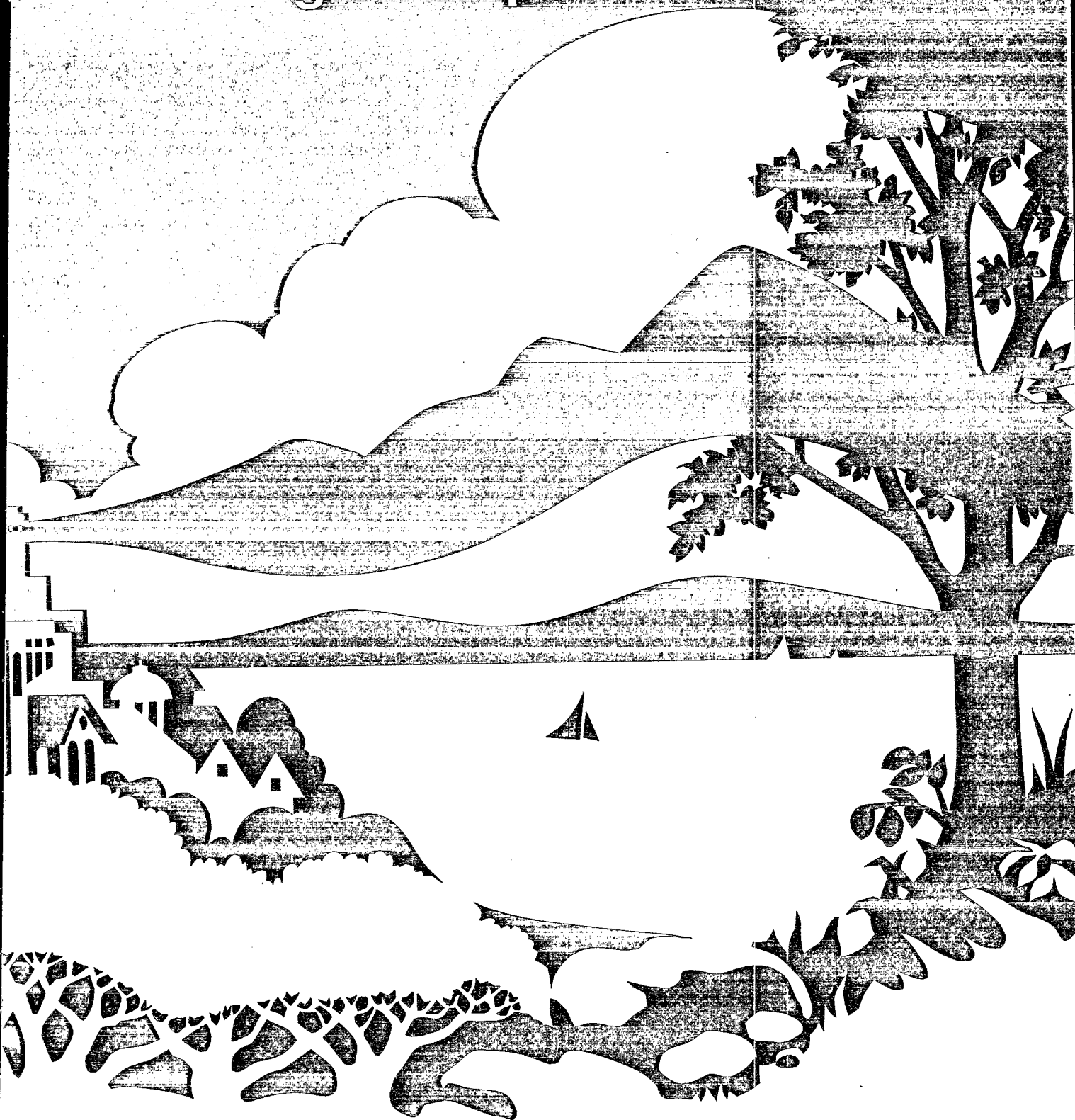
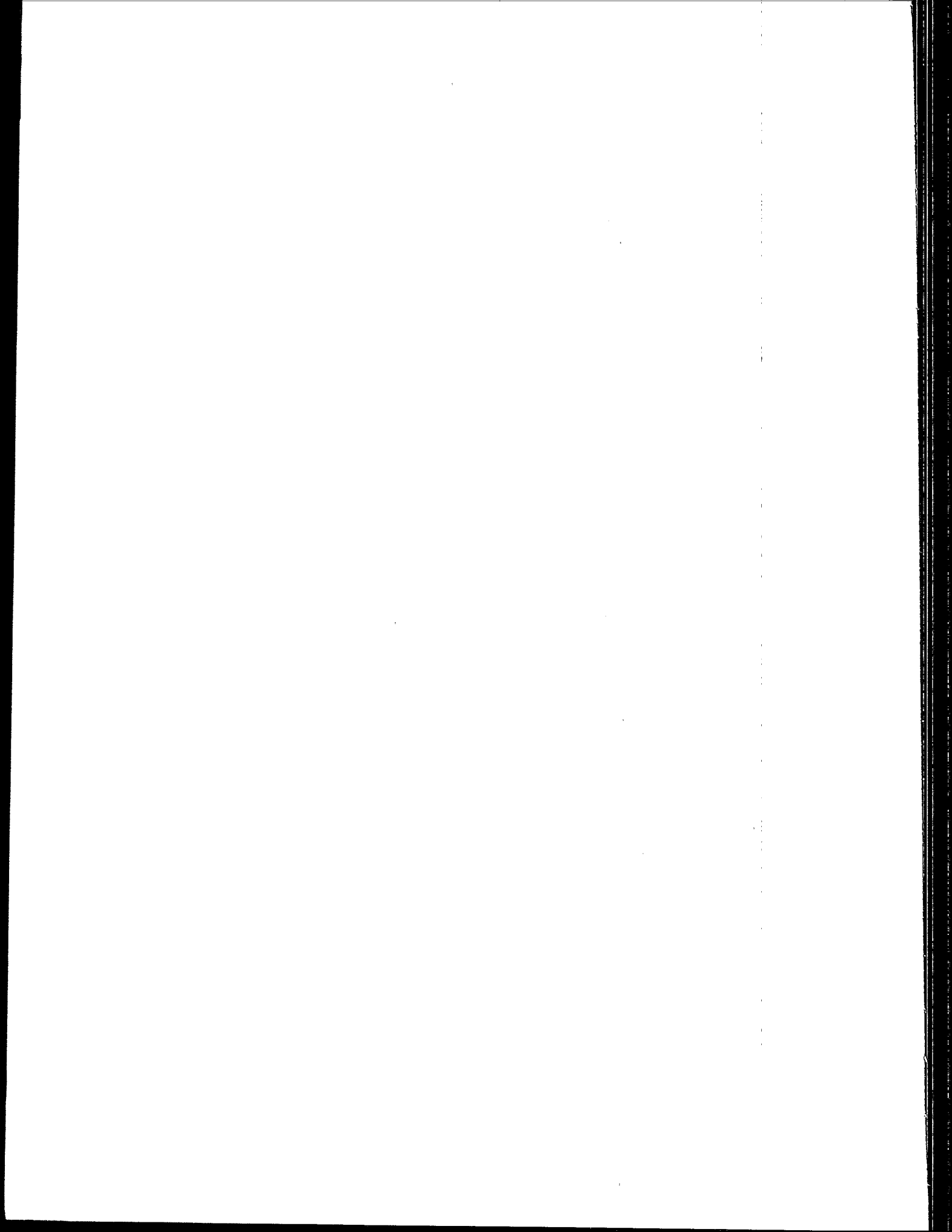


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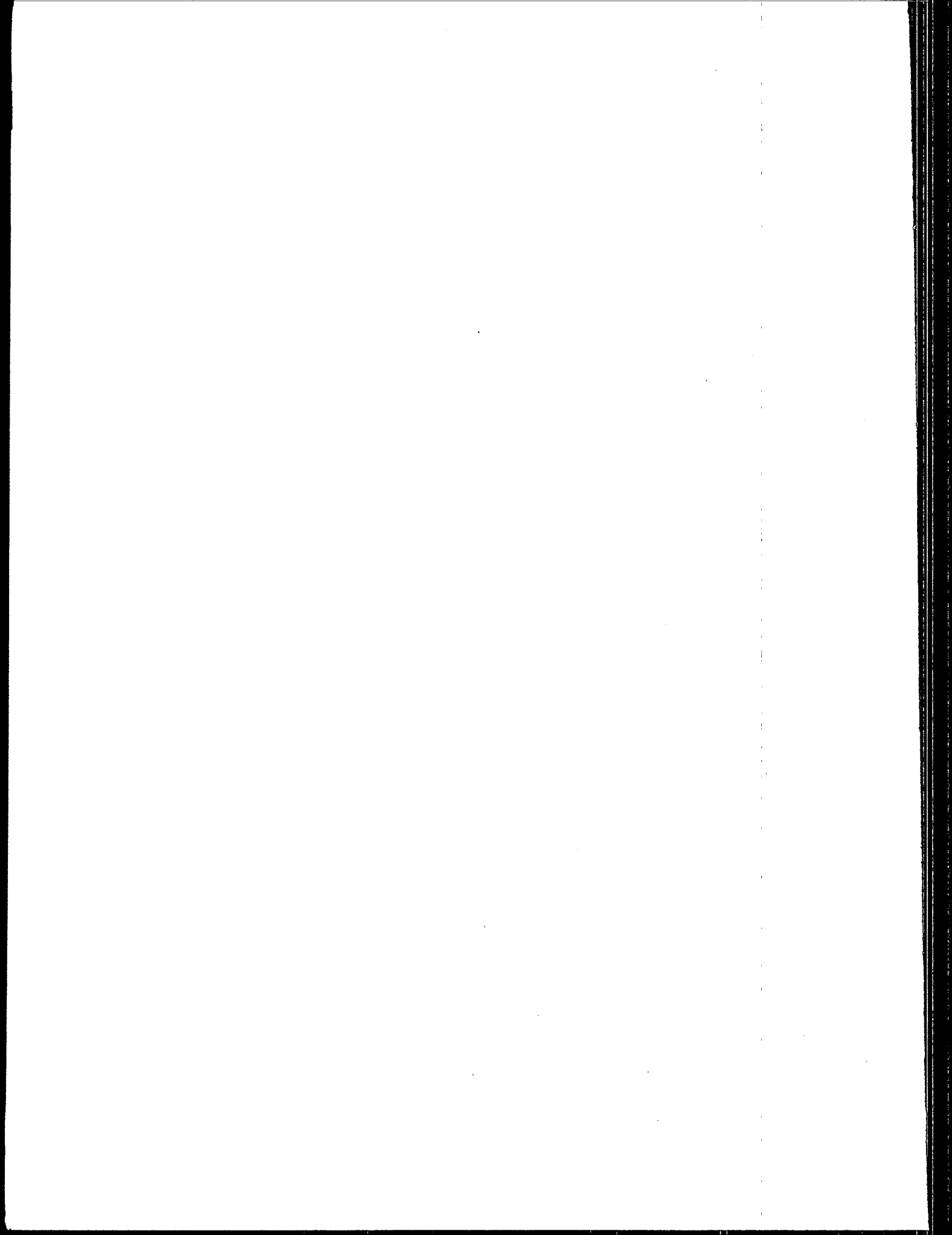
Pesticide Reregistration Progress Report





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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 of the fiscal year¹ and cumulatively.

This issue of the Progress Report describes the status of reregistration through the third quarter fiscal year 1994 (FY 94). Sixty-one REDs have been completed since 1991 representing 99 chemicals/active ingredients (AIs), 3,091 products, and 263 tolerances. Approximately 411 products have completed the process and have been reregistered. Please see Appendix A for a more detailed cumulative summary.

¹The fiscal year runs from October through September, and is divided into four quarters: the first quarter consists of October, November, December; the second quarter consists of January, February, March; the third quarter consists of April, May, June; and the fourth quarter consists of July, August, September.

I. PESTICIDE REREGISTRATION

A. Reregistration Process Background

EPA is required by law to reregister existing pesticides that originally were registered years ago when the standards for government approval were less stringent than they are today. This comprehensive reevaluation of pesticide safety is critical to protecting human health and the environment. In 1988, Congress amended the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to strengthen and accelerate EPA's reregistration program. The nine-year reregistration scheme mandated by "FIFRA '88" applies to each registered pesticide product containing an active ingredient initially registered before November 1, 1984.

In 1988, approximately 600 groups of related pesticide active ingredients, or "cases," representing 1,150 active ingredients in 45,000 formulated products, required reevaluation. As FIFRA '88 directed, EPA divided these 600 cases into four lists: List A, B, C and D.

List A - List A consisted of the 194 chemical cases (or 350 individual active ingredients) for which EPA had issued Registration Standards prior to the effective date of FIFRA '88. Most pesticides with food-related uses are on List A.

List B, C and D - The remaining pesticides were divided into three lists based upon their potential for exposure and other factors, with List B being of highest concern and D of least. Some of the classification criteria included potential for residues of concern in food or drinking water, significance of outstanding data requirements, potential for worker exposure, Special Review or restricted use status, and unintended adverse effects to animals and plants.

FIFRA '88 established mandatory reregistration timeframes and duties. The five phases of the reregistration process are:

Phase 1: Listing of Active Ingredients - EPA published Lists A, B, C, and D within 10 months of FIFRA '88 and asked registrants of these pesticides whether they intended to seek reregistration.

Phase 2: Declaration of Intent and Identification of Studies - Registrants were required to notify EPA whether or not they intended to reregister their products; to identify and commit to providing necessary new studies; and to pay the first installment of the reregistration fee. During this phase, EPA issued guidance to registrants for preparing their Phase 2 and Phase 3 responses. Phase 2 activities were completed in 1990.

Phase 3: Summarization of Studies - Registrants were required to submit summaries and reformatted acceptable studies, "flag" studies indicating adverse effects, re-commit to satisfying all applicable data requirements, and pay the final installment of the reregistration fee. Phase 3 ended in October 1990.

Phase 4: EPA Review and Data Call-In's - In Phase 4, EPA reviewed all Phase 2 and 3 submissions and required registrants to meet any unfulfilled data requirements within four years. Phase 4 was completed in 1993.

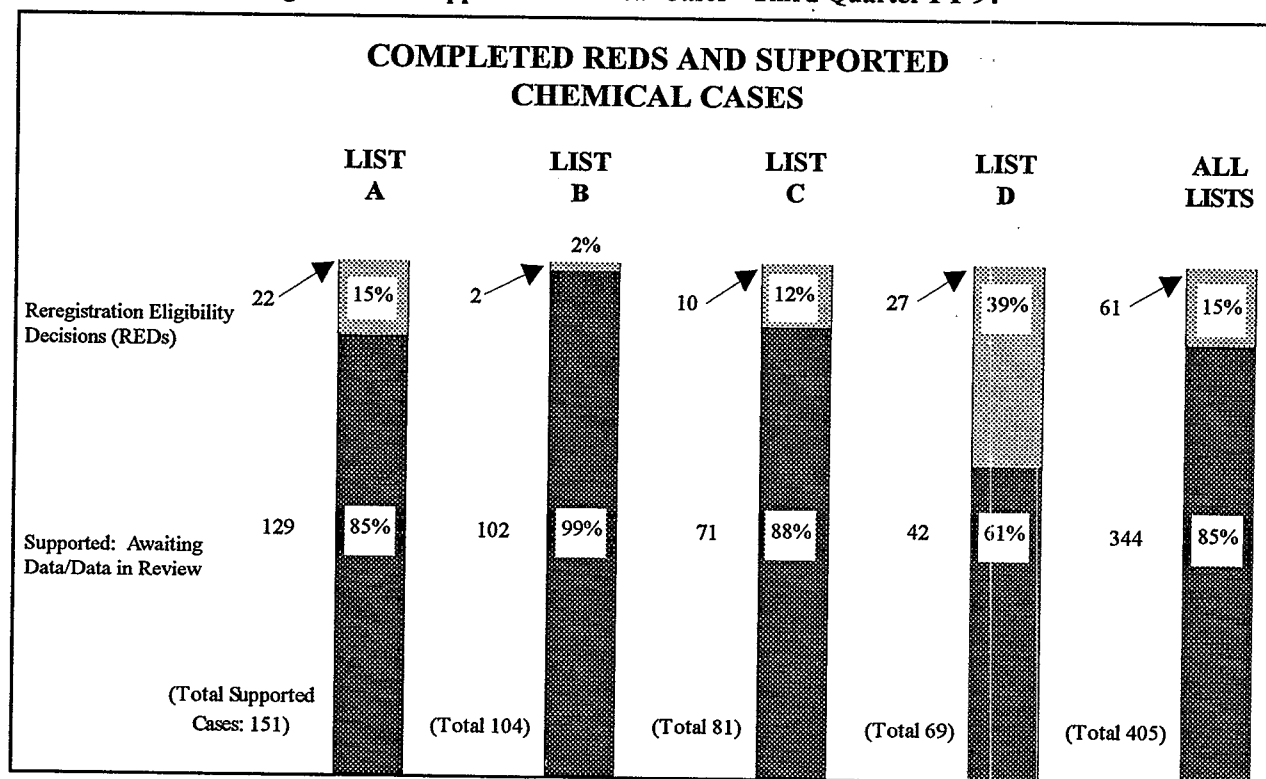
Phase 5: Reregistration Decisions - In this phase, EPA reviews all the studies that have been submitted for a chemical case, and decides whether or not to reregister products containing the active ingredients in that case. A pesticide will be considered eligible for reregistration if its data base is substantially complete, and if it does not cause unreasonable adverse effects to people or the environment when it is used according to product label directions and restrictions.

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 end of the third quarter fiscal year 1994. Each column shows the total number of supported chemical cases currently on each list. Also shown are the numbers and percentages of those cases that have REDs completed, and cases that are in the category of

Awaiting Data/Data in Review. Of the total of 612 cases² (representing 1,138 AI's) that were eligible for reregistration in 1988, 405 (representing 590 AI's) still are supported while 207 are not supported by their registrants. A list of REDs completed appears in Appendix A, Cumulative Summary of Reregistration Actions.

Figure 1
Current Status of Reregistration - Supported Chemical Cases - Third Quarter FY 94



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

² This number was originally 611 cases, which became 612 when two active ingredients were separated to become individual cases.

II. REREGISTRATION PROGRESS

A. REDs Completed This Quarter

This section summarizes RED production during the third quarter of fiscal year 1994, and summarizes the information in the individual REDs.

In reviewing pesticides for reregistration, EPA gathers a substantially complete set of data on each chemical case, examines related health and environmental effects, and attempts to mitigate effects of concern. This evaluation and risk management process is complete when EPA is satisfied that the pesticide(s), used in accordance with approved labeling, will not pose unreasonable risks to human health or the environment.

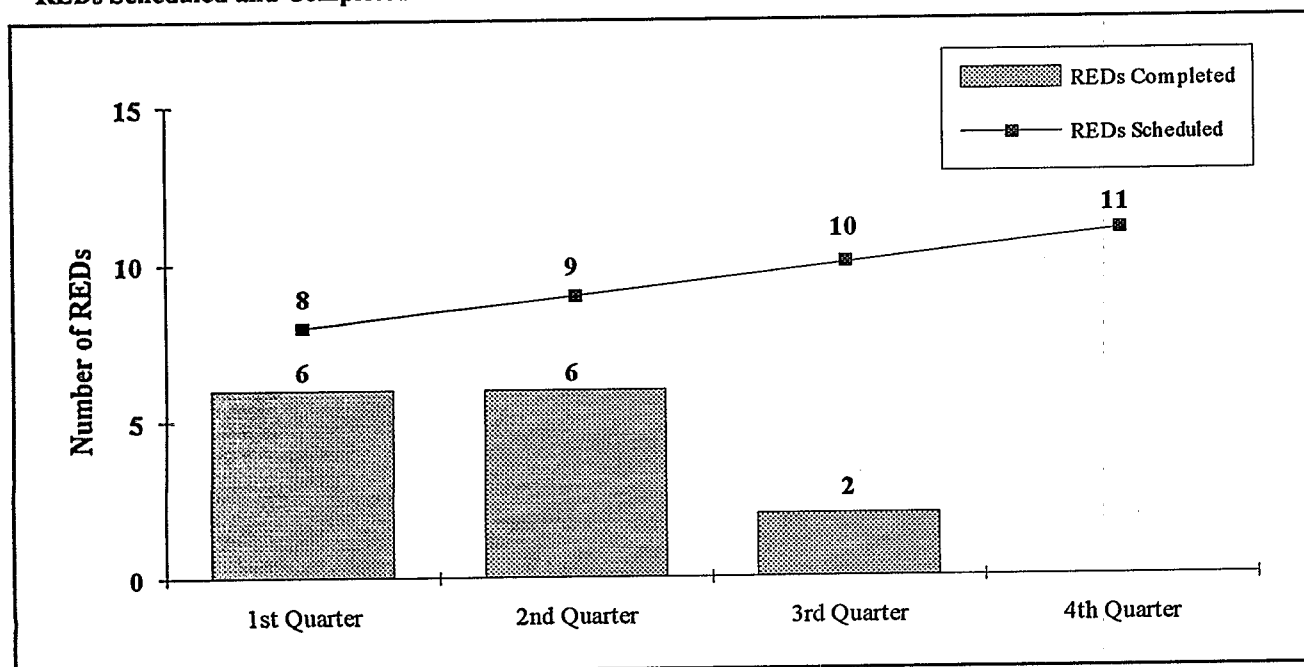
When some or all uses of a pesticide are determined to be eligible for reregistration (or when another regulatory conclusion has been reached), EPA issues a Reregistration Eligibility Decision (RED), usually embodied in a RED document. About 14 months later, once certain product-specific data and revised labeling are submitted

and approved, EPA begins reregistering single-active ingredient products containing the pesticides included in these REDs. Products that contain active ingredients in addition to these will not be reregistered until all of their active ingredients are eligible for reregistration.

FY 94 REDs Production

Figure 2 shows the number of REDs scheduled to be completed by quarter during fiscal year 1994, and the number actually completed through the third quarter. Two REDs were completed in the third quarter, covering a total of 3 chemicals and 28 products. So far, 14 REDs have been completed in fiscal year 1994. The target for the fiscal year is 38 REDs. A total of 61 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 - FY 94



3rd Quarter RED Summaries

During the third quarter of fiscal year 1994, EPA completed the REDs summarized below.

Maleic Hydrazide - Maleic hydrazide is a plant growth regulator and herbicide that is used to inhibit sprouting of potatoes and onions, suckers in tobacco, and weeds, grasses and trees on/ among lawns, turf, ornamentals, non-bearing citrus trees, rights-of-way, airports and industrial land. Most maleic hydrazide used in the U.S. is applied to tobacco crops. All uses of currently registered products containing maleic hydrazide are eligible for reregistration.

Maleic hydrazide is of low acute toxicity, but contains the contaminant hydrazine which has been shown to induce tumors. Between 1976 and 1982, EPA conducted a Special Review of maleic hydrazide which resulted in administrative suspension and cancellation of the DEA-MH formulation, and establishment of a 15 ppm upper limit for hydrazine in the technical grade product. This level alleviates any concern of lifetime cancer risk from both dietary and worker exposure.

Although it does not pose risks to ground water, maleic hydrazide has the potential to

contaminate surface water and to drift. EPA is requiring a surface water advisory statement to address these concerns. Also, to mitigate risks to non-target plants, the Agency is limiting application rates at several sites to once per year. For additional information, please contact Suzanne Cerrelli at (703) 308-8077.

N6-Benzyladenine - N6-Benzyladenine is a plant growth regulator used on certain trees, calla lily tubers and spinach grown for seed. It is considered a biochemical because it resembles natural plant growth regulators and uses a non-toxic mode of action. All registered uses are eligible for reregistration.

N6-Benzyladenine is of moderate to low acute toxicity but causes developmental and maternal toxicity in laboratory animals. The potential for dietary exposure is negligible, and applicator risk will be mitigated by use of personal protective equipment and restricted entry interval. Use of N6-Benzyladenine is not expected to pose a significant risk to terrestrial or aquatic organisms, or to endangered species. For additional information, please contact Ruby Whithers at (703) 308-8079.

B. RED Candidates for Fiscal Years 1994 and 1995

Table 1 shows the RED candidates for fiscal year 1994. It is likely that for some of these chemicals, REDs will be postponed until the next fiscal year. EPA completed REDs for two of these chemical cases in the third quarter for a cumulative total of 14 REDs completed so far in

fiscal year 1994. The target for this fiscal year is a total of 38 REDs.

Table 2 shows the proposed RED candidates for fiscal year 1995.

Table 1
RED Candidates for FY 94

<u>List A</u>				
Amitraz	Difenzoquat	Maleic Hydrazide ***	Metolachlor	Pronamide **
Barium Metaborate *	Fenitrothion	Metalaxyl	Oryzalin	Tebuthiuron **
Bentazon	Hexazinone	Methiocarb **	Picloram	Vendex
<u>List B</u>		<u>List C</u>		
Ethalfuralin	N6-Benzyladenine ***	Chloron-m-xenol	Lithium Hypochlorite *	
Fosamine Ammonium	Terbuthylazine	DBNPA	Piperalin	
Mercaptobenzothiazole		DCDIC	Sodium Cyanide	
		Limonene		
		2- [(Hydroxymethyl)Amino] Ethanol **		
<u>List D</u>				
2,4-Xylenol	Chlorine	m-Cresol	Muscalure	Peroxy Compounds *
Bromine *	Hexacadienol Acetates **	Mineral Acids *	Periplanone B **	Vegatable and Flower Oils *

* REDs were completed for these chemical cases during the first quarter of FY 94.

** REDs were completed for these chemical cases during the second quarter of FY 94.

*** REDs were completed for these chemical cases during the third quarter of FY 94.

Table 2
RED Candidates for FY 95

List A				
Alachlor	Chlorpyrifos	Diquat Dibromide	Nabam	
Amitrole	Copper Compounds II	EPTC	Naled	Propanil
Asulam	Copper Sulfate	Ethephon	Napthalene	Sulprofos
Benomyl	Coumaphos	Fenamiphos	Nitrapyrin	Terbacil
Bromacil	Cryolite	Fluometuron	Norflurazon	Terbufos
Captan	DCPA	Linuron	Paraquat Dichloride	Tetrachlorvinphos
Chlorothalonil	Dicofol	Methomyl	Phenmedipham	Trichlorfon
Chlorpropham	Diflubenzuron	Metribuzin	Prometryn	Trifluralin
List B				
Bis(trichloromethyl)sulfone	Dibromodicyanobutane	NPV Inclusion Bodies	Troysan KK108A	
Bronopol	Methyl Isothiocyanate	Oxadiazon	Vinclozolin	
Butralin	Methylene bis(thiocyanate)	Starlicide		
List C				
Alkyl Imidazolines	Chlorhexidine Derivatives	Methyl Nonyl Ketone	Propamocarb	
Ancymidol	Cosan 145	Methyloxazolidines	Sodium Fluoroacetate	
BHAP	Dowicil 100	Oil of Citronella	Tanol Derivatives	
Busan 74	Hydroxyethyl Octyl Sulfide	p-Chloro-m-Cresol	Triethylhexahydrotriazine	
Cellosolve Esters				
List D				
Agrobacterium Radiobacter	Aliphatic Alcohols, C1-C5		Polybutene	

C. Suspended Chemical Cases

EPA may issue a Notice of Intent to Suspend (NOITS) a pesticide product based on a finding that the registrant has failed to submit data under the requirement(s) of a FIFRA section 3(c)(2)(B) or a 4(d)(6) Data Call-In (DCI). Events that may result in the issuance of a NOITS include failing to provide adequate responses or data on time during the reregistration process or 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 713 NOITS actions for non-compliance with FIFRA resulting in 112 product suspensions from November 1989 to July 1994. 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.

D. Data Submitted for Reregistration

While EPA has formally evaluated the risks of only 61 chemical cases for which REDs have been completed, the Agency actually has obtained a substantial amount of information on the remaining chemicals.

Figure 3 shows the total number of studies received and reviewed by discipline for List A chemicals. The studies were submitted in re-

sponse to the Registration Standards issued prior to FIFRA '88, as well as subsequent Data Call-In Notices.

Figures 4, 5, and 6 show the total number of studies received and reviewed so far for List B, C, and D chemicals respectively in response to Data Call-Ins under FIFRA '88.

Figure 3
List A - Total Studies Received and Reviewed as of Third Quarter FY 94

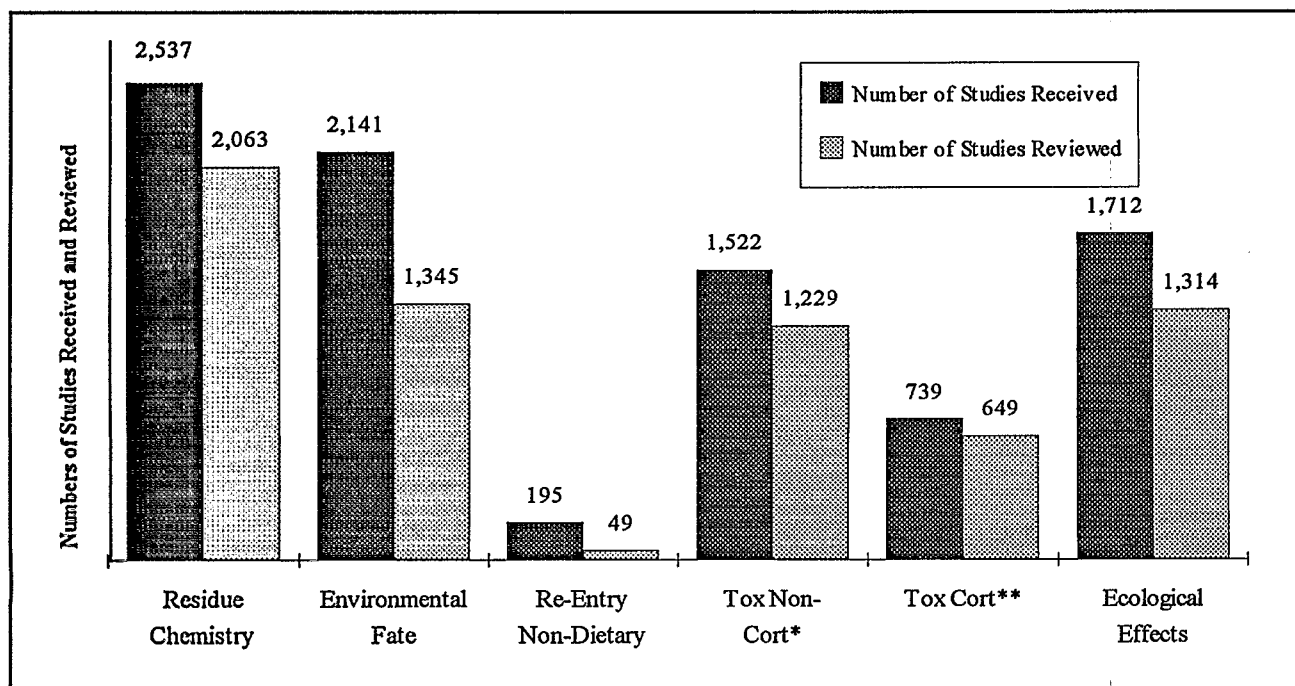
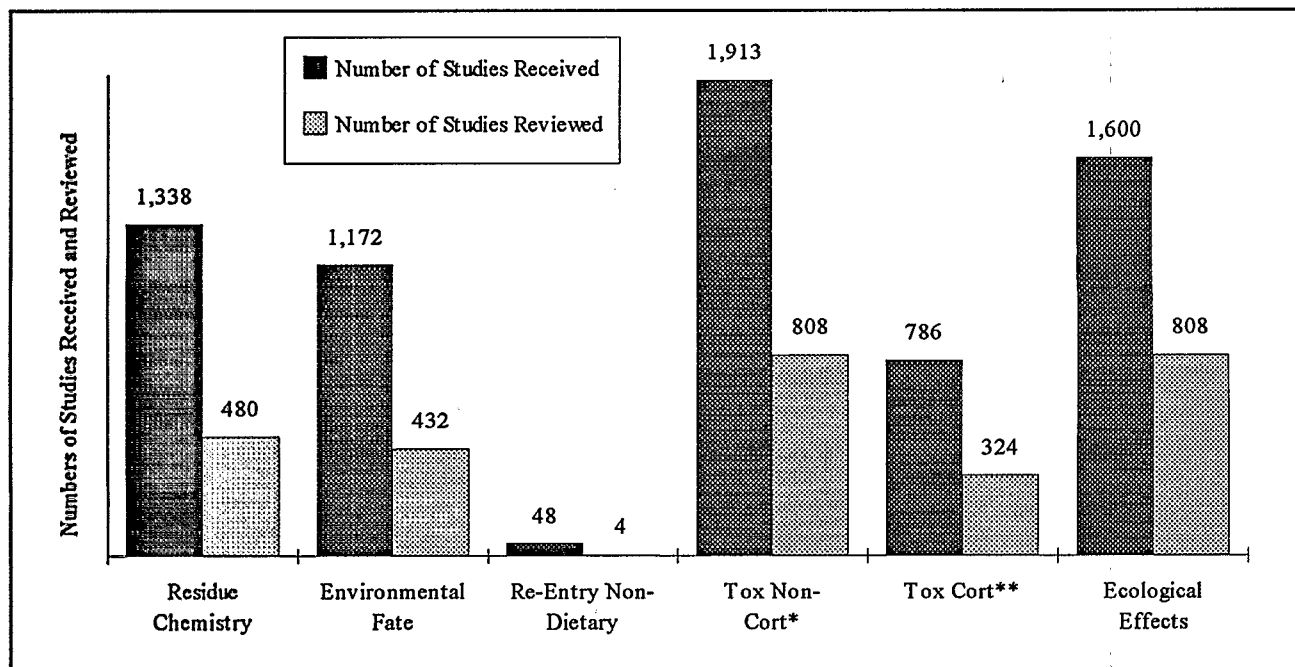


Figure 4
List B - Total Studies Received and Reviewed as of Third Quarter FY 94



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

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

Figure 5

List C - Total Studies Received and Reviewed as of Third Quarter FY 94

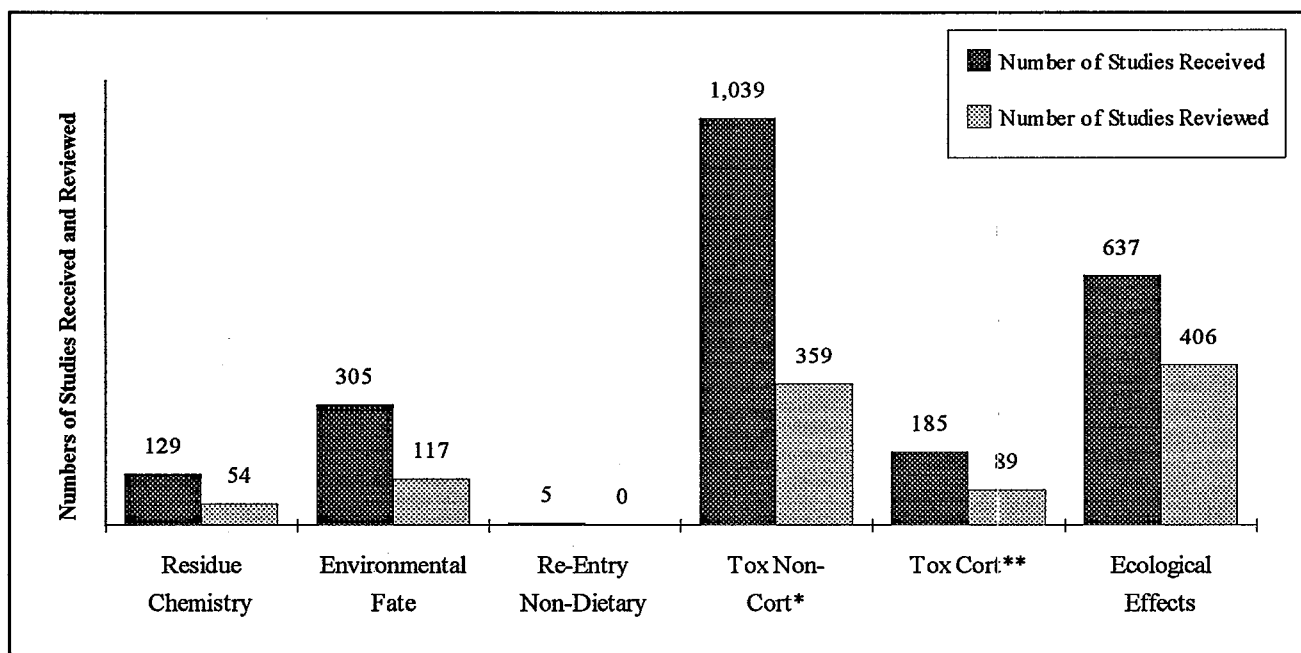
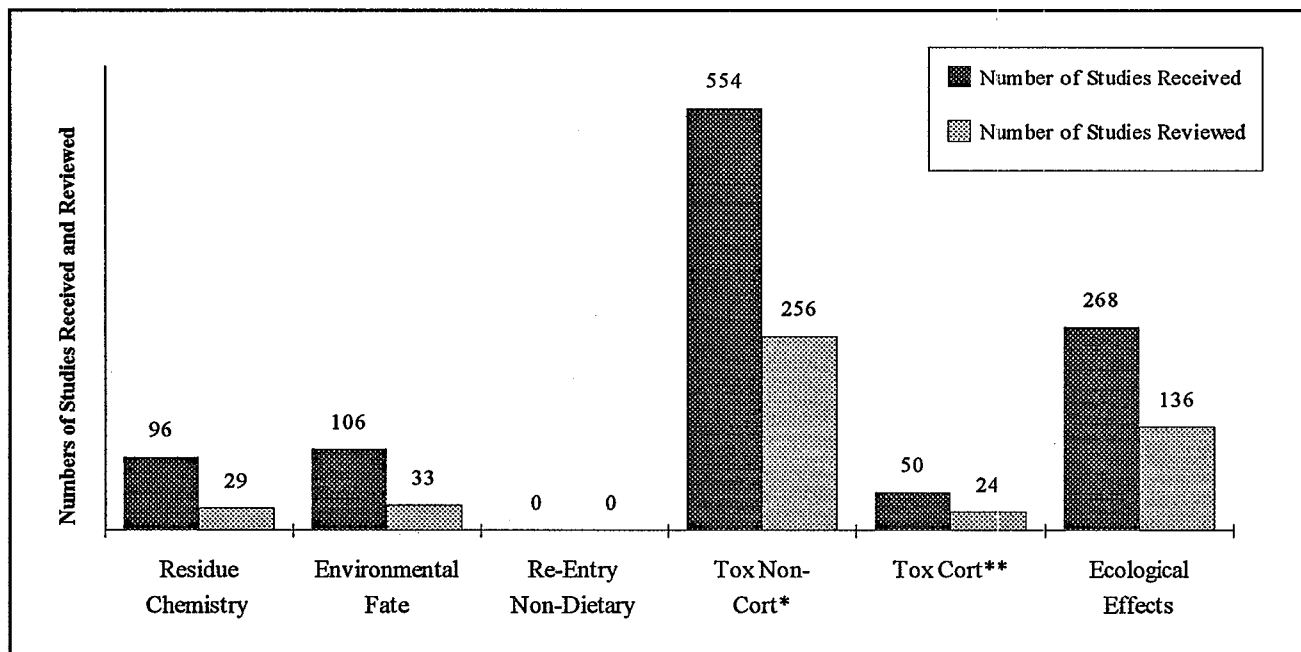


Figure 6

List D - Total Studies Received and Reviewed as of Third Quarter FY 94



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

*** 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). The Reregistration Notification Network (RNN) provides information to interested parties on recent or impending pesticide

cancellations. The information here was first published in the RNN, May 1994. For further information on any of the following pesticides, contact your NAPIAP State Liaison Representative or USDA at 301-504-8846.

Table 2
Proposed Use Cancellations or Tolerance Revocations - Third Quarter FY 94

Chemical	Products	Affected Uses
Benomyl	Benlate	DuPont Company plans to delete MUSHROOMS from all labels of the fungicide, benomyl, due to the cost of reregistration. They have recently notified EPA of this action, but EPA has not yet accepted this deletion. DuPont will consider supporting this use if another party wishes to develop the required data.
Dicofol	Kelthane	EPA is staying (postponing) the effective date of a final rule revoking the food additive tolerance for dicofol in or on DRIED TEA. This revocation has been postponed because of petitions submitted by the Dicofol Task Force (Makhteshim-Agan of North America, Inc., and Rohm and Haas Company) and NACA.
EBDCs	Mancozeb, Maneb, Metiram	EPA has announced that it plans to hold a hearing concerning the request of Elf Atochem and Griffin Corporations to amend all product labels of maneb, mancozeb, and metiram, which were affected by the final EBDC Cancellation Order. The amendment of these fungicide labels was requested to allow the use of more than one EBDC active ingredient per season per crop. Currently, these labels state, "If this product is used on a crop, no other product containing a different EBDC active ingredient may be used on the same crop during the same growing season." The proposed amendments would not change the current maximum allowable amount of EBDCs.
Granular Carbofuran		EPA has proposed to deny the request from FMC Corporation to reinstate the use of granular carbofuran on CORN and SORGHUM, but to grant FMC's request for an extension of two years to the phase-out period on RICE. These three uses of granular carbofuran are currently being phased out according to the terms on an Agreement in Principle between FMC Corp., and EPA that concluded the Special Review of granular carbofuran in 1991. EPA finds no basis for reinstating either corn or sorghum uses of granular carbofuran and the final date of use on these crops remains 9/1/94. EPA is proposing the extension of use on rice until 9/1/97 because there are currently no efficacious alternatives. Registration of reduced risk alternatives to control rice weevil is being encouraged.

Table 2, cont.

Proposed Use Cancellations or Tolerance Revocations - Third Quarter FY 94

Chemical	Products	Affected Uses
Methazole	Probe	EPA has extended the existing stocks provision for the cancellation of methazole for one year. This herbicide was registered for use on COTTON. Retailers still have an inventory of approximately 2,000 pounds of methazole and in order to deplete existing stocks, EPA is allowing the distribution, sale, and use of the remaining methazole product with revised supplemental labeling until 12/31/94.
Mevinphos	Phosdrin	EPA has received from Amvac Chemical Corporation, the sole technical registrant of mevinphos, an insecticide and miticide, a request to delete 26 sites from their labels and waive the 90-day comment period. Therefore, these deletions are effective as of 4/20/94. The deleted sites are ALFALFA, APPLES, BEANS, BEETS, CARROTS, CHERRIES, CLOVER, CORN, CUCUMBERS, DRIED PEAS, EGGPLANT, GRAPEFRUIT, OKRA, ONIONS, ORANGES, PEACHES, PEARS, PEPPERS, PLUMS, POTATOES, RASPBERRIES, SORGHUM, SUMMER SQUASH, TOMATOES, TURNIPS (ALL), and WALNUTS. EPA will notify you as soon as the final dates for the sale, distribution, and use of the existing stocks of mevinphos products labeled for these uses are finalized. A petition has been submitted by the Sierra Legal Defense Fund and the Farmworker Justice Fund to the EPA to immediately suspend and cancel all uses of mevinphos due to worker incidents. The Agency is currently considering this request among other options.
Pentachloronitrobenzene	PCNB	EPA has revoked the tolerance for residues of PCNB on BANANAS as of 4/13/94. This action has been taken because no registered use for this fungicide on bananas exists or has existed for more than six years.

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 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 should minimize the reoccurrence of deficiencies in

future studies as the Agency enters the major data submission phase of reregistration.

The Residue Chemistry, Toxicology, Environmental Fate, and Occupational and Residential Exposure Chapters of the Rejection Rate Analysis all have been completed and are available from U.S. EPA NCEPI, telephone (513) 891-6561, Fax (513) 891-6685. See Appendix B, Other Sources of Information, for the publication numbers of these documents.

The Ecological Effects chapter will be completed this summer.

C. Product Reregistration Status

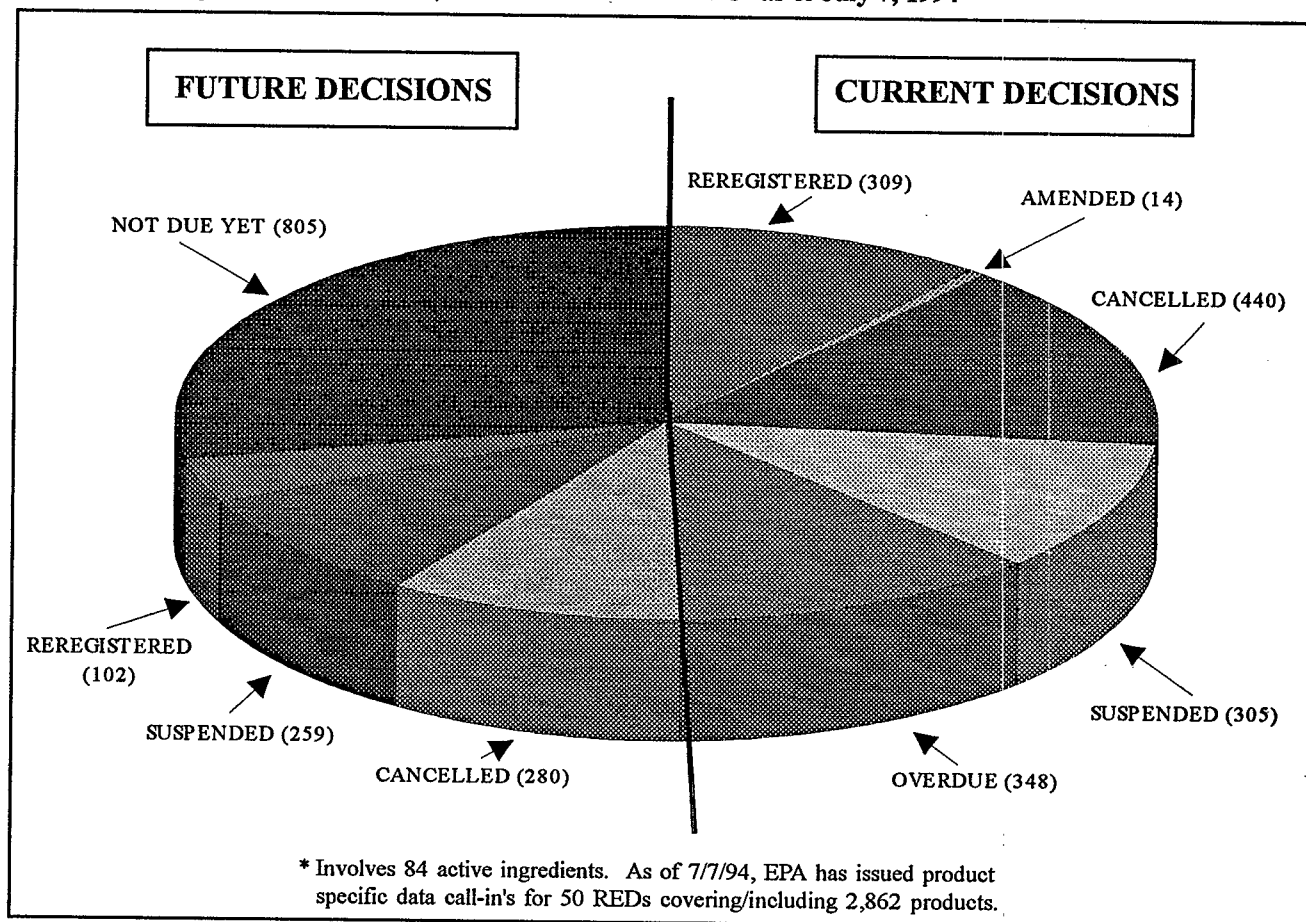
Figure 7 shows the status of products subject to Reregistration Eligibility Decisions (REDs) issued to date. "Current Decisions" covers those products for which EPA should have made a decision to reregister as of July 7, 1994.³ In this category, 309 products have been reregistered, 14 registrations have been amended, 440 products have been voluntarily cancelled, 305 product registrations have been suspended, and 348 still need a decision, for a total of 1,416 products. "Future Decisions" includes the 1,446 products

for which the Agency's product reregistration decision is not yet due. In this category, 280 products have been voluntarily cancelled, 259 suspended, 102 reregistered, and 805 are progressing toward a reregistration decision.

So overall, a total of 411 products have been reregistered, 720 have been voluntarily cancelled, 564 have been suspended, and 1,153 are pending.

Figure 7

Product Reregistration Status of 2,862 Products for 50 REDs* as of July 7, 1994



³ According to FIFRA, the Agency should reach a reregistration decision on each product 14 months after issuance of a RED, provided that the registrant(s) submit(s) acceptable data on time.

IV. TOPICS OF THE QUARTER

A. Minor Use Report Lists Unsupported Uses

In April, EPA and the Interregional Research Project No. Four (IR-4) presented an updated report on the status of certain minor use pesticides to the Minor Use Pesticide Working Group at USDA. Members from this workgroup represent the National Agricultural Chemical Association (NACA), and the Chemical Producers and Distributors Association (CPDA) and various grower groups concerned with minor use pesticide issues.

The report included a printout of IR-4's candidate database which had been updated using EPA's reregistration database. The updating resulted in 250 modifications to IR-4's database. The report listed 5000 Agricultural uses categorized into four groups: use retained, use cancelled, use not supported, and use currently supported by IR-4.

Once these categories are confirmed by the registrants for each pesticide, USDA's National Agricultural Pesticide Impact Assessment Program (NAPIAP) will notify grower groups

concerning those pesticides with unsupported uses via the Reregistration Notification Network (RNN). If you would like to receive notices of the RNN concerning these unsupported pesticide uses, call Kent Smith (USDA) at (301) 504-8846.

Minor uses are uses of pesticides on crops (hops and pineapples, for example) that are generally grown on small acreages where revenues from pesticide sales are too small for a pesticide manufacturer to seek or continue registration of a pesticide for production of that crop. These pesticide uses have been especially hard hit by reregistration. Many registrants have elected not to support the reregistration of these uses due to the cost of the required studies. The IR-4 program is a national agricultural program formed to obtain residue tolerances for minor use pesticides. The IR-4 program will continue to use this updated database to identify and prioritize unsupported pesticide uses for inclusion in the IR-4 minor use program.

B. OPP Workshop - Summary of Closing Remarks

For those who were unable to attend the final session of the OPP Workshop, the following is a summary of closing remarks by Dan Barolo, Director of the Office of Pesticide Programs.

I have enjoyed "the honeymoon," if you could call it that--my first several weeks in this position. However, it is now time to start making decisions, and this inevitably will piss people off.

In dealing with OPP, be aware that I am asking the staff to conduct business guided by the following principles:

- Teamwork - Work as a team with other Divisions and Branches, rather than defensively guarding your territory.
- Take Pride/Have Some Fun - Unlike those who work for public interest groups or private industry, OPP employees have no opportunity to be outraged. That's not our job or our role. We are here to listen to both sides, and then to make reasonable decisions that fall somewhere between the extremes. This is not an excuse for us to be bureau-

crats, however; we must act, and act responsibly, taking pride in our work.

People outside the Program are reminded that the OPP staff is a good one. Let them get on with their work, rather than besieging them with phone calls, special requests, etc.

- Open Up - I am committed to making information available to the public. Let us know how you think this can be done more effectively.
- Make Decisions - OPP will make earlier and timelier decisions. And be forewarned: the Agency also will take earlier, timelier enforcement actions. (For example, when studies are not received on time or are not acceptable, products will be suspended.)

It is my intention to:

- Open Up the Decision Process - Involve users/growers and others in OPP's registration and reregistration decisions.
- Target Resources - OPP does not have enough resources to do everything. We must and will drop some of our current projects/activities so that we can do others better.
- Automate - OPP should be able to have access to (and provide) fact sheets on every registered pesticide chemical, on an automated system that is updated regularly.
- Make Consistent Decisions - In sports, no one likes it when the same plays are called differently every time. The same is true in pesticide regulatory matters, and we will try to do a better job in this respect.

- Communicate our Accomplishments - OPP is criticized roundly for what is NOT YET DONE. The fact is that we have a LOT going on (such as issuing REDs, reassessing tolerances, registering new, safer chemicals, etc.). We need to publicize what IS going on, more widely.

- Delegate Authority - The authority to make decisions is going to be pushed down to the real people in the organization, so that our decisions will be better grounded in solid experience, and so the staff can take pride in making these decisions work.
- Take Enforcement Action - We will suspend products for which there are overdue or rejected studies. Users are asked to make sure their registrants (registrants of the pesticides they depend upon) are delivering the required studies.

- Knowingly Respect Others - We respect the agricultural community in the U.S. We are aware that you are not there pouring every pesticide you can get everywhere in sight. On the other hand, please understand and respect our duty to protect.

Finally, this is what I expect from you:

- Users - Maintain pressure on registrants. Make sure the registrants of pesticides you use understand your local needs. Also, press your user association to represent you fully.
- Environmental Groups - Understand the limitations of the law. We need to find a way to put a set of FIFRA amendments together that will fill the holes that now exist in the law.

-
- Registrants - Bring users into the picture. Consider what they want and need as you make product development plans and product support decisions.
 - OPP - Don't be afraid to make decisions. Answer questions; provide information in a usable form (such as fact sheets).
 - Media - We don't have an active, informed, involved media to carry our messages to the

world, or to let the public know what is going on. We need your involvement.

- Other Agencies - We need to build our partnerships at both the Federal and State level. USDA/Extension Service, FDA, the States, etc., all need to be fully involved. Help us find a way to accomplish this.

V. SPECIAL REVIEW DECISIONS

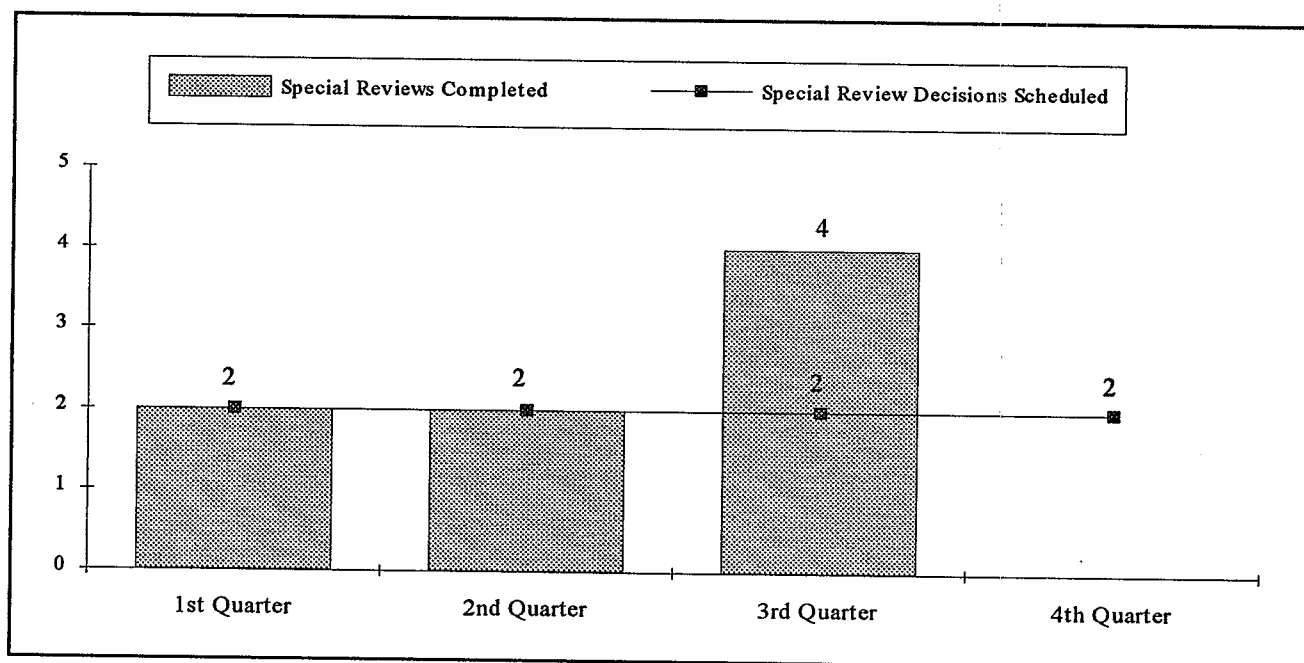
This section summarizes the significant regulatory decisions made on chemicals in the Special Review process during the third quarter, fiscal year 1994. The formal Special Review process for chemicals which have met or exceeded risk criteria of unreasonable adverse effects is set forth in 40 CFR Part 154.

Special Review decisions represent major EPA actions which may ultimately cancel, deny, or reclassify the registration of pesticide products, because uses of the products 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.

Figure 8, Special Review Decisions Scheduled and Completed, shows that OPP exceeded the scheduled target completing four special review decisions for the third quarter of FY 94. The target for FY 94 is a total of eight special review decisions. For further information on Special Review chemicals, please call (703) 308-8010.

Figure 8
Special Review Decisions Scheduled and Completed - FY 94



3rd Quarter Special Review Decision Summaries

Delaney Action (Final Rule, Denial of Stay) - EPA responded to objections and hearing and stay requests filed in response to a final rule revoking certain food additive regulations (tolerances) under section 409 of the Federal Food, Drug, and Cosmetic Act. EPA is denying the objections and hearing and stay requests on the

following section 409 food additive regulations: 1) benomyl- raisins and processed tomato products; 2) trifluralin - peppermint and spearmint oil; 3) mancozeb - bran of wheat; and 4) phosmet - cottonseed oil. As a result of this denial action, the above food additive regulations have been revoked.

Delaney Action (Proposed Rule Revoking Certain Food Additive Regulations) - EPA proposed to revoke certain food additive regulations for several pesticides which EPA has determined "induce cancer" within the meaning of the Delaney Clause. The food additive regulations being proposed for revocation include captan, ethylene oxide, mancozeb, oxyfluorfen, propargite, propylene oxide and simazine.

Delaney Action Final Rule; Mancozeb on Raisins; Removal of Food Additive Regulation - EPA removed the food additive regulation for mancozeb on raisins in 40 CFR 185.6300. Data show that this regulation is not needed because any residues of mancozeb on raisins are covered by the tolerance set for the corresponding raw commodity (grapes).

Simazine (Notice of Intent to Cancel) - EPA announced its intent to cancel the remaining pesticide registrations for simazine products used in swimming pools, hot tubs and whirlpool baths. This action has been taken because the Agency believes that the use of the products has the potential to cause cancer and non-cancer effects as a result of exposure to simazine in swimming pools. The Agency believes that the risks from this particular use exceed the benefits derived from the use. The notice of intent to cancel was signed on June 28 and published in the FR on July 6. The cancellation becomes effective in 30 days unless a hearing is requested. No further sale, distribution, or use of existing stocks of the cancelled products will be allowed. All other registrations for these uses of simazine were previously voluntarily cancelled.

Wyoming Toad Issue - The Wyoming toad has been on the Endangered Species list since 1984. A March 1994 revised Biological Opinion by the Fish and Wildlife Service (FWS) listed 43 active ingredients as likely to jeopardize the continued

existence of the Wyoming toad, and recommended that EPA implement "reasonable and prudent alternatives" to protect the toad from these pesticides. EPA headquarters worked in conjunction with EPA Region 8, the Wyoming Toad Recovery Group, FWS, and the U.S. Department of Agriculture to coordinate the 1994 Toad Protection Program. As a result of the program, a number of steps have been taken this year to protect the toad:

- 1) Agreements were reached with all Wyoming landowners within the range of the toad to search high quality potential habitat.
- 2) Landowners and Albany County Wyoming mosquito districts agreed not to apply pesticides in high quality habitat areas until searches were completed and no toads were discovered.
- 3) During June and early July, all of the properties containing high quality habitat were searched for toads.
- 4) No new toad populations were identified, so spraying was allowed in areas where the toad was not found.

The 1994 Toad Protection Program is a good example of federal, state, and local officials working together to implement provisions of the Endangered Species Act.

Tolerance Revocations

During the third quarter of fiscal year 1994, SRRD processed two tolerance related actions. A description of each of those follows.

Pentachloronitrobenzene - The Agency revoked the interim tolerance (40 CFR 180.319) for residues of the fungicide pentachloronitrobenzene (PCNB) in or on bananas. No registered uses for PCNB on bananas remained

trobenzene (PCNB) in or on bananas. No registered uses for PCNB on bananas remained and the use was not being supported for reregistration. The notice, a final rule, was published in the Federal Register on April 4, 1994 (59 CFR 17486).

Perthane - The Agency proposed to revoke the tolerances listed at 40 CFR 180.139 for residues

of the pesticide 1,1-dichloro-2,2-bis(p-ethylphenyl)ethane (also known as Perthane, Ethylan, or diethyl diphenyl dichloroethane) in or on raw agricultural commodities. The action is being proposed because all registrations of Perthane have been cancelled. The proposed notice was published in the Federal Register on June 1, 1994 (59 FR 28326).

VI. CALENDAR OF EVENTS (FY 1994)

4th Quarter FY 94

- Twenty-four REDs are scheduled to be completed, for a total of 38 since the beginning of FY 94.
- Two special review decisions are scheduled to be completed for a total of 10 since the beginning of FY 94.
- The Ecological Effects chapter of the Rejection Rate Analysis is scheduled to be completed.

Appendix A. Cumulative Summary of Reregistration Actions

The following is a cumulative summary of the reregistration actions completed to date. OPP has completed REDs and summary fact sheets for each of the pesticides (cases) listed below. Copies of the REDs and the fact sheets may be obtained during the public comment period from the Docket, Public Response and Program Resources Branch, Field Operations Division (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, 5285 Port Royal Rd., Springfield, VA 22161 Tel: (703) 487-4650. RED documents issued since April 1994 are available free of charge while supplies last from the National Center for Environmental Publications and Information (NCEPI), P.O. Box 42419, Cincinnati, OH 45242 Tel: (513) 891-6561, Fax: (513) 891-6685.

CUMULATIVE RED TOTALS

Total REDs = 61
Total Chemicals/AI's Covered = 99
Total Products Covered = 3,091
Total Tolerances Reassessed = 263

DATA CALL-IN SUMMARY

<u>Fiscal Year</u>	<u>Number of DCIs Issued</u>
FY 1990	27
FY 1991	159
FY 1992	97
FY 1993	93
FY 1994	72
Total	448

FY 91 REDs Summary

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

* 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

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

** Voluntarily cancelled

FY 93 REDs Summary

<u>RED Case Name</u>	<u>List</u>	<u>Date Signed</u>	<u># Chemicals/AIs Covered</u>	<u># Products* Covered</u>	<u>Total Tolerances</u>
29. Biobor	C	6/93	2	12	0
30. Boric Acid	A	9/93	7	189	1
31. Butylate	A	9/93	1	14	3
32. Cedarwood Oil	C	9/93	1	5	0
33. Daminozide	A	9/93	1	4	0
34. Eugenol***	D	9/93	1	5	1
35. Glyphosate	A	9/93	2	56	126
36. Inorganic Halides	D	9/93	2	35	0
37. Iron Salts	D	3/93	3	5	0
38. Menthol	D	9/93	1	1	1
39. OBPA	A	6/93	1	15	0
40. Oxalic Acid	D	12/92	1	4	0
41. Oxytetracycline	A	3/93	3	7	2
42. PEP(phenylethyl Propionate)***	C	9/93	1	5	0
43. Silver	D	7/93	1	65	0
44. Sodium Lauryl Sulfate	D	9/93	1	2	1
45. Sulfuryl Fluoride	A	9/93	1	1	0
46. Thymol	C	9/93	1	5	0
47. Tris(hydroxymethyl)nitromethane	C	9/93	1	9	0
Totals			32	439	135

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

** Voluntarily cancelled.

*** Exempted from regulation as pesticides under Section 25(b) of FIFRA.

FY 94 REDs Summary

<u>RED Case Name</u>	<u>List</u>	<u>Date Signed</u>	<u># Chemicals/AIs Covered</u>	<u># Products* Covered</u>	<u>Total Tolerances</u>
48. Barium Metaborate	A	12/93	1	3	0
49. Bromine	D	12/93	1	4	1
50. Lithium Hypochlorite	C	12/93	1	40	0
51. Mineral Acids	D	12/93	4	212	0
52. Peroxy Compounds	D	12/93	3	23	0
53. Vegetable and Flower Oils	D	12/93	6**	32	0
54. 2-[(Hydroxymethyl) Amino] Ethanol or Ethanolamine	C	3/94	2	3	0
55. Hexadecadienol Acetates	D	3/94	2	18	0
56. Methiocarb	A	3/94	1	22	0
57. Periplanone B	B	3/94	1	1	0
58. Pronamide	A	3/94	1	18	46
59. Tebuthiuron	A	3/94	1	12	15
60. Maleic Hydrazide	A	6/94	2	26	4
61. N6-Benzyladenine	B	6/94	1	2	0
Totals			27	416	66

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

** One A.I., "essential oils" will become 24 A.I.s after the RED is issued; many of these will eventually be declared inert ingredients.

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

Fax: (513) 891-6685

- Catalog of OPP Publications and Other Information Media, March 1994
Publication Number: EPA 730-B-94-001
Lists titles and ordering information for many types of documents published by the Office of Pesticide Program.
- Pesticide Reregistration Pamphlet, May 1992
Publication Number: EPA 700-K92-004
- Status of Pesticides in Reregistration and Special Review (Rainbow Report), June 1994
Publication Number: EPA 738-R-94-003
- Rejection Rate Analysis, Residue Chemistry Chapter, June 1992
Publication Number: EPA 738-R-92-001
- Rejection Rate Analysis Residue Chemistry Guidance on Conducting Plant and Livestock Metabolism Studies
Publication Number: EPA 738-B-92-001
July 1992.
- Rejection Rate Analysis Residue Chemistry Guidance for:
Storage Stability
Theoretical Concentration Factors
Raw Data Guidance
Publication Number: EPA 737-R-93-001
February 1993.
- Rejection Rate Analysis Residue Chemistry/Environmental Fate Guidance for:
Conducting Rotational Crop Studies
Publication Number: EPA 738-B-93-001
February 1993.
- Rejection Rate Analysis, Environmental Fate Chapter, August 1993
Publication Number: EPA 738-R-93-010
- Rejection Rate Analysis Toxicology Chapter, July 1993
Publication Number: EPA 738-R-93-004
- Rejection Rate Analysis Occupational and Residential Exposure Chapter, August 1993
Publication Number: EPA 738-R-93-008
- Rejection Rate Analysis Residue Chemistry Guidance for:
Updated Livestock Feed Tables
Aspirated Grain Fractions
Calculating Livestock Dietary Exposure Number and Location of Domestic Crop Field Trials
Publication Number: EPA 738-K-94-001
June 1994.

Federal Register Publication of Lists A, B, C
and D

List A: FR 2/2/89, pages 7740-7750
List B: FR 5/25/89, pages 22706-22714
List C: FR 7/24/89, pages 30846-43396
List D: FR 10/24/89, pages 43388-43396
For information contact: (703) 305-5805

Status of Chemicals in Special Review,

April 1994

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

Comments

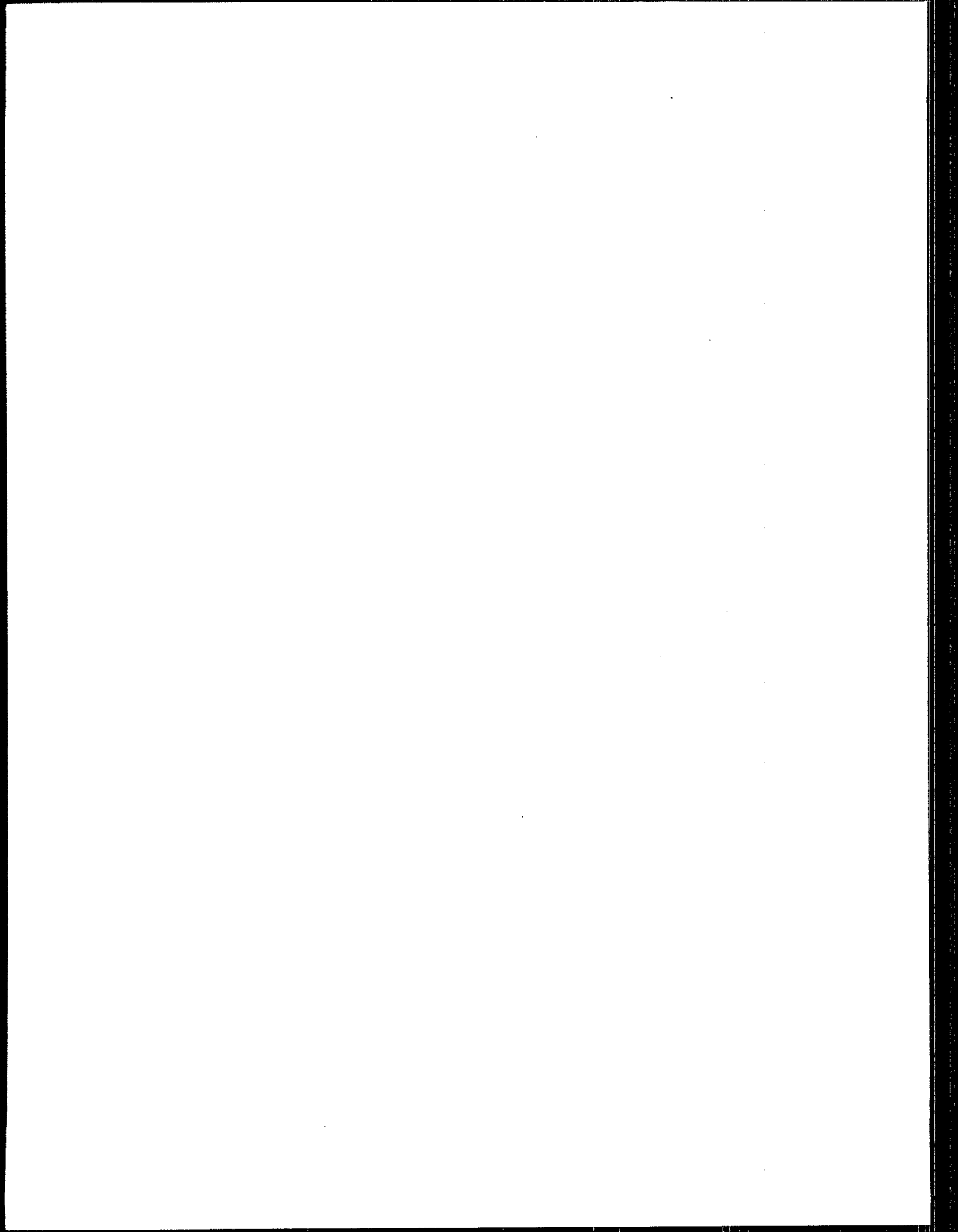
EPA welcomes your comments on this progress report or on activities related to reregistration.
Please address your comments to the following:

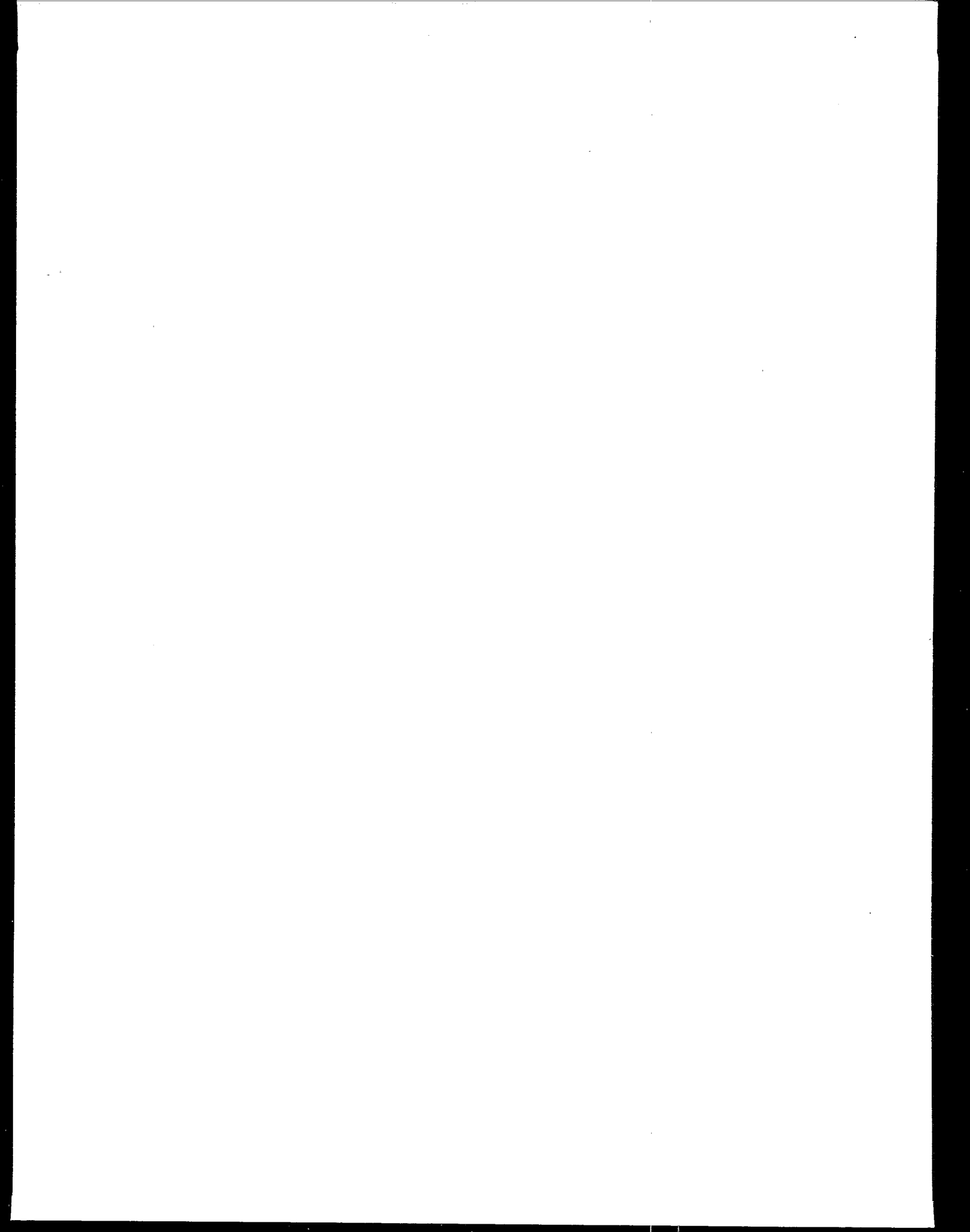
Attention: Ed Setren

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

For more copies of this report (Publication Number: EPA 738-R-94-014) or to be added to the
"SRRD MABELS" mailing list, please write or fax to the following address:

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