United States
Environmental Protection
Agency

Pesticides and
Toxic Substances
(H-7508W)

700-R-92-001 B
April 1992

EPA

Pesticide Reregistration Progress Report

Contents

I. INTRODUCTION

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

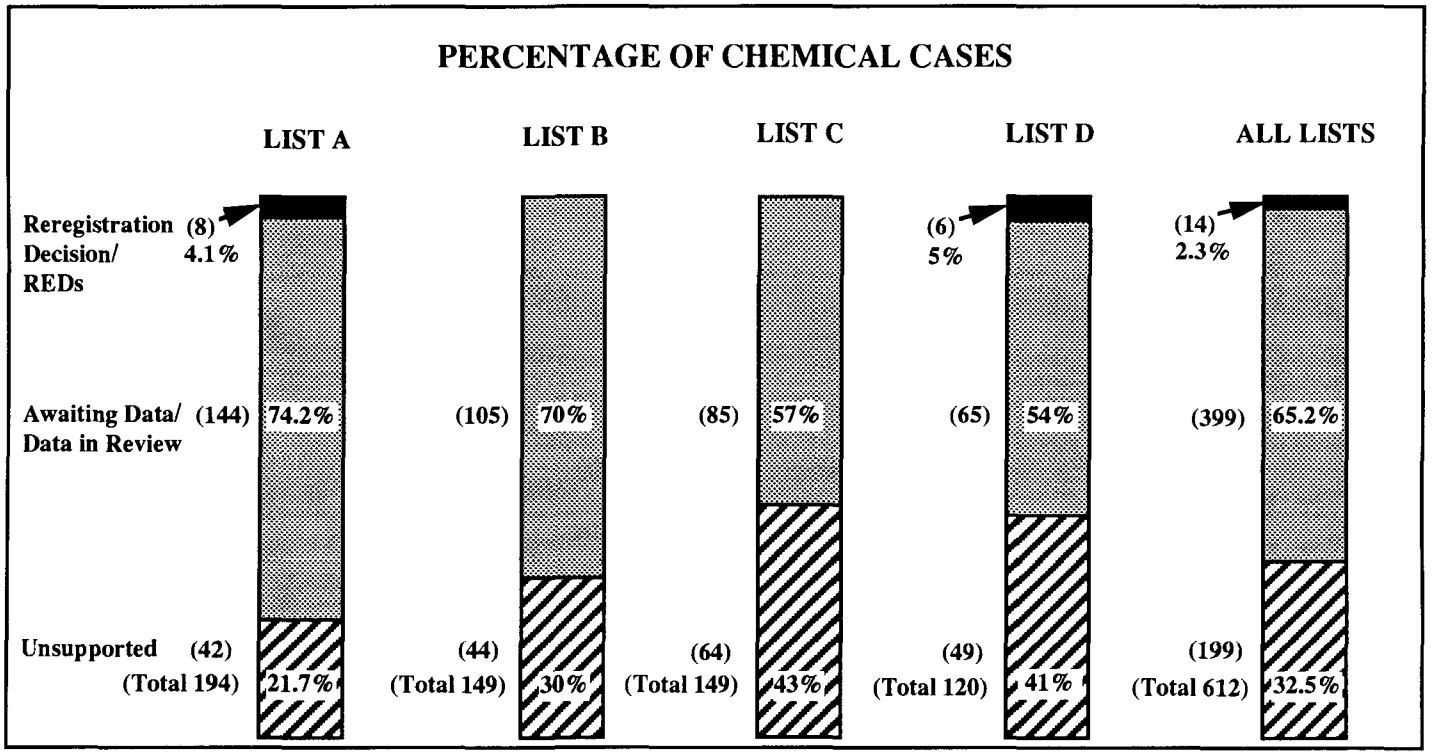
This report will show the status of reregistration through the second quarter of the 1992 fiscal year.

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. 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 second 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 VI, Further Information.

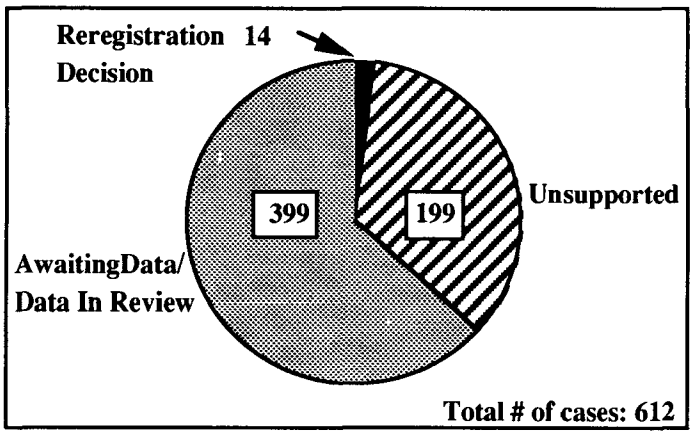
Figure 1
Current Status of Reregistration - Chemical Cases - Second Quarter FY 92



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 second quarter fiscal year 1992.

Figure 2
Total Chemical Cases - Second 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 proposed to be 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

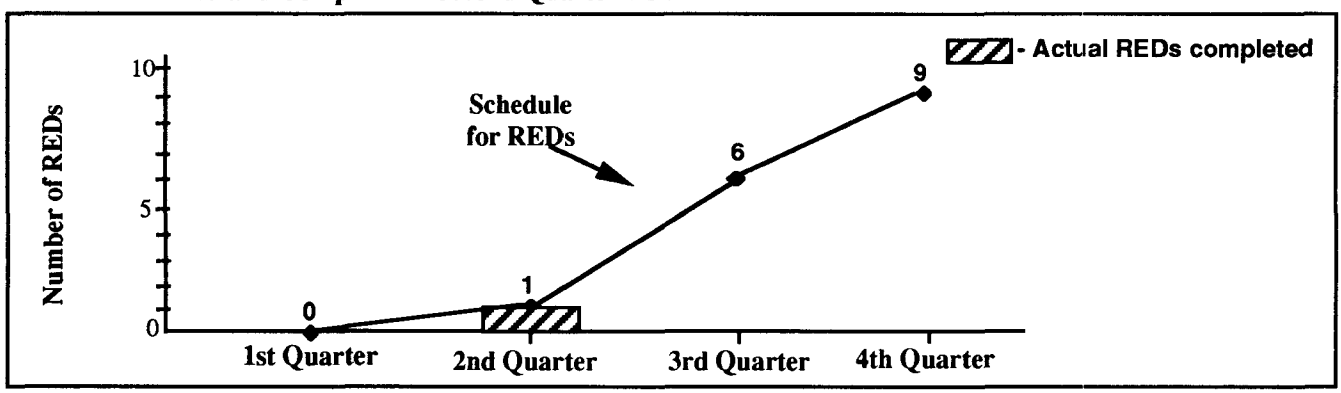
Once all of the data are evaluated and all the requirements are met for a chemical case, EPA makes a reregistration decision in the form of a Reregistration Eligibility Document (RED). This report measures progress in terms of issuing REDs or reregistration eligibility decisions.

II. REREGISTRATION PROGRESS

A. REDs Schedule

Figure 3 shows the REDs scheduled and completed by quarter for fiscal year 1992. One RED was completed in the second quarter fiscal year 1992. A total of 14 REDs have been completed to date.

Figure 3
REDs Scheduled and Completed - Second 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. E/

Table 1
Risk Reduction Measures Brought About by the REDs Completed - Second 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
Heptachlor									▒	

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

Table 2
Results of Reregistration (Cumulative Summary) - Second 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	6				1	3				5	
Total	14			4	2	6		2		12	

Source: Reregistration Eligibility Documents (REDs)

C. Minor Uses

Table 3 lists the chemicals and products that are proposed to be canceled and the uses that would be affected by these cancellations.

Information on the early notification network is described in the Technical Appendix. F\

Table 3
Proposed Cancellations Affecting Minor Uses - Second Quarter FY 92

Chemical	Products	Affected Uses
Fenthion	Baytex	Alflafa, Clover, Pasture grasses, Rice, Ornamentals
Nicotine	Bonide Tobacco Dust	Raspberries, Strawberries, Blackberries, Peas, Beans, Tomatoes, Cucumbers, Peppers, Onions, Squash
Parathion	Ethyl Parathion	Alfalfa, Barley, Canola, Corn, Cotton, Sorghum, Soybeans, Sunflowers, Wheat
EBDCs	Mancozeb, Maneb, Nabam, Metiram	Apricots, Carrots, Celery, Collards, Mustard Greens, Nectarines, Peaches, Rhubarb, Spinach, Succulent Beans, Turnips
Methyl Bromide		

D. Reregistered Products

Table 4 shows the first products that were reregistered in January 1992. These products are reregistered in the Registration Division of OPP upon completion of applicable product-specific data and compliance with the terms and conditions specified in the REDs. As OPP accelerates its REDS completion rate, the number of products eligible for reregistration will increase dramatically.

Table 4
Reregistered Products - Second Quarter FY 92

Chemical with RED	Products
Aliette	Aliette Fungicide, Aliette WDG Fungicide

E. Suspended Chemical Cases

EPA may issue Notice of Intent to Suspend (NOIS) based on finding that a registrant has failed to submit data under the requirement(s) of a section 3(C)(2)(B) DCI. Events that may result in the issuance of a NOIS include failing to meet any of the data requirements in Phases 2, 3, 4, and 5 of the reregistration process.

Table 5 illustrates the suspension actions from August 1991 to February 1992. This table lists the total number of NOIS issued to companies during this time period, and the breakdown of actions that have resulted from the NOIS. A total of 14 final actual suspensions resulted from the NOIS. The reasons for suspending these 14 chemical cases included: (1) failure to submit generic data and (2) failure to submit Phase 5 product specific data.

Table 5
Suspension Actions - August 1991 to February 1992

Results of NOIS	
• Complied with requirements:	53
• Pending:	3
• Suspension Actions Final:	14*
Total NOIS sent to companies:	70
***Reasons for Suspensions**	
• Due to failure to submit generic data:	6
• Due to failure to submit Phase 5 product specific data:	8
Total Final Suspensions:	14

III. OTHER MEASURES OF PROGRESS

A. Rejection Rate Study

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

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

Residue Chemistry - These studies measure the amount of pesticide remaining on a crop or commodity and how the pesticide is broken down within the crop or domestic animal.

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

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

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

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

IV. SIGNIFICANT REGULATORY DECISIONS

This section gives a summary of significant regulatory decisions made on Special Review chemicals in the second 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.

Parathion - On January 17, 1992, EPA extended the deadline from December 31, 1991 to July 31, 1992 that commercial applicators and end users can legally use existing stocks of certain canceled parathion products (i.e., products other than emulsifiable concentrates). EPA extended the deadline when it learned that end users would have to hold large amounts of canceled product on December 31 because many distributors declined to recall canceled stocks. These products being voluntarily canceled, rather than suspended, legally deprives EPA of authority to impose a recall of end users' product. EPA believes that the hazards and risks of end users indefinitely storing these products would outweigh those risks of allowing use for a limited time, and thus extended the use deadline. The amendment did not allow any further sale or distribution of the canceled product.

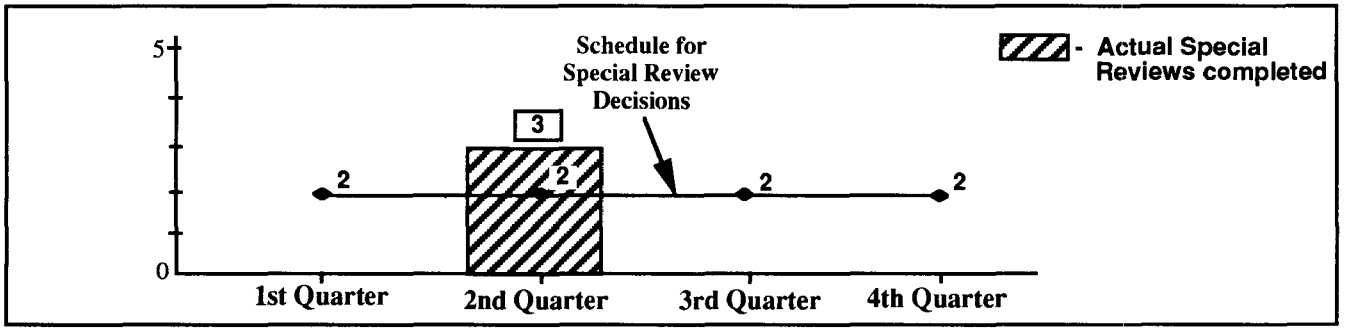
Aldicarb - On January 30, 1992, EPA reached a settlement agreement on the uses of Aldicarb which posed dietary risk concerns. As a result of the agreement, the registrant decided to voluntarily cancel the use of aldicarb on bananas by not paying the required annual maintenance fee for that use. In addition, the registrant agreed to amend the registration for potatoes, sweet potatoes, oranges, and grapefruit and to submit additional data to support these uses. Dietary concerns will be reevaluated using the additional data.

EBDCS - On February 13, 1992, the Agency announced its final determination for the Special Review of ethylene bisdithiocarbamates (EBDCs), a group of fungicides widely used on food crops. The announcement reversed the EPA's preliminary determination issued in 1989 to cancel 55 food crop uses. Additional market basket data developed since the preliminary determination lead to the final decision that the dietary risks from residues on harvested crops were not as great as originally believed. The final determination included the folowing actions: 1) cancellation of 11 food crop uses for mancozeb, maneb, and metiram, 2) continuation of 45 other food crop uses, contingent upon modifications being made to these registrations, 3) continuation of all industrial uses of nabam, and 4) cancellation of homegarden uses of mancozeb on turf and fruit with other EBDC homegarden uses remaining registered, but subject to certain conditions. The final determination was published in the Federal Register on 3/2/92.

Figure 4 shows the Special Review decisions scheduled and completed by quarter for fiscal year 1992. **G/**

The Special Review Branch (SRB) has completed a report on "The Status of Pesticides in Special Review," which describes the status of pesticides now undergoing EPA's intensive, risk/benefit balancing, Special Review process. This report also lists and describes the outcomes of past Special Reviews. For copies of this report, please contact Joe Bailey at (703) 308-8173.

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



V. CALENDAR OF EVENTS (FY 92)

3rd Quarter 1992	4th Quarter 1992
1. The second public Reregistration Workshop will be held. 2. Some chapters of the Rejection Rate Study are scheduled for completion. 3. The revised Rainbow Report is scheduled for completion. **H/**	1. A total of 16 REDs will be completed by the end of the fiscal year. 2. A total of 8 Special Review decisions will be completed by the end of the fiscal year. 3. A total of 77 List C DCIs will be completed by the end of the fiscal year.

Announcement: Reregistration Workshop

The EPA is sponsoring a Reregistration Workshop, on May 26-28, 1992. This is the second Reregistration Workshop; the first was held in September 1990. The purpose of the workshop is to provide a forum for discussion and input for parties interested in reregistration. For further information contact: Marilyn Millane at Walcoff and Associates (703) 684-5588 or Carol Stangel at EPA (703) 308-8007.

VI. FURTHER INFORMATION

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

Pesticide Reregistration pamphlet, April 1991
Available from SRRD/OPP, U.S. EPA,
or from EPA's Public Information Center (PIC)
401 M Street, SW (PM-2118)
Washington, DC 20460
(202) 260-7751

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

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

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

Rainbow Report
For information contact: (703) 308-8000

Rejection Rate Study
For information contact: (703) 308-8000

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

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

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

1. Fosetyl-Al (Aliette) ..... January 1991
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 (Sodium and Potassium Nitrates)... September 1991
10. Carbon and Carbon Dioxide (See 2 separate fact sheets)..... September 1991
11. Silicon Dioxide and Silica Gel.... September 1991
12. Propionic Acid..... September 1991
13. Sodium Diacetate..... September 1991
14. Heptachlor..... March 1992

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

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 and by paying maintenance fees.

Phase 3: Registrants summarize and reformat existing studies and certify access to raw data. The registrants flag potential adverse effects data and pay an additional fee to keep chemicals registered.

Phase 4: EPA reviews Phase 2 and 3 submissions and identifies additional data needs. EPA publishes lists of missing studies and notifies registrants of required studies.

Phase 5: All chemical studies must be submitted before this phase. Product-specific studies are required. Once these studies are reviewed and deemed acceptable, products will be reregistered.

(C) When a chemical is unsupported, it is proposed for cancellation and may ultimately be canceled by EPA. The number of unsupported chemicalcases is constantly changing. Chemical cases can drop out of the reregistration process if a registrant decides it is not cost effective to produce the necessary data. However, it is possible for another registrant to support a chemical case by submitting the appropriate data and fees to EPA. This is considered a "revived case."

The formal review process is different for List A chemical cases than for Lists B, C, and D. List A chemical cases had Registration Standards completed prior to the 1988 FIFRA amendments.

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

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

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

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

I. Dietary Exposure

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

B. Pre-Harvest Interval Adjustment: This measure refers to the amount of time since the last pesticide application before a crop can be harvested. Adjustment usually would result in the establishment of a longer period of time to avoid 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 would result from requiring workers to delay entering a field where crops have been treated with pesticides.

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

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

III. Environmental Fate and Ecological Effects

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

(F) An early notification network was jointly established by the U.S. Department of Agriculture (USDA), EPA , and the National Agricultural Chemicals Association (NACA). This network communicates registrant actions that would impact on pesticide usage to those affected, particularly the pesticide users. This notification is intended to afford end users of pesticides sufficient time to try to influence decisions. EPA can be contacted for further information on minor uses, reregistration, and growers' minor use pesticide needs. The EPA telephone lines are (703) 308-8068 and (703) 308-5310.

(G) Special Review decisions represent major EPA actions which may ultimately cancel, deny, or reclassify the registration of pesticide products, because uses of the product may cause unreasonable adverse effects on human health or the environment. In addition, Special Review decisions may include other major documents that establish policy or guidelines on which other environmental decisions relating to pesticide registrations are based.

(H) Rainbow Report

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