

ANNUAL REPORT OF COOPERATIVE INTERREGIONAL RESEARCH PROJECT

IR-4

JANUARY 1 TO DECEMBER 31, 1985

1. PROJECT: IR-4 - A National Agricultural Program: Clearances of Animal Drugs, Biorationals (Microbials and Biochemicals), and Pesticides for Minor or Specialty Uses.

2. COOPERATING AGENCIES AND PRINCIPAL LEADERS:

Interregional Administrative Advisory Committee (AA):

Table with 2 columns: Name and Title, and Represents. Lists members like Dr. N.P. Thompson (Chairman) representing Southern Region, and others representing various regions and agencies like USDA-CSRS and ARS.

Technical Committee (TC):

Table with 2 columns: Name and Title, and Represents. Lists members like Dr. P.H. Schwartz, Jr. (Chairman) representing USDA-ARS, and others representing National Headquarters, Northeastern Region, and various USDA-CSRS divisions.

Supporting Committees:

Ad Hoc Animal Drug Advisory Staff

Table with 2 columns: Name and Title, and Represents. Lists members like Dr. M.H. Bealeu (Chairman) representing Southern Region, and others representing Northeastern Region, USDA-ARS, and Northcentral Region.

Consultants Staff

Table with 2 columns: Name and Title. Lists consultants like Dr. K.R. Hill (USDA-ARS), Mr. H.L. Jamerson (EPA-OPP-RD), and others.

Environmental Protection Agency (EPA) Advisors

Table with 2 columns: Name and Title. Lists advisors like Dr. J.A. Moore (Assistant Administrator), Mr. S. Schatzow (Director), and others.

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Food and Drug Administration (FDA) Advisors

Dr. L.M. Crawford, FDA-CVM, Director
Dr. G.B. Guest, FDA-CVM, Deputy Director
Dr. M.A. Norcross, FDA-CVM-NADE, Associate Director
Dr. D.A. Gable, FDA-CVM-TDFA, Director
Dr. T.V. Raines, FDA-CVM-APDB, Vet. Medical Officer

National Headquarters Staff (201) 932-9575

The National Headquarters Staff is located at the New Jersey Agricultural Experiment Station, Cook College, Rutgers, The State University of New Jersey, New Brunswick, NJ 08903.

Dr. R.H. Kupelian, National Director
Prof. G.M. Markle, National Coordinator and
Recording Secretary to the Project
Dr. R.T. Guest, National Coordinator
Dr. M.E. Burt, Associate Coordinator (to 6/85)
Dr. J.E. Elson, Associate Coordinator
Dr. W.L. Biehn, Assistant Coordinator
Mr. D.M. Baker, Jr., EPA Liaison
Dr. E.E. Viera, FDA Liaison
Mr. R.R. Libby, Pesticide Consultant

Dr. J.S. Farnham, Animal Drug Consultant
Dr. A. Marei, Pesticide Metabolism Consultant
Mr. L.E. Mitchell, Pesticide Consultant
Mr. P.L. Pontoriero, Pesticide Consultant
Dr. S.E. Katz, Animal Drug EIS Consultant
Mrs. P.A. Sarica, Administrative Assistant
Mrs. D.K. Infante, Information Specialist
Mrs. R.T. Harvey, Secretary
Ms. C.L. Guise, Secretary
Mrs. G.G. Peterson, Secretary

IR-4 REGIONAL COORDINATORS AND STATE/FEDERAL LIAISON REPRESENTATIVES

IR-4's field research personnel includes (I) a Regional Field Research Coordinator and Laboratory Residue Analysis Coordinator for each of the four regions, i.e. Northeastern, Southern, Northcentral and Western, (II) four USDA-ARS scientists per region representing the disciplines of entomology, plant pathology, weed science and pesticide residue and metabolism 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 Virgin Islands. The 55 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 pest and livestock disease control technology 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, etc.), fibers, feeds, ornamentals, nursery stock, forestry seedlings and fur-bearing animals.

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On 15 SEP 82, the Committee of Nine officially approved the addition of an animal drug clearance program to the IR-4 Project which would be coordinated by the existing IR-4 administrative and research structure as a Project objective. Personnel added to provide an appropriate expertise base includes (IV) a Regional Animal Drug Coordinator for each of the four regions appointed by the respective regional Administrative Advisor and Technical Committee Representative; (V) a Veterinarian and Secretary at IR-4 HQ; and (VI) a Regional AD-HOC Drug Advisory Staff member for each of the four regions appointed by the respective SAES Director and a combination Drug Advisor/Coordinator for USDA-ARS.

Regional Ad Hoc Drug Advisors

Dr. C. Seymour Card, NE Region
(814) 865-7696
Specialty Area: Veterinary Pathology

Dr. Frederick W. Oehme, NC Region
(913) 532-5679
Specialty Area: Toxicology

Dr. Marshall H. Beleau, Southern Region
(601) 686-9311
Specialty Area: Aquatic Animal Medicine

Dr. Peter J. South, Western Region
(208) 885-7981
Specialty Area: Extension Veterinarian

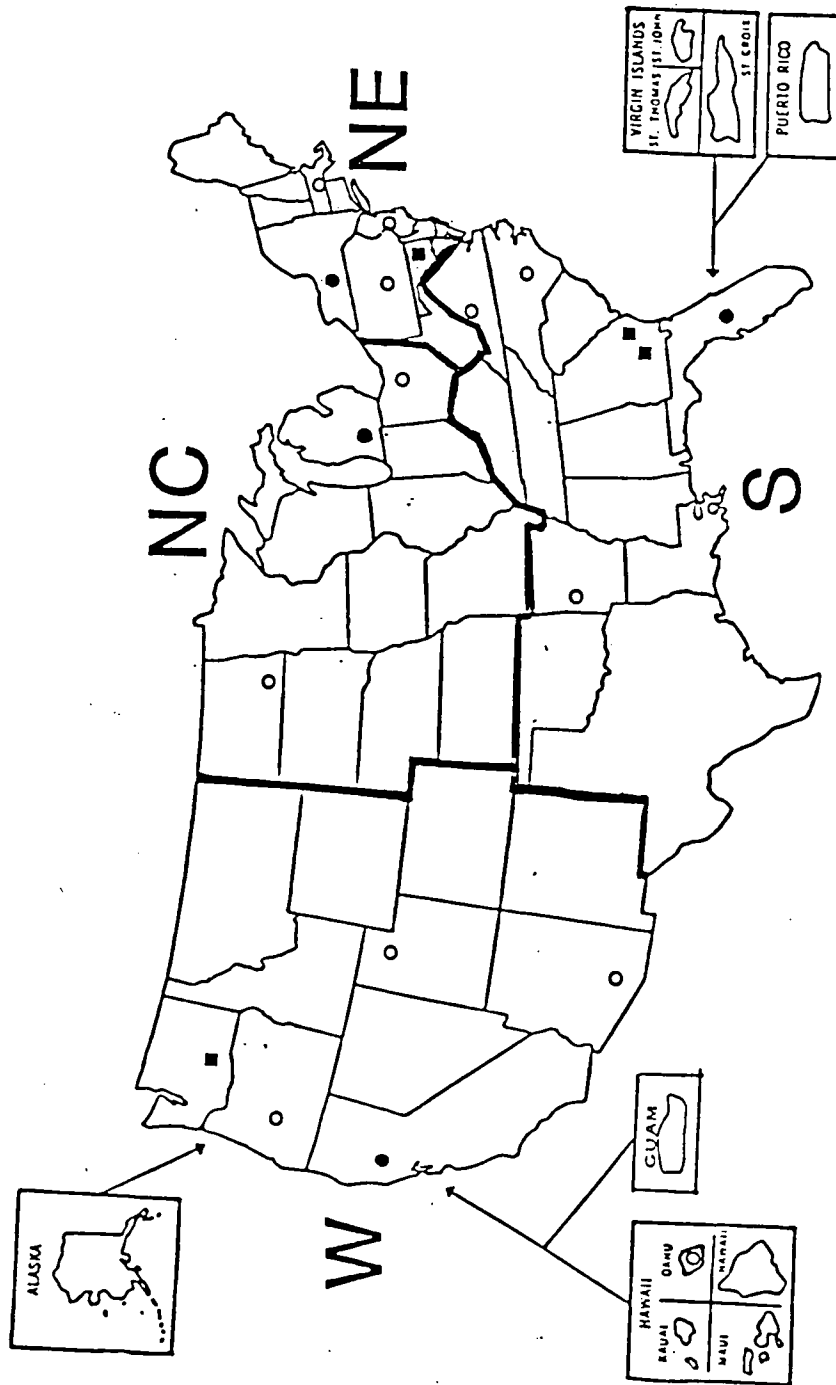
Dr. Roger Gerrits, USDA/ARS
(201) 344-3066
Specialty Area: Reproductive Physiology

FIELD 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 on the following pages. Regional Coordinators are physically located at their respective regional laboratories.

NAME	STATE	TELEPHONE	SPECIALTY AREA
<u>Northwestern Region</u>			
Dr. John B. Bourke.....	Regional Lab. Director.....	(315) 787-2281.....	Chemistry
Dr. Paul B. Baker.....	Pesticide Coordinator.....	(315) 787-2327.....	Entomology
Dr. John B. Babish.....	Animal Drug Coordinator.....	(607) 256-6341.....	Drug & Foreign Compound Metabolism
Dr. Terry Spittler.....	Supervisory Chemist.....	(315) 787-2283.....	Chemistry
Dr. Richard A. Ashley.....	(203) 486-3435.....	Plant Science
Mr. Mark R. Graustein.....	(302) 451-2526.....	Entomology
Mr. Grady McDonald.....	(202) 282-7372.....	Horticulture
Dr. James F. Dill.....	(207) 581-7980.....	Entomology
Dr. James J. Linduska.....	(301) 742-8788.....	Entomology
Dr. Charles F. Brodel.....	(617) 295-2212.....	Entomology
Dr. James Bowman.....	(603) 862-1159.....	Entomology
Dr. Gerry Chidiu.....	(609) 455-3100.....	Entomology
Dr. Paul B. Baker.....	(315) 787-2327.....	Entomology
Dr. Kean S. Goh.....	(607) 256-3283.....	Entomology
Dr. Ralph O. Mumma.....	(814) 863-4435.....	Entomology
Mr. J. Lincoln Pearson.....	(401) 792-2358.....	Horticulture
Dr. A.R. Gotlieb.....	(802) 656-2630.....	Plant Pathology
Dr. Joe E. Weaver.....	(304) 293-6023.....	Entomology
Dr. Ralph E. Webb.....	USDA-ARS.....	(301) 344-2269.....	Entomology
Dr. Julius Feldmesser.....	USDA-ARS.....	(301) 344-3662.....	Nematology/Plant Pathology
Mr. J. Ray Frank.....	USDA-ARS.....	(301) 663-7132.....	Weed Science
Dr. Kenneth R. Hill.....	USDA-ARS.....	(301) 344-2495.....	Residue Chemistry
<u>North Central Region</u>			
Dr. Fumio Matsumura.....	Regional Lab. Director.....	(517) 353-9430.....	Entomology
Dr. Satoru Miyazaki.....	Pesticide Coordinator.....	(517) 353-9497.....	Pest. Analysis & Entomology
Dr. R.K. Ringer.....	Animal Drug Coordinator.....	(517) 355-8414.....	Avian & Fur-bearing Physiology/Toxicology
Dr. Richard Leavitt.....	Supervisory Chemist.....	(517) 353-6377.....	Analytical Chem.
Dr. David E. Foster.....	(515) 294-1101.....	Entomology
Dr. David J. Williams.....	(217) 333-2126.....	Horticulture
Dr. Paul C. Pecknold.....	(317) 494-4628.....	Plant Pathology
Dr. Don Cress.....	(913) 532-5891.....	Entomology
Dr. Satoru Miyazaki.....	(517) 353-9497.....	(See above)
Dr. Leonard B. Hertz.....	(612) 373-1103.....	Horticulture
Dr. N.J. Natarella.....	(314) 882-7511.....	Ext. Floriculturist
Dr. John D. Nalewaja.....	(701) 237-7971.....	Weed Science
Dr. Roger Gold.....	(402) 472-1446.....	Entomology
Dr. Acie Waldron.....	(614) 422-7541.....	Entomology (Chem. Control)
Mr. Leon J. Wraage.....	(605) 688-5121.....	Agronomy, Weed & Plant Science
Dr. John Wedberg.....	(608) 262-3226.....	Entomology
Dr. T.L. Ladd.....	USDA-ARS.....	(216) 263-3898.....	Entomology
Dr. Charles Krause.....	USDA-ARS.....	(614) 363-1129.....	Plant Pathology/Nematology
Dr. Loyd M. Wax.....	USDA-ARS.....	(217) 333-1277.....	Weed Science
Dr. William M. Doane.....	USDA-ARS.....	(309) 685-4011.....	Physical Chem.
<u>Southern Region</u>			
Dr. Willis B. Wheeler.....	Regional Lab. Director.....	(904) 392-1978.....	Biochemistry
Dr. Charles W. Meister.....	Pesticide Coordinator.....	(904) 392-1978.....	Plant Pathology
Dr. Steve F. Sundlof.....	Animal Drug Coordinator.....	(904) 392-1841.....	Veterinary Toxicology
Dr. Fromode Bardalaye.....	Supervisory Chemist.....	(904) 392-1978.....	Res. Chemistry
Dr. Michael Williams.....	(205) 826-4850.....	Entomology
Dr. Terry L. Lavy.....	(501) 575-3955.....	Weed Science
Dr. Sam S. Fluker.....	(904) 392-4721.....	Entomology
Dr. Emmett D. Harris.....	(404) 542-1765.....	Entomology
Dr. Chris M. Christensen.....	(606) 258-5955.....	Entomology
Dr. Lowell L. Black.....	(504) 388-1464.....	Plant Pathology
Dr. James M. McGuire.....	(601) 325-3138.....	Plant Pathology
Dr. T. Jack Sheets.....	(919) 737-3391.....	Weed Science
Dr. O. Norman Nesheim.....	(405) 624-5531.....	Entomology/Plant Pathology
Miss Nilisa M. Acin.....	(809) 767-9705.....	Chemistry
Dr. William D. Buse.....	(803) 656-5042.....	Entomology
Miss Nancy Taylor.....	(615) 974-7138.....	Plant Pathology
Dr. Rodney L. Holloway.....	(409) 845-7028.....	Entomology
Dr. Michael J. Weaver.....	(703) 961-6543.....	Plant Pathology
Mr. Walter I. Knausenberger.....	Virgin Islands.....	(809) 778-0246.....	Pest Management
Dr. James M. Schalk.....	USDA-ARS.....	(803) 556-2210.....	Entomology
Dr. Alva W. Johnson.....	USDA-ARS.....	(912) 386-3372.....	Nematology
Dr. Norman Glaze.....	USDA-ARS.....	(912) 386-3355.....	Plant Physiology
Dr. Donald Wauchope.....	USDA-ARS.....	(912) 386-3462.....	Residue Chemistry
<u>Western Region</u>			
Dr. James Seiber.....	Regional Lab. Director.....	(916) 752-1142.....	Chemistry
Mr. Harold G. Alford.....	Pesticide Coordinator.....	(916) 752-7010.....	Entomology
Dr. Arthur L. Craigmill.....	Animal Drug Coordinator.....	(916) 752-1142.....	Environ. Veterinary Toxicology
Dr. Thomas Archer.....	Supervisory Chemist.....	(916) 752-1142.....	Chemistry
Dr. Jeff Conn.....	(907) 479-7614.....	Weed Science
Dr. David N. Byrne.....	(602) 621-1131.....	Entomology
Mr. Harold G. Alford.....	USDA-ARS.....	(916) 752-7010.....	(See above)
Dr. Bert L. Bohmont.....	USDA-ARS.....	(303) 491-5237.....	Ag. Chemistry & Weed Science
Dr. Claron Bjork.....	(671) 734-2575.....	Entomology
Dr. John W. Hylin.....	(808) 948-8352.....	Biochemistry
Dr. Gene P. Carpenter.....	(208) 885-6595.....	Entomology
Dr. Michael J. Jackson.....	(406) 994-3517.....	Agronomy
Dr. Ellis Huddleston.....	(505) 646-3225.....	Entomology
Dr. Harry G. Smith.....	(702) 784-6911.....	Ent. & Parasitology
Dr. James M. Witt.....	(503) 754-2564.....	Ag. Chem. & Toxicology
Dr. Howard Deer.....	(801) 750-1598.....	Pest. & Toxic Substances
Mr. Richard C. Maxwell.....	(509) 335-2995.....	Entomology
Mr. Everett Spackman.....	(307) 766-4261.....	Entomology
Dr. Robert G. Linderman.....	USDA-ARS.....	(503) 757-4544.....	Nematology/Plant Pathology
Dr. Eric Halfhill.....	USDA-ARS.....	(509) 575-5982.....	Entomology
Dr. Leslie M. McDonough.....	USDA-ARS.....	(509) 575-5970.....	Pest. Chemistry

MINOR USES PROJECT RESIDUE LABORATORIES



RESIDUE LABORATORIES

- IR-4 REGIONAL
- IR-4 SATELLITE
- USDA/ARS

NORTHEASTERN REGION

- Cornell University, Geneva NY
- University of Massachusetts
- Pennsylvania State University
- Rutgers University, New Brunswick, NJ
- USDA/ARS, Beltsville, MD

SOUTHERN REGION

- University of Florida
- Virginia Polytechnic Institute & State University
- North Carolina State University
- University of Arkansas
- USDA/ARS, Savannah, GA
- USDA/ARS, Tifton, GA

NORTHCENTRAL REGION

- Michigan State University
- Ohio State University, OARDC, Wooster
- North Dakota State University

WESTERN REGION

- University of California, Davis, CA
- Oregon State University
- Utah State University
- University of Hawaii
- University of Arizona
- USDA/ARS, Yakima, WA

3. PROGRESS OF WORK AND PRINCIPAL ACCOMPLISHMENTS:

(A) FOOD USE RESEARCH PROJECTS

There are currently 2946 total IR-4 food-use requests, an increase over the 2694 requests reported last year. Of these, 712 are characterized as researchable projects. During 1985, the four regions and USDA-ARS scheduled research on 208 food-use projects, from which residue samples went to 14 state and USDA-ARS cooperating laboratories and 10 chemical company laboratories. With the completion of 1985 and prior research projects, data requirements will be fulfilled for an additional 105 minor use needs. Research protocols for 227 requests were prepared or revised and the following pesticides/commodities were researched in 1985:

(1) BIORATIONALS:

Codling moth granulosus virus (CMGV)/apple, pear, walnut - Cephalosporium lecanii/cucumber.

(2) FUNGICIDES AND NEMATICIDES:

Benomyl/endive, cauliflower, non-bell pepper - Carboxin/carrot - Chlorothalonil/parsnips, Chinese broccoli, eggplant, peppers - Copper hydroxide/dill - Etriazole/lettuce, pepper - Iprodione/leek, lettuce, cabbage, Chinese cabbage, cauliflower, collard, cucumber - Mancozeb/radish, turnip, endive, dill, parsley, bok choy - Nitrapyrin/lettuce, spinach, broccoli, cabbage, mustard greens, tomato - PCNB/sugarbeets, turnip - Sodium chlorite/Brassica vgs. - Thiabendazole/lettuce - Triadimefon/peppers - Triforine/asparagus - Fenamiphos/onion, Chinese cabbage, eggplant, pepper, strawberry - Oxamyl/strawberry.

(3) HERBICIDES AND PLANT GROWTH REGULATORS:

Acifluorfen/tomato - Ametryn/arracacha - Chlorsulfuron/safflower - DCPA/Bok choy, Chinese cabbage, kohlrabi - Diclofop methyl/buckwheat, carrot, turnip, Swiss chard, cabbage, cauliflower, collards, mustard greens, kale - Diquat/pepper, cucurbits, taro - Diuron/rhubarb, avocado, prickly pear cactus - Fluazifop/rutabaga, turnip, celery, endive, rhubarb, spinach, Brussels sprouts, cabbage, Chinese cabbage, mustard greens, kale, beans, peas, eggplant, pepper, Japanese millet, cucumber, asparagus, tyfon - Glyphosate/yam - Metolachlor/carrot, rutabaga, onion, cabbage, sweet sorghum, cauliflower, mustard greens, nectarines, peach, caneberry, strawberry, lupine - Metribuzin/carrot, chick pea - Oxyfluorfen/broccoli, cabbage, mustard greens - Paraquat/cassava, snapbeans - Prometryn/sesame, sunflower, dill - Pronamide/blueberry - Propachlor/radish, rutabaga, mustard greens - Propanil/crawfish - Propazine/fennel, coriander, dill - Pyrazon/Swiss chard - Sethoxydim/sweet potato, carrot, rutabaga, endive, rhubarb, spinach, Chinese cabbage, cauliflower, collard, kale, eggplant, watermelon, blueberry, artichoke, asparagus, mint - Simazine/kiwifruit - 2,4-D/soybean, sweet sorghum, cranberry.

(4) INSECTICIDES AND MITICIDES

Acephate/edible podded pea, asparagus - Bacillus thuringiensis/mung bean, clover - Calcium cyanide/honey - Carbaryl/yam, Chinese cabbage, basil, dill - Carbofuran/eggplant, grape, sweet sorghum, clover, mint - Chlorpyrifos/leek, broccoli, cabbage, cauliflower, snapbeans, asparagus, cherimoya, guava, hops, sapote, pea - Cypermethrin/broccoli - Diazinon/ginseng, yam, asparagus, sugarcane - Dicrotophos/chestnut - Dimethoate/mung bean, squash, blackberry, raspberry, filbert, asparagus - Disulfoton/turnip, celery, Chinese cabbage - Endosulfan/acerola - Fenthion/sheep - Fenvalerate/mung bean, tomato, strawberry, clover - Hexakis/tomato, blueberry, sweet corn - Methidathion/kiwi, carrot, endive, Swiss chard, bok choy, squash, dill, asparagus - Methiocarb/chestnut - Methomyl/yam - Mevinphos/endive - Oxamyl/non-bell pepper, strawberry - Permethrin/watermelon, non-bell pepper, blueberry - Propargite/avocado, jojoba, tomato, sweet corn - Parathion/jojoba - sodium fluoaluminate/kiwifruit.

3 Continued

(B) DEVELOPMENT AND REGULATORY SUCCESSES:

IR-4 HQ prepared 40 tolerance petitions in calendar year 1985. Thirty-four (34) tolerance petitions were written and submitted to EPA and six petitions are still under review by the manufacturers (eventual label registrants) prior to EPA submission. Additionally, 13 major petition amendments were submitted to EPA. The amendments to previously submitted IR-4 petitions answered EPA's responses for the need for additional residue data, and in some cases, for toxicology data.

During 1985, IR-4 petition submissions resulted in pesticide clearances representing 41 tolerances. These are reviewed in detail below:

(1) FUNGICIDES AND NEMATOCIDES (15 tolerances)

Chlorothalonil/cranberry - Fenamiphos/garlic - Sodium Chlorite/Brassica leafy vegetables & radish

(2) HERBICIDES AND PLANT GROWTH REGULATORS (13 tolerances)

Glyphosate/fruited vegetables - Metolachlor/chili pepper - Napropamide/pomegranate - Potassium Ricinoleate/catfish.

(3) INSECTICIDES (13 tolerances)

Carbofuran/artichoke - Chlorpyrifos/Brassica leafy vegetables - Fenvalerate/collard, radish top & root - Permethrin/watercress.

Additionally, 38 tolerances were proposed. These proposals will become clearances in 1986.

Certain tolerances requested by IR-4 have not been established because EPA has indicated that the existing data bases were not adequate to support the tolerances at this time; e.g. metabolism studies, toxicology, etc. These data gaps have surfaced because of the new guidelines which must be addressed for all the products on the market. Some of the older pesticides will be eliminated from the market place because of these new requirements. In most cases, these new studies are being addressed by the manufacturers, but the studies may take up to four years to complete. The requirement to have these studies completed and reviewed before any new uses (major or minor) can be registered has placed a damper on the progress of minor use clearances.

Additionally, EPA is requiring more data for the clearance of minor uses. In line with these concerns, IR-4 is having a meaningful dialogue with the Residue Chemistry Branch on projects that are nearing completion in order to preclude the need for additional residue data after the petition has been submitted to EPA.

(C) ORNAMENTAL RESEARCH AND DEVELOPMENT

During the 8 1/2 years the IR-4 Ornamentals Program has been in existence (APR 77 - NOV 85), IR-4 has undertaken 10,051 ornamental research trials. During 1985, 817 ornamental research trials were funded through the IR-4 Program. Data from research completed to date have made it possible for IR-4 to write registration packages for 27 insecticides, 22 fungicides and 25 herbicides. During 1985, IR-4 supplied data in support of 151 ornamental pesticide registrations, bringing the total number of label registrations on ornamentals to 2,011 or an average of 20 clearances per month. Ornamental registrations that were supported by IR-4 data in 1985 include:

3 Continued

(C) ORNAMENTAL RESEARCH AND DEVELOPMENT: (continued)

Mancozeb (Fore® and Dithane® M-45) for the control of foliar diseases (leaf spots, blights, etc.) on a wide variety of shrubs, shade trees, conifers, flowers and foliage plants; bifenox (Modown®) for weed control in forest tree nursery seedbeds (label expanded from regional to national use); chlorpyrifos (Dursban® 50W) for use as a foliar spray to control insects on a wide variety of greenhouse grown ornamentals; bendiocarb (Dycarb®) for control of black vine weevil larvae on a wide variety of container grown nursery plants; and carbofuran (Furadan® 4F) for control of root weevil larvae on a wide variety of container grown nursery plants.

(D) BIORATIONAL RESEARCH AND DEVELOPMENT

September, 1985 marks the completion of three years of the IR-4 Biorationals Program. In 1985, IR-4 funded field testing of the Codling Moth Granulosis Virus (CMGV) in commercial apple, pear and walnut orchards under an Experimental Use Permit (EUP) in order to assess the effectiveness of the MicroGeneSys formulation of CMGV in large scale field trials. The EUP and temporary exemption of CMGV from the requirement of a tolerance (Federal Register 6 MAR 85) were based on a petition written by IR-4.

In 1985, IR-4 also funded efficacy research on the following biorational research projects:

Beauveria bassiana on ornamentals for control of the black vine weevil larvae; Cephalosporium lecanii (Vertalec® strain) on chrysanthemum for control of aphids; and Cephalosporium lecanii (Mycotal® strain) on cucumbers for control of whiteflies.

(E) ANIMAL DRUG RESEARCH AND DEVELOPMENT:

Since January 1983, 127 drug requests have been submitted to IR-4 HQ. Three have been approved and thirty five drug requests are in the research stage. Eighty-six drug requests are in various stages of evaluation and three cannot be cleared because of significant data gaps. The 35 research projects which were established in cooperation with 16 universities, USDI-Fish & Wildlife Service, USDA-Agricultural Research Service and 15 pharmaceutical companies are as follows:

<u>ADR #</u>	<u>Livestock</u>	<u>Disease</u>	<u>Drug Needed</u>	<u>Cooperating Inst.</u>
** 1	Angora goats	Coccidiosis	Monensin	Texas A&M Univ. & Eli Lilly Company
* 2	Pheasants	Coccidiosis	Amprolium	Penn State University Merck & Co., Inc.
3	Feedlot-lambs	Coccidiosis	Monensin	Texas A & M University & Eli Lilly Company
** 4	Catfish	<u>Aeromonas hydrophila/</u> <u>Edwardsiella ictaluri</u>	Sulfadimethoxine + Ormetoprim	Mississippi State Univ. Hoffman-LaRoche, Inc.
* 5	Pheasants	Gapeworms	Thiabendazole	Penn State University & Merck & Company, Inc.
8	Goats	Liver flukes	Albendazole	Washington State Univ. & Smith Kline Animal Health Products

3 Continued

<u>ADR #</u>	<u>Livestock</u>	<u>Disease</u>	<u>Drug Needed</u>	<u>Cooperating Inst.</u>
9	Ducks	<u>P. anatipestifer</u>	Lincomycin	Cornell University & The Upjohn Company
10	Ducks	Erysipelas	Penicillin	Cornell University
* 11	Reindeer	Warble flies	Ivermectin	University of Alaska & Merck & Company, Inc.
12	Sheep & Goats	Muellerius capillaris & Trichuris	Fenbendazole	American Hoechst
13	Cattle	Acute Bovine Pulmonary Emphysema & Edema	Monensin	Washington State Univ. & Eli Lilly Company
14	Feedlot-lambs	Coccidiosis	Decoquinatate	Washington State Univ. & Rhone-Poulenc Company
** 15	Lobsters	Gaffkemia	Oxytetracycline	University of Maine & The Pfizer Company
17	Goats	Gastrointestinal worms	Ivermectin	University of Nebraska & Merck & Company, Inc.
18	Salmonid fishes	Bacterial gill disease	Chloramine-T	USDI, Fish & Wildlife Se & Wisconsin Pharmacal Co
19	Alligators	Bacterial diseases	Oxytetracycline	University of Florida & The Pfizer Company
30	Quail	Ulcerative enteritis	Bacitracin	University of Florida & A.L. Laboratories
31	Wild ducks	Schistosomiasis	Praziquantel	Hope College & Bayvet Labs.
33	Dairy goats	Bacterial infections	Amoxicillin Trihydrate	University of California & Beecham Laboratories
36	Dairy goats	Bacterial enteritis	Ampicillin (Injection)	University of California & Bristol Laboratories
42	Dairy goats	Bacterial infections	Oxytetracycline	University of California & Pfizer & Company
59	Dairy goats	Bacterial Pneumonia	Sulfamethazine	University of California & Norden Laboratories
61	Dairy goats	Bacterial infections	Tylosin (Injection)	University of California & Eli Lilly Company
63	Dairy goats	Mastitis	Benzathine Cloxacillin	University of California & Bristol Laboratories
66	Dairy goats	Mastitis	Novobicin & Procain Penicillin	University of California & The Upjohn Company
74	Sheep	Bacterial Pneumonia	Sulfamethazine	University of Idaho & Bristol Laboratories

. 3 Continued(E) ANIMAL DRUG RESEARCH AND DEVELOPMENT: (continued)

<u>ADR #</u>	<u>Livestock</u>	<u>Disease</u>	<u>Drug Needed</u>	<u>Cooperating Institution</u>
87	Sheep	Bacterial Pneumonia	Amoxicillin Trihydrate	University of California Beecham Laboratories
88	Sheep	Bacterial Pneumonia	Ampicillin	University of California & Bristol Laboratories
111	Goats	Coccidiosis	Decoquate	Washington State Univ. & Rhone-Poulenc Co.
112	Goats	Fascioliasis	Clorsulon	Florida State University & Merck & Company, Inc.
113	Quail	Coccidiosis	Amprolium	Agricultural Res. Ser. & Merck & Co., Inc.
114	Quail	Coccidiosis	Monensin	Agricultural Res. Ser. & Eli Lilly Company
115	Quail	Coccidiosis	Salinomycin	Agricultural Res. Ser. & A.H. Robbins Company
117	Goats	Coccidiosis	Lasalocid	University of Tennessee Hoffman-LaRoche, Inc.
118	Trout	Redmouth disease	Tiamulin	U.S. Fish & Wildlife Ser & SDS Biotech, Inc.
121	Dairy goats	Mastitis	Amoxicillin	University of California & Beecham Laboratories
122	Rabbits	Coccidiosis	Lasalocid	University of Arkansas & Hoffman-La Roche, Inc.
125	American bison	Hypodermosis	Ivermectin	Michigan State University & Merck & Company, Inc.

* Public Master File published in the Federal Register.

** Public Master File under review by FDA.

Three new animal drugs uses were cleared by IR-4 in 1984. IR-4's first submission approved by FDA/Center for Veterinary Medicine (CVM), (ADR #5) thiabendazole/pheasants for gapeworm control was published in the Federal Register on 25 JUL 84. The next two clearance submission approved by FDA/CVM, (ADR #2) amprolium/pheasant for the prevention of coccidiosis, and (ADR #11) ivermectin/reindeer for the treatment and control of warbles were published in the Federal Register on 24 DEC 84.

In 1985, FDA approved the IR-4 Public Master File (petition) on oxytetracycline for the control of gaffkemia in lobsters (ADR #15). The cooperating institutions were the University of Maine and Pfizer. Additionally the following 2 Public Master Files are under review by FDA

<u>ADR #</u>	<u>Drug</u>	<u>Research Claim</u>	<u>Species</u>	<u>Cooperating Institutions</u>
1	Monensin	Coccidiosis	Goats	Eli Lilly Co/Texas A&M
4	Sulfadimethoxine/ Ormetoprim	E. Ictaluri Infection	Catfish	Hoffman-La Roche/ Mississippi State Univ.

3 Continued

(E) ANIMAL DRUG RESEARCH AND DEVELOPMENT: (continued)

The IR-4 Regional Animal Drug Coordinators and HQ scientists met on 16-17 July 85 in Davis, CA to review the candidate research projects, to review priority procedures for the 1986 IR-4 Animal Drug Research Program, and to review the proposed agenda for the Third IR-4/FDA Workshop.

The Third IR-4/FDA Workshop was held at the Holiday Inn, Rockville, MD on 25-26 SEP 85. One hundred and eighty-five scientists from academia, pharmaceutical industry, FDA's Center for Veterinary Medicine and animal producers met to discuss areas of common interest for the future of the minor species. The discussions were centered on the revised minor use animal drug guidelines concerning data requirements, protocol design, drug approval process and establishing a new list of drug priorities for each minor species. There was a general consensus that a fourth IR-4/FDA Workshop is needed. The workshop was made possible by a grant from FDA to IR-4 HQ at Rutgers University .

The following sessions were held during the two day meeting:

- a. Coccidiosis Symposium
- b. Aquaculture
- c. Pharmacokinetics in Ruminant and Minor Species
- d. Avian
- e. Comparison of Metabolism Pattern in Sheep and Cattle
- f. Fur Bearing Animal and Honey Bee

The USDA-CSRS has provided a grant of \$25,000 to IR-4 HQ, Rutgers University, to renew the services of an environmental consultant. The consultant will prepare the environmental impact statement for each Public Master File (PMF) to be submitted to FDA/CVM for minor use drugs and he will also be available to advise the IR-4 Project in matters related to environmental issues. Dr. Stanley Katz, Chairman of the Department of Biochemistry and Microbiology, Cook College, Rutgers University, was selected for this position.

(F) COORDINATION WITH FEDERAL AND STATE AGENCIES:

Agricultural Research Service (ARS) scientists cooperated with SAES scientists on 75 food, 230 ornamental and 3 animal drug specialty use projects. This team work approach is providing the farmers, ranchers, growers, nurserymen and homeowners with the technologies that will result in increased production efficiency. Eight-six percent (86%) of the states participated in the 1985 research projects.

The Third IR-4/EPA Food Use Workshop was held in Arlington, VA on 17-18 SEP 85 and the Third IR-4/FDA Animal Drug Workshop was held in Rockville, MD on 25-26 SEP 85. These Workshops were made possible by grants from EPA and FDA, respectively. Additionally the second IR-4/EPA Petition Writing Workshop was held in Arlington, VA on 14-15 JAN 85. These workshops provide the federal and state scientists with the necessary forums to prioritize requests on a national basis and to expedite the development of data for needed uses.

4 USEFULNESS OF FINDINGS:

Without the field work conducted by the SAES and USDA-ARS and the subsequent successful tolerance establishment, minor commodity 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 drug, pesticide and biorational control materials they need to produce commercial yields of high quality

4 USEFULNESS OF FINDINGS: (continued)

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 are the backbone of integrated pest management (IPM) systems. The biorational research, including microbials and biochemical control agents, also supports the organic or alternative farming systems.

5. WORK PLANNED FOR NEXT YEAR:

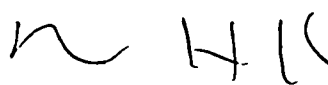
IR-4 will continue to develop data required by EPA and/or FDA for the establishment of minor use tolerances, including IPM materials, and animal drug approvals, as necessary, appropriate and as funds permit. Additionally, a similar effort will be expended in developing nonfood uses, i.e. ornamental registration data packages. In that funding levels for food and nonfood uses are not adequate to address more than 25% of the researchable food-use projects on the books, we 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. Additionally, funding levels for the animal drug and biorational programs are not adequate to address more than 29% and 50%, respectively, of the researchable projects on the books. The research program in ornamentals has been reduced by 40% because of the funding shortfall.

In order to gain maximum benefit from a limited funding base, IR-4 works closely with EPA, FDA and the pesticide and animal drug industries. Requests are screened carefully so that projects involving chemicals 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.

6. PUBLICATIONS:

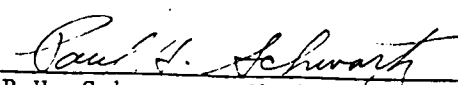
- a. IR-4 Newsletter (Quarterly)
- b. Burt, M.E., G.M. Markle and R.H. Kupelian, 1985. The Clearance of Glyphosate for Use on Minor Crops in the United States. In The Herbicide Glyphosate (Edited by Grossbard and D. Atkinson, Kent, U.K., Butterworth).
- c. Frank, J.R. and M.E. Burt, 1985. The Clearance of Herbicides on Minor Crops. Weeds Today 16:4.

December 31, 1985

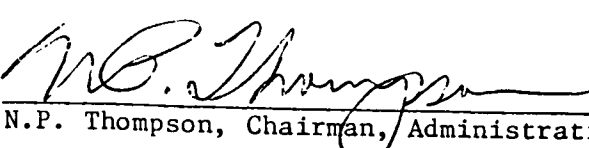

R.H. Kupelian, National Director

Approved:

Jan 28, 1986
Date


P.H. Schwartz, Chairman, Technical Committee

1/24/86
Date


N.P. Thompson, Chairman, Administrative Advisors