United States
Environmental Protection
Agency

Prevention, Pesticides, And
Toxic Substances
(H-7508W)

700-R-92-001
April 1992

EPA

Pesticide Reregistration Progress Report

Pesticide Reregistration Progress Report

Resource ID#: 3341

Contents

I. INTRODUCTION

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

This report shows the status of reregistration through the third quarter of the 1992 fiscal year.

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. Definition of Reregistration

On May 22, 1992 SRRD issued the following detailed definition of Reregistration:

I. Introduction

In 1988, FIFRA was amended to accelerate the reregistration of pesticide products containing active ingredients present in products that were originally registered prior to November 1, 1984. The amended Act provided a schedule for the reregistration process, but left many of the details of reregistration unspecified.

An issue basic to successfully carrying out the reregistration program is the definition of when a chemical is eligible for reregistration. This definition describes the criteria that EPA will use in making reregistration decisions under the FIFRA '88 mandate.

II. Background - FIFRA '88 Mandate

Under FIFRA, all pesticides must be registered with EPA before they may be sold or distributed in commerce. FIFRA sets an overall risk/benefit standard for pesticide registration, requiring that pesticides perform their intended functions, when used according to labeling directions, without posing unreasonable adverse effects to public health and the environment.

FIFRA was first enacted in 1947. Thousands of products have been registered since then. However, the standards for pesticide registration have not remained the same, but have evolved in tandem with science and public policy. In particular, test data requirements for pesticides have become increasingly complex in light of advances in such areas as toxicology and analytical chemistry.

To ensure that previously registered pesticides measure up to current scientific and regulatory standards, FIFRA requires the review and reregistration of pesticides. This amended Act dramatically reshaped the process and the pace at which reregistration must be accomplished.

III. Criteria for Reregistration Eligibility Decisions

In the final phase of reregistration, FIFRA requires EPA to review data submitted by registrants and available relevant data concerning an active ingredient of a pesticide and to determine whether pesticide products containing that chemical are eligible for reregistration. That is, before a pesticide product may be reregistered, its active ingredient(s) must be declared "eligible" for reregistration.

EPA has two broad criteria for determining eligibility for reregistration of a pesticide active ingredient:

1) the data base is substantially complete; and

2) based on the data submitted, EPA does not believe that the pesticide causes unreasonable adverse effects to people or the environment when it is used according to its label specifications.

Substantially Complete Data Base
(The Target Data Base)

This first criterion ensures that the Agency has sufficient information with which to conduct a risk assessment on endpoints of concern. In establishing a target data base for reregistration, EPA acknowledges that a fixed set of data requirements may become outdated as scientfic knowledge increases or regulatory requirements change. On the other hand, a moving target of constantly changing requirements makes it difficult to establish objective and consistent criteria for reregistration. Since EPA has an ongoing responsibility to require submission of and assessment of new information concerning potential risks after a chemical is reregistered, the Agency has decided to establish a fixed target data base to be applicable to the current accelerated reregistration efforts.

To support reregistration, the target data base shall consist of all applicable studies, as listed in 40 CFR Part 158, and as further defined in Part B of the Reregistration Phase 2 Response Worksheet (often referred to as Phase 2 Guidance). This worksheet was compiled by EPA to help registrants identify studies that would be needed to support reregistration. It consists of the data requirements of 40 CFR Part 158 and data not currently in Part 158, but routinely required for registration of new products. The worksheet shows how requirements are triggered by the major use groups that comprise the sites registered for pesticide products.

All studies submitted to support reregistration shall be reviewed and evaluated by EPA according to: any product or study-specific protocols agreed to by EPA and the registrant prior to initiation of the study; or according to criteria defined in the applicable published Pesticide Assessment Guidelines, Data Reporting Guidelines, Standard Evaluation Procedures, Pesticide Regulation Notices, and Good Laboratory Practices that were in place at the time of the Phase 2 Guidance, whichever comes later.

The target data base designated for reregistration does not represent the ultimate data base. It does include a significant amount of data and will bring chemicals up to a level which most closely reflects standards applied currently for registration of new products.

The reregistration eligibility decision for an active ingredient will not be delayed by:

1) requirements for submission of non-target data base studies identified by EPA as necessary to support continued registration;

2) acceptability of such non-target data base studies that are submitted and reviewed prior to the target date for the reregistration eligibility decision unless significant issues of health or environmental risk are raised by those studies; or

3) additional data required as a result of changes in guidelines or testing protocols for target or non-target studies, subsequent to initiation of the respective studies, assuming that studies submitted meet their protocols and guidelines as outlined in the second paragraph under "Target Data Base."

For such situations (1 - 3), the additional data requirements must be imposed under FIFRA Section 3(c) (2) (B), independently of the accelerated reregistration data requirements of FIFRA Section 4, and shall not influence or delay the reregistration of the active ingredient, except in cases where significant issues of health or environmental risk are raised.

Completion of Risk Assessment

The data base for reregistration will be considered substantially complete when EPA has sufficient information to make a reasonable worst case risk assessment for all endpoints of concern. This includes higher tier data if, after reviewing the initial data, EPA determines that additional data are necessary for a risk assessment. For example, some required data may not have to be submitted if EPA receives or has comparable information, or if best professsional judgement determines there would be no value added to the risk assessment.

The endpoints of concern are:

For human health effects:
- Dietary risks (food and drinking water)
- Non-dietary risks to mixers, loaders, applicators, other persons potentially exposed.

For ecological effects:
- Toxic effects (including adverse reproductive effects) on nontarget organisms.
- Risks to endangered or threatened species.

For environmental fate:
- The fate, transport, and dissipation of the chemical in the environment.

IV. Outcomes of Reregistration Eligibility Decisions

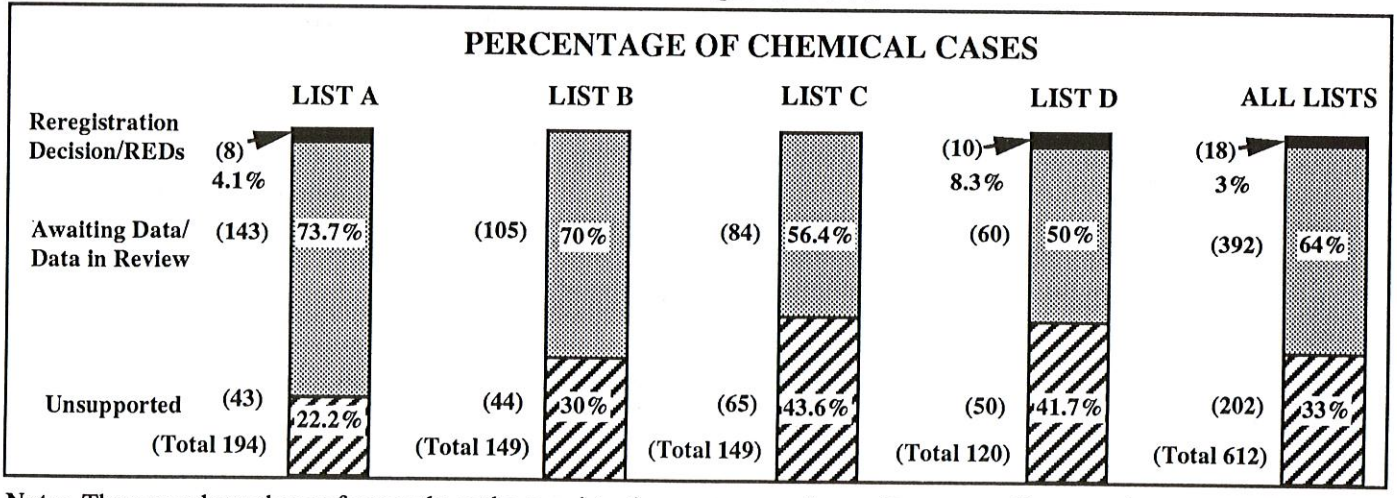
A determination of reregistration eligibility signifies that a rigorous review of the supporting data has been completed and a risk assessment has been done for all endpoints of concern. There are five possible outcomes of a reregistration review:

- Products for all registered uses containing only the one active ingredient are eligible for reregistration and no additional generic data are required.
- Products for all registered uses containing only the one active ingredient are eligible for reregistration but additional data are required to confirm the reregistration assessment.
- Products for some registered uses containing only the one active ingredient are eligible for reregistration; remaining products for remaining uses are not eligible until additional data are submitted, assessed, and deemed adequate.
- No products for any registered uses containing the active ingredient are eligible for reregistration until additional data needed to complete the risk assessment are submitted, assessed, and deemed adequate.
- No products for any registered uses containing the active ingredient are eligible for reregistration because the risk assessment indicates a potential for unreasonable adverse effects.

B. 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 third quarter fiscal year 1992. Each column shows the total number of chemical cases currently on the list, as well as the percentage of cases in each stage of the process. The five-phase process described in the Technical Appendix has been compressed in Figure 1 into three general stages: Unsupported, Awaiting Data/Data in Review, and Reregistration Decision . **B/** A list of all reregistration decisions can be found in Section VII, Further Information.

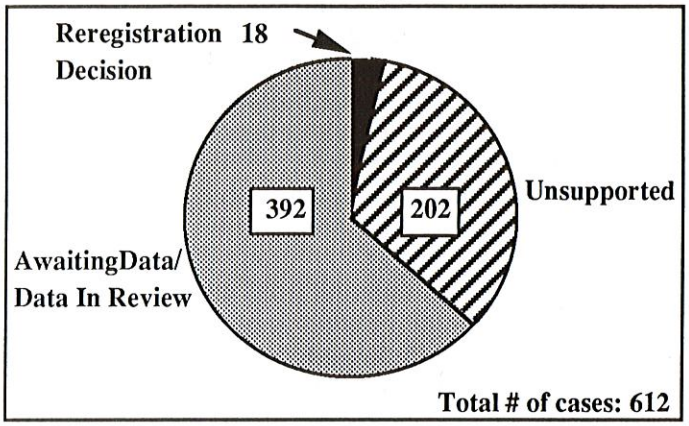
Figure 1
Current Status of Reregistration - Chemical Cases - Third Quarter FY 92



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

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

Figure 2
Total Chemical Cases - Third Quarter FY 92



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

Unsupported

A chemical case is considered unsupported and products containing its active ingredients are canceled if the registrant (pesticide producer registering the chemical with EPA) fails to commit to submit data required for reregistration. This process for requesting data is referred to as a "Data Call-In" (DCI) request. **D/**

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 and issues a Reregistration Eligibility Document (RED). This progress report tracks the number or REDs issued.

For the current status of chemicals in the Reregistration Program, consult the Rainbow Report. **E/**

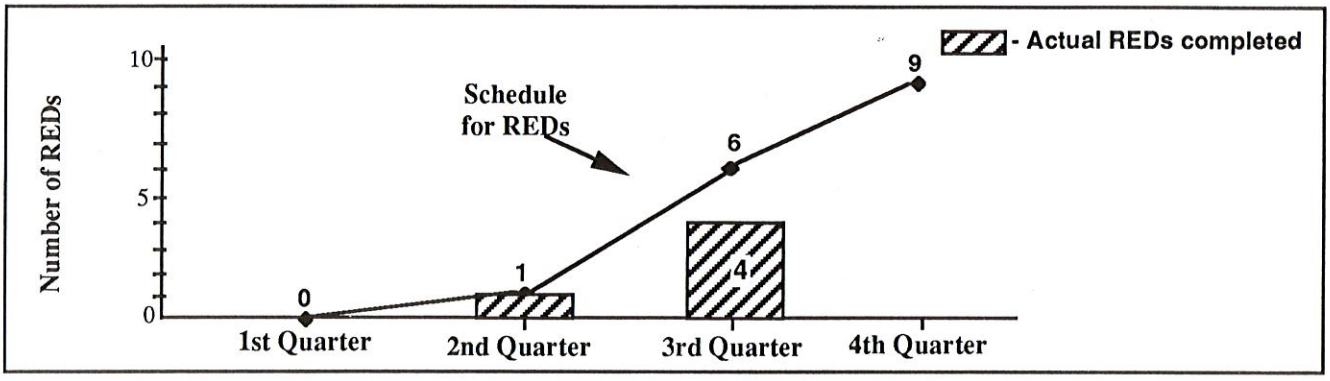
II. REREGISTRATION PROGRESS

A. REDs Schedule

Figure 3 shows the REDs scheduled and completed by quarter for fiscal year 1992.

Four REDs were completed in the third quarter fiscal year 1992. A total of 18 REDs have been completed to date.

Figure 3
REDs Scheduled and Completed - Third Quarter FY 92



B. Chemical Cases with REDs

Table 1 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 degree of change. The table summarizes the risk reduction measures with regard to dietary exposure, non-dietary exposure, and environmental fate and ecological effects. F/

Table 1
Risk Reduction Measures Brought About by the REDs Completed - Third Quarter FY 92

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
Allium Sativum										
Putrescent Whole Egg Solids										
Citric Acid										
Capsaicin										

Source: Reregistration Eligibility Documents (REDs)
Key: Based on risk assessment

☐ — **No changes/Not applicable**
▨ — **Major changes**
▩ — **Minor changes**

Table 2 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. Since for each list, chemical cases can fall into multiple categories, the numbers in the risk reduction columns may not equal the total number of cases. For example, a single 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 2
Results of Reregistration (Cumulative Summary) - Third Quarter FY 92

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	8			4	1	3		2		7	
List B											
List C											
List D	10				1	3				6	
Total	18			4	2	6		2		13	

Source: Reregistration Eligibility Documents (REDs)

C. Minor Uses

Table 3 provides information from the U.S. Department of Agriculture, National Agricultural Pesticide Impact Assessment Program (NAPIAP). This is a reregistration notification network that provides information to interested parties on recent or impending pesticide cancellation. For further information on any of the following pesticides, contact your NAPIAP State Liaison Representative or the USDA at (301) 504-8846. G/

Table 3
Proposed Canceled Uses - Third Quarter FY 92

Chemical	Products	Affected Uses
Anilazine	Dyrene	Celery, Cucumber, Gladiolus, Green Onions, Lawns and Turf, Potatoes, Strawberries, Summer Squash, and Tomatoes
Fluvalinate	Spur	Alfalfa, Asparagus, Beets, Broccoli, Brussels Sprouts, Cabbage, Carrots, Cauliflower, Collards, Fruit Trees, Kale, Lettuce, Nut Trees, Onions, Parsnips, Radishes, Rutabagas, Spinach, Sugar Beets, Swiss Chard, Tobacco, Turnips, Vineyards
Simazine	Aquazine, Princep	All aquatic uses, Non-cropland, Asparagus, Artichokes, and Sugarcane

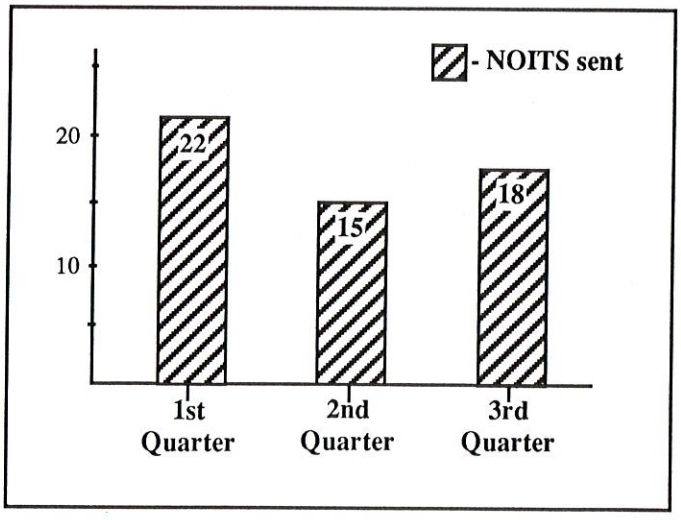
Correction Note: The April 1992 issue of the Pesticide Reregistration Progress Report made an error in listing the nine remaining uses of Parathion in the Minor Use Table (Table 3, page 4) as proposed to be canceled. Those uses including alfalfa, barley, canola, corn, cotton, sorghum, soybeans, sunflowers, and wheat, make up the only remaining uses of the product Ethyl Parathion. In the same table of the same issue, the Tobacco Dust should have been listed as the chemical, while Nicotine should have been listed as the product. For further information call: (703) 308-8175.

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 any of the data requirements in Phases 2, 3, 4, and 5 of the reregistration process.

Table 4 shows all suspension notices sent out by OPP in FY 92. A total of 18 NOITS's were sent out in the third quarter. The 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.

Table 4
Suspension Actions in OPP FY 92



III. OTHER MEASURES OF PROGRESS

A. Rejection Rate Study

Rejected studies have been identified as being the most significant factor in delaying the reregistration of pesticides as mandated under the FIFRA '88 Amendments. Completion of a Reregistration Eligibility Decision (RED) (a formal determination that a pesticide is safe for use on one or more use sites) requires that reasonable risk assessments be performed for all relevant human health and ecological end points for each chemical. These risk assessments require a "substantially complete" data base composed of acceptable quality studies.

In order to reduce the current high rate of study rejections, the Office of Pesticide Programs in conjunction with industry scientists have undertaken an effort to identify the underlying causes, understand why they occur and determine how best to address each problem. OPP staff, for the past year, have been conducting a guideline-by-guideline assessment of rejected studies to identify those factors that most frequently have caused studies required for reregistration to be rejected. This information will enable OPP to (a) provide registrants with the information on rejection factors to minimize their recurrence in future studies, (b) reassess the adequacy of existing guidance, (c) determine the appropriate regulatory response to a future rejected study, and (d) make any internal changes in process, procedures, or criteria deemed appropriate.

Teams of registrant scientists have been organized to review the rejection factors for each discipline, explain what are the underlying problems causing the occurrence of each rejection factor, provide an assessment, from a users perspective, of the adequacy of the existing guidance that addresses each rejection factor and suggest how best to resolve each problem. OPP considers all of this information in determining what changes in guidance, process, or procedures is most appropriate. These changes are then implemented.

To date, the Residue Chemistry chapter has been completed. The Environmental Fate and Worker Exposure chapters should be completed this summer, and the Toxicology and Ecological Effects chapters are scheduled for completion this fall.

This project is an effort to implement total quality management principles and procedures. In essence, it is an effort to lay out the data production process for reregistration, use quantitative analysis to identify problems in the production process, identify and involve users (in this case the registrant scientists who use EPA guidance to conduct the required studies) in the problem identification and problem resolution stages, and implement those changes deemed most appropriate to address each problem. A significant reduction in rejection rates is necessary if the Agency is to meet the statutory mandates imposed in the FIFRA '88 Amendments.

In conjunction with the Rejection Rate Study, OPP is encouraging individual industry firms and related organizations like IR-4 to conduct assessments of their own rejection rates. EPA believes that this voluntary commitment will contribute to lower rates of rejected studies for individual firms as well as contribute to the overall lowering of the rejection rate for the reregistration program.

The following firms have committed to conduct their own rejection rate analysis:

1. **Rhone Poulenc**
2. **Nor-Am**
3. **ICI**
4. **CIBA-GEIGY**
5. **Miles (Mobay)**
6. **Monsanto**
7. **IR-4**
8. **Rohm & Haas**
9. **Dupont**
10. **Cyanamid**
11. **Hazleton**
12. **ABC Laboratories**
13. **ETI**
14. **DowElanco**
15. **ISK BIOTECH**
16. **Sumitomo/Chevron/Valent**
17. **Uniroyal**
18. **FMC**

EPA commends these firms for their commitment to lowering the rejection rate and welcomes any other firms to join in the effort. For firms interested in conducting their own rejection rate studies, EPA suggests that they follow procedures similar to those used in the Agency's rejection rate report. These procedures are as follows:

1) assess the data evaluation records (DERs) for your rejected studies;
2) extract from each DER the factors that caused that study to be rejected;
3) for each guideline, tabulate the rejection factors and rank them in order of frequency of occurrence;
4) use the Agency's individual rejection rate chapters to help address the problems that you have identified, and
5) develop and implement your own quality improvement strategy. For more information call (703) 308-8000.

IV. SIGNIFICANT REGULATORY DECISIONS

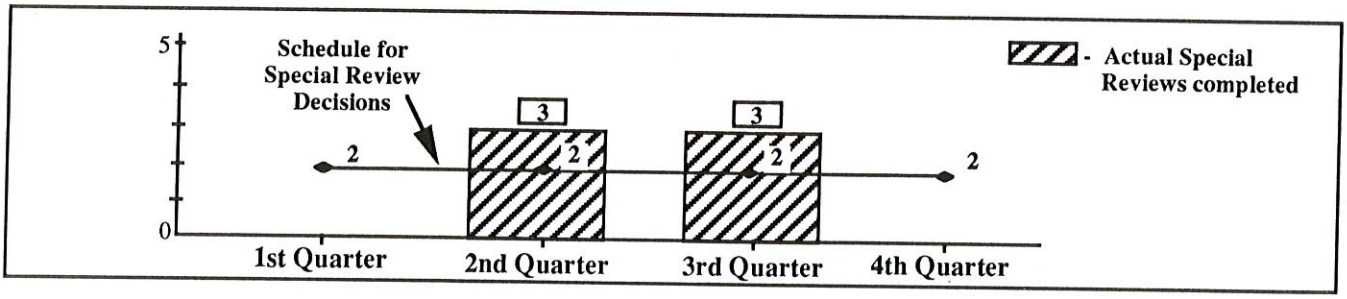
This section gives a summary of significant regulatory decisions made on Special Review chemicals in the third quarter fiscal year 1992. The Special Review process for chemicals which have met or exceeded the risk criteria of unreasonable adverse effects is set forth in 40 CFR 154. For further information on Special Review chemicals, call (703) 308-8010. H/

Methyl Bromide - The Agency announced on April 3 that a voluntary agreement had been reached with the registrants and manufacturers of methyl bromide to amend the labels for products used to fumigate domestic dwellings for control of wood-destroying structural pests. The amendments are aimed at reducing risks to occupants returning to homes after treatment with methyl bromide. Results of monitoring studies have indicated that levels of methyl bromide tend to rise after structural treatment and may require several days for the levels to dissipate completely. The increase in levels of the gas may pose unacceptable risks to those who reenter structures before the gas has completely dissipated. The label amendments will reduce possible exposure to the residual gas by requiring applicators to aerate homes and structures for 72 hours to 7 days after the tarp is removed, depending on aeration methods used and test results before reentry. Applicators are also required to provide occupants of fumigated structures with information explaining the potential hazards of methyl bromide fumigation.

Atrazine - On April 3, the Agency reached agreement for voluntary risk reduction label amendments for atrazine products. The amendments will serve to reduce surface water contamination by lowering the maximum application rate for corn and sorghum, deleting non-crop industrial uses (highways and rights-of-way), requiring a 50 feet set-back from lakes and reservoirs for mixing/loading, requiring a 200 feet application set-back from lakes and reservoirs, and a 66 feet application set-back from points where field run-off enters streams and rivers. The set-backs must be vegetated if the soil is highly erodible. When properly designed and installed according to Soil Conservation Service requirements, these vegetated filter strips may qualify the grower for financial assistance under the Conservation Reserve Program administered by the United States Department of Agriculture (USDA). The label amendments are to be effective for the 1993 growing season.

Avian Granular Analysis - The Agency published a Federal Register notice on May 29 announcing the availability of The Comparative Analysis of Acute Avian Risk from Granular Pesticides. The Analysis describes the Agency's approach for screening granular pesticides to identify those that may pose acute lethal risk to birds. Pesticide toxicity and exposure were factors used to identify 14 pesticides of concern for potentially high risk to birds. They are aldicarb, bendiocarb, carbofuran, chlorpyrifos, diazinon, disulfoton, ethoprop, ethyl parathion, fenamiphos, fonofos, isofenphos, methomyl, phorate, and terbufos. As follow-up to the notice of availability, on June 19 the Agency met with major producers of the chemicals identified in the Analysis to encourage them to consider risk reduction measures which may help mitigate possible avian risks by lowering availability of the toxicant to birds and to assess data needs to support the measures or further define the risk. All registrants have indicated their intent to submit voluntary label amendments by August 20.

Figure 4
Special Review Decisions Scheduled and Completed - Third Quarter FY 92



V. CALENDAR OF EVENTS (FY 92/93)

4th Quarter 1992	1st Quarter 1993
1. A total of 16 new REDs are scheduled to be completed by the end of the fiscal year. 2. A total of 8 Special Review decisions will be completed by the end of the fiscal year. 3. Environmental Fate and Worker Exposure chapters of the Rejection Rate Analysis will be completed.	1. The International Pesticide Reregistration Workshop will be held. **I/** 2. The Ecological Effects and Toxicology chapters of the Rejection Rate Analysis will be completed.

VI. REPORT ON THE PESTICIDE REREGISTRATION WORKSHOP

SRRD held the second Pesticide Reregistration Workshop in Arlington, Virginia from May 26-28, 1992. The workshop provided an overview of the reregistration program and an update on its current status.

Each break-out session provided an opportunity for discussion of problems, issues, and solutions. This information from these sessions was captured and discussed during a plenary session at the end of the workshop. The following discussion includes a brief summary of the break-out sessions, key issues identified in each session, and action items which address the issues.

Break-out Session #1 - Study Rejection Rates

This session concentrated on the preliminary results of OPP's study designed to identify the factors that most frequently cause required studies to be rejected.

As part of this session, EPA scientists and an industry representative discussed the first chapter of the Rejection Rate Study, which reports on residue chemistry.

The purpose of this study is for OPP to:

- provide registrants with information on reasons studies are rejected to minimize their recurrence;
- reassess the adequacy of its guidance available for each guideline requirement;
- make any appropriate internal changes in the review process, procedures, or criteria.

The breakout session also involved a discussion of some of the specific factors that have led studies to be rejected.

Action Plan

The following guidance materials will be developed as a result of issues identified in the Rejection Rate Study:

Topic	Schedule
Residue Chemistry Chapter	July 1992
Residue Chemistry Guidance	
Metabolism Guidance	July 1992
Acute Toxicity Tolerance Guidance	Fall 1992
Storage Stability Guidance	December 1992
Theoretical Concentration Factors	December 1992
Raw Data Guidance	December 1992
Revision of Table II	Mid-1993
Industry Proposal of Number of Sites and Geographic Distribution of Crop Field Trials for EPA Review	August 1992
Environmental Fate Chapter	September 1992
Occupational and Residential Exposure Chapter	August 1992
Ecological Effects Chapter	September/October 1992
Toxicology Chapter	October 1992
Workshop on Rejection Rate Study Results - All Disciplines	December 1992
Provide companies with listing of computerized studies to allow internal rejection rate analyses, publicize commitments	Ongoing

Break-out Session #2 - Ecological Effects and Environmental Fate Data Requirements and Risk Methodologies

This session focused on the ecological and environmental fate data required to support reregistration for various use patterns, along with the need for higher tier studies, ecological endpoints of concern, and the use of these data in conducting a risk assessment.

This session identified and prioritized key isssues, then made recommendations to address them. The following issues were identified in this session:

- Data waiver requests
- Study protocol development and acceptance
- Study deadlines
- Field studies
- Terrestrial field studies - avian
- Mesocosm studies - aquatic field studies
- Field dissipation studies
- Worst case versus realistic exposure estimates
- Regulatory endpoints for ecological effects
- Negligible risk and acceptance risk for avian and/or aquatic species

Action Plan

An Ecological Effects Task Force has been established in response to the many issues surrounding ecological effects testing, exposure, and risk assessments. The Task Force is chaired by the Deputy Administrator for the Office for Prevention, Pesticides and Toxic Substance and composed of senior managers from the Office of Pesticide Programs.

The Task Force has completed a review of the environmental fate and ecological effects guidelines and has produced several flowcharts that present the testing schemes and describe the conditions that trigger higher tier studies.

Using the testing guidelines as a foundation, the group has identified six major issues and plans to develop issue papers and action plans on each issue. These issues are presented below:

1. Value of Avian Studies
   Items for discussion and decision include: value of acute toxicity tests and field studies and the appropriateness of using lab study results to meet Special Review criteria.

2. Value of Mesocosm Study
   Items for discussion and decision include: the value of information provided for risk management and whether the information refutes the presumption of risk;

3. Role of Risk Mangement in the Groundwater Testing Scheme

4. Calculation of the Environmental Concentration Levels in Terrestrial and Aquatic Environments

5. Role of Mitigation in Terrestrial and Aquatic Risk Management

6. Interaction and Communication between Risk Assessors and Risk Managers

The Task Force has targeted completion of the project by the end of September 1992.

The issue regarding data waiver requests concerns EPA's timely response to these requests. Appropriate OPP scientists and chemical review managers are meeting in August and September to address and make decisions on the vast majority of the pending requests. Decisions will be communicated to registrants as soon as possible thereafter but no later than October 1. These initial meetings are intended to deal with backlogged waiver requests. Incoming waiver requests will be handled in the same manner and should be responded to within 60 days of receipt.

In regard to communication issues, a series of internal and external actions are occurring to address and communicate our findings. These will be regularly reported on in appropriate OPP publications, including the quarterly progress reports for the reregistration program.

Break-out Session #3 - Health Risk Data Requirements and Assessments

This session discussed the toxicity and exposure data required to support reregistration for various use patterns and endpoints of concern, including neurotoxicity and ocular effects, the peer review processes within OPP, and the risk assessment decision process.

The key issues identified in this session are numbered below, followed by action items developed to address each issue:

1. Cancer peer review process
   -Action Item: The Health Effects Division is currently writing a Peer Review Manual which will discuss the process, including notification of the Registration Division and Special Review and Reregistration Division, for all chemicals scheduled for Peer Review.

RD and SRRD can then notify appropriate registrants of the schedule. The manual is expected to be completed by the end of 1992.

EPA is assessing the need for and cost-effectiveness of SAP review of all chemicals. The assessment will include an analysis of previous EPA/SAP reviews and criteria on when chemicals should be presented to the SAP. This analysis will be completed by December 1992.

The topic of dose selection for chronic studies will be discussed at the International Reregistration Workshop, October 1992.

2. Worker exposure
   -Action Item: In the June 1992 reorganization of the Health Effects Division, the concept of Chemical Managers was implemented. The Chemical Manager's role will be to coordinate and integrate the disciplines related to human health assessment. One area that will be strengthened is evaluating worker exposure and determining as soon as possible the need for additional data for risk assessment.

   In September 1991, EPA established the Incident Data System (IDS) to track incidents of problems from usage of pesticide products and to produce reports from this data.

3. Neurotoxicity
   -Action Item: Under development.

4. Data requirements for non-food use chemicals
   -Action Item: Under development.

5. Use of non-GLP data
   -Action Item: EPA will determine on a case-by-case basis, whether non-GLP data should be used to trigger data requirements.

Break-out Session #4 - Product Reregistration

This session concentrated on the process of product reregistration including data required to support products and data/label submission and review timelines.

This session identified and prioritized key issues, then made recommendations to address them. The issues are numbered below, followed by action items developed to address each issue:

1. Impact of product reregistration on normal registration activities.
   -Action Item: Resources for registration and reregistration programs are allocated in EPA's budget and spending processes. Management is responsible for monitoring resources to assure that they are used according to plan. The Registration Division is also exploring ways to gain efficiency in processing registration applications.

2. Advance notice of RED for batching labeling, etc.
   -Action Item : SRRD is planning to list chemicals that are candidates for reregistration in the next fiscal year in the next quarterly reregistration progress report .This notification will provide interested and/or affected parties information on the schedules of chemicals in reregistration review to allow preparation for batching of end-use products for toxicity testing, labels changes, etc. Due to Confidential Business Information considerations it is not possible to allow registrants to participate in developing the batching testing scheme.

3. Which product chemistry requirements must meet GLP?
   -Action Item: The Reregistration Support Branch, Registration Division, is currently in the process of identifying which product chemistry requirements must meet GLP requirements. Guidance on this subjects is expected to be available by September 1992. This information will be disseminated in the next quarterly report published on reregistration activities, the EPA's Blue Book on how to register pesticides, and added as a standard paragraph to RED's issued in 1993.

4. How long to process waiver requests?
   -Action Item: Registration Division intends to respond to product specific waiver requests associated with RED's within 60 days of receipt. All waiver requests are handed in at one time so that decisions are made consistently and at the same time. The 60 day turnaround time will be incorporated into the cover letter transmitting the RED to the registrant.

5. Nominal concentration versus lower certified limit --which should be used?
   -Action Item: The current policy to be

followed regarding whether nominal or lower certified limits should be used for products going through reregistration was issued in PR-Notice 92-1. The policy is that products going through reregistration must declare the nominal concentration on the label. EPA is currently reconsidering this policy and expects to make a decision by September 1992. However, until a decision is made the policy is to use nominal concentration on all product labeling.

6. Products with multiple active indgredients.
   -Action Item: EPA has decided to call in and review product specific data for every product when the first active ingredient is subject to a RED. This issue will be discussed in the Reregistration Progress Report to be issued in October 1992.

7. Ground rules for waiver requests.
   -Action Item: EPA is working on a general statement regarding data waiver requests, with examples, as well as data waivers based on low volume and minor uses. This guidance will be published in EPA's Blue Book on how to register pesticides and in RED documents as soon as it is available.

8. Labeling for agricultural versus consumer products.
   -Action Item: EPA's labeling regulations do not distinguish between agricultural and consumer product labeling. However, EPA Product Managers have latitude to approve variations in labeling to meet the intent of the regulations and to assist the primary users of the product.

9. Would EPA accept bridging for acute toxicity data?
   -Action Item: Reregistration Support Branch, Registration Division is looking into the feasibility and extent that it can use bridging data to fulfill product specific acute toxicity testing requirements. Guidance on this issue is expected by October 1, 1992.

Break-out Session #5 - Grower Group's Reregistration Issues and Opportunities

This session focused on issues that growers and/or grower groups have regarding various aspects of the reregistration process, and will explore opportunities for them to become more involved.

This session identified and prioritized key issues, then made recommendations to address them. The issues are numbered below, followed by action items developed to address each issue:

1. Communication
   -Action Item: Mail-out listing of reregistration chemicals and chemical review manager assignments - September 1992.
   -Action Item: Establish work group within OPP to address reregistration communication issues - September 1992.

2. Data Issues
   -Action Item: EPA is reviewing the economic schemes used to evaluate low volume minor use waivers - Fall 1992.
   -Action Item: EPA is revising crop grouping schemes.

3. Process Issues
   -Action Item: OCM will review current GLP's and issue guidance for field situations where current guidance is impractical.

4. Time
   -Action Item: Current proposals would extend timeframes for submission of data to support the reregistration of minor uses as well as the time a chemical could be used on unsupported uses. There is no way to project the timing and outcome of these initiatives.

5. Resources
   -Action Item: Additional funding was appropriated in Fiscal Year 1992 to support the IR-4 program.

6. Critical Chemicals
   -Action Item: A process will be established to identify critical chemicals, by use, by the end of 1992.

VII. FURTHER INFORMATION

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

Pesticide Reregistration pamphlet, May 1992
Available from SRRD/OPP, U.S. EPA
Tel: (703) 308-8007

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

Intent to Remove Certain Active Ingredients and to Cancel Pesticides Containing Those Ingredients
List B, C, D: FR 07/31/90, pages 31164-31170
FR 10/04/91, pages 50422-50437
FR 10/04/91, pages 50438-50463
U.S. Government Printing Office
732 North Capitol Street, NW
Washington, DC 20401

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

Minor Uses
For information contact: (703) 305-5310
(703) 308-8068

Status of Pesticides in Reregistration and Special Review (Rainbow Report) **NOW AVAILABLE**
For information contact: (703) 308-8007

Rejection Rate Study , Residue Chemistry Chapter **NOW AVAILABLE**
For information contact: (703) 308-8175

Reregistration Script, Overview Session, Reregistration Workshop - May 1992
For information contact: (703) 308-8080

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

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

OPP has completed REDs and summary fact sheets for the following pesticides. Copies of these documents may be obtained from the Public Response and Program Resources Branch, Field Operations Division (H-7506C), Office of Pesticide Programs, U.S. Environmental Protection Agency, Washington, DC 20460 Tel: (703) 305-5805

1. Fosetyl-Al (Aliette) ..... January 1991
2. Heliothis zea NPV..... January 1991
3. Methoprene ..... May 1991
4. Sulfur ..... May 1991
5. Potassium Bromide ..... June 1991
6. Warfarin ..... June 1991
7. Sodium and Calcium Hypochlorite Salts..... September 1991
8. Dried Blood..... September 1991
9. Inorganic Nitrate/Nitrite..... September 1991 (Sodium and Potassium Nitrates)
10. Carbon and Carbon Dioxide..... September 1991
11. Silicon Dioxide and Silica Gel.... September 1991
12. Propionic Acid..... September 1991
13. Sodium Diacetate..... September 1991
14. Heptachlor..... March 1992
15. Allium Sativum..... June 1992
16. Putrescent Whole Egg Solids..... June 1992
17. Citric Acid..... June 1992
18. Capsaicin..... June 1992

TECHNICAL APPENDIX

(A) FIFRA is the statute under which EPA regulates the marketing and use of pesticides in the United States.

(B) **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.

(C) 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."

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 has determined that the active ingredient does or 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 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.

(D) DCI is a term which refers to EPA's request for studies on a chemical case.

(E) **Rainbow Report**

This annual report will list and describe the status of each pesticide in the reregistration process and under Special Review. For a copy of the Rainbow Report, contact Carol Stangel at (703) 308-8007.

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

I. Dietary Exposure

A. Tolerance Reduction: This measure indicates that EPA has reduced the maximum allowable residue level on food/feed products below the previously allowable level.

TECHNICAL APPENDIX, continued

B. Pre-Harvest Interval Adjustment: This measure refers to the amount of time which must elapse 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 consumer dietary exposure to unacceptable levels of pesticide on a crop.

C. Other: This measure primarily tracks label modifications or other tolerance changes.

II. Non-dietary Exposure

A. Re-entry: This measure requires workers to delay entering a field where crops have been treated with pesticides.

B. Protective Clothing: This measure is intended to reduce pesticide exposure to mixers, loaders, applicators, and field workers.

C. Restricted Use: This classification generally limits sale and use of a pesticide to certified applicators or persons under their direct supervision.

III. Environmental Fate and Ecological Effects

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

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

(H) 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. Special Review decisions may establish policy or guidelines on which other environmental decisions relating to pesticide registrations are based.

(I) The International Pesticide Reregistration Workshop, sponsored by the Office of Economic Cooperation and Development (OECD) and hosted by the EPA, is scheduled for October 26-28, 1992 in Arlington, Virginia. This workshop is by invitation only and will focus primarily on interaction and cooperation between governments.

Comments

EPA welcomes your comments on this progress report or on activities related to reregistration. Please address your comments to Moana Appleyard-Haddad: (703) 308-8175

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