

IR-4 - A National Agricultural Program
to Clear Pest Control Agents and
Animal Drugs for Minor Uses.

IR-4 Headquarters Report Table of Contents

<u>P</u> a	<u>age</u>
Executive Summary	1
Crop Protection Update: Petition Successes and Progress	11
1989 Report on IR-4 Food Use Research	17
IR-4/EPA Liaison Update	20
IR-4 Biorational (Microbial and Biochemical) Program 2	21
Ornamental Minor Use Program Update3	32
IR-4 Animal Drug Clearances 3	38
FIFRA 88 Documentation	20

26th IR-4 Annual Meeting

IR-4 Crop & Animal Protection Clearance Overview

Food Commodity Successes

In calendar year 1988 and the first quarter of 1989, IR-4 petition submissions resulted in pesticide clearances representing 109 tolerances (pesticide/crop), including 6 crop definitions. IR-4 continued to account for about 50% of all the new use petitions approved by EPA for raw agricultural commodities during 1988. Additionally, IR-4 HQ continues to submit regulatory crop group definition petitions to the Agency. These types of requests expedite the clearances of many minor crops by establishing regulations that can be used by IR-4 for petitions, and registrants for labels.

The IR-4 Biorational program continues to develop the necessary toxicology and environmental data for the clearance of the CMGV for use in orchard crops. The EUP is in the process of being extended for two more years. Funding from IR-4 HQ has been used as seed money to obtain matching dollars from the state of CA for the CMGV project. IR-4 has also been successful in obtaining an EUP for the Grape Berry Moth Pheromone.

During the same period, IR-4 Animal Drug petition (Public Master File) submissions resulted in four (4) approvals as follows:

Bacitracin MD/Quail/University of FL and A.L. Labs. Fenbendazole/Bighorn Sheep/WA State University and Hoechst-Roussel Agri-Vet. Co. Salinomycin/Quail/USDA-ARS and A.H. Robins Co. Ivermectin/Goat/University of NE and Merck & Co.

<u>Issues</u>

Funding GLP Reregistration & FIFRA 88 NACA Proposal to EPA Need for IR-4

Funding

There is little need to dwell on the costs of adding reregistration, GLP, etc. to IR-4. In terms of time, we can figure that the protocol and petition writing requirements at HQ will have to increase with the increased requirements and the need to complete more projects. The management and financial resources currently are strained by just carrying on our normal activities. These additional issues (GLP, etc.) must have additional monies and personnel. More full time people and space are needed at HQ to address the reregistration (FIFRA 88) issue as follows:

- Reformatting old IR-4 petitions that were written prior to 1987.
- Reregistration petitions.
- Addressing proposed cancellations of needed uses.
- GLP, including archives.
- More projects.

At this meeting, we will be presenting to the AA/TC a proposal to fund an interactive on-line computer program for the pesticide and animal drug programs. The proposal was developed around the new mainframe computer which is housed at Cook College.

Our first increase in funding for the pesticide program since 1982 is proposed for FY 90 (additional \$631K). We thank the WSSA for their outstanding support of the IR-4 funding issue. Without their input our chance of an increase for FY 90 would have been a dream. Of course, credit is given to a lot of people and organizations for supporting the Project.

The funding for the drug program needs to be increased. With new funds, an animal scientist could be hired at HQ to conduct the necessary national coordination of the protocols and PMF, NADA and vaccine research, including EA and FOI as well as handling all the coordination requirements for the program. There needs to be a national SAES focus in order to interface with <u>all</u> federal and state agencies.

Additionally, stable funding is a requirement for IR-4 in order for it to move forward. PL 89-106 is not supplying that needed stable funding base.

Funding (Con't)

In order to increase our funding, we must present the average cost of a representative project for clearance purposes. In developing an asking budget, we need to establish a base-line cost for regional and interregional projects. Presently, we have over 1000 researchable food use pesticide projects on the books with half being regional in nature. Cost estimates to clear these projects under GLP's are, as a general example:

-	Field (each location) Laboratory (each location) (25 samples x 2 injections X (includes QC, residue & stora		\$ 3,500 7,500
	analyses) For one location (TOTAL)		\$11,000
-	Regional use registration cost \$11,000 x 2 locations	=	\$22,000
-	National use registration cost \$11,000 x 4 locations	=	\$44,000
	Therefore,		
-	500 regional registration proj equate to: 500 x \$22,000 = \$	ects would	
-	500 national registration proj	ects would	

- 500 national registration projects would equate to: 500 x \$44,000 = \$22,000,000

TOTAL \$33,000,000

These are conservative estimates and they do not include HQ costs to develop protocols, and review and evaluate data to write petitions and the Regional Laboratories indirect costs.

We need, at this meeting, to fix a cost estimate to be able to present a unified picture, including states & ARS of what we need in the way of funds to support the needs of the growers and the food safety concept for the U.S. consumer.

GLP

IR-4 GLP programs (field & lab) are not set in stone. As we gain experience in the program, we can modify as needed. But the program elements as required by the Agencies are in place.

We note the outstanding job done by Dr. Baron in coordinating the field GLP program, Dr. Schwartz for the ARS program, the Technical Committee for the Lab GLP's, and Dr. Boyd for his valuable input for both the field and lab GLP's. GLP's are also in place for the animal drug program.

In line with these GLP programs, additional responsibilities have been incorporated as follows:

- Field Study Director SOP's
- Pesticide Regional Coordinators/representative -Field QA
- Laboratories SOP's & QA
- HQ GLP protocol packages, certification of GLP, archives & coordination of GLP program on a national level.

GLP's are now! Everyone, including Cos., EPA, FDA, is taking it very serious. The tracking is a must. Standardized reporting forms for field and lab data are necessary.

Pesticide Reregistration & FIFRA 88

The new amendments to the law require that reregistration must be accelerated and completed by 1997. The clock is running now. The time frame calls for industry to evaluate the current data base, identify data requirements and pay their fees three months after publication of the lists. With the deadlines for continuation of products and uses accelerated, the decision time by the manufacturers is the next 10 months. Can the manufacturers do all the work in the next 4 years for all their products? It is very questionable with lab. space and personnel at their disposal. Therefore, the reregistration of many minor uses will fall on IR-4 & the growers, let alone the reformatting of IR-4 petition data submitted prior to 1987. Of course, under our present funding situation, this is not a satisfactory solution. Without legislative relief, things will get worse.

EPA is beefing up its scientist staff to review the new data; we need to do the same.

EPA is helping the growers by putting IR-4 in the reregistration loop by incorporating in the reregistration quidance packages to registrants the following alternatives:

- to pursue crop groups that include minor crops
- to pursue crop definitions that include minor crops
- review all data to see if the body of data can support minor uses
- contact IR-4 to determine if we have any data to support reregistration of minor crops

Presently, IR-4 is informing the growers of potential cancellation of products and uses via the "IR-4 Red Alert". EPA plans to distribute the "IR-4 Red Alert" to a growing mailing list of interested parties, including growers.

People, including agencies, are recognizing the important part IR-4 will play (& is playing) in aspects of leadership and management to address the reregistration question.

Summary of NACA Proposal to EPA Concerning Minor Uses

- A. Definition of Minor Uses retain economic concept
- B. Administrative Improvements by EPA
 - Petition fees exemption of all minor uses regardless of submitter.
 - Expedite all minor use registrations & do not impose new data requirements when label is amended to include minor uses.
 - Solicit more input from grower groups prior to cancellation.
 - Accept all minor use residue data submitted by IR-4 regardless of whether or not it was developed by IR-4, grower groups, registrants, or other state or federal agencies.
- C. Reduce data requirements by extrapolation to existing data.
 - Allow residue data from ground applications to suffice for aerial use.
 - Eliminate requirements for minor metabolite analysis. Extrapolate from parent/metabolite data ratios.
 - Use of sunset tolerances.
- D. Registrant Activities
 - Continue to support IR-4 through either funding to universities, conducting analyses or sharing of data.
 - Support permanent funding for IR-4.
 - Develop guidelines for addressing liability issue.
 - Advise growers immediately when a decision has been reached to <u>not</u> defend a product or use.
- E. Third Party Registrations
 - Growers are encouraged to get involved in supporting the defense of desired products & uses, develop agreements for releasing liability, and set up check-off program to support development of data.

Need for IR-4 Continues

IR-4 has the <u>established</u> state/federal/industry (both Cos. and growers) contacts and organization that can react to the needs of the growers which in turn reflects on food safety. We understand the need for food and environmental safety, and crop and animal protection.

We continue to support (in context with our limited funding) the needs of the growers via the SAES with the following:

- Alternative crops, <u>i.e.</u>, mayhaw, kenaf, crambe, oriental crops, etc.
- Reregistration.
- Crop groups and crop definitions.
- LISA (Low-Input Sustainable Agriculture) to remain competitive, growers may need to take the surviving pesticides and combine them with cultural practices to solve pest problems. IPM programs will require the retention of certain pesticides under reregistration.
- New pesticide uses to replace some of the products that will be dropped.
- New animal drug uses.

NOTES

Summary of IR-4 Research

R.T. Guest

In terms of IR-4 minor food use needs, the IR-4 Project is alive and well. During the past 12 months, we received 266 new requests which, although down from last year, matches our 11 year average. As a result, we now have a backlog of about 1113 researchable projects, about 45% of which are national needs and 55% local or regional needs. Currently, we have 125 reregistration requests, of which 11 are considered to be researchable projects.

For the 1989 crop season, we have scheduled through the four regional offices and USDA-ARS, about 185 research projects involving more than 300 individual field trials. This is down over the five year average of 237 projects and reflects the tight money situation. Six of the research projects this year involve reregistration. All field research will be conducted according to IR-4 GLP procedures.

Activity in the ornamentals area is down. Only 97 new projects were added during the past 12 months with about 490 field trials involving 370 ornamentals requests funded in 1988. During the past year, 153 ornamental registrations were obtained based on IR-4 data, which is considerably fewer than normal. Two factors have negatively impacted on the IR-4 Ornamentals Program: one is the short fall in funding; the other is the fact that pesticide manufacturers are diverting manpower from ornamentals registrations to reregistration of food uses.

IR-4 funded two biorational projects in 1988: the continuing California research on the codling moth Granulosis virus, and a research project in Michigan with Xanthomonis compestris for control of annual bluegrass in turf. The CMGV project should be completed with labelling anticipated by 1991. The Xanthamonis project will be repeated in 1989 because of the 1988 drought.

IR-4 held EPA/IR-4 Workshop XII at Newport Beach, CA on March 14-16, 1989. About ninety people attended this workshop with good representation from the agricultural chemicals and food producers industries. The objectives of the workshop were to introduce a representation of our research cooperators to IR-4 Field Good Laboratory Practice procedures, and to review and prioritize IR-4 food use requests. Dr. J. Blair Bailey was instrumental in demonstrating the GLP procedures used by himself and his technicians for IR-4 field trials conducted at the University of California South Coast Research Station.

Continued.....

Page 2

Summary of IR-4 Research (Cont'd.)

The disciplinary working groups reviewed 525 candidate food use projects for national labelling and established "HIGH" priorities for 105 insecticides, 64 fungicides and 97 herbicides. In addition, 625 LDI requests were briefly reviewed for additional state interest. This information, together with that provided by EPA at our annual review, will be included in the researchable project printouts distributed to liaison representatives for use at the 1989 regional and USDA-ARS meetings.

IR-4 is grateful to EPA for once again providing grant funding to support this workshop, and to Dr. Marty Kovacs, Mr. Hoyt Jamerson and Mr. Drew Baker for serving as EPA resource persons on the review panels.

4/4/89

IR-4 Annual Meeting April 13-14, 1989

CROP PROTECTION UPDATE: PETITION SUCCESSES AND PROGRESS

G.M. Markle, J.J. Baron, W.L. Biehn, P.L. Pontoriero

Successes

In calendar year 1988 and the first quarter of 1989, IR-4 petition submissions resulted in pesticide clearances representing 109 tolerances including 6 crop definitions. These are reviewed in detail below:

- (1) FUNGICIDES AND NEMATICIDES (6 tolerances):
 Fenamiphos/kiwifruit (R), non-bell pepper (R) Metalaxyl/
 papaya (R) PCNB/collard (R), kale (R), mustard greens (R)
- (2) HERBICIDES (56 tolerances): Clomazone/pumpkin, succulent pea - DCPA/Brassica leafy vegetables - Fluazifop/asparagus (R), coffee (R), endive (R), rhubarb (R), spinach - Glyphosate/asparagus, atemoya, beet, bulb vegetables, carambola, carrot, chicory, horseradish, Jerusalem artichoke, parsnip, potato, radish, rutabaga, salsify, sugar apple, sugar beet, sweet potato, yam - Metolachlor/cabbage, Napa cabbage - Oxyfluorfen/macadamia nut (R) - Pendimethalin/garlic (R) - Prometryn/dill (R) - Pronamide/winter pea (R) - Sethoxydim/ artichoke (R), lentil - Sodium Chlorate/dry beans, Southern pea
- (3) INSECTICIDES AND MITICIDES (28 tolerances): Carbaryl/dill (R) - Cryolite/kiwifruit (R) - Diazinon/Chinese radish (R) - Diflubenzuron/range grass (R), walnut -Methidathion/citrus - Menthol/beeswax & honey - Methomyl/ Brassica leafy vegetables, leek - Parathion/lentil -Permethrin/avocado (R), cucurbits, dry onion, garlic, papaya (R) - Phosmet/crab apple (R)
- (4) CROP DEFINITIONS (19 tolerances): Blackberries = boysenberry, dewberry, marionberry, olallieberry, and varieties and/or hybrids of these; Caneberries = blackberry, loganberry, red and black raspberries, youngberry, and varieties and/or hybrids of these; Green Onion = green shallot or green eschalot, Japanese bunching onion, leek, spring onion or scallion; Lentil = pea; Onion = dry bulb onion, garlic and green onion; Oregano = marjoram

Additionally, 3 tolerances have been proposed. These proposals will become clearances in this calendar year. The EPA Minor Use Policy Statement which was published in the 2 APR 86 Federal Register included a list of low dietary intake crops for which tolerances can be established on a geographically limited label (GLL) basis. In line with this policy, the above clearances which have the (R) designation are tolerances with regional registrations.

IR-4 continued to account for about 50% of new use petition successes for raw agricultural commodities (RAC) during 1988. In 1988, a total of 51 (both major & minor uses) tolerance documents were published by EPA. In 1985, 1986 and 1987, the total number of documents (IR-4 & Industry) published were 42, 39, and 47, respectively.

PROGRESS

IR-4 wrote 62 tolerance and reregistration petitions between 1 JAN 88 and 31 MAR 89. Fifty-two (52) petitions were submitted to EPA (Table A) and 10 petitions are still under review by the manufacturers who are the eventual label registrants (Table B). Additionally, 9 major petition amendments were submitted to EPA (Table A). The amendments to previously submitted IR-4 petitions answered EPA's responses for the need for additional residue or toxicology data. EPA responses to IR-4 petitions during this period are summarized in Table C.

In addition to the above petitions, IR-4 continues to request crop group extensions; we have submitted petitions requesting the following changes in the regulations:

- a) Add definition of pumpkin to include winter squash, butternut squash, calabaza.
- b) Include the crop, calabaza, in the established squash definition.
- c) Add definition of head lettuce to include tight head varieties of lettuce, crisphead lettuce, butterhead lettuce, radicchio, red chicory and Italian chicory.
- d) Add definition of leaf lettuce to include escarole, endive, cos (romaine) lettuce, stem lettuce, asparagus lettuce and celtuce.
- e) Include the crop, mayhaw, in the established pome fruit crop group.

IR-4 requests such changes or additions to crop definitions in order to expedite pesticide registrations for many minor crop uses. The incorporation of these concepts into the <u>Code of Federal Regulations</u> or <u>EPA Opinion Letters</u> permits great savings in time, manpower and financial resources for both IR-4 and EPA and better serves the needs of the U.S. Farmers, as well as, the U.S. Consumers.

EPA's mandated reregistration of pesticides continues to affect the progress of IR-4 in obtaining clearances of minor use pesticides for older chemicals. Again, certain tolerances requested by IR-4 have not been established because EPA has indicated that existing toxicology or methodology data bases were not adequate to support new tolerances at that time.

TABLE A IR-4 TOLERANCE PETITIONS AND MAJOR AMENDMENTS SENT TO EPA JANUARY 1, 1988 TO MARCH 31, 1989

FUNGICIDES

CHEMICAL	CROP	DATE SENT
1. METALAXYL 2. IPRODIONE 3. IPRODIONE 4. IPRODIONE 5. IPRODIONE 6. FENAMIPHOS 7. FENAMIPHOS 8. METHYL BROMIDE +	PAPAYA (HI ONLY) SWEET CHERRY (POST HARVEST) NECTARINE (POST HARVEST) PEACH (POST HARVEST) PLUM (POST HARVEST) BEET (EAST OF MISSISSIPPI RIVER) EGGPLANT GINGER	1-18-88 3-2-88 5-18-88 5-18-88 5-18-88 6-7-88 6-7-88 10-20-88
CHLOROPICRIN		

HERBICIDES

CHE	MICAL	CROP	DATE SENT
1.	CLOMAZONE	SUCCULENT PEA	1-25-88
2.	METOLACHLOR		2-23-88
3.	FLUAZIFOP	PARSLEY (NJ, MD, DE ONLY)	3-7-88
4.	FLUAZIFOP		3-14-88
	CLOMAZONE	SWEET POTATO	3-23-88
	METOLACHLOR		4-21-88
7.	FLUAZIFOP	COFFEE (HI ONLY)	7-1-88
8.	OXYFLUORFEN		7-30-88
9.	ORYZALIN	COFFEE (HI ONLY)	9-1-88
10.	2,4-D	RASPBERRY (MN ONLY)	10-31-88
	METOLACHLOR	CUBANELLE PEPPER (PR ONLY)	11-9-88
12.	GLYPHOSATE	LONGAN, MAMEY SAPOTE,	12-6-88
		LYCHEE, SAPODILLA,	
		PASSION FRUIT	
13.	OXYFLUORFEN	PERSIMMON	12-13-88
14.	OXYFLUORFEN	DRYLAND TARO (HI ONLY)	12-13-88
	PARAQUAT	DRYLAND TARO (HI ONLY)	2-21-89
	FLUAZIFOP	MANGO	2-22-89
17.	FLUAZIFOP		2-22-89
18.	GLYPHOSATE	DATE, BREADFRUIT, JABOTICABA,	3-22-89
		JACKFRUIT, PERSIMMON, BLACK	
		SAPOTE, WHITE SAPOTE, SOURSOP,	
		TAMARIND, CANISTEL	
19.	OXYFLUORFEN	HORSERADISH	3-23-89

TABLE A PETITIONS.....CON'T

INSECTICIDES

CHEMICAL	CROP	DATE SENT
1. OXAMYL 2. AZINPHOSMETHYL 3. PHOSMET 4. PERMETHRIN 5. ESFENVALERATE 6. DIAZINON 7. CRYOLITE 8. OXYDEMETONMETHYL 9. MENTHOL 10. PERMETHRIN 11. ESFENVALERATE 12. ZINC PHOSPHIDE 13. ESFENVALERATE 14. CARBOFURAN 15. ZINC PHOSPHIDE 16. CYROMAZINE	CUCURBIT VEGETABLES PINEAPPLE (PR ONLY) PISTACHIO KIWIFRUIT (CA ONLY) SWISS CHARD (CA ONLY) HONEY & BEESWAX RASPBERRY (OR, WA ONLY) CRANBERRY (DRY HARVEST ONLY) ARTICHOKE (CA ONLY) STRAWBERRY MINT (ID, OR, WA ONLY)	2-29-88 3-10-88 4-15-88 5-2-88 5-17-88 6-15-88 7-27-88 7-28-89 9-27-88 12-21-88
	REREGISTRATION PETITIONS	
CHEMICAL	CROP	DATE SENT
2. GLYPHOSATE 3. GLYPHOSATE 4. GLYPHOSATE 5. GLYPHOSATE	BULB VEGETABLES BRASSICA LEAFY VEGETABLES TURNIP SWEET POTATO (POST) BLUEBERRY	3-29-88 3-29-88 5-20-88 7-22-88 7-30-88 8-10-88 9-22-88 2-9-89 3-9-89
	MAJOR AMENDMENTS	
CHEMICAL	CROP	DATE SENT
1. CARBARYL 2. FLUAZIFOP 3. FOSETYL-AL 4. OXAMYL 5. DIURON 6. METOLACHLOR 7. IPRODIONE 8. METHIDATHION 9. FLUAZIFOP	POTATO (POST HARVEST) ASPARAGUS (NC, VA, DE, NY ONLY) GINSENG (WI ONLY) NON-BELL PEPPER RHUBARB BELL PEPPER SWEET CHERRY KIWIFRUIT (CA ONLY) PARSLEY	1-27-88 5-11-88 9-20-88 10-3-88 11-1-88 10-3-88 11-11-88 12-2-88 2-21-89

TABLE B
IR-4 PETITIONS SUBMITTED AND STILL UNDER REVIEW BY INDUSTRY
JANUARY 1, 1988 TO MARCH 31, 1989

CHE	MICAL	CROP	DATE SENT
1.	THIOBENCARB	BOK CHOY (FL ONLY)	6-6-88
2.	DIQUAT	TABASCO PEPPER (LA ONLY)	9-23-88
3.	ORYZALIN	PAPAYA	10-3-88
4.	SETHOXYDIM	SWEET POTATO	11-15-88
5.	PERMETHRIN	RADICCHIO	12-12-88
6.	PERMETHRIN	CARDOON	12-12-88
7.	ESFENVALERATE	SWEET POTATO	3-2-89
8.	PERMETHRIN	MULTIWALL BAGS	3-7-89
9.	METHIDATHION	LONGAN, CARAMBOLA	3-20-89
10.	SETHOXYDIM	RHUBARB (MI, IL, IN, OH, WI, MN ONLY)	3-24-89

TABLE C EPA RESPONSES TO IR-4 PETITIONS JANUARY 1, 1988 TO MARCH 31, 1989

RESIDUE CHEMISTRY DATA GAPS

1. CARBOFURAN HOP ADDITIONAL RESIDUE DATA 2. BNOA TOMATO ANALYTICAL METHOD 3. FLUAZIFOP JALAPENO PEPPER STORAGE STABILITY (GA ONLY) 4. ESFENVALERATE OKRA (NC ONLY) ADDITIONAL RESIDUE DATA	
3. FLUAZIFOP JALAPENO PEPPER STORAGE STABILITY (GA ONLY)	ΓA
(GA ONLY)	ΓA
A DOEDNIZATEDAME OVDA (NO ONIV) ADDITIONAT DESTRITE DATE	ΓA
5. OXAMYL NON-BELL PEPPER ANALYTICAL METHOD &	
(PR ONLY) STORAGE STABILITY	
6. CARBARYL POTATO (POST HARVEST) ADDITIONAL RESIDUE DATA	ГΑ
7. METOLACHLOR BELL PEPPER ADDITIONAL RESIDUE DATA	ГΑ
8. FOSETYL-AL GINSENG STORAGE STABILITY DATA	A
9. FLUAZIFOP BROCCOLI STORAGE STABILITY &	
ADDITIONAL RESIDUE DAY	ATA
10. FLUAZIFOP PARSLEY STORAGE STABILITY &	
(NJ, MD, DE ONLY) ADDITIONAL RESIDUE DAY	ATA
11. CLOMAZONE SWEET POTATO PLANT METABOLISM DATA	
12. METHIDATHION KIWIFRUIT STORAGE STABILITY	
13. GLYPHOSATE LEAFY VEGETABLES ADDITIONAL RESIDUE DATA	
14. DIAZINON PISTACHIO ADDITIONAL RESIDUE DAT	
15. AZINPHOSMETHYL POMEGRANATE PLANT METABOLISM DATA	
16. 2,4-D SOYBEAN (PREPLANT) PLANT METABOLISM DATA	
17. ESFENVALERATE PINEAPPLE ADDITIONAL RESIDUE DAT	TΑ
18. PERMETHRIN RASPBERRY ADDITIONAL RESIDUE DAT	m 3

TOXICOLOGY DATA GAPS

CROP CHEMICAL

ASPARAGUS 1. ACEPHATE 2. METHAMIDOPHOS **ASPARAGUS** SWISS CHARD 3. OXYDEMETONMETHYL TOMATO, STRAWBERRY 4. BNOA

IR-4 Annual Meeting April 13-14, 1989

1989 Report on IR-4 Food Use Research
R.T. Guest, R.R. Libby, D.K. Infante, W.L. Biehn

Current Food Use Requests

The numerical growth of IR-4 Project requests is steady. The addition to Table 1, which shows cumulative figures from 1977, now totals 3942. Since the 1988 report, we have received 266 new requests and the total researchable projects has increased from 1060 to 1113. A leveling off of predominance of Low Dietary Intake (LDI) projects is suggested as the percentage the last three years has been 56% (1986), 57% (1987) and 55% (1988).

IR-4 is responding to reregistration requests for which registrations in a number of cases were obtained initially through IR-4. The reregistration process has emphasized the need for IR-4 to coordinate the defense of needed minor use reregistrations where the registrants have chosen not to do so. Currently we have received a total of 125 reregistration requests. As of now, 11 are active research projects, 35 are under review by the mfg. and 4 are complete. The balance are either mfg. objectives or requests that cannot be registered at this time. For 1989 there are 6 reregistration projects scheduled to produce the required residue samples to be used to maintain the registration.

There was a reduction in the total number of food use research reports received during the past year. In 1988, Headquarters received 452 individual field and laboratory reports. The totals the previous two years were 609 (1986) and 515 (1987).

Food Use Research Program

The annual process of establishing the researchable projects for the forthcoming cropping seasons (12 months) commences with the National Research Planning Meeting, which was held November 29 - December 1, 1988. Prior to the meeting, the attendees received a printout of all researchable projects. The printout was separated into the different major product categories; fungicides, insecticides, herbicides, as well as the minor categories, nematicides, PGR's and others. Emphasis was placed on the non-LDI projects requiring multi- region involvement.

The process moved smoothly with about 185 projects conditionally accepted. The break-out into non-LDI and LDI was almost equal. The conditional status of these projects normally evolves to firm commitments as the regional coordinators successfully find cooperators and the available funding is adequate.

A meaningful interpretation of these approximately 185 projects is found in recognizing that they involve roughly 300 individual state/federal research trials. Performance data (efficacy, phytotoxicity yield) will result from over 90 trials and residue samples from at least 200 trials. If all are completed, the state/federal analytical laboratories are scheduled to receive residue samples from about 185 trials and residue samples from the remainder will be shipped to industry laboratories.

Protocols

IR-4 is in the process of meeting GLP. Thus we are updating many of the previously prepared research protocols. Over the past twelve months, 295 protocols were updated and 88 new protocols were written for a total of 383.

EPA/IR-4 Workshop XII

An EPA/IR-4 Workshop was held in Newport Beach, CA, on March 14-16, 1989. The objectives of this workshop, which was funded by a grant from EPA, were to present the IR-4 Field Good Laboratory Practice Program to a representation of IR-4 research cooperators; and to review and prioritize IR-4 food use requests. About 90 people attended this workshop with a good representation from the agricultural chemicals industry and food production industry.

The first day of the workshop was devoted to GLP. The morning classroom session was a detailed review of the IR-4 GLP program. The afternoon session was held at the University of California South Coast Field Station and involved a demonstration of the practices utilized by Dr. J. Blair Bailey and his technicians when carrying out IR-4 field research under field GLP.

The remainder of the workshop was devoted to the review and prioritization of food use project by three disciplinary working groups. The main emphasis was on projects requiring geographically representative (national) data. A total of 525 requests were reviewed with 266 ranked "HIGH" priority, 54 ranked "MEDIUM" priority, and 129 ranked "LOW" priority. The workshop committees recommended that 35 requests be dropped and the remainder were not classified. Changes in priority rankings will be included in the next printout.

A total of 625 "low dietary intake" crops, were reviewed briefly with an opportunity provided for participants to include additional state/regional interest. Comments on the LDI food use requests will be included with material to be distributed for action at the 1989 regional meetings.

IR-4 Annual Meeting April 13-14, 1989

TABLE 1

FOOD USE REQUESTS

February 1989	3942	266	1113
February 1988	3676	412	1060
February 1987	3264	304	821
March 1986	2960	222	742
March 1985	2738	157	699
April 1984	2581	261	447
April 1983	2320	315	473
April 1982	2005	229	315
April 1981	1776	200	627
April 1980	1578	265	538
April 1979	1311	145	465
April 1978	1166	396	399
April 1977	770		310
	Cumulative No. Requests	New Requests Each Year	Researchable Projects

IR-4 Annual Meeting April 13-14, 1989

Comments by Drew Baker
EPA liaison to IR-4

According to FIFRA 88, the deadline for EPA is Christmas Eve, 1997, when every thing must be reregistered. Of course the data must be received and reviewed before then. If IR-4 is going to get much data for old uses, great efforts are needed to start most of the field work next year. Meanwhile, IR-4 has to maintain its efforts to get new uses but its pace is not increasing significantly. I review all the residue reports that IR-4 received and the number remains more or less the same for the fourth year.

IR-4 BIORATIONAL (MICROBIAL AND BIOCHEMICAL) PROGRAM

W.L. BIEHN

MARCH 31, 1989

This meeting marks the completion of six and one-half years of the IR-4 Biorationals Program. During this time IR-4 has received 35 clearance requests for biorationals and 20 biorational research proposals (Table 1). During the last 6 years IR-4 has funded 11 biorational research proposals representing 7 different biorationals. The status of the projects funded through the IR-4 Program are presented in Table 2.

IR-4 Headquarters funded research on the following biorational projects in 1988:

1) Evaluation of <u>Xanthomonas</u> <u>campestris</u> for control of annual bluegrass in turf.

Cooperator: Dr. David L. Roberts
Michigan State University
East Lansing, MI

2) Codling Moth Granulosis Virus - Safety Testing in Support of Registration.

Cooperator Dr. Louis A. Falcon University of California Berkeley, CA

The status of the projects worked on in 1988 and future activities are discussed below.

Status of Codling Moth Granulosis Virus (CMGV) Project on Apples

Pears, Walnuts and Plums

The University of California and the IR-4 Program are continuing their efforts to obtain a clearance for the CMGV on apples, pears, walnuts and plums. The University of California is considered the potential registrant for CMGV and has received grants from the state of California to conduct the Tier I toxicology studies required by EPA.

The following four acute studies have been completed:

- acute oral toxicity/pathogenicity study
- 2) acute intravenous toxicity/pathogenicity study
- 3) acute dermal toxicity study
- 4) primary eye irritation/infectivity study

The acute pulmonary toxicity/pathogenicity study is in progress. The avian oral pathogenicity test, the avian injection pathogenicity test and the nontarget insect testing for pathogenicity to insect predators and parasites will be initiated in the near future. The cell culture toxicology study is still in the planning stages. The Association for Sensible Pest Control will hopefully provide funds to do the freshwater fish pathogenicity study and the freshwater aquatic invertebrate pathogenicity test. Dr. Falcon of the University of California at Berkeley received a grant from IR-4 HQ in 1988 to cover the cost of bioassaying tissue samples from the acute oral, acute pulmonary and the acute intravenous studies for the presence of CMGV as well as to cover the cost of conducting the required storage stability studies. Refer to Table 3 for the proposed CMGV safety testing timetable.

Plans are to have the Experimental Use Permit (EUP) for CMGV that expires on May 14, 1989 renewed for two more years. This EUP, extension, if approved by EPA, will allow further large scale field testing of CMGV in CA, WA, CO and OR on apples, pears and walnuts.

Status of the Grape Berry Moth Pheromone

One way IR-4 can help in the commercial development of biorationals is to assist researchers in obtaining Experimental Use Permits (EUP) from EPA that allow large scale field testing of a biorational and selling of the treated crop. For example, in 1988 EPA granted an EUP for the Grape Berry Moth Pheromone for use in New York State based on a petition prepared by IR-4 in conjunction with Drs. T. Dennehy and W. Roelofs of the New York Agricultural Experiment Station. Under the EUP, the Grape Berry Moth Pheromone dispensers (GB-ROPE) are being evaluated for the control of the grape berry moth on approximately 100 acres of grapes in New York in 1988 and 1989. GB-ROPE is selective for the grape berry moth and the recommended application rates are 200 to 400 dispensers (ties) per acre. One application per year will suffice. The polyethylene dispensers, which permit a slow release of the pheromone, are twisted onto the top wire of the grape trellis.

Status of Xanthomonas campestris for Control of Annual Bluegrass in Turf

This project is in progress. The completion date for the project has been extended until the fall of 1989.

Status of the Western Grapeleaf Skeletonizer Granulosis Virus

The University of California and the IR-4 Program are continuing their efforts to obtain an Experimental Use Permit for this virus. The state of California is providing funds to the University of California to evaluate the Western Grapeleaf Skeletonizer Granulosis Virus for toxicity to Honey Bees.

Other Biorational Projects

- 1) IR-4 has received a clearance request and efficacy data from California for the use of marigold plant material (as an extract) or as marigold plant residue added to the soil to control nematodes in vineyards and orchards (including grapes, kiwi, almond, peach, plum, nectarine, walnut, apple and citrus). IR-4 plans to submit a petition to EPA requesting an exemption from the requirement of a tolerance for this use.
- 2) IR-4 has also received a clearance request and efficacy data from California for the use of sucrose and fructose to control nematodes in vineyards and orchards. IR-4 plans to pursue an exemption of sucrose and fructose from FIFRA requirements.

Table 1.

SIX AND ONE HALF YEAR SUMMARY OF IR-4 BIORATIONAL PROGRAM

STATUS OF BIORATIONALS REQUESTS AND PROPOSALS	<u>March 1985</u>	March 1986	March 1987	<u>March 1988</u>	March 1989
Total Number of Requests (cumulative)	19	25	28	59	35
Total Number of Proposals (cumulative)	11	17	18	19	20
SUMMARY OF BIORATIONALS RESEARCH					
Total Funded Research Proposals	S	7	6	6	11
Registrations/Clearances (cumulative) Supported by IR-4 Data*	m	м	ĸ	က	4

Biorational registrations supported by IR-4 data since 1982 include: 1) Experimental Use Permit (EUP) for Codling Moth Gramulosis Virus (CMGV) on apples and pears based on a petition proposing a temporary exemption of CMGV from the requirements of a tolerance Written by IR-4, 2) Bacillus popillae on pastures and rangelands for the control of Japanese beetle, 3) Methyl engenol in combination with malathion to control or eliminate oriental fruit fly infestations and 4) Experimental Use Permit (EUP) for Grape Berry Moth Pheromone based on a petition proposing a temporary exemption of the Grape Berry Moth Pheromone from the requirements of a tolerance written by IR-4.

TABLE 2. SUMMARY OF THE STATUS OF BIORATIONALS FUNDED THROUGH THE IR-4 PROJECT SINCE $1982^{\overline{\rm A}/}$

ACTIVE PROJECTS	OBOD(s) /prem	RESEARCH	POTENTIAL RECISTRANT	STRATUS	FUTURE WORK/COMMENTS
Codling Moth Gramulosis Virus	Apple, Pear, Plum Walnut/Codling Moth	ర	Univ. of CA Microgenesys	Efficacy work completed. Four acute tox tests completed.	Refer to Table 3 entitled CMGV Safety Testing Timetable
Bacillus sphaericus	Aquatic/Habitats Culex Mosquitoes	NJ - 1986	Duphar Abbott	Efficacy Good - Industry is proceeding with registration.	Duphar is planning to complete the remainder of the Tier I toxicology tests.
Xanthomonas campestris	Turf Annual bluegrass	MI - 1988	Several Companies	Efficacy – under evaluation.	Efficacy trials.
INACTIVE PROJECTS	ROJECTS				
<u>Beauveria</u> <u>bassiana</u>	Ornamentals/Black Vine Weevil	CA - 1983, 1984 1985	Abbott Mycogen	Efficacy good but Mfg will not support further research at present	Abbott is still working with several strains of Beauveria and will not supply for research. Abbott is working on
<u>Beauveria</u> <u>bassiana</u>	Turf/Chinch Bug	KS - 1984	Abbott Mycogen	Mfg will not support further research at present.	potatoes and if they decide to commercialize Beauveria on potatoes, they will consider reactivating the projects on ornamentals, turf and other crops.
Vertalec (Strain of <u>Cephalosporium</u> <u>lecanii</u>)	Ornamentals and Occumbers in Green- house/Aphids	FL - 1984 GA - 1984 CA - 1985	Novo Labs	On hold by Mfg.	Novo Labs purchased Microbial resources who was developing . Vertalec and Mycotal.
Mycotal (Strain of <u>Cephalosporium</u> lecanni	Ornamentals and Qucumbers in Green- house/Whiteflies	GA - 1984 CA - 1985	Novo Labs	On hold by Mfg.	Performance was fair. Novo Labs hasn't yet decided whether to register these products in the U.S.
<u>Metarhizium</u> anisopliae	Ornamentals/Black Vine Weevil	CA - 1984	Mycogen	This microbial is not sufficiently effective against the black vine weevil.	Beauveria bassiana was much more effective than Metarhizium anisopliae for the control of black vine weevil.

 $rac{A}{N}$ Refer to the attached computer printout for more information regarding the status of biorational projects.

TABLE 3. PROPOSED CODLING MOTH GRANULOSIS VIRUS (CMGV) SAFETY TESTING TIMETABLE

	Target or Dat	Completion e
Testing protocols submitted to EPA for five acute tests	03/87	(Done)
EPA and cooperators reach agreement on dermal and eye irritation study protocols	09/87	(Done)
EPA and cooperators reach agreement on acute intravenous study protocol and study initiated	d 02/88	(Done)
Submit to CDFA and IR-4 a request for additional funding for non-target organism and tissue culture toxicology studies and for bioassaying tissue samples from the acute oral, acute pulmonary and acute intravenous studies	g	(Done)
EPA and cooperators reach agreement on acute pulmonary study protocol and study initiated	12/88	(Done)
Dermal and eye irritation studies, acute oral study and acute intravenous study are completed.	02/89	(Done)
EPA and cooperators reach agreement on avian oral pathogenicity test, avian injection pathogenicity test and nontarget insect testing for pathogenicity to insect predators and parasites and studies initiated.	06/89	
EPA and cooperators reach agreement on fresh- water fish pathogenicity study and freshwater aquatic invertebrate pathogenicity study and studies initiated	11/89	
Cell culture toxicology requirement resolved or initiated (The University of California may request a waiver of all or part of this requirement from EPA)	01/90	r
All of the above studies are completed	08/90	1
Petition submitted to EPA	10/90	1
Label Issues	12/91	

IR-4 BIORATIONAL REQUESTS

- HEADINGS .

STATE

STATES REQUESTING USE OR INTERESTED
IN USE
*=AN ASTERICK NEXT TO REQUESTING
STATE_INDICATES FORMAL RESEARCH
PROPOSAL RECEIVED AT HEADQUARTERS

RESEARCH

LOCATION YEAR AND STATE IN WHICH RESEARCH IS
CONDUCTED OR SCHEDULED
*=AN ASTERISK NEXT TO RESEARCH
LOCATION INDICATES DATA RECEIVED

AT HEADQUARTERS

POTENTIAL REGISTRANT

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COMMENTS	FUNDED BY IR-	FUNDED:9/84.ABBOTT WILL NOT SUPPORT FURTHER RESEARCH AT THIS TIME:1/87.	NOT APPROVED:11/83. No registrant.	PROPOSAL NO. 5 HAS PRIORITY OVER THIS PROPOSAL. NO REGISTRANT.	FUNDED IN 83,84 & 85 THE WESTERN REGION. PROJECT IS COMPLETE.	NOT APPROVED:4/84.(BETA-EXOTOXIN) HAS SOME TOXICITY TO ANIMALS. TOXICITY HAS TO BE CLARIFIED.	NOT APPROVED:11/83.	FL PROPOSAL FUNDED:9/84. ON HOLD BY MFG:2/87.	CA PROPOSAL FUNDED:6/85. ON HOLD BY MFG:2/87.	GA PROPOSAL FUNDED:9/84. CA PROPOSAL FUNDED:6/85. ON HOLD BY MFG:2/87.
PET/REG STATUS	EUP									
RESEARCH LOCATION		84:KS*		84:CA*	83:CA* 84:CA* 85:CA			84:FL	85:CA	84:GA* 85:CA
SOMP ANY	MICROGENESYS PRO.AGR-SYS. UNIV.OF CA	ABBOTT MYCOGEN	NONE	NONE	ABBOTT	ABBOTT ZOECON	NONE	MOVO LABS	NOVO LABS	NOVO LABS
STATE	CA *	KS*	GA.	*	*	÷	Qu	FL* OH	7. 9. 9.	6A * CA *
BR	05/82	05/82	09/82	09/82	09/82	11/82	06/83	07/83	07/83	05/82
1 02/28/89 IR-4 BIORATIONAL REQUESTS)	CODLING MOTH GRANULOSIS VIRUS APPLE, PEAR, WALNUT CODLING MOTH	BEAUVERIA BASSIANA TURF CHINCHBUG	PUCCINIA CANALICULATA NDRTICULTURAL CROPS NUTSEDGE	METARHIZIUM ANISOPLIAE ORNAMENTALS BLACK VINE WEEVIL LARVAE	BEAUVERIA BASSIANA ORNAMENTALS BLACK VINE WEEVIL LARVAE	BACILLUS THURINGIENSIS VAR THUR. TOMATO COLORADO POTATO BEETLE	TRICHODERMA VIRIDE MUTANT T-1-R9 CHRYSANTHEMUM FUSARIUM WILT	VERTALEC (STRAIN OF C.LECANNI) TOMATO, CUCUMBER, SQUASH, PEPPER APHIDS	MYCOTAL (STRAIN OF C.LECANNI) TOMATO, CUCUMBER, SQUASH, PEPPER WHITEFLIES	VERTALEC (STRAIN OF C.LECANNI) ORNAMENTALS APHIDS
PAGE	0000 1B	000028	000038	000048	000058	000008	000078	000088	860000	000108

reg US COMMENTS	GA PROPOSAL FUNDED:9/84. ON HOLD BY MFG:2/87.	1/81 TOX STUDIES NEED: IV,IC, 1/82 & HYPERSENSITIVITY. TISSUE CULTURE TOX. STUDIES TO EPA:11/84.		BETA-EXOTOXIN.HAS SOME TOXICITY TO ANIMALS. TOX HAS TO BE CLARIFIED: 4/84.	NOT APPROVED:4/85. MFG WILL NOT SUPPORT:1/87.	MFG IS HANDLING.	BETA-EXOTOXIN HAS SOME TOXICITY TO ANIMALS. TOX HAS TO BE CLARIFIED: 4/84.	6E1692 LABELED. RULE:9/82 LABEL:6/83	1E2478 (FIELD,BRUSH,FOREST) RULE:3/82 PROPOSAL FOR ALL RAC. LABELED.	NOT APPROVED:11/85. MFG WILL NOT SUPPORT:1/87.
PET/REG STATUS		SUB:3/81 RE:5/82						GE 1692 RULE:9 LABEL:	1E2478 RULE:3	
RESEARCH LOCATION	84:GA*	70:AZ* 73:MQ*, SC*,VA* 75:AL*,	84 C. C. A. C. C. C. A. C. C. C. A. C.							
COMPANY	NOVO LABS			ABBOTT BIOCHEM SANDOZ	ABBOTT	ABBOTT Mycogen	ABBOTT	FAIRFX	dVn	ABBOTT
STATE	GA CA	× N × N	V	I A	1 **	A L	A F	Q I Z S Z	E I S	* V
BR RECD	02/83	03/75	11/75	06/84	06/84	10/84	10/84	01/75	11/77	05/85
2 02/28/89 IR-4 BIORATIONAL REQUESTS) PESTICIDE/COMMODITY/PEST	MYCOTAL (STRAIN OF C.LECANNI) ORNAMENTALS WHITEFLIES	AUTOGRAPHA CALIFORNICA NPV VEGETABLES, SOYBEAN, COTTON LEPIDOPTEROUS LARVAE	GRANULOSIS VIRUS ALMOND, PEANUT, WALNUT INDIAN MEAL MOTH	BACILLUS THURINGIENSIS VAR THUR. SWEET CORN EUROPEAN CORNBORER, BLACK CUTW ARMYWORM, CORN EARWORM	BEAUVERIA BASSIANA SWEET CORN EUROPEAN CORNBORER, BLACK CUTW ARMYWORM, CORN EARWORM	BEAUVERIA BASSIANA POTATO, EGGPLANT COLORADO POTATO BEETLE	BACILLUS THURINGIENSIS VAR. THUR. POTATO COLORADO POTATO BEETLE	BACILLUS POPILLAE PASTURE GRASES JAPANESE BEETLE	METHYL EUGENOL NONCROPPED AREAS ORIENTAL FRUIT FLY	BEAUVERIA BASSIANA SOUTHERN PEAS, SNAPBEANS COWPEA CURCULIO
PAGE BR#	81118	000128	000138	000158	000 168	000178	000 188	000 198	000208	0002 18

COMMENTS	FUNDED IN 86 BY IR-4 HQ.	MFG WILL NOT SUPPORT:1/87.	REGISTERED.	NOT APPROVED:3/86. NO REGISTRANT.	ON HOLD:4/87.			APPROVED:11/87.	GRAPE,KIWI,ALMOND,PEACH, PLUM,NECTARINE,WALNUT, APPLE & CIRTUS FRUITS.	GRAPE,KIWI,ALMOND,PEACH, PLUM,NECTARINE,WALNUT, APPLE & CIRTUS FRUITS.
PET/REG STATUS						EUP SUB: 11/86 RE:8/87	EUP SUB: 7/87			
RESEARCH LOCATION										
NA P	BIOCHEM	ABBOTT	VIKWOOD		9 -၁		SHIN-ETSU	ABBOTT CHEVRON ECOGEN		
CTATE	, 5 , 5	QA	Q	¥ QW	* C	∀	ž	* E	4 0	V
BR CFC	10	08/85	09/83	09/85	02/86	98/60	98/60	07/87	88/90	88/90
3 02/28/89 IR-4 BIORATIONAL REQUESTS)		BEAUVERIA BASSIANA PECAN PECAN WEEVIL	NEEM (AZADIRACHTIN) CHRYSANTHEMUM LEAFMINER	LAGENIDIUM GIGANTEUM RICE FIELDS, AQUATIC HABITATS MOSQUITO LARVAE	BIPOLARIS SORGHICOLA CORN, SORGHUM, SOYBEANS JOHNSONGRASS	GRAPELEAF SKELETONIZER GRAPES GRANULOSIS VIRUS	(2)-11 TETRADECENYL ACETATE + (2)-9 DODECE Grapes Grape berry moth	XANTHOMONAS CAMPESTRIS TURF ANNUAL BLUEGRASS	SUCROSE/FRUCTOSE VINEYARDS, ORCHARDS NEMATODE CONTROL	MARIGOLD EXTRACT VINEYARDS, ORCHARDS NEMATODE CONTROL
ш	6K# 000228	000238	000248	000258	000268	000278	000288	000298	906000	000318

	COMMENTS	GRAPE,KIWI,ALMOND,PEACH, PLUM,NECTARINE,WALNUT, APPLE & CIRTUS FRUITS.	GRAPE,KIWI,ALMOND,PEACH, PLUM,NECTARINE,WALNUT, APPLE & CIRTUS FRUITS.	NEED EFFICACY DATA TO EVALUATE:2/89.	NEED EFFICACY DATA TO EVALUATE:2/89.
PET/REG	STATUS				
RESEARCH	LOCATION				
	COMPANY				
	STATE	₹	4 0	▼	4 O
88	_	06/88 CA	88/90	68/60	68/60
4 02/28/89 IR-4 BIORATIONAL REQUESTS)	PESTICIDE/COMMODITY/PEST	POPPY EXTRACT VINEYARDS, ORCHARDS NEMATODE CONTROL	VETCH EXTRACT VINEYARDS, ORCHARDS NEMATODE CONTROL	OOO34B D-LIMONENE TURF, ORNAMENTALS NEMATODE CONTROL	GERANIOL TURF, ORNAMENTALS NEMATODE CONTROL
PAGE 4	BR#	000328	000338	000348	000358

IR-4 ANNUAL MEETING APRIL 13-14, 1989

ORNAMENTAL MINOR USES PROGRAM UPDATE (March 1988 to March 1989)

J.E. ELSON and R.T. GUEST

SUCCESSES

Since the last annual meeting, 153 ornamental registrations were obtained based on data generated in the IR-4 Program. This number is down from previous years due to most registrant's time and personnel being devoted to reregistration endeavors to defend labels in the food use area. Ornamental registrations, that were supported by IR-4 data, included expanded labels for: acephate (ORTHENE^R), fenamiphos (NEMACUR^R), fosetyl Al (ALIETTE^R), metalaxyl (SUBDUE^R), metolachlor (PENNANT^R), oxyfluorfen (GOAL^R), PCNB (TERRACLOR^R), simazine (PRINCEP^R) and trifluralin (TREFLAN^R). The specific ornamental species and uses registered during the past year are listed in Table A.

REGISTRATION PACKAGES

Registration data packages containing research reports for 583 trials were sent to registrants since the last annual meeting for review and eventual labeling. These registration packages represented 4 fungicides, 9 herbicides, 17 insecticides and 1 plant growth regulator.

STATUS OF ORNAMENTALS REQUESTS

The number of ornamental registration needs (researchable pesticide clearance requests) that remain to be addressed is presently 714. Researchable requests (projects) include those requests (pesticide/ornamental species combinations) which the manufacturer will label once IR-4 gathers the necessary phytotoxicity and efficacy data required for registration. During the past year we added 97 new priority needs to the list of researchable projects and removed 284 requests from the researchable category.

RESEARCH PROGRAM

During 1988 there were 490 ornamental research trials funded through the Regional Laboratories and the USDA-ARS Programs. There are 472 research trials tentatively scheduled for research during 1989. The reduction in the number of active research trials for the past several years is due to funding limitations which the IR-4 Project is experiencing.

TABLE A PESTICIDE REGISTRATION ON ORNAMENTALS SUPPORTED BY IR-4 DATA March 1, 1988 to March 31, 1989

CHEMICAL (BRAND NAME)	ORNAMENTAL USE OR SPECIES REGISTERED
Acephate (ORTHENER)	To control various insects on dahlia, lily, pachysandra, peony and sedum.
Fenamiphos (NEMACUR ^R)	To control nematodes in rose production.
Fosetyl Al (ALIETTE ^R)	To control diseases caused by Pythium spp . and Phytophthora sp . on andromeda, aphelandra, arborvitae, aucuba, birch, blueberry (ornamental), camellia, ceanothus, dieffenbachia, dogwood, Fraser fir, laurel, philodendron, pine and yew.
Metalaxyl (SUBDUE ^R)	To control damping off and stem & root rot diseases caused by Pythium and Phytophthora in container, field, and greenhouse grown anthurium, artemisia, columbine, daisy, delphinium, dianthus, ficus, foxglove, gaillardia, petunia, phlox, primrose, sempervivum and yew.
Metolachlor (PENNANT ^R) (liquid & 5G)	To control annual grass and some broadleaf weeds in the production of ash, birch, Douglas fir, hemlock and leather leaf fern.
Oxyfluorfen (GOAL ^R)	To control weeds in seed beds of Monterey pine.
PCNB (TERRACLOR ^R)	To control stem rots (Rhizoctonia) of aphelandra, boxwood, dahlia, dieffenbachia, dracena, English ivy, ficus, fittonia, geranium, gynura, holly, hoya, juniper, kalenchoe, marigold, peperomia, petunia, pine, portulaca, pothos, rhododendron, salvia, schefflera, synconium, tradescantia, vinca and zinnia.
Simazine (PRINCEP ^R)	To control weeds in azalea and rhododendron plantings.
Trifluralin (TREFLAN ^R)	To control annual grasses and broadleaf weeds in rose production.

TABLE B IR-4 ORNAMENTAL PESTICIDE REGISTRATIONS SINCE 1977

APPROXIMATE NUMBER OF SPECIES OR USES REGISTERED OVER THE

CHEMICAL NAME	PRODUCT NAME	TYPE*	MANUFACTURER	REGISTERED OVER THE LAST 12 YEARS
Abamectin	AVID	I	MSD Ag Vet	45
Acephate	ORTHENE T&O	I	Valent	72
Alachlor	LASSO, LASSO II	Н	Monsanto	16
Bacillus thuringiensis	DIPEL	I	Abbott	10
Bendiocarb	FICAM W	I	NOR-AM	28
Bendiocarb	DYCARB	I	Sierra	28
Bifenox	MODOWN	H	Rhone-Poulenc	8
Carbofuran	FURADAN	I	FMC	28
Chlormequat	CYCCCEL	PGR	American Cyan	amid 2
Chlorothalonil	DACONIL 2787	F	Fermenta	162
Chlorothalonil	EXOTHERM TERMIL	F	Wilbur-Ellis	13
Chlorpropham	FURLOE 20G	Н	Chevron	19
Chlorpyrifos	DURSBAN	I	Dow	50
Copper hydroxide	KOCIDE 101	F	Kocide	27
Diazinon	KNOX OUT	I	Pennwalt	27
Diflubenzuron	DIMILIN	I	Uniroyal	2
Dienochlor	PENTAC	I	Sandoz	15
Dimethoate	DIMETHOATE 267	I	American Cyan	amid 1
Dodemorph	MILBAN	F	Sierra	11
Etridiazole	TRUBAN 30W, 25E,5G	F	Sierra	154
Etridiazole + thiophanate methy	BANROT 1	F	Sierra	110
Fenvalerate	PYDRIN	I	DuPont	41
Fluazifop	FUSILADE	Н	ICI	83
Fosetyl-Al	ALIETTE	F	Rhone-Poulenc	45

TABLE B (CON'T)

IR-4 ORNAMENTAL PESTICIDE REGISTRATIONS SINCE 1977

APPROXIMATE NUMBER OF SPECIES OR USES REGISTERED OVER THE

CHEMICAL NAME	PRODUCT NAME	TYPE*	MANUFACIURER	GISTERED OVER THE LAST 12 YEARS
Glyphosate	ROUNDUP	Н	Monsanto	132
Iprodione	CHIPCO 26019	F	Rhone-Poulenc	157
Mancozeb	FORE, DITHANE M-45	F	Rohm & Haas	65
Mancozeb	MANZATE 200	F	DuPont	69
Metalaxyl	SUBDUE 2E,5G	F	CIBA-GEIGY	49
Methomyl	LANNATE, LANNATE L	F	DuPont	164
Metolachlor	DUAL 8E,25G	Н	CIBA-GEIGY	69
Metolachlor	PENNANT	Н	CIBA-GEIGY	16
Metolachlor + Simazine	DUAL + PRINCEP	Н	CIBA-GEIGY	28
Napropamide	DEVRINOL 50W,50	Н	ICI	248
Oryzalin	SURFLAN 75W	Н	Elanco	121
Oxadiazon	RONSTAR G	Н	Rhone-Poulenc	103
Oxadiazon	PROGROW I	Н	Scott	103
Oxamyl	VYDATE L I	,N	DuPont	98
Oxamyl	OXAMYL 10G I	,N	Pratt	50
Oxyfluorfen	GOAL 2E	Н	Rohm & Haas	8
Oxyfluorfen + Oryzalin	ROUT	Н	Sierra	10
PCNB	TERRACLOR	F	Uniroyal	43
Permethrin	POUNCE	I	FMC	32
Pronamide	KERB	Н	Rohm & Haas	7
Resmethrin	SBP 1382	I	Penick	44
Sethoxydim	POAST	Н	BASF	8
Simazine	PRINCEP	Н	CIBA-GEIGY	2
Streptomycin	STREPIOMYCIN 17	F	United Agri. Pro	oducts 4

TABLE B (CON'T)

IR-4 ORNAMENTAL PESTICIDE REGISTRATIONS SINCE 1977

APPROXIMATE NUMBER OF SPECIES OR USES REGISTERED OVER THE

CHEMICAL NAME	PRODUCT NAME	TYPE*	MANUFACTURER	IAST 12 YEARS
Triadimefon	BAYLETON	F	Mobay	63
Triclopyr	GARLON	Н	Dow	4
Trifluralin	TREFLAN	Н	Elanco	6
Triforine	TRIFORINE EC	F	Valent	10
Vinclozolin	ORNALIN	F	Sierra	68

H = herbicide

I = insecticide

N = nematicide

PGR = plant growth regulator

^{*} F = fungicide

TABLE C

SUMMARY OF IR-4 ORNAMENTALS RESEARCH PROGRAM

IOTAL SINCE 1979	11,628	2,756*
	11	8
MARCH 1988-89	490	153
MARCH 1987-88	671	229
MARCH 1986-87	552	292
MARCH 1985-86	817	223
MARCH 1984-85	732	175
APRIL 1983–84	1223	167
APRIL 1982-83	1334	230
APRIL 1981–82	1211	197
APRIL 1980-81	1342	355
APRIL 1979–80	1410	741
APRIL 1977-79	1846	
	Funded Research Trials (chemical site/location)	Registrations Supported by IR-4 Data (species or uses registered)

* Refer to Table B for a listing of the number of ornamental registrations, by pesticide product.

December 1988

&EPA

Pesticides and Toxic Substances **Highlights** Of the 1988 Pesticide Law

The Federal Insecticide, Fungicide, and Rodenticide Act **Amendments** Of 1988

n October 25, 1988, the President signed into law the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Amendments of 1988. The 1988 amendments to FIFRA, which is administered by the Environmental Protection Agency (EPA), strengthen the Agency's authority in several major areas of pesticide regulation. Among other things, the amendments require a substantial acceleration of the reregistration process for previously registered (licensed) pesticides and authorize the collection of fees to support reregistration activities. The law also changes EPA's responsibilities and funding requirements for the storage and disposal of suspended and cancelled pesticides and the indemnification of holders of remaining stocks of such cancelled pesticides. Most provisions of the 1988 amendments are effective December 24, 1988.

Background on FIFRA

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 function, when used according to labeling directions, without posing unreasonable risks of adverse effects on human health or the environment. In making pesticide registration decisions, EPA is required by law to take into account the economic, social, and environmental costs and benefits of pesticide uses.

FIFRA was first enacted in 1947. Thousands of pesticide products have been registered since then. However, the standards for pesticide registration have not remained the same since 1947, but have evolved in tandem with science and public policy. In particular, test data requirements for pesticides have become increasingly stringent in light of advances in such areas as toxicology and analytical chemistry. Under FIFRA, pesticide registrants (companies that hold pesticide registrations) are responsible for providing all test data necessary to satisfy EPA's registration requirements.

To ensure that previously registered pesticides measure up to current scientific and regulatory standards, FIFRA requires the review and "reregistration" of all existing pesticides. This has proved to be a massive undertaking. A combination of factors has impeded the Agency's progress in carrying out the reregistration

mandate, including inadequate resources and the sheer magnitude of the task. Of the approximately 600 pesticide active ingredients that require reregistration under FIFRA, EPA has issued "Registration Standards" for about 185. A Registration Standard includes a comprehensive review of all the available data on an existing chemical, a list of additional data needed for full reregistration, and the Agency's current regulatory position on the pesticide.

FIFRA authorizes EPA to cancel the registration of an existing pesticide if test data show that it causes unreasonable adverse effects on human health or the environment. In addition, under certain circumstances, EPA may take action to suspend the registration of a pesticide to prevent an imminent hazard.

Until the 1988 amendments, EPA was required under FIFRA to accept certain suspended and cancelled pesticides for disposal at government expense. In addition, an indemnification provision required EPA to reimburse holders of such suspended and cancelled pesticides for financial losses suffered, up to the cost of the pesticide.

The 1988 FIFRA Amendments

Reregistration Provisions

Reregistration provisions are the principal focus of the 1988 amendments. These provisions establish requirements with very tight deadlines. A sequence of deadlines applies to pesticide registrants, who are responsible for supplying the complete test data bases necessary for EPA to make pesticide reregistration decisions. EPA must also meet very specific deadlines in analyzing data submissions and deciding whether or not to reregister currently registered pesticides. Reregistration will take place in five phases, as follows:

- Phase 1: EPA is required to publish lists of pesticide active ingredients subject to reregistration and to ask registrants of pesticide products containing those active ingredients whether they intend to seek reregistration. These lists must be published in four installments over a 10-month period after the effective date of the 1988 amendments.
- Phase 2: Registrants are required to respond to EPA concerning their intention to seek reregistration. For each active ingredient,

registrants seeking reregistration must also identify missing and inadequate scientific studies required to satisfy EPA's current data requirements, formally agree to fill these "data gaps" according to prescribed deadlines, and pay the first portion of a reregistration fee. Phase 2 responses are required within three months after EPA publishes each chemical list. If a registrant decides not to seek reregistration, the registration will be cancelled.

- Phase 3: Registrants are required to summarize and reformat key existing studies to facilitate EPA review, to certify that they possess or have access to "raw data" (such as laboratory records) from studies, to "flag" any studies that indicate adverse effects, to make a commitment either to generate or to share the cost of generating new test data where studies are missing or inadequate, and to pay the final reregistration fee. Registrants are required to accomplish these Phase 3 requirements within one and one-half to two years after passage of the 1988 amendments. Registrants must then fulfill remaining data requirements within designated time periods.
- Phase 4: EPA is required to complete its review of submissions made by registrants under Phases 2 and 3, to independently identify data gaps, and to issue requirements for registrants to fill those gaps. This will take place over a period of two to four years after enactment of the 1988 amendments.
- Phase 5: This phase culminates the reregistration process under FIFRA as amended in 1988. It requires EPA to conduct a thorough, comprehensive examination of all data submitted in support of pesticide reregistration. Based on this review, the Agency will either reregister a pesticide or take other appropriate regulatory action. This phase will occur over a span of approximately three to nine years after enactment of the 1988 amendments, depending on such variables as the complexity of the studies required for reregistration and the time required for registrants to complete and for EPA to review these studies.

Expedited Registration

The 1988 amendments also require EPA to give expedited consideration to applications for initial

or amended registration of products which are similar to pesticides already registered with EPA. "Similar" products include not only those which are identical in composition to currently registered products, but also those which differ from registered products only in ways that would not significantly increase the risk to public health and the environment. In addition, the Agency is required to expedite certain minor amendments to existing product registrations.

Under the expedited review provisions, an applicant will be notified, within 45 days after the Agency receives an application, whether the application is complete. Within 90 days after the Agency has received a fully complete application, the registrant will be notified in writing whether the request is granted or denied; if it is denied, the specific reasons for denial will be given. A portion of the fees collected by EPA will be made available to the Agency for the purpose of carrying out expedited processing of similar applications and minor amendments to registrations.

Fees

Reregistration is a complex regulatory process that is expected to cost about \$250 million over the nine years of the 5-phase process. Approximately \$110-120 million of that cost is expected to come from a continuation of the current level of EPA's budget for reregistration activities. The remaining funds will come from the pesticide industry through two kinds of fees: a reregistration fee for each active ingredient, and an annual fee for registration maintenance to be paid for each registered product.

For each active ingredient intended for use on major food or animal feed crops, registrants will be required to pay reregistration fees totalling \$150,000. In most cases, an initial payment of \$50,000 is due during Phase 2, and the balance in Phase 3. For pesticide active ingredients not intended for major food or feed uses, registrants will be required to pay a fee of not more than \$150,000 and not less than \$50,000. (The exact fee depends on, among other things, whether a Registration Standard has already been issued for the pesticide and the extent of data required for reregistration.) Active ingredient fees are to be apportioned among registrants of each active ingredient, based on market share.

Reregistration fee reductions or waivers will be

granted for certain pesticide registrants. Any antimicrobial active ingredient for which the annual level of production does not exceed 1 million pounds is exempt; also exempt is any active ingredient for which the value or volume of use is considered minor. In addition, for any "small business" registrant (any company with 150 or fewer employees and average annual chemical sales of \$40 million or less over the three-year period prior to reregistration), the reregistration fee will be based on a graduated rate ranging from 0.5 to 1.5 percent of average annual pesticide sales.

Unlike the reregistration fee, which is levied on the basis of active ingredients, the annual maintenance fee is assessed for each individual pesticide product. For up to 50 product registrations held by a registrant, the annual fee has been tentatively calculated to be \$425 per product. For up to 200 products, the fee would be \$425 per product for the first 50 and \$100 for the rest. However, there are maximum limits on the total annual maintenance fees payable by any registrant: the maximum possible total in maintenance fees for any registrant for up to 50 product registrations is \$20,000; and the absolute maximum total in maintenance fees for any registrant for any number of product registrations is \$35,000.

The objective of the maintenance fee program is to generate approximately \$14 million annually in additional operating funds for the Agency. In the event that there are not enough pesticide product registrations to raise \$14 million, EPA must increase these annual maintenance fees. However, regardless of any increase in per-product fees, the maximum limits of \$20,000 and \$35,000 will continue to apply.

During the nine-year period that these fee provisions are in effect, the Agency is prohibited from levying any other fee for the registration of a pesticide. (The registration fees established by regulation in May 1988 will be in abeyance during this period.) However, the payment of fees for the establishment of tolerances (maximum legal limits) for pesticide residues in food or feed products, required by the Federal Food, Drug, and Cosmetic Act, is not affected by the 1988 amendments to FIFRA.

Storage and Disposal of Suspended or Cancelled Pesticides

The 1988 amendments expand EPA's authority to regulate the storage, transportation, and disposal of pesticides. In addition to the authority to require data on storage and disposal methods, EPA is authorized to establish labeling requirements for transportation, storage, and disposal of the pesticide and its container. The new law also enables EPA, for the first time, to take direct enforcement action against violations of storage, disposal, and transportation requirements.

The 1988 amendments eliminate from FIFRA the requirement that EPA, upon request, must accept suspended and cancelled pesticides and dispose of them at government expense. Under the new law, EPA may require registrants and distributors to recall suspended and cancelled pesticide products. The Agency is authorized to require registrants to give evidence of their financial capacity to carry out such a recall. To facilitate any recalls of this kind, EPA may require all persons who sell, distribute, or commercially use pesticides to notify EPA and state and local officials of the quantities and locations of suspended and cancelled pesticides in their possession.

A registrant who wishes to become eligible for reimbursement of storage costs incurred as a result of a recall must submit a plan for storage and disposal of the pesticide that meets criteria to be established by EPA. Registrants will be reimbursed for portions of their storage costs that are attributable to delays in approval of storage plans.

In order to lessen the problems associated with pesticide container disposal, the amendments require EPA to conduct a study of options to encourage or require:

- The return, refill, and reuse of pesticide containers.
- The development and use of pesticide formulations that facilitate the removal of pesticide residues from containers.
- The use of bulk storage facilities to reduce the number of pesticide containers requiring disposal.

The 1988 amendments also authorize EPA to regulate procedures for storage, transport, and disposal of containers, rinsates (such as water used to clean a pesticide container), or other materials used to contain or collect excess or spilled pesticides. Additionally, in order to promote the safe storage and disposal of pesticides, EPA is directed to issue, within three years, regulations for the design of pesticide containers. These forthcoming regulations will facilitate the safe use, disposal, and refill and reuse of pesticide containers.

Indemnity Payments

Prior to the 1988 amendments, if EPA suspended and cancelled the registration of a pesticide, the Agency was required under FIFRA to indemnify holders of the pesticide for losses suffered, up to the cost of the pesticide. Moreover, FIFRA was silent as to the source of funding for any indemnification (or disposal) payments that might occur. Persons previously covered by indemnification included "end users" (such as farmers and commercial pesticide applicators) as well as pesticide formulators, pesticide dealers and distributors, and registrants.

The 1988 amendments end automatic entitlement to indemnity payments for all persons other than certain end users, and provide that all indemnity payments made will come from the Judgment Fund of the Treasury, not from EPA's operating budget. End users, such as farmers, will continue to be eligible for indemnification through the Judgment Fund.

Indemnification to anyone other than an end user may be paid under the 1988 amendments, only if Congress provides a line-item appropriation. The 1988 amendments also require all sellers of a pesticide (including registrants and wholesalers) to reimburse the buyer for the purchase price of a product whose registration is suspended and cancelled, unless at the time of purchase the seller told the buyer in writing that the seller would not make such refunds. If EPA determines that a business insolvency or bankruptcy makes such reimbursements impossible, dealers and/or distributors will also be eligible for indemnification from the Judgment Fund.

Miscellaneous Provisions

The 1988 amendments also contain a number of other provisions designed primarily to make it easier for EPA to implement the major provisions described above, including:

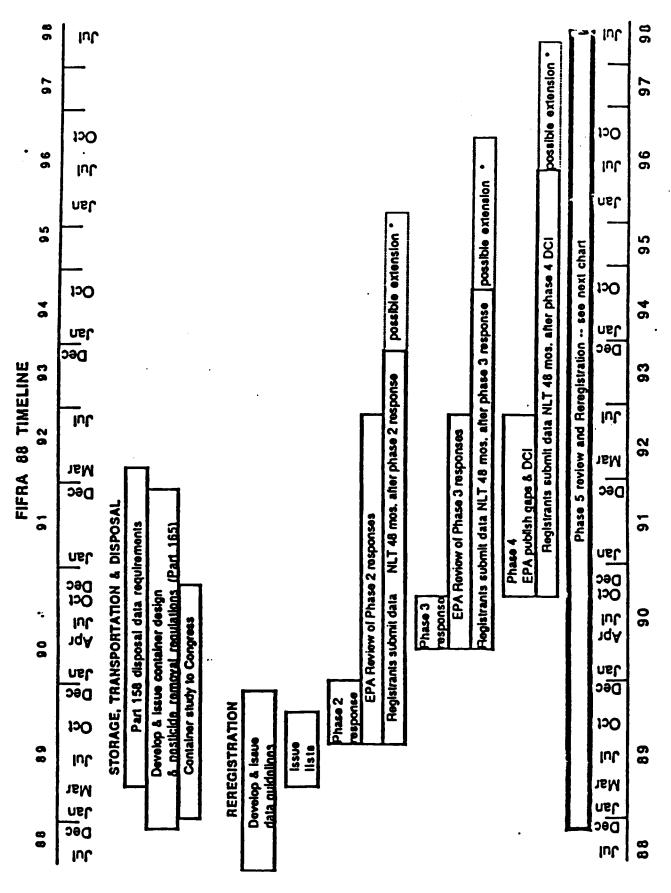
- Penalties: Criminal penalties are increased for registrants, applicants for registration, or other pesticide producers who knowingly violate the pesticide law.
- Unlawful acts: The 1988 amendments provide that certain acts, such as submitting false test data, violating suspension or cancellation orders, and failure to submit required records or allow inspection, will be unlawful.
- Records and inspection: To help ensure compliance with storage and disposal provisions, additional authority is provided for EPA to request records and to inspect places where pesticides are being kept.
- Unregistered pesticides: The Agency is given new authority to regulate unregistered pesticides.
- Scientific Advisory Panel (SAP): The 1988 amendments provide that the FIFRA SAP, a panel of outside experts convened by EPA to review major pesticide decisions or regulations, will be permanent. Prior to the 1988 amendments, the SAP required reauthorization every five years.
- Congressional review: The 1988 amendments shorten the period of Congressional review of final regulations from 60 days of continuous Congressional session to 60 days.

REREGISTER PRODUCT 6 MONTHS LATER

PESTICIDE REREGISTRATION PROCESS

Page 1.

PHASE 5	EPA	REVIEW ALL DATA	Reregister or take other action					AFTER ALL DATA IN (FOR ALL LISTS) 1 YEAR FOR REVIEW OF DATA	Product Specific	DATA DUE 8 MOS. LATER	REVIEW OF PRODUCT SPECIFIC DATA IN 90 DAYS
PHASE 4	ĖA	REVIEW SUBMISSIONS (2 & 3)	IDENTIFY DATA GAPS	Pur ish data gaps	Issue DCI			SECOND ROUND REVIEW	10/24/90	7/24/91	7/24/92
PHASE 3	REGISTRANT	SUMMARIZE AND REFORMAT	CERTIFY RAW DATA	"FLAG" DATA	PAY FEE			N/A [FEES (?)]	4/24/90	7/24/90	10/24/90
PHASE 2	REGISTRANT	Respond	Identify Data gaps	AGREE TO FILL GAPS	PAY FEE	EPA	6UTELINES 12/24/89	N/A Fees (?)	7/24/89	10/24/89	1/24/90
PHASE 1	EPA	Pur.ish Lists	·					3/4/89	4/24/89	7/24/89	10/24/89
								List A:	List B:	List C:	List D:



*extensions will be granted only in extraordinary circumstancos

REREGISTRATION OPTIONS

y ,			
EXAMPLE 1	EXAMPLE 2	EXAMPLE 3	EXAMPLE 4
Data Inadequate for Product Reregistration	Data Inadequate for Product Reregistration	Data Inadequate for Product Reregistration	Data Inadequate for Product Peregistration
·			
Registrant Does Not Support Reregistration	Registrant Submits Data for Major Uses (No Data Additional Data Reguired for Minor Uses)	Registrant Submits Data for Major Uses But Not for Minor Uses	Registrant Submits Data for Major Uses
Registration Voluntarily Withdrawn or Cancelled	Data for Major Uses Supports Minor Uses	Registrant Withdraws Registration for Minor Uses	Registrant or Third Party Submits Data for Reregistration of Minor Uses
	Major and Minor Uses	Product Reregistered for Major Uses	Product Reregistered for Major Uses and Minor Uses

Twenty-sixth IR-4 Annual Meeting

April 13-14, 1989

Hyatt Regency/DFW International Parkway DFW Airport, Texas 75261-9014

Tel: (214) 453-8400

AGENDA

Thursday, April 13, 1989

8:00 AM - 12:00 Noc	8:00	AM	_	12:00	Noon
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1.	Call to Order/Introduction
	Adoption of agenda
	Adoption of 1988 minutes

- N. Thompson
- 2. Comments Chairman, Admin. Advisors
- 3. Technical Committee Report
- 4. EPA Report
- 5. FDA Report
- 6. USDA-CSRS Report
- 7. USDA-ARS Report
- 8. Headquarters Report
- 9. Regional Reports

NER NCR SOR WSR

- 10. IR-4 Meritorious Service Awards N. Thompson
- 12:00 1:00 PM

1:00 - 5:00 PM

- 11. Discussion Group Sessions
 - a. Combined A.A's/T.C.
 - b. Pesticide Committee R.C's, SLC's, Consultants, EPA Liaison
 - c. Animal Drug Committee R.C's FDA-CVM Liaison

- N. Thompson
- W. Wheeler
- D. Campt/representative
- G. Guest/representative
- J. Parochetti
- P. Schwartz
- R. Guest/G. Markle
- J. Bourke
- R. Hollingworth
- W. Wheeler J. Seiber

Lunch

- N. Thompson, W. Wheeler
- D. Baker, F. Boyd, H. Jamerson, L. Lim
- C. Meister
- S. Sundlof E. Viera

Continued.....

AGENDA (CONT'D.)

Friday, April 14, 1989

8:00 AM - 12:00 Noon

- 12. Discussion Group Reports
 - a. Combined A.A's/TC
 - b. Pesticide Committee
 - c. Animal Drug Committee
- 13. Election of Officers
- 14. Resolutions Committee Report
- 15. Site Selection Committee Report
- 16. Summary Remarks
 - a. Chairman, A.A's
 - b. Chairman, T.C.
- 17. Adjournment