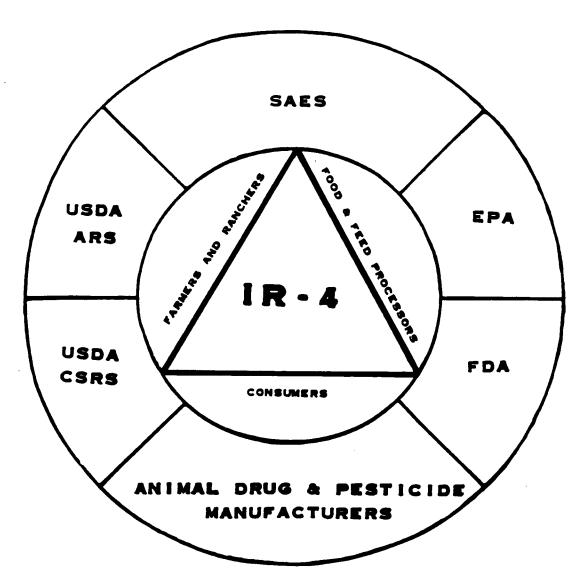
INTERREGIONAL RESEARCH PROJECT NO. 4 1990 ANNUAL REPORT



A NATIONAL AGRICULTURAL PROGRAM

TO CLEAR PEST CONTROL AGENTS AND ANIMAL DRUGS

FOR MINOR USES

ANNUAL REPORT OF COOPERATIVE INTERREGIONAL RESEARCH PROJECT NO. 4 IR-4 JANUARY 1 TO DECEMBER 31, 1990

1. PROJECT: IR-4 - A National Agricultural Program to Clear Pest

Control Agents and Animal Drugs for Minor Uses.

PRINCIPAL SOURCES OF FUNDS: Hatch Act & PL 89-106

3. ADMINISTRATION (PRINCIPAL LEADERS):

Administrative Advisory Committee:

Dr. R.E. Wyse, Rutgers University, Chair

Dr. J.P. Jordan, CSRS Administrator

Dr. K.M. Kerr, The Ohio State University

Dr. R.D. Plowman, ARS Administrator

Dr. N.P. Thompson, University of Florida

Dr. G.W. Ware, Jr., University of Arizona

Technical Committee:
Dr. P.H. Schwartz, Jr., USDA-ARS/Beltsville, Chair (Staff Scientist, Pesticide Assessment Staff)

Dr. R.T. Guest, Rutgers University (National Director, IR-4 Project)

Dr. R.M. Hollingworth, Michigan State University (Northcentral IR-4 Regional Laboratory Director)

Prof. G.M. Markle, Rutgers University (Executive Secretary)

Dr. L.R. Miller, USDA-CSRS

Dr. J.V. Parochetti, USDA-CSRS

Dr. J.N. Seiber, University of California (Western IR-4 Regional Laboratory Director)

Dr. T.D. Spittler, Cornell University/Geneva (Northeastern IR-4 Regional Laboratory Director)

Dr. W.B. Wheeler, University of Florida

(Southern IR-4 Regional Laboratory Director)

4. CONSULTANTS COMMITTEE:

Mr. D.M. Baker, Jr., EPA Liaison to IR-4, Chair

Ms. K. Davis, EPA-OPP-SRRD Liaison

Dr. D.A. Espeseth, USDA-APHIS Adviser

Dr. M.T. Flood, EPA-OPP-HED-DEB Liaison

Mr. H.L. Jamerson, EPA-OPP-RD, Minor Use Officer

Dr. L.A. Leach, AHI Representative

Mr. N. Somma, NACA Representative

Dr. E.E. Viera, FDA Liaison to IR-4

Represents

Northeastern Region

USDA-CSRS

Northcentral Region

USDA-ARS

Southern Region Western Region

USDA-ARS

National

Northcentral Region

National

USDA-CSRS (Animal Drugs) USDA-CSRS (Pesticides)

Western Region

Northeastern Region

Southern Region

5. COOPERATING REGULATORY AGENCIES:

Environmental Protection Agency (EPA):

Mr. D.D. Campt, EPA-OPP, Director

Ms. A.E. Lindsay, EPA-OPP-RD, Division Director

Ms. F.S. Bishop, EPA-OPP-RD-RSB, Branch Chief

Dr. R.D. Schmitt, EPA-OPP-HED-DEB, Branch Chief

Ms. R.S. Cool, EPA-OPP-RD-RSB-ERMUS, Section Head

Food and Drug Administration (FDA):

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Dr. R.H. Teske, FDA-CVM, Deputy Director

Dr. D.A. Gable, FDA-CVM-TDFA, Director

Dr. R.C. Livingston, FDA-CVM-DMRCH, Director

Dr. N.K. Das, FDA-CVM, Minor Use Officer

United States Department of Interior (USDI)/Fish and Wildlife Service: Ms. R.A. Schnick, USDI-Fish & Wildlife Service, Information Specialist

United States Department of Agriculture (USDA)/Animal & Plant Health Inspection Service (APHIS):

Dr. D.A. Espeseth, USDA-APHIS, Deputy Director, Veterinary Biologics

FAX: (908) 932-8481 6. NATIONAL HEADQUARTERS: (908) 932-9575 The National Headquarters is located at the New Jersey Agricultural Experiment Station, Cook College, Rutgers - The State University of New Jersey, New Brunswick, NJ 08903-0231.

Dr. R.T. Guest, National Director Prof. G.M. Markle, Associate Director and Recording Secretary to the Project Dr. J.J. Baron, National Coordinator

Dr. W.L. Biehn, Coordinator

Dr. R.G. Choban, Coordinator

Mr. R.R. Libby, Coordinator Mr. D.M. Baker, Jr., EPA Liaison

Dr. S.E. Katz, Animal Drug EIS Consultant

Mr. L.E. Mitchell, Pesticide Consultant

Mr. P.L. Pontoriero, Pesticide Consultant

Mrs. P.A. Sarica, Administrative Assistant

Mrs. D.K. Infante, Information Specialist

Mrs. C.L. Ferrazoli, Secretary

Mrs. J.R. Streisand, Secretary

Mrs. J.A. Eato-Griffin, Secretary

7. IR-4 REGIONAL COORDINATORS AND STATE/FEDERAL LIAISON REPRESENTATIVES:

IR-4's field research personnel include - (I) a Pesticide Regional Coordinator, an Animal Drug Regional Coordinator, and a Laboratory Regional Coordinator for each of the four regions, i.e., Northcentral, Northeastern, Southern, and Western; (II) four USDA-ARS scientists per region representing the disciplines of entomology, plant pathology, weed science, and pesticide analytical chemistry, and (III) an IR-4 State Liaison Representative for each of the 50 states and the U.S. Territories, including the District of Columbia, Guam, Puerto Rico, and the Virgin Islands. These 54 IR-4 State Liaison Representatives are scientists appointed by the Director of their respective State Agricultural Experiment Station (SAES). Their mission is to define the crop and animal protection needs of the farmers, growers, ranchers and homeowners in their states with respect to the production of foods (i.e., fruits, vegetables nuts, berries, grains, spices, meat, fish, honey, etc.), fibers, feeds, ornamentals, nursery stock, forestry seedlings, and fur-bearing animals.

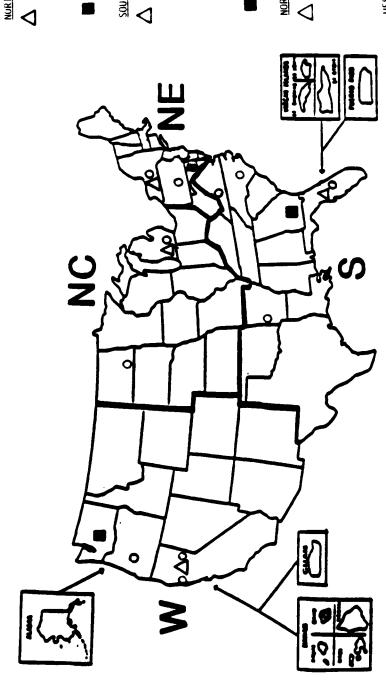
REGIONAL RESEARCH PERSONNEL

The names and affiliations of the field research personnel described above and the location of the four regional laboratories and associated USDA-ARS laboratories are shown below. Regional Coordinators are physically located at their respective regional laboratories.

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MINOR USES PROJECT RESIDUE LABORATORIES



NORTHEASTERN REGION

- Cornell University, Geneva, NY
- O Cornell University, Ithaca, NY O Pennsylvania State University
- USDA/ARS, Beltsville, MD

SOUTHERN REGION

- University of Florida
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- University of Arkansas University of Florida (College of Veterinary Medicine) North Carolina State University Virginia Polytechnic Institute & 00
 - State University
- USDA/ARS, Tifton, GA

NORTHCENTRAL REGION

- A Michigan State University
- O Michigan State University (College of Veterinary Medicine)
 O North Dakota State University

WESTERN REGION

- University of California, Davis, CA 4
- O University of California, Berkeley, CA
 O University of California, Davis, CA
 (School of Veterinary Medicine)
 O University of Hawaii
 O Oregon State University

A IR. 4 ME GIONAL IR-4 BATELLITE

USDA / ARS

USDA/ARS, Yakima, WA

8. PROGRESS OF WORK AND PRINCIPAL ACCOMPLISHMENTS:

(A) FOOD USE RESEARCH PROJECTS:

There are currently 4980 total IR-4 food-use requests, an increase of 925 over the 4055 requests reported last year. Of these, 1672 are characterized as researchable projects. During 1990, the four IR-4 Regions and USDA-ARS scheduled research on 210 food-use projects, from which residue samples for 161 projects went to state and USDA-ARS cooperating laboratories and samples for 29 projects went to chemical company laboratories. With the completion of 1990 and prior research projects, data requirements will be fulfilled for an additional 193 minor use needs. Field research protocols for 294 projects and 114 Lab. protocols were prepared or revised and the following pesticides/commodities were researched in 1990:

(1) FUNGICIDES AND NEMATICIDES:

FUNGICIDES: Benomyl/collard, mint, passion fruit, potato (Irish), spinach, turnip greens - Captan/blackberry, lettuce, onion (green), raspberry - Chlorothalonil/balsam pear, gourd (edible), mango, mint, mushroom, papaya, passion fruit - DCNA/blackberry - Ferbam/cherry (sour, sweet), cranberry, grape, mango - Fosetyl-Al/cranberry, grape - Iprodione/collard, cucumber - Metalaxyl/raspberry - Myclobutanil/ bean (snap), strawberry (annual, perennial) - Nitrapyrin/cabbage, cauliflower, lettuce (head, leaf), pepper (bell)- PCNB/radish, rutabaga, turnip (root and top) - Propiconazole/mint - Thiabendazole/chicory, cantaloupe - Vinclozolin/onion (green) - Ziram/grape, pepper (bell), spinach, tomato.

NEMATICIDES: Ethoprop/mint - Fenamiphos/asparagus, blueberry (highbush), cabbage, kiwifruit, onion (bulb), pea (green), squash (summer), watermelon - Methyl Bromide/pea (green).

(2) HERBICIDES AND PLANT GROWTH REGULATORS (PGR's):

HERBICIDES: Acifluorfen/bean (snap) - Ametryn/cassava, tanier, yam -Bentazon/apple - Clomazone/bean (snap), cabbage, cucumber, kenaf, squash (summer) - Clopyralid/cabbage, cauliflower, cherry, cranberry, leek, onion (bulb, green), pea, peach, plum, strawberry - DCPA/coriander, dill - Diquat/tomato - Fluazifop/blackberry, canola, Chinese mustard, coffee, collard, coriander, daikon (Japanese radish), kale, kenaf, okra, pea (pigeon), pea (succulent), pepper (bell), pineapple, rutabaga, strawberry, tanier, watermelon - Fomesafen/bean (snap), pea (pigeon) - Glyphosate/Chinese cabbage (napa), cacao, cassava, celery, collard, endive, parsley, pea (pigeon), spinach, swiss chard, tanier - Hexazinone/blueberry - Lactofen/bean (snap) -Linuron/fennel, horseradish, parsley - Methazole/onion (bulb) Metolachlor/blueberry, broccoli, carrot, cauliflower, kenaf MSMA/kenaf - Napropamide/basil, dill, marjoram, potato (sweet), rosemary, sage, tarragon - Norflurazon/hop - Oxyfluorfen/cacao, pepper (chili), strawberry - Paraquat/bean (lima), cabbage, cacao, lentil - Pendimethalin/kenaf, lupine - Phenmedipham/ cabbage - Pronamide/beet (sugar) - Quizalofop/mint - Sethoxydim/basil, Chinese mustard, radish. rutabaga, turnip (root and top) - Thiobencarb/Chinese cabbage (bok choy and napa) - Trifluralin/kenaf.

PGR's: Ethephon/blueberry, fig, peach.

8A. Continued

(3) INSECTICIDES, MITICIDES, MOLLUSCICIDES AND RODENTICIDES:

INSECTICIDES AND MITICIDES: Abamectin/hop - Bacillus thuringiensis/basil, chives - Bifenthrin/hop - Carbaryl/basil, leek - Chlorpyrifos/apple (non-bearing), atemoya, bean (snap), coffee, crambe, eggplant, onion (bulb, green), pepper (bell), pineapple, sugar apple, tomato - Cyfluthrin/hop - Cyhalothrin/strawberry - Cypermethrin/clover - Cyromazine/bean (lima and snap), pea (southern) - Diazinon/blueberry, fig - Dicofol/raspberry - Dimethoate/tomato - Esfenvalerate/Chinese cabbage (bok choy), kale, kiwifruit, kohlrabi, okra, pea (pigeon) - Fluvalinate/blueberry, hop - Fonofos/watermelon - Hexakis/bean (long), pepper (bell), potato (sweet) - Malathion/atemoya - Methomyl/chicory, cranberry, greens (rape), kohlrabi, passion fruit - Naled/eggplant, hop, turnip (root and top) - Parathion (ethyl and methyl)/hop, Parathion (ethyl)/cranberry - Permethrin/carrot, papaya - Petroleum Oil/pistachio - Phorate/hop - Thiodicarb/Chinese cabbage (bok choy), potato (sweet), turnip (root and top).

RODENTICIDE: Zinc phosphide/beet (sugar).

In summary, the IR-4 Project sponsored research on over 94 individual commodities in 1990.

In October, the IR-4 State & Federal Liaison Representatives in the Regional Committees selected the active research projects for 1991. reviewed and prioritized the national (multi-regional) researchable projects and the researchable projects for low dietary intake (LDI) crops for their Tolerances and labels are possible for LDI crops on the basis of region. regional or even state data. Each region struck a balance in funding between projects requiring national data and projects requiring only regional data. Prior to the National Research Planning Meeting (NRPM) which was held at the IR-4 Headquarters 27-29 NOV 90, the Headquarters staff identified the researchable reregistration projects for 1991 from the total list of reregistration projects prioritized by the scientists who attended the IR-4/EPA/USDA Food Use Workshop on 12-14 NOV 90 in St. Louis, Missouri. At the NRPM, the IR-4 Headquarters Pesticide Program Scientists, the IR-4 Pesticide Regional Coordinators, the IR-4 Laboratory Regional Coordinators, the USDA-ARS Staff Scientist, and the USDA-ARS Laboratory Chemists formulated a cooperative research program to establish field research and designate laboratories to analyze residue samples.

(B) RESEARCH DEVELOPMENT AND REGULATORY SUCCESSES:

IR-4 Headquarters prepared 76 regulatory packages during the 1990 calendar year. These regulatory packages included 49 new tolerance petitions, 26 reregistration petitions, and 1 crop definition petition. In addition, 7 major amendments were made to petitions during the year in response to EPA requests for additional residue data.

Thirty-seven new tolerance petitions were submitted to EPA and an additional 12 are currently under review by manufacturers (eventual label registrants) prior to submission to EPA. Additionally, 26 reregistration packages were prepared and sent to industry. These reregistration packages included reformats and summaries which were required in 1990 under Phase 3 of reregistration. These packages have been submitted to EPA by the manufacturer as part of an IR-4/Industry cooperative effort in the handling of minor use

8B. Continued

reregistration requirements. Cooperation between IR-4 and industry is further demonstrated by an additional 68 reformats and summaries which have or will be prepared and submitted by various manufacturers utilizing IR-4 generated data.

During 1990, IR-4 Headquarters petition submissions resulted in pesticide actions representing 96 pesticide/commodity tolerances, including 1 crop definition. These are reviewed in detail below:

- (1) FUNGICIDES AND NEMATICIDES (3 tolerances):
 -Fenamiphos/table beet (root & top) (R)
 -Iprodione/Chinese mustard (R)
- (2) HERBICIDES (23 tolerances):
 - -Metolachlor/bell pepper
 - -Paraquat/taro (R)
 - -Fluazifop/endive, macadamia nut
 - -Glyphosate/breadfruit, canistel, date, jaboticaba, jackfruit, persimmon, sapote (black and white), soursop, tamarind
 - -Sethoxydim/rhubarb (R)
 - -Oxyfluorfen/papaya (R), taro (corm and leaves) (R), persimmon, horseradish, feijoa
 - -Linuron/parsley (R)
 - -2,4-D/raspberry (R)
- (3) INSECTICIDES AND MITICIDES (7 tolerances):
 - -Azinphosmethyl/pomegranate (R)
 - -Methidathion/kiwifruit (R), carambola (R), longan (R)
 - -Chlorpyrifos/cherimoya (R), feijoa (R), sapote (R)
- (4) CROP DEFINITIONS (63 tolerances):
 -Alfalfa = birdsfoot trefoil, sainfoin

Clearances which have the (R) designation are tolerances with regional registration. See EPA Minor Use Policy in the 2 APR 86 <u>Federal</u> <u>Register</u> for details.

Additionally, 7 tolerances were proposed. These proposals are expected to become clearances in 1991.

Pesticide reregistration continues to have an impact on IR-4 regulatory activities. Reregistration requirements often require additional residue data. IR-4 has submitted reregistration packages with additional residue data for diazinon on cranberry and folpet on avocado.

The 1988 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA '88) necessitated that IR-4 reallocate resources to the defense of critical minor uses. This procedure required the reevaluation of data that were previously submitted to EPA in support of tolerance petitions which were subsequently approved by EPA. To meet these requirements, we contacted field and laboratory researchers to certify the availability of the raw data supporting all of the subject petitions. In some cases, IR-4 determined that additional data would be required to retain specific uses.

8B. Continued

Requirements under Phase 3 of reregistration mandated the reformatting and/or summarizing of 99 IR-4 minor use pesticide petitions. This formidable task was completed through a cooperative effort between IR-4 and various pesticide companies. A full-time effort was required to address the Phase 3 reformats and summaries. This represented a significant increase in workload at the regional laboratories and at IR-4 Headquarters.

Reregistration has also affected the time frame in which the agricultural chemical industry and EPA reviews our submissions. Registrants are facing major challenges during reregistration and, in some cases, minor use needs receive low priorities. In other cases, there have been agreements to develop multi-company "Task Force" committees to cost-share the data requirements mandated by reregistration for certain pesticides. These Task Force committees need to review and approve all IR-4 activities for the respective pesticides. Since Task Force committees may meet only infrequently, responses to IR-4 can be delayed.

IR-4 continues to have meaningful dialogue with EPA's Health Effects, Registration, and Special Review and Reregistration Divisions concerning current residue and toxicology data requirements for various pesticide uses. These discussions have aided IR-4 in the selection of research projects. This is very important because of funding limitations.

EPA's expanded Good Laboratory Practice (GLP) regulations were finalized in October 1989. IR-4 field and laboratory procedures were modified, as noted below, over the last few years to meet the current requirements. All IR-4 cooperators are now utilizing written standard operating procedures, and are being reviewed by qualified quality assurance units.

There continue to be cases where pesticide manufacturers are unwilling to register a pesticide on a minor crop due to potential crop damage liability concerns. Several individual growers, grower groups, and other organizations in New Mexico, Louisiana, Wisconsin, Florida, and New York have set a precedent by formulating 3rd party registration agreements with the agricultural chemical companies to limit the potential crop damage liability of the primary registrant. In addition, a few pesticide formulator companies have worked out agreements with the primary registrants to assume the potential crop damage liability and sell the pesticide in the minor use market.

Based on the current success of the working arrangements, there is considerable interest for the expansion of third party registrations. Currently, negotiations are continuing in several states in order to develop agreements with the primary registrants.

8B. Continued

IR-4 actively supports 3rd party registrations and encourages all parties to investigate this possibility when feasible. EPA requires a tolerance or exemption from the requirement of a tolerance before a pesticide can be registered on a food or feed crop. IR-4 can be of assistance in instances where tolerances or exemptions do not exist. It can take up to 5 years from the start of a project until a tolerance is established, therefore, IR-4 must be informed of potential third party registrations at the initiation of tentative agreements.

(C) ORNAMENTAL RESEARCH AND DEVELOPMENT:

During the 13 1/2 years the IR-4 Ornamentals Program has been in existence (APR 77 - NOV 90), IR-4 has undertaken 12,406 ornamental research trials. In 1990, the IR-4 Project funded 401 ornamental research trials, and IR-4 HQ prepared registration packages for 5 pesticides (1 insecticide and 4 herbicides) containing 238 reports. These registration packages were sent to registrants for review and eventual labeling. During 1990, IR-4 data were used to support 110 ornamental pesticide registrations. Since 1977, the total number of label registrations on ornamentals is 2,914. Ornamental registrations that were supported by IR-4 data in 1990 include:

PESTICIDE	ORNAMENTAL USES OR SPECIES REGISTERED
Cyfluthrin (TEMPO ^R)	To control insect pests on trees, shrubs, flowers, and foliage plants.
Clopyralid (STINGER ^R)	To control broadleaf weeds in Christmas tree plantations and nurseries.
Fenpropathrin (TAME ^K)	To control insects and mites on bedding plants, chrysanthemum, columbine, snapdragon, and foliage plants grown in greenhouse, lathhouse, and shadehouse, where plants are grown in containers.
Bentazon (BASAGRAN ^R)	Directed spray to control weeds in ornamental crops including arborvitae, Chinese holly, white pine, cotoneaster, forsythia, juniper, rhododendron, azalea, and spirea.
Metolachlor (PENNANT ^R) (liquid and 5G)	To control weeds on field and liner grown red cedar.
Fluazifop (FUSILADE ^R 2000)	To control weeds on flame amur maple, sugar maple, begonia, white birch, orange coronet, trailing hottentot-fig, hackberry, flowering quince, coleus, white ash, green ash, gladiolus, Golden-rain tree, Mahonia, Smash hit red geranium, loblolly pine, Virginia pine, sycamore, potentilla, Douglas fir, Weeping willow, purple willow, Thunberg Spiraea,

linden, wayfaring tree, nannyberry, and mazzard cherry.

8C. Continued

PESTICIDE	ORNAMENTAL	USES OR	SPECIES	REGISTERED

Fosetyl Al (ALIETTER)

To control diseases caused by <u>Pythium</u> spp. and <u>Phytophthora</u> spp. in field, greenhouse, and landscape grown bedding plants; including begonia, vinca, zinnia, petunia, geranium, impatiens, salvia, snapdragon, carnation, and other ornamentals including chrysanthemum, gloxinia, gypsophila, peperomia, mugho pine, poinsettia, pothos, camellia, and african violet.

(D) BIORATIONAL RESEARCH AND DEVELOPMENT:

The IR-4 Biorationals Program was established to help develop biological (microbial and biochemical) control agents for economically important pests. September, 1990 marks the completion of eight years of the IR-4 Biorationals Program.

In 1990, IR-4 funded research to allow completion of the safety testing required to register the Codling Moth Granulosis Virus (CMGV). IR-4 plans to submit a petition to EPA requesting a full exemption of CMGV from the requirement of a tolerance in 1991.

In July, 1990 EPA established a full exemption from the requirement of a tolerance for residues of the Grape Berry Moth Pheromone based on a petition submitted by Mitsubishi International. The Grape Berry Moth Pheromone dispensers had been previously evaluated under an Experimental Use Permit and temporary exemption from the requirement of a tolerance in NY, which was based on a petition prepared by IR-4 in conjunction with Drs. T. Dennehy and W. Roelofs of the New York Agricultural Experiment Station. The Grape Berry Moth Pheromone (GB-ROPE) dispensers provide control of the grape berry moth via mating disruption.

(E) ANIMAL DRUG RESEARCH AND DEVELOPMENT

Since the IR-4 Animal Drug Program was established in 1982, 15 uses have been cleared. The 15 clearances, listed below, have been published in the Federal Register. Additionally in 1990, eight projects (listed below) are under review as Public Master Files (PMF) with FDA-Center for Veterinary Medicine (CVM), three (listed below) are complete and the data will be filed with FDA-CVM, and 20 are ongoing research projects. Additionally, the 5th IR-4/FDA Workshop for Minor Use Drugs (Aquaculture) was held in Bethesda, MD on 15-16 OCT 90.

Public Master Files (PMF) for the following 15 projects were published in the $\underline{\text{Federal}}$ Register (F.R.) as clearances:

<u>PMF</u>	DISEASE/SPECIES	<u>DRUG</u>	DATE F.R. PUBLICATION
3857	Gapeworm/Pheasant	Thiabendazole	02/22/84
3883	G.I. Parasites/Goat	Ivermectin	03/24/89
3887	Coccidiosis/Pheasant	Amprolium	12/14/84
3895	Warbles/Reindeer	Ivermectin	12/14/84

8E. Continued

<u>PMF</u>	DISEASE/SPECIES	<u>DRUG</u>	DATE F.R. PUBLICATION
5012	Coccidiosis/Goat	Decoquinate	02/18/87
5014	Coccidiosis/Quail	Monensin	04/14/87
5020	Coccidiosis/Quail	Salinomycin	03/22/89
5028	Gaffkemia/Lobster	Oxytetracycline	01/03/86
5042	Coccidiosis/Rabbit	Lasalocid	03/15/90
5055	Coccidiosis/Goat	Monensin	12/19/86
5056	Enteric Septicemia /Catfish	Sulfadimethoxine/ Ormetoprim	04/16/86
5071	Lungworms/Bighorn Sheep	Fenbendazole	02/14/89
5117	G.I. Parasites/Goat	Levamisole Hcl	09/08/89
5178	Ulcerative Enteritis/Quail	Bacitracin	02/22/88
5258	Coccidiosis/Sheep	Decoquinate	09/28/90

Public Master Files for the following eight projects are currently under review by FDA-Center for Veterinary Medicine (CVM):

<u>PMF</u>	DISEASE/SPECIES	DRUG
3543 5059 5118 5157 5206 5307 5316 5321	External Parasites/Shrimp Hypodermosis/American Bison G.I. Parasites/Goat Coccidiosis/Chukar Partridge Bacterial Pneumonia/Goat Ear Mites/Ranch Fox Bacterial Pneumonia/Goat Bacterial Pneumonia/Sheep	Formalin Ivermectin Fenbendazole Sulfadimethoxine/Ormetoprim Sulfamethazine Ivermectin Oxytetracycline/LA-200 Oxytetracycline/LA-200
	, ,	,

The research for the following three projects under Investigational New Animal Drug (INAD) applications is complete and data will be filed with FDA-CVM:

<u>INAD</u>	DISEASE/SPECIES	<u>DRUG</u>
4447	Bacterial Pneumonia/Goat	Amoxicillin
4449	Bacterial Pneumonia/Sheep	Amoxicillin
6119	Mastitis/Goat	Novobiocin/Procaine Penicillin G

(F) COORDINATION WITH FEDERAL AND STATE AGENCIES:

Continued excellent cooperation with federal research agencies was again evidenced in 1990. Of the research noted, the USDA-ARS minor use program conducted field trials on 72 food projects, analyzed residue samples from 24 projects, and researched 225 ornamental projects. Additionally, the USDA Fish and Wildlife Service scientists cooperated in two minor animal clearance projects. This team-work approach is providing the farmers, ranchers, growers, nurserymen, and homeowners with the necessary tools that will result in food and environmental safety while increasing production efficiency. Seventy percent of the states participated in the 1990 research program.

9. USEFULNESS OF FINDINGS:

Without the field and laboratory research conducted by the IR-4/SAES and USDA-ARS scientists and the subsequent successful tolerance establishment, minor commodity uses including alternative crop uses would seldom, if ever, be cleared due to the negative economic factors confronting industrial manufacturers. In this sense, IR-4 serves a valuable "bridging" role between American farmers and ranchers, pesticide and drug producers, and regulatory agencies, i.e., no other federal or state mechanism exists to assure that the animal, fruit, vegetable, and ornamental growers, both large and small, have the safe and efficacious pest control materials they need to produce commercial yields of high quality and wholesome commodities. IR-4 continues to be the clearinghouse and communication center for the clearance of safe animal drugs and safe crop protection chemicals, including biorationals, which in conjunction with cultural practices, scouting, and conventional pesticides are frequently used in integrated pest management (IPM) systems. The biorational research, which includes the development of biological (microbial and biochemical) control agents, also provides alternatives and supports organic or sustainable farming systems.

10. WORK PLANNED FOR NEXT YEAR:

Since IR-4 is mission oriented with its focus on food and environmental safety, as well as, crop and animal protection, we will continue to develop data required by EPA and FDA for the establishment of minor use tolerances, including IPM materials and animal drug approvals, as necessary and when appropriate and as funds permit. Additionally, a similar effort will be expended in developing nonfood uses, i.e., ornamental registration data packages. Since funding levels can only address approximately 15% of the existing researchable food-use projects, IR-4 will continue to work on the highest priority needs and maintain the food-use program at the expense of the ornamental or nonfood use program. Also, funding levels for the animal drug and biorational programs are not adequate to address more than 15% and 5%, respectively, of the researchable projects on the books. The research program in ornamentals has been reduced and only 35% of the researchable projects have active research underway.

In order to gain maximum benefit from a limited funding base, IR-4 works closely with EPA, FDA, and the pesticide, animal drug and commodity production industries. Requests are screened carefully so the projects, involving pesticides and drugs having significant data gaps, can either be eliminated or delayed as the situation dictates. By doing this, the overall efficiency of all operations will be improved, so that time and money are not expended on projects which cannot be successfully concluded at the present time.

IR-4 is proposing the establishment of a Reregistration Notification Network which will be addressed in two phases. The first phase will be a feasibility study and the second phase will be the implementation of the communications network. This network proposal has the potential to serve as a rapid communication link between pesticide registrants and targeted groups of commodity producers.

11. PUBLICATIONS:

Baron, J.J. 1990. IR-4 Pesticide Reregistration Alert (Update NO. 7). IR-4 Headquarters, New Brunswick, NJ, pp 42.

Markle, G.M. (Editor). IR-4 Newsletter (Quarterly).

December 31, 1990

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Attachment:

Glossary of Abbreviations used in this Report

1990 IR-4 ANNUAL REPORT Glossary of Abbreviations used in this Report

AHI - Animal Health Institute APHIS - Animal and Plant Health Inspection Service ARS - Agricultural Research Service CMGV - Codling Moth Granulosis Virus CSRS - Cooperative State Research Service CVM - Center for Veterinary Medicine DMRCH - Division of Drug Manufacturing and Residue Chemistry EIS - Environmental Impact Statement EPA - Environmental Protection Agency ERMUS - Emergency Response Minor Use Section EUP - Experimental Use Permit FDA - Food and Drug Administration GLP - Good Laboratory Practice HED - Health Effects Division HQ - Headquarters IPM - Integrated Pest Management IR-4 - Interregional Research Project Number 4 LDI - Low Dietary Intake NACA - National Agricultural Chemicals Association NRPM - National Research Planning Meeting OPP - Office of Pesticide Programs PGR - Plant Growth Regulator PL - Public Law PMF - Public Master File R - Regional RD - Registration Division RSB - Registration Support Branch SAES - State Agricultural Experiment Station SRRD - Special Review and Reregistration Division

TDFA - Division of Therapeutic Drugs for Food Animals

USDA - United States Department of Agriculture USDI - United States Department of Interior