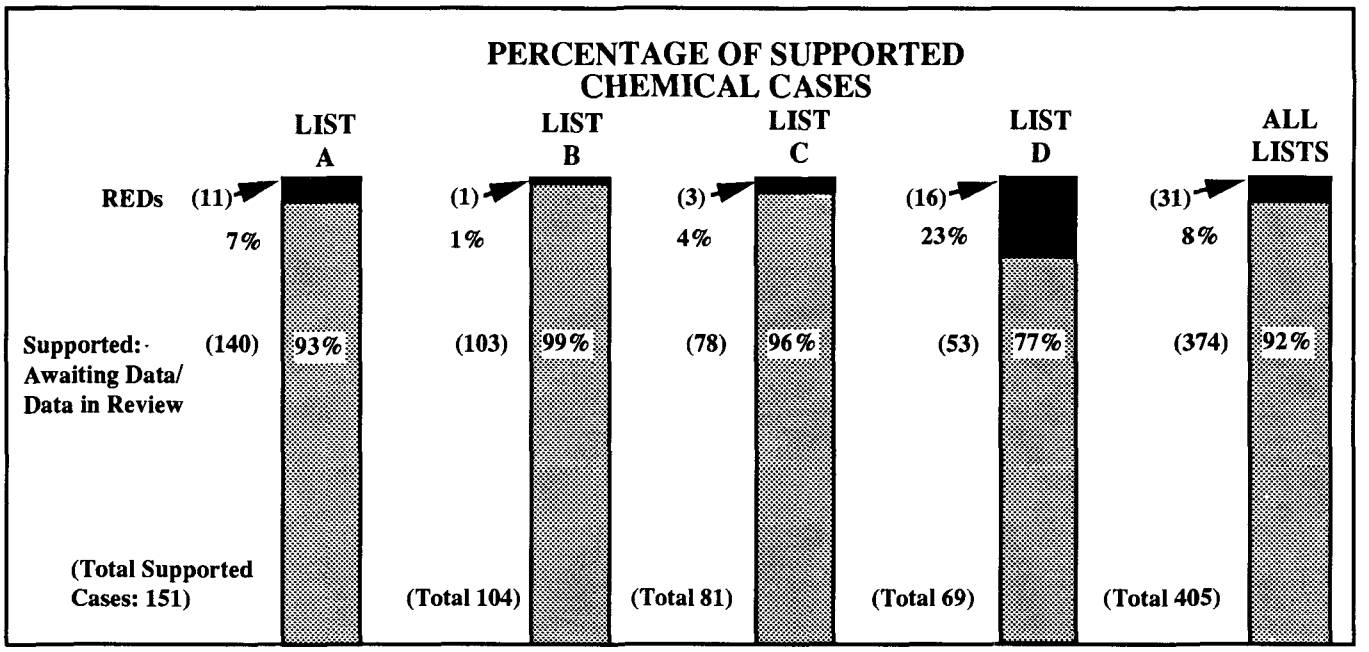
If you have comments, please direct them to Moana Appleyard, Pesticide Reregistration Progress Report, Special Review and Reregistration Division (H7508W), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460.

B. Current Status of Reregistration

Figure 1 shows the status of supported chemical cases in Lists A, B, C, D, and all lists combined through the second quarter of fiscal year 1993. Each column shows the total number of supported chemical cases currently on each list. Also shown are the number and percentages of those cases that have REDs completed and cases that are in the category of Awaiting Data/Data in Review. Of the original 613 cases that were eligible for reregistration in 1988, 206 are not supported by their registrants.

A description of the reregistration process is presented in Appendix C, Technical Terms. A list of REDs can be found in Appendix A, Cumulative Summary of Reregistration Actions.

Figure 1
Current Status of Reregistration - Supported Chemical Cases - Second Quarter FY 93



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

II. REREGISTRATION PROGRESS

A. REDS Completed

This section summarizes the information in the REDs that were completed in the second quarter of fiscal year 1993.

REDs are produced once a substantially complete set of data on a chemical case have been received and 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, to call in product-specific and/or generic data, or to take other regulatory action. When a chemical case has a completed RED, EPA has determined that some or all uses of the active ingredients do not pose any unreasonable risk when used under established terms and conditions of their registrations. Through the reregistration process, SRRD/OPP makes a determination that products which contain a particular active ingredient are or are not 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 the RED.

Iron Salts - This case consists of the three related pesticide active ingredients Iron (III) sulfate, Iron (II) sulfate monohydrate, and Iron (II) sulfate heptahydrate. All three compounds are eligible for reregistration.

The iron salts are used as herbicides to control moss on lawns, turf, ornamental herbaceous plants, woody shrubs, and vines. However, their major use in the U.S. is non-pesticidal, primarily as a fertilizer micronutrient. They also have numerous uses in agriculture, industry, textile manufacturing, water purification, and sewage treatment.

Iron salts occur naturally in the environment. Iron is the fourth most abundant element and the second most abundant metal in the earth's crystal rocks. Iron is present in foods naturally and through ingredients added as flavoring agents and nutrient supplements. Iron salts have an inherent function in the metabolic systems of humans and domestic animals.

The iron salts are of low acute toxicity. Proper use of the iron salts as pesticides should not result in dietary exposure, and should not pose any hazard beyond that from ordinary exposure. Exposure of mixers, loaders, and applicators is considered to be insignificant.

The use of iron salts as herbicides is not expected to contribute significantly to the chemistry and fate of the compounds existing naturally in the environment. No adverse effects to avian, mammalian, or aquatic populations are anticipated. End-use products will be required to bear a statement designed to protect surface waters.

The registered products that contain iron salts as active ingredients will be reregistered once the required generic (Product Chemistry Studies) and product-specific data and revised labeling are received and accepted by the EPA. For additional information regarding the RED, please contact Yvonne Brown at (703) 308-8073. For information concerning product reregistration, contact Joanne Miller at (703) 308-7830.

Hydroxytetracycline Monohydrochloride and Oxytetracycline Calcium - The compounds of this case, which are related to the antibiotic drug oxytetracycline, are registered as pesticides for use in controlling bacteria, fungi, and diseases in pear, peach, and nectarine crops and in palms. They also are added to marine paints to prevent the growth of barnacles. All registered pesticide products that contain these two active ingredients are eligible for reregistration. A third active ingredient in this case, oxytetracycline, has no active registrations. This RED applies to the other two related active ingredients.

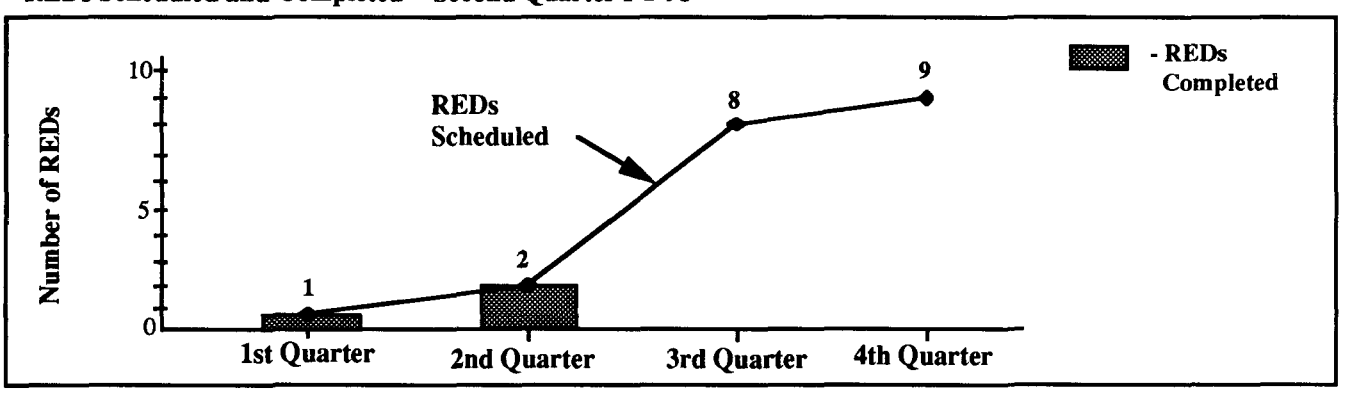
The two compounds are of low acute toxicity. EPA has classified oxytetracycline as a "Group D" carcinogen - one that is "not classifiable as to human carcinogenity" - because of the equivocal nature of the available studies. However, since dietary exposure resulting from the pesticide uses of these chemicals is insignificant, EPA is requiring no further testing, and any risk is expected to be negligible. Applicators' exposure will be limited by appropriate product label directions and precautions. Because of their low toxicity and the low-level environmental concentration expected to result from their use as pesticides, it is unlikely that the two chemicals pose undue risks to non-target organisms.

Registered products containing hydroxytetracycline monhydrochloride and oxytetracycline calcium will be reregistered once product-specific acute toxicity and product chemistry studies and revised labeling are received and accepted by EPA. For additional information regarding the RED, please contact Mario Fiol at (703) 308-8049. For information concerning product reregistration, contact Ben Chambliss at (703) 305-6900.

B. REDs Schedule

Figure 2 shows the REDs scheduled and completed by quarter for fiscal year 1993. In the second quarter, the two scheduled REDs were completed. The two REDs include a total of six chemicals, and cover a total of 12 products. One RED was completed in the first quarter of fiscal year 1993. A total of 31 REDs have been completed to date. Further information about the completed REDs can be found in Appendix A, Cumulative Summary of Reregistration Actions.

Figure 2
REDs Scheduled and Completed - Second Quarter FY 93



C. REDs Candidates for Fiscal Year 1993

Table 1 shows a revised list of preliminary REDs candidates for fiscal year 1993. It is likely that some of these chemicals will be dropped from this list and their completion postponed until the next fiscal year. It is also possible for some chemicals to be added. The target for fiscal year 1993 is a total of 20 REDs.

Table 1
REDs Candidates for FY 93

List A	List C	List D
Daminozide	Hydrometh-N-propanediol	Silver Compounds
Boric Acid	Bromohydroxyacetophenone	Menthol
Glyphosate	Disodium cyanodithioimidocarbonate	Eugenol
Butylate	Biobor	Bromine
OBPA	Lithium hypochorite	Sodium lauryl sulfate
Methiocarb	Cedarwood oil	Sodium bromide/Sodium chloride
	Thymol	
	Furanone	

D. Suspended Chemical Cases

EPA may issue a Notice of Intent to Suspend (NOITS) based on a finding that a registrant has failed to submit data under the requirement(s) of a FIFRA section 3(c)(2)(B) or a 4(d)(6) DCI. Events that may result in the issuance of a NOITS include failing to adequately provide responses on submitted data on time in the reregistration process or during the Special Review process.

Suspension is an Agency action which affects the legal status of a pesticide product registration. After a suspension becomes final and effective, the pesticide registrant subject to suspension may not legally distribute, sell, use, offer for sale, hold for sale, ship, or deliver to any person the product(s) subject to the suspension. The product registration, however, remains in existence.

Suspension of the registration of each product will become final unless, within 30 days of receipt, one of the following actions is taken by the registrant: 1) compliance with the Agency's requirements is shown, 2) the registration is withdrawn, or the use which triggered the requirements is withdrawn, or 3) a hearing with EPA is requested.

EPA's Office of Compliance Monitoring (OCM) has initiated 566 NOITS actions for non-compliance with FIFRA resulting in 145 present suspensions from November 1989 to February 1993. In other cases, various outcomes resulted; for example, suspensions did not occur because data were submitted after the NOITS's were issued, or the matters were settled resulting in data submission.

E. Data Submitted for Reregistration

While EPA has formally evaluated the risks of only 31 chemical cases for which REDs have been completed, the Agency actually has a substantial amount of information on the remaining chemicals. Figure 3 shows the total number of studies received by discipline for List A chemicals.

These studies were submitted in response to the Registration Standards, prior to FIFRA 88, as well as subsequent Data Call-In Notices. Figure 4 shows the total number of studies received so far for List B chemicals in response to Data Call-Ins under FIFRA 88.

Figure 3 - List A Studies Received in Response to Reregistration Standards and Data Call-In Notices by Discipline

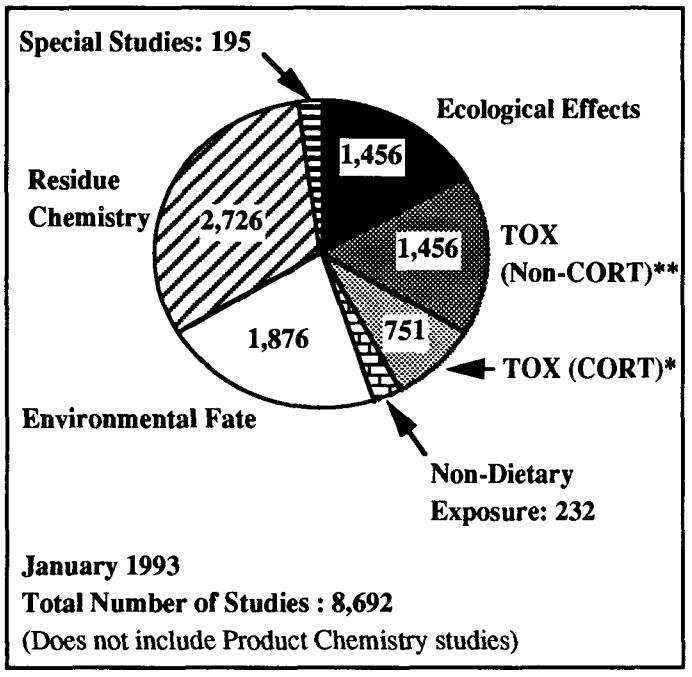
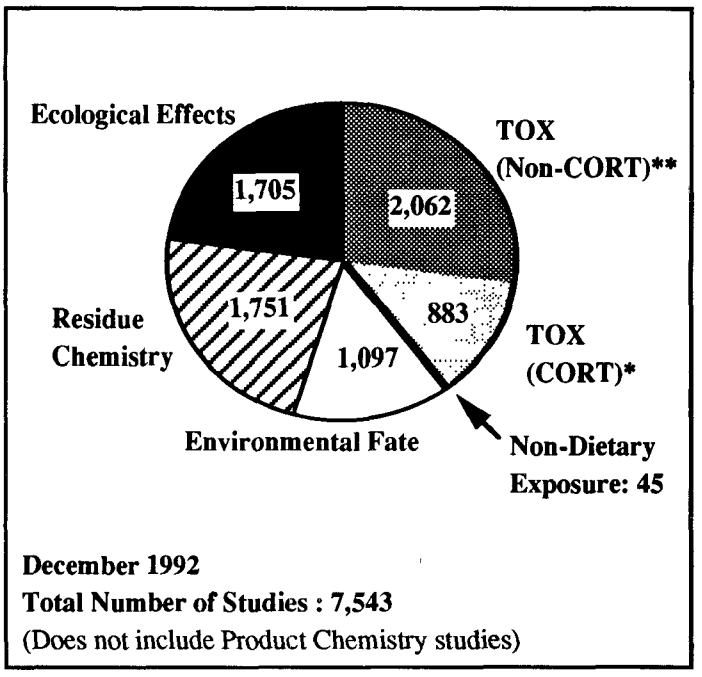


Figure 4 - List B Studies Received in Response to FIFRA 88 by Discipline



* NOTE: TOX (CORT): Chronic Feeding, Carcinogenicity (Oncogenicity), Reproduction, and Developmental Toxicity (Teratology).

** NOTE: TOX (Non-CORT): These studies measure toxicity of pesticides in other than CORT studies.

III. OTHER MEASURES OF PROGRESS

A. Minor Uses

Table 2 provides information from the U.S. Department of Agriculture, National Agricultural Pesticide Impact Assessment Program (NAPIAP). This is a notification network that provides information to interested parties on recent or impending pesticide cancellations. For more information on product cancellation or use deletions, see Section IV.D, Topics of the Quarter. For further information on any of the following pesticides, contact your NAPIAP State Liaison Representative or USDA at (301) 504-8846.

Table 2
Proposed Canceled Uses or Tolerances - Second Quarter FY 93

Chemical	Products	Affected Uses
Arsenic Acid		Cotton
Fluazifop-butyl	Fusilade	Spinach
Sulprofos	Bolstar	Soybeans
Methazole	Probe	Cotton
Zineb		All tolerances for residues in or on agricultural commodities (except grapes for wine use).
Methyl bromide		EPA proposed under the Clean Air Act that methyl bromide importation and production for domestic use be phased out by January 1, 2000. Under the proposal, a freeze at 1991 importation and domestic production levels will be implemented through 1999, until they cease by the year 2000. Use is not affected. Methyl bromide can be used after the deadline if users or producers can find sources of supply through recycling or existing inventories. Export production will be allowed to developing countries if not re-exported. This proposal was published in the Federal Register on March 18, 1993, 58 Fed. Reg. 15014.

B. Rejection Rate Analysis

The Rejection Rate Analysis was developed to address the high rate of rejected studies submitted to OPP during the reregistration process. EPA discovered that the submission of unacceptable studies is the most significant factor in delaying the Agency's REDs. Conducting replacement studies can add several years to the reregistration process.

EPA's study of rejection rates, with the cooperation and active involvement of the pesticide industry, is an intensive effort to analyze rejected studies and understand the reasons for rejection. The resulting reports for each discipline will minimize reoccurrence of study deficiencies as the Agency enters the major data submission phase of reregistration.

The following update on each chapter of the study includes a chart showing the estimated rejection rate for all studies combined in that discipline.

Residue Chemistry Chapter

The Residue Chemistry Chapter was completed in June 1992. Three follow-up guidance documents are part of the Residue Chemistry Chapter including: Guidance for Conducting Plant and Livestock Metabolism Studies, July 1992; Guidance for Storage Stability, Theoretical Concentration Factors, Raw Data Guidance, February 1993; and Guidance on Conducting Rotational Crop Studies, February 1993. For information on obtaining copies, see Appendix B.

Figure 5 indicates that the overall rejection rate for residue chemistry studies reviewed since 1988 studies is estimated at 12%.

Toxicology Chapter

The Toxicology Chapter and charts are in the final draft phase and should be available in the third quarter of fiscal year 1993. In the second quarter, EPA and industry scientists reviewed the latest draft of the chapter and developed action items to be incorporated in the final chapter.

Figure 6 indicates that the overall rejection rate for toxicology studies is 7% and that the rejection rate for supplemental studies is 12%.

Occupational and Residential Exposure Chapter

The Occupational and Residential Exposure Chapter is in the final draft phase and should be available in the third quarter of fiscal year 1993.

In the second quarter, EPA and industry scientists met to review the latest draft of the chapter and to develop action items to be incorporated into the final chapter.

Environmental Fate Chapter

In fiscal year 1992, EPA and industry scientists met to review the latest draft of the chapter and to develop action items to be incorporated in the final chapter. The chapter and charts should be completed in the third or fourth quarter of fiscal year 1993. Figure 7 shows the percentage rate of rejection from pre-1986 to post 1988, as well as the total number of studies reviewed during each of the measured periods.

Ecological Effects Chapter

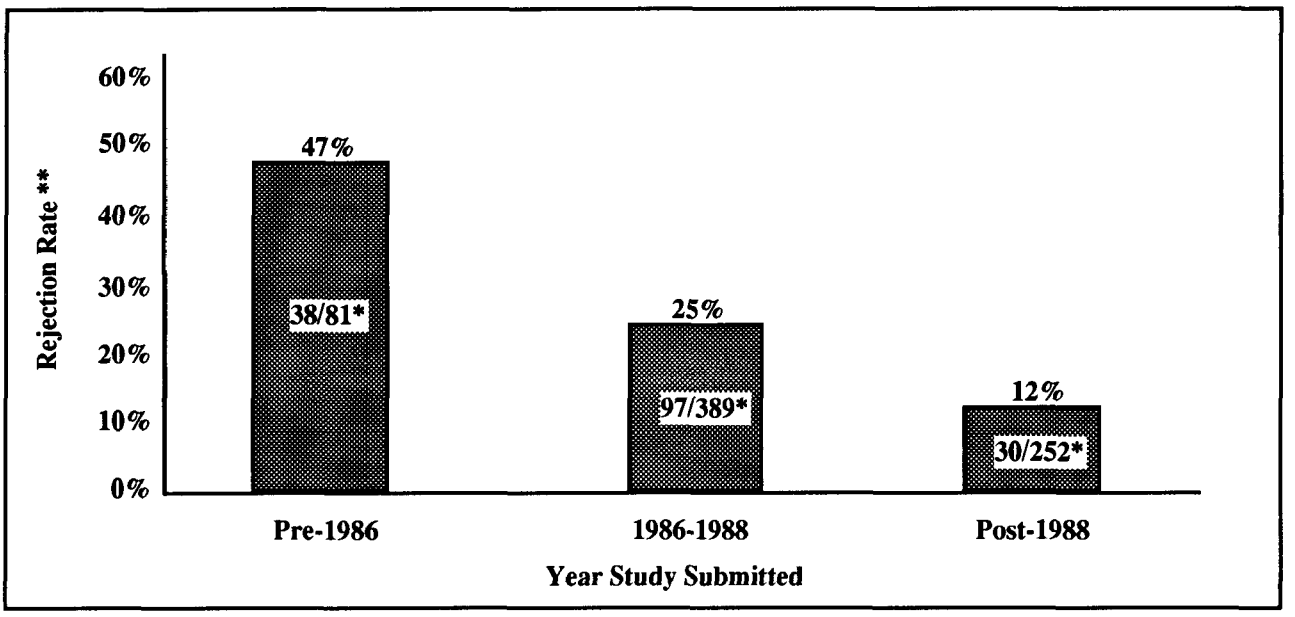
The Agency has compiled the rejection factors for this discipline, which have been commented on by industry scientists. The two parties have not met to discuss the final draft.

The final chapter should be completed in the fourth quarter of fiscal year 1993.

Figure 8 indicates that the overall rejection rate for ecological effects studies submitted since 1988 is 21%.

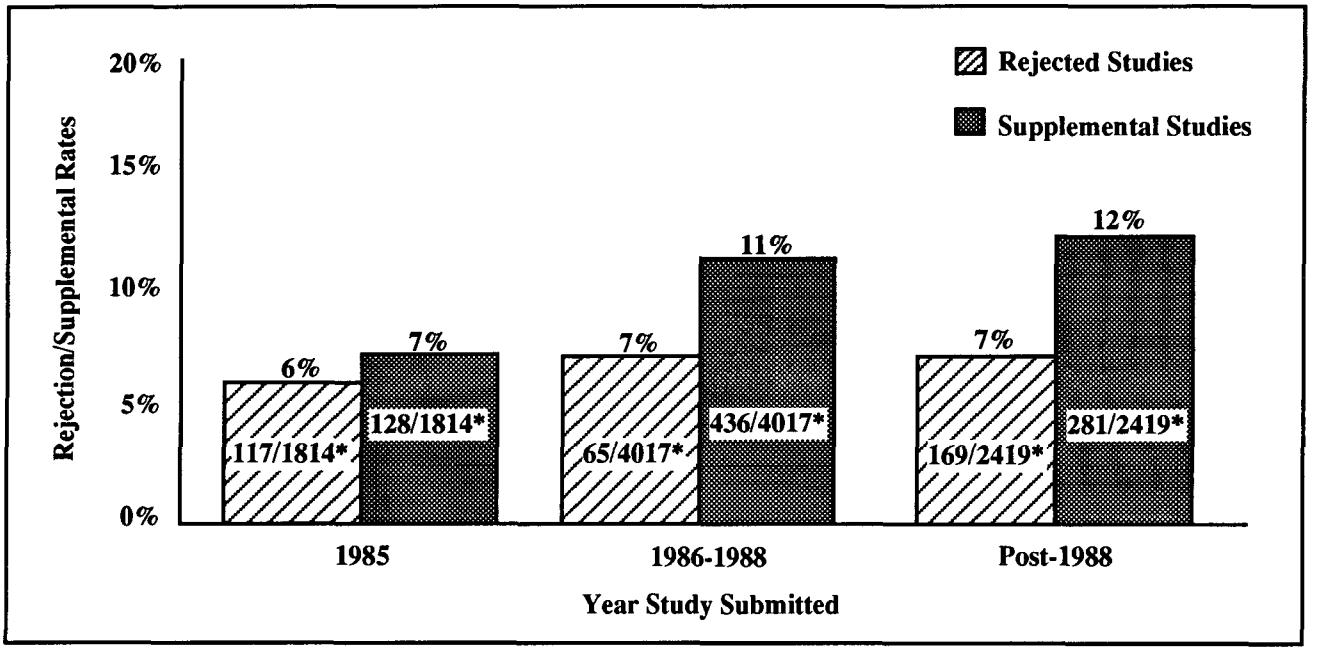
Unless otherwise noted, copies of future Rejection Rate Chapters will be available from U.S. EPA, NCEPI, telephone (513) 891-6561, fax (513) 891-6685. See Appendix B, Other Sources of Information.

Figure 5
List A - Rejection Rates for all Residue Chemistry Guideline Requirements



* Number of rejected studies/Number of studies reviewed
** Of the total studies reviewed for all guidelines, the percentage of studies that were rejected.
NOTE: Rejection rates do not include studies submitted prior to Registration Standards.

Figure 6
Rejection and Supplemental Rates for all Toxicology Guideline Requirements



* Number of rejected studies/Number of studies reviewed
NOTE: Studies reviewed include studies for Lists A, B, C, and D chemicals as well as for chemicals registered after 1984.

Figure 7
Rejection Rate for all Environmental Fate Guideline Requirements

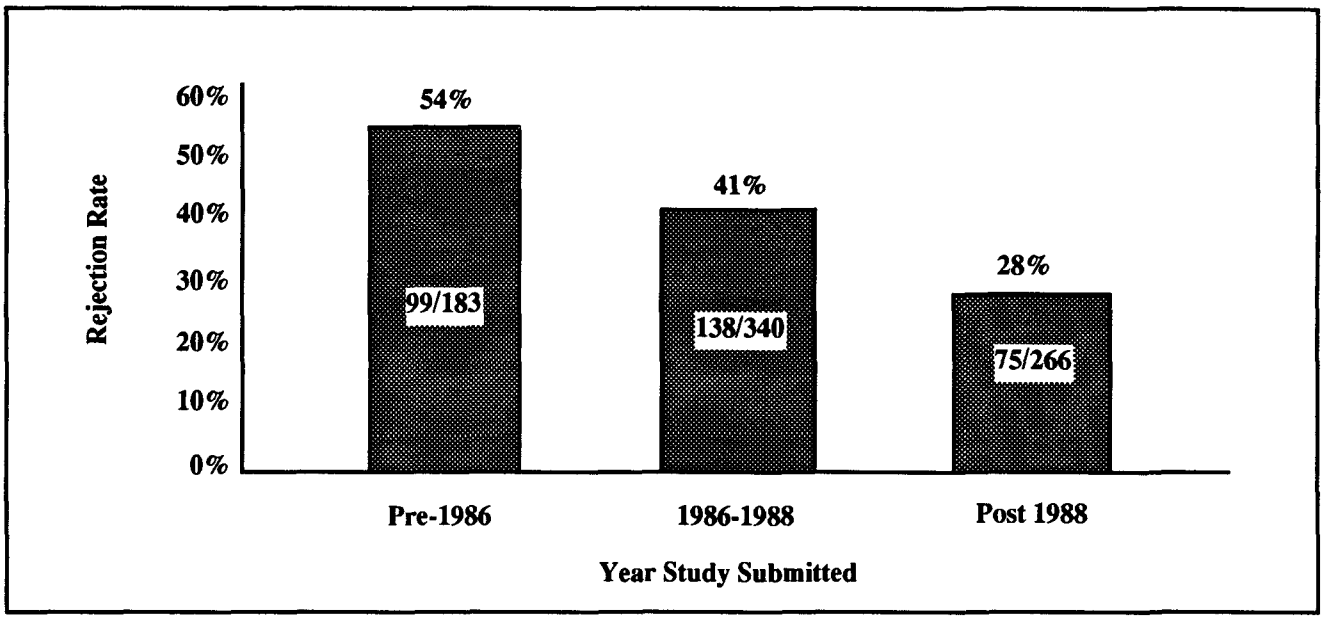
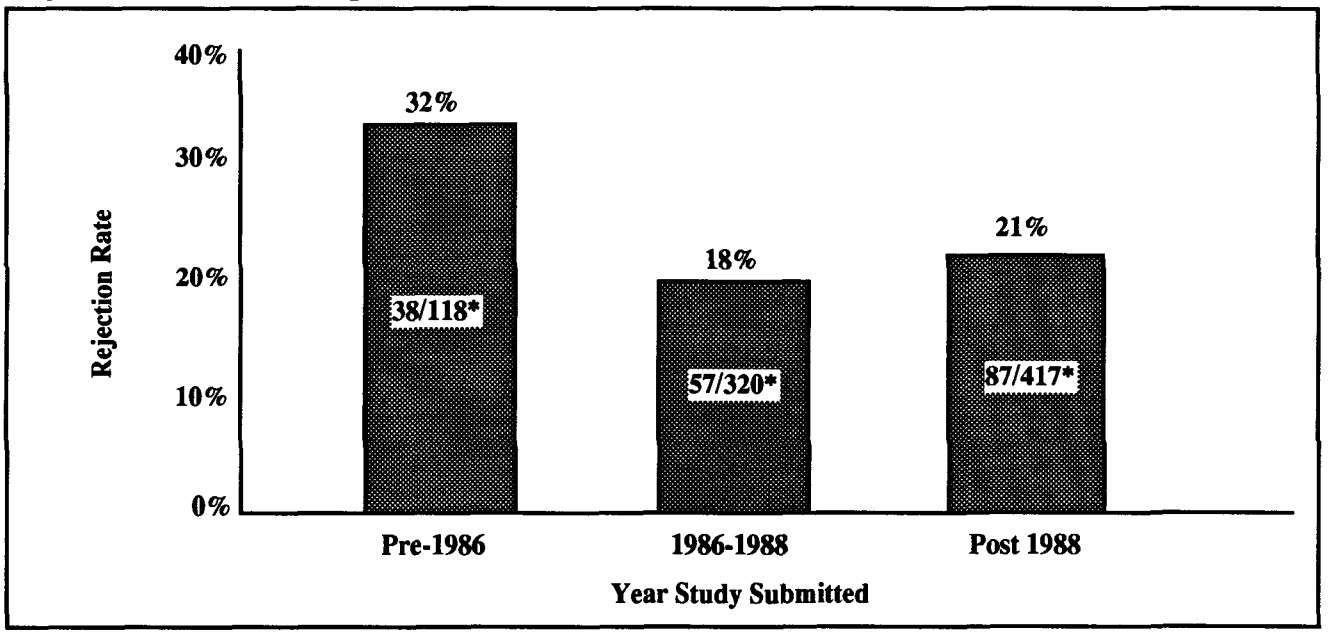


Figure 8
Rejection Rates for all Ecological Effects Guideline Requirements



*** Number of rejected studies/Number of studies reviewed**
NOTE: Rejection rates include List A studies reviewed as of 12/1/92, but do not include studies submitted prior to Registration Standards.

IV. TOPICS OF THE QUARTER

This is a new section that will report on the status of various projects related to the reregistration process. Topics covered in this section are likely to change in every issue, depending on the events that took place during that quarter.

A. Pesticide Reregistration Pilot Program with the Organization of Economic Cooperation and Development (OECD)

Background

An OECD workshop on pesticide reregistration was hosted by the United States on October 26-28, 1992, to explore opportunities for sharing information on reregistration activities and for harmonizing reregistration standards and approaches. At the end of the workshop there was general agreement on the need to increase international cooperation and coordination in reregistration activities. The long-term goal of this work would be for OECD Member countries to share the reregistration burden by agreeing to use each other's reregistration reviews.

As a result of the various workshop recommendations, the OECD has initiated a pilot project to compare, for a selected number of pesticides, the reregistration data reviews done by OECD Member countries or other international organizations.

Objectives of the Pilot Project

The objectives of the pilot project are to:

a) collect general information on pesticide review processes in Member countries;

b) gain an appreciation of the type of data reviews produced (i.e., are reviews reported on individual studies, groups of studies or for all test areas for a given pesticide?);

c) compare documents reviewing the same study or general test area in order to determine where major similarities and differences in scientific review may occur, to identify the basis of any significant difference; and thereby to

d) recommend future work to improve international cooperation and harmonization in pesticide reregistration.

It should be noted that the purpose of the pilot project is not to review data, but to compare existing reviews covering common or substantially similar data submissions on a pesticide.

Pesticides Selected for the Pilot Project

The pilot project is focusing on seven pesticides for which Member countries or international organizations have indicated that recent reviews are available. The chemicals include: Amitraz; Dinocap; Dicofol; Diazinon; Iprodione; Endosulfan; and Pyridate. For the purposes of the pilot project, data reported are limited to reviews concerning the technical active ingredient rather than formulations, except in cases where data are available and reviews have been conducted on formulations only.

Management of the Pilot Project and Roles of Participants

The Secretariat's letter of December 9, 1992 (ENV/D/92.618) invited Member countries to participate in the pilot project and asked them to indicate their level of interest. From the responses received, workgroups and lead countries have been established for each of the seven pesticides selected.

In summary, the role of the lead country is to compare the data reviews submitted by the participating countries, draft a report comparing similarities and differences in review processes and data reviews, incorporate comments on the draft from participating countries, and prepare the final report. Lead countries will also contact the registrants of the pesticides in order to request their support in providing additional information when considered necessary. The role of participating countries is to provide data reviews and information on their review process, and to comment on draft reports prepared by the lead country. Other countries or international organizations indicated that they had data reviews available which they would submit.

Participation of Member countries or international organizations which have not yet responded to the Secretariat's invitation is still possible. Those concerned should directly contact the lead country(ies) of the pesticide(s) in which they have interest.

The United States has agreed to take a lead role in the pilot project for the chemical Endosulfan and questions may be directed to Kennan Garvey of the U.S. EPA at telephone (703) 305-7106 or fax (703) 305-6244.

B. Reregistration Status "Report Card"

In our efforts to improve communications between the Agency and registrants, SRRD is planning to provide each registrant satisfying generic data requirements with a reregistration status Report Card. The Agency will provide a Report Card by individual company for each of their chemicals undergoing reregistration. The purpose of this Report Card will be to facilitate more efficient co-management of the reregistration process. It is hoped that a mutual understanding of the status of a chemical's data base development towards reregistration will result from the registrants' responding with their agreement or disagreement with the Report Card.

The first reregistration status Report Card is scheduled for distribution by the Summer or Fall of 1993. The Report Card will contain information such as:

- chemical and company identifications
- list of required guidelines (both name and number)
- science/regulatory status of each guideline:
  - data gap, due date
  - data received, MRID numbers, and status (e.g., under review, acceptable, upgradeable, deficient)
  - status of guideline (fulfilled or unsatisfied)
  - waiver granted (if applicable)
  - brief description of any significant pending issues
  - Chemical Review Manager's name and phone number and Branch Chief name.

SRRD is working with industry associations to obtain ideas from their members for the first report.

Please take the time to write SRRD with your ideas on the proposed reregistration Report Card.

All comments will be appreciated. Please send comments to the attention of Kathleen Depukat, Report Card Work Group, Accelerated Reregistration Branch, Special Review and Reregistration Division (H7508W), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.

C. Data Waiver Requests

In September 1992, OPP established a committee of representatives from each division to expedite processing of requests for data waivers and time extensions received from registrants during the reregistration data review process. The committee was originally created to reduce the substantial backlog of data waiver requests; however, this expedited review process has now become the standard operating procedure.

Figures 9 and 10 show the pending and completed waivers in List A and Lists B, C, and D respectively. The waiver requests are listed by scientific discipline. For each discipline, the total number of waiver requests processed is divided into completed and pending columns. The pending column represents waiver requests on which the committee has not yet reached a consensus.

Figure 9
List A - Pending and Completed Waiver Requests

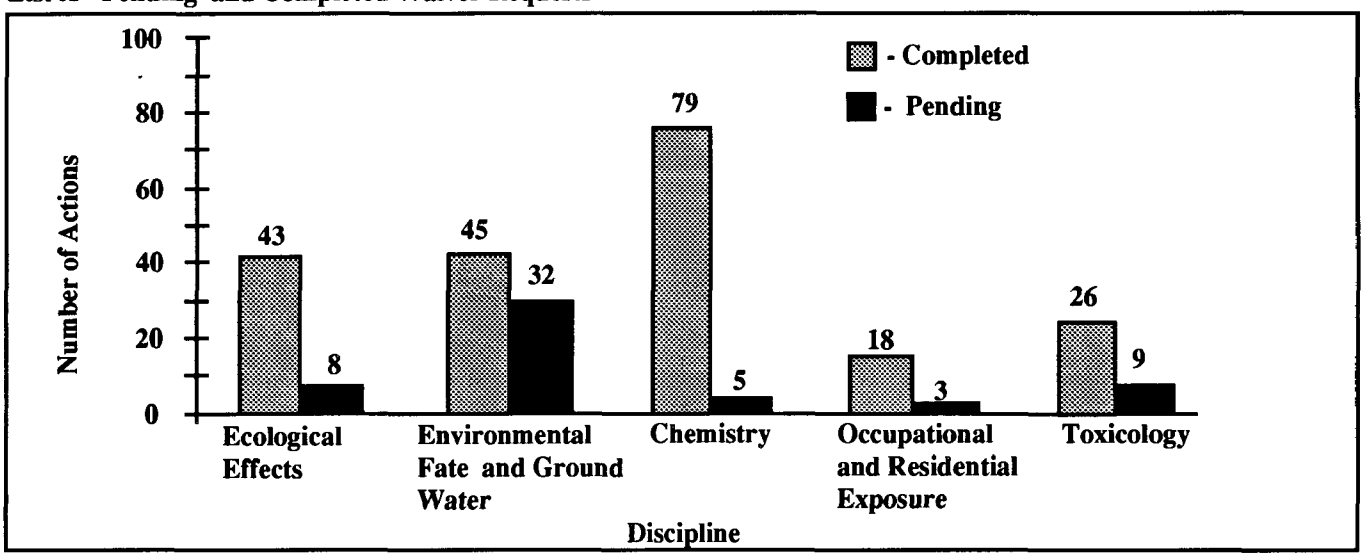
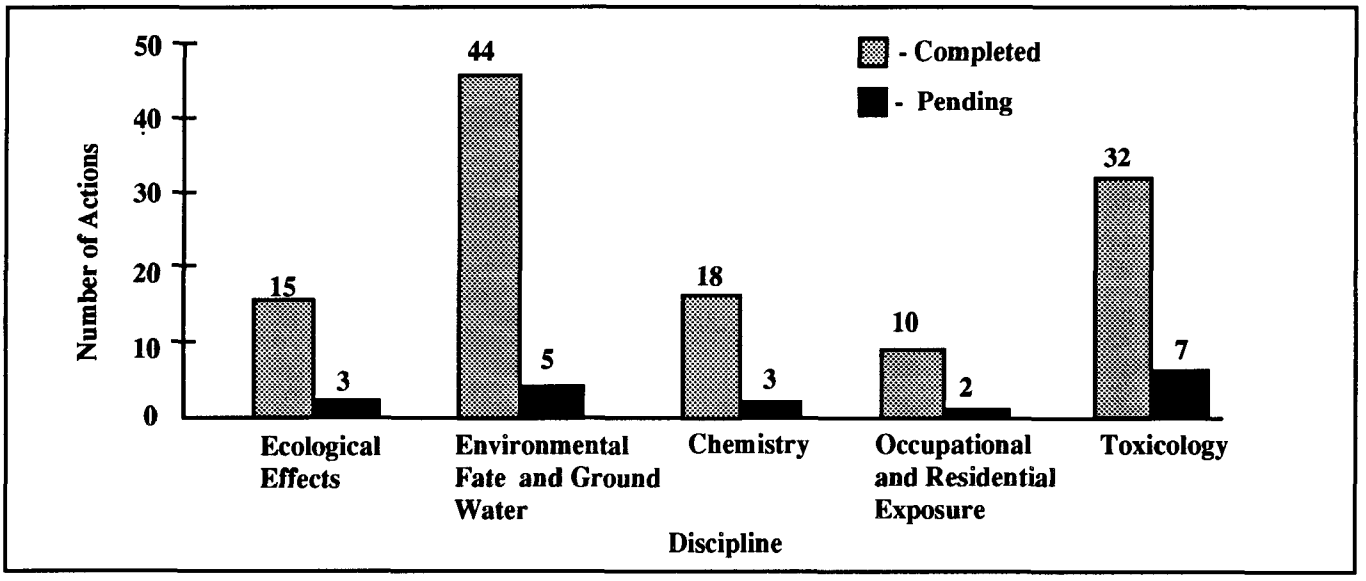


Figure 10
List B, C, D Chemicals Pending and Completed Waiver Requests



***Note: These numbers do not represent the waiver requests for List B, C, and D chemicals that were addressed in Phases 2 and 4.**

D. Product Cancellations or Use Deletions Affecting Minor Uses

The reregistration program mandated by the 1988 amendments to FIFRA has had a significant impact on the number of pesticide registrations. Minor uses are especially vulnerable. Registrants facing difficult reregistration decisions may elect not to support the minor uses for their chemicals due to the costs involved. Growers of minor crops understand the potential effect of losing these important pest control tools. When pesticide users have prior knowledge of the potential loss of a valuable product or use, they may be able to take action to keep the chemical or use. For example, growers have sometimes been able to retain unsupported uses and chemicals. OPP helps the user community in part by providing notification of industry requests for voluntary cancellation of pesticide products or uses.

Once a registrant decides not to support a particular use or to voluntarily cancel a pesticide product, the registrant notifies EPA by sending a letter to the appropriate Registration Division Product Manger. The Product Manager then forwards the letter to our Information Services Branch where a Federal Register notice listing this product or use is drafted. Voluntary cancellation and use deletion notice publications average about one each per month. The Federal Register notice is then circulated to the Registration Division and Special Review and Reregistration Division for review. This review also serves as notification to these Divisions so that they can prepare their records for changes. When these Divisions concur on the notice, it is sent to the Federal Register for publication.

Upon publication, a copy of the notice is sent to the NAPIAP of the United States Department of Agriculture. NAPIAP then notifies each of the State Department of Agriculture Programs which, in turn, notify about 2000 users. In addition, NAPIAP notifies about 200 individuals or organizations with potential interest and the ability to notify additional users. Interested parties have a 90-day comment period specified in the Federal Register notice during which they can persuade either the registrant or another party to retain the use or the product. In some cases, grower groups working with registrants have successfully developed field studies needed to retain important food uses of pesticides, or have themselves become "third party" registrants.

In this report, Section III.A of Other Measures of Progress has NAPIAP's information on proposed cancelled uses or tolerances for the second quarter of fiscal year 1993.

OPP also notifies the public of minor use related actions other than routine voluntary cancellations and use deletions. For this purpose, the Communications Branch of our Field Operations Division maintains a notification list of about 125 organizations.

V. SPECIAL REVIEW DECISIONS

This section summarizes the significant regulatory decisions made on chemicals in the Special Review process during the second quarter fiscal year 1993. The formal Special Review process for chemicals which have met or exceeded risk criteria of unreasonable adverse effects is set forth in 40 CFR Part 154.

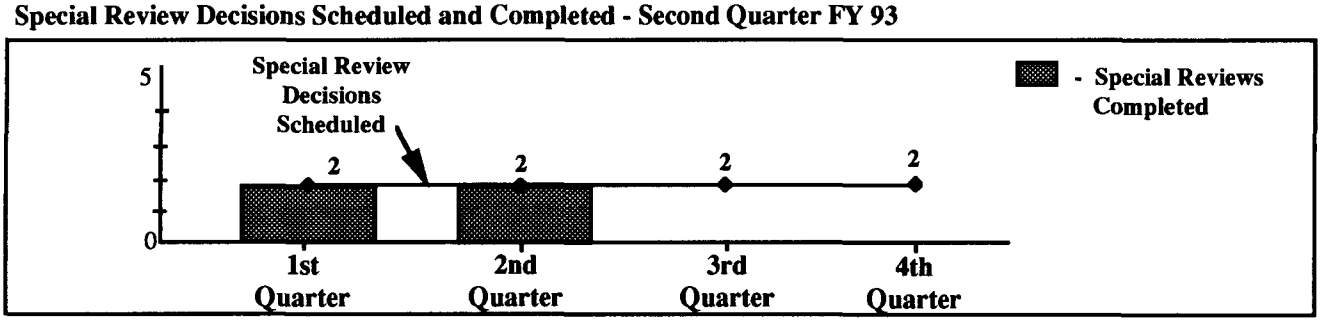
Special Review decisions represent major EPA actions which may ultimately cancel, deny, or reclassify the registration of pesticide products, because uses of the product may cause unreasonable adverse effects on human health or the environment. In addition, Special Review decisions may establish policy or guidelines on which other environmental decisions relating to pesticide registrations are based. For further information on Special Review chemicals, call (703) 308-8010.

Delaney - On January 19, 1993, the Administrator signed a Federal Register notice announcing the receipt of and solicitation of comments on a petition filed by the National Food Processors Association requesting EPA to change its policies related to establishing tolerances for raw and processed foods under the Federal Food, Drug, and Cosmetic Act (FFDCA). In addition, the notice sought comments on a number of related issues raised by the Agency. The petition followed a court decision involving the Delaney Clause of the FFDCA which requires EPA to revoke tolerances for certain cancer-causing pesticides in processed foods. EPA's current policy generally does not allow a pesticide to be used on any raw commodity for which a food additive regulation for a food processed from that commodity is barred by the FFDCA. The petition challenges this policy.

Triphenyltin hydroxide (TPTH) - After risk reduction negotiation discussions with the Agency, the TPTH registrants submitted applications to amend registrations to provide for mechanical transfer or water soluble packages for all applications in the 1994 growing season. In addition, the registrants submitted a draft of their Exposure Reduction Training Program for mixer/loader/applicators for Agency review and committed to develop a new study regarding the dermal developmental effects of this pesticide.

Figure 11 shows the Special Review decisions scheduled and completed, by quarter, for fiscal year 1993.

Figure 11
Special Review Decisions Scheduled and Completed - Second Quarter FY 93



VI. CALENDAR OF EVENTS (FY 1993-1994)

3rd Quarter 1993	4th Quarter 1993
• Eight REDs are scheduled to be completed. • Two Special Review decisions are scheduled to be completed. • The Environmental Fate, Toxicology, and Worker Exposure Chapters of the Rejection Rate Analysis are scheduled to be completed.	• Nine REDs are scheduled to be completed. • Two Special Review decisions are scheduled to be completed. • The Ecological Effects Chapter of the Rejection Rate Analysis is scheduled to be completed. • Phase 4 of Lists B, C, and D is scheduled to be completed.
1st Quarter 1994	
• OPP workshop on pesticide reregistration, registration and special review. With special emphasis on reduced risk pesticides, the revised worker protection standards, the Rejection Rate Analysis, and other key topics.	

VII. UPDATE ON 1992 REREGISTRATION WORKSHOP ACTION PLAN

A. Overview

This section of the Progress Report monitors the Reregistration Action Plan, which was an outcome of the OPP-sponsored Pesticide Reregistration Workshop held on May 26-28, 1992. The actions listed below were raised as concerns within the break-out sessions. All the actions described below are scheduled to be completed within 1993. To date, the Plan is about 65% completed.

B. Study Rejection Rates

See Section III.B, Other Measures of Progress for information on the Rejection Rate Analysis.

C. Ecological Effects and Environmental Fate Data Requirements and Risk Methodologies

Action Plan	Schedule
An Ecological Effects Task Force was established in response to the many issues surrounding ecological effects testing, exposure, and risk assessments.	Completed (See January 1993 Progress Report)

D. Health Risk Data Requirements and Assessments

The following topics and action items are being developed in response to issues raised in the break-out session:

Topic/Action Item	Schedule
1. Cancer Peer Review Process. Peer Review Manual	Summer 1993

Topic/Action Item	Schedule
2. Worker Exposure. Chemical Managers integrate the disciplines related to human health assessment, including the evaluation of worker exposure to determine the need for additional data for risk assessment.	Completed
The Incident Data System (IDS) was developed to track incidents of problems from usage of pesticide products.	Completed
3. Data Requirements for non-food use chemicals.	Fiscal Year 1993
4. Use of Non-Good Laboratory Practices (GLP) data. EPA determines on a case-by-case basis whether non-GLP data should be used to trigger data requirements.	Ongoing

E. Product Reregistration

The following topics and action items are being developed in response to issues raised in the break-out session:

Topic/Action Item	Schedule
1. Impact of product reregistration on normal registration activities. An internal survey has been completed.	Completed (See October 1992 Progress Report)
2. Advance notice of RED for batching labeling. SRRD has developed a list of chemicals that are candidates for reregistration for FY 93.	Completed
3. Which product chemistry requirements must meet GLP? Reregistration Division (RD) has identified which studies must meet GLP requirements.	Completed (See January 1993 Progress Report)

Topic/Action Item	Schedule
4. Time frame to process data requests. RD now responds to waiver requests within 60 days of receipt.	Completed
5. Nominal concentration versus lower certified limit: which should be used? The policy in **PR-Notice 91-2** has been reviewed and will remain EPA's policy on this issue.	Completed
6. Products with multiple active ingredients. An internal Standard Operating Procedure (SOP) has been developed.	Completed (See October 1992 Progress Report)
7. Rules for waiver requests. EPA is working on a statement regarding data waiver requests, including those based on low volume and minor uses.	July 1993 (Scheduled for Progress Report)
8. Labeling for agricultural versus consumer products. EPA's labeling regulations do not distinguish between agricultural and consumer product labeling. However, EPA Product Managers can approve variations in labeling, on a case-by-case basis.	Completed
9. Bridging for acute toxicity data. RD has developed guidance on this issue.	Completed (See January 1993 Progress Report)

F. Grower Groups' Reregistration Issues and Opportunities

The following topics and action items are being developed in response to issues raised in the break-out session:

Topic/Action Item	Schedule
1. Communication.	
List of reregistration chemicals and chemical review manager assignments.	Completed (September 1992)
Work group established within OPP to address reregistration communication issues.	Completed
2. Data Issues.	
EPA is reviewing the economic schemes used to evaluate low volume minor use waiver requests.	Ongoing
EPA is reviewing crop grouping schemes.	Ongoing
3. Resources.	
EPA has reviewed proposals to extend timeframes for data submission to support the reregistration of minor uses as well as the time a chemical could be used on unsupported uses.	Completed
4. Minor Use Chemicals.	
A process to identify critical chemicals by use.	Ongoing

VIII. APPENDICES

Appendix A. Cumulative Summary of Reregistration Actions

The following list is a cumulative summary of the reregistration actions completed to date. OPP has completed summary fact sheets for each of the REDs. Copies of the fact sheets and the REDs may be obtained during the comment period 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) 305-5805. After the comment period, documents are available from the National Technical Information Service (NTIS), Attention: Order Desk, 5185 Port Royal Rd., Springfield, VA 22161 Tel: (703) 487-4650.

CUMULATIVE TOTALS

Total REDs = 31
Total Chemicals/AI's Covered = 47
Total Products Covered = 2,252
Total Tolerances = 62

FY 91 REDs Summary

RED Case Name	List	Date Signed	# Chemicals/AIs Covered	# Products*1 Covered	Total Tolerances
1. Fosetyl-Al (Aliette)	A	12/90	1	2	24
2. Heliothis zea (NPV)	A	12/90	1	1	0
3. Sulfur	A	3/91	1	332	0
4. Methoprene	A	3/91	1	63	23
5. Warfarin	A	6/91	2	76	0
6. Potassium Bromide	A	6/91	1	2	0
7. Sodium and Calcium Hypochlorites	A	9/91	2	770	0
8. Sodium Diacetate	D	9/91	1	2	0
9. Silicon Dioxide/Silica Gel	D	9/91	2	75	0
10. Dried Blood	D	9/91	1	3	0
11. Carbon and Carbon Dioxide	D	9/91	2	9	0
12. Propionic Acid	D	9/91	1	14	0
13. Sodium and Potassium Nitrates	D	9/91	2	6	0
Totals			18	1,355	47

*1 NOTE: The number of products listed reflects the number registered at the time the RED was completed. This number is constantly changing.

FY 92 REDs Summary

RED Case Name	List	Date Signed	# Chemicals/AIs Covered	# Products*1 Covered	Total Tolerances
14. Heptachlor	A	3/92	1	2	0
15. Allium Sativum (Garlic)	D	6/92	1	4	0
16. Putrescent Whole Egg Solids	D	6/92	1	6	1
17. Citric Acid	D	6/92	1	3	0
18. Capsaicin	D	6/92	1	8	0
19. Alkyl Amine Hydrochloride	C	8/92	1	3	0
20. Indole-3-Butyric Acid (IBA)	B	8/92	1	31	0
21. Zinc Salts	D	8/92	2	7	0
22. Sodium Hydroxide	D	9/92	1	9	0
23. Streptomycin	A	9/92	2	26	14
24. Chlorinated Isocyanurates	A	9/92	5	741	0
25. Nosema/Locustae	D	9/92	1	6	0
26. Ethylene	C	9/92	1	8	0
27. Soap Salts	D	9/92	2	25	0
28. Bone Oil	C	----*	1	2	N/A
Totals			22	881	15

* Voluntarily canceled

FY 93 REDs Summary

RED Case Name	List	Date Signed	# Chemicals/AIs Covered	# Products*1 Covered	Total Tolerances
29. Oxalic Acid	D	12/92	1	4	0
30. Iron Salts	D	3/93	3	5	0
31. Oxytetracycline	A	3/93	3	7	0
Totals			7	16	0

*1 NOTE: The number of products listed reflects the number registered at the time the RED was completed. This number is constantly changing.

DATA CALL-IN SUMMARY

Fiscal Year	Number of Cases with DCIs Issued
FY 1990	27
FY 1991	159
FY 1992	97
FY 1993 (Through the Second Quarter)	32
Total	315

Appendix B. Other Sources of Information

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

The following publications are available from:

NCEPI
P.O. Box 42419
Cincinnati, OH 45242-0419
Tel: (513) 891-6561.

- Pesticide Reregistration pamphlet, May 1992
  Publication Number: EPA 700-K92-004

- Rejection Rate Analysis, Residue Chemistry Chapter, June 1992
  Publication Number: EPA 738-R-92-001

- Rejection Rate Analysis
  Residue Chemistry Guidance for:
  Storage Stability
  Theoretical Concentration Factors
  Raw Data Guidance
  Publication Number: EPA 737-R-93-001

- Rejection Rate Analysis
  Residue Chemistry Guidance on Conducting Rotational Crop Studies
  Publication Number: EPA 738-B-93-001

- Rejection Rate Analysis
  Guidance for Conducting Plant and Livestock Metabolism Studies
  Publication Number: EPA 738-B-92-001

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
For information contact: (703) 305-5805

Status of Pesticides in Reregistration and Special Review (Rainbow Report), March 1992
For information contact: (703) 308-8166

Status of Chemicals in Special Review
For information contact : (703) 308-8173

National Pesticide Telecommunications Network (NPTN)
For information about pesticide poisoning symptoms and general information:
Tel: 1-800-858-7378; Fax: 806-743-3094

APPENDIX C. Technical Terms

1. **Formal Pesticide Reregistration Process:**
For List B, C, and D active ingredients:

Phase 1: EPA publishes lists of pesticides.

Phase 2: Registrants decide to support chemicals by agreeing to conduct the required studies.

Phase 3: Registrants summarize and reformat existing studies and certify access to raw data. The registrants flag potential adverse effects data.

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.

2. **Unsupported Chemical Cases**
When a chemical is unsupported, products containing it are proposed for cancellation and may ultimately be canceled by EPA. The number of unsupported chemical cases is constantly changing. Chemical cases often drop out of the reregistration process if a registrant decides it is not cost effective to produce necessary data. However, it is possible for another registrant to support a chemical by submitting the appropriate data and fees to EPA providing the affected registrations are not already canceled. This is considered a "revived case."

3. **Data Call-In**
DCI is a term which refers to EPA's requirement for studies on a chemical case.

Comments

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

Attention: Moana Appleyard
Pesticide Reregistration Progress Report
Special Review and Reregistration Division (H-7508W)
United States Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

For more copies of this report or to be added to the "SRRD MABELS" mailing list, write or fax the following address:

U.S. EPA, NCEPI
P.O. Box 42419
Cincinnati, OH 45242-0419
Telephone: (513) 891-6561
Fax: (513) 891-6685
Publication Number: EPA 730-R-93-001