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# ANNUAL REPORT OF COOPERATIVE INTERREGIONAL RESEARCH PROJECT

IR-4
JANUARY 1 TO DECEMBER 31, 1984

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

# 2. COOPERATING AGENCIES AND PRINCIPAL LEADERS:

Interregional Administrative Advisory Committee (AA):

Dr. J.P. Mahlstede, Iowa State University, Chairman

Dr. D.J. Burns, Rutgers University

Dr. J.P. Jordan, CSRS Administrator

Dr. T.B. Kinney, ARS Administrator

Dr. R.H. Kupelian, IR-4 National Director

Dr. D.E. Rolston, University of California

Northcentral Region

Technical Committee (TC):

Dr. P.H. Schwartz, Jr. USDA-ARS/Beltsville, Chairman
(Staff Scientist, Pesticide Impact Assessment Staff)
Dr. R.H. Kunelian, Rutgers University, Franctic County

Dr. R.H. Kupelian, Rutgers University, Executive Secretary (National Director, IR-4 Project)

Dr. J.B. Bourke, Cornell University/Geneva (Northeastern IR-4 Regional Pesticide Lab. Director)

Dr. K.P. Dorschner, USDA-CSRS

Dr. J.P. Mahlstede, Iowa State University Dr. Fumio Matsumura, Michigan State University

Dr. N.P. Thompson, University of Florida

(Northcentral IR-4 Regional Pesticide Lab. Director)

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

Dr. H.S. Teague, USDA-CSRS

Dr. W.B. Wheeler, University of Florida
(Southern IR-4 Regional Pesticide Lab. Director)

Supporting Committees:

Ad Hoc Animal Drug Advisory Staff

Dr. M.H. Beleau, Mississippi State University, Chairman

Dr. C.S. Card, Pennsylvania State University

Dr. R. Gerrits, Animal Production, National Program Director (National Program Staff)

Dr. F.W. Oehme, Kansas State University

Dr. P.J. South, University of Idaho

Consultants Staff

Dr. K.R. Hill, USDA-ARS, Analytical Chemistry Lab., AEQI, Director

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

Dr. R.E. Ridsdale, NACA Representative

Mr. D.R. Stubbs, EPA-OPP-RD

Dr. J.R. van Diepen, PPA Representative

Environmental Protection Agency (EPA) Advisors

Ms. F.S. Bishop, EPA-OPP-RD-RSERB, Chief

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

Mr. S. Schatzow, EPA-OPP, Director

Mr. J.G. Touhey, EPA-OPP, Advisor

USDA-ARS

Southern Region

Represents

National Headquarters

Northeastern Region

USDA-CSRS (Pesticides) Administrative Advisors Northcentral Region

Western Region

USDA-CSRS (Animal Drugs) Southern Region

Southern Region Northeastern Region USDA-ARS

Northcentral Region Western Region

#### 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, Acting 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. M.E. Burt, Associate Coordinator

Dr. J.E. Elson, Associate Coordinator

Dr. R.T. Guest, Associate Coordinator

Dr. W.L. Biehn, Assistant Coordinator

Mr. D.M. Baker, Jr., EPA Liaison

Dr. E.E. Viera, FDA Liaison

Dr. J.A. Farnham, Animal Drug 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. S.D. Ford, Secretary (To 1 DEC 84)

Mrs. R.T. Harvey, Secretary

Ms. Y. Colon, 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.

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

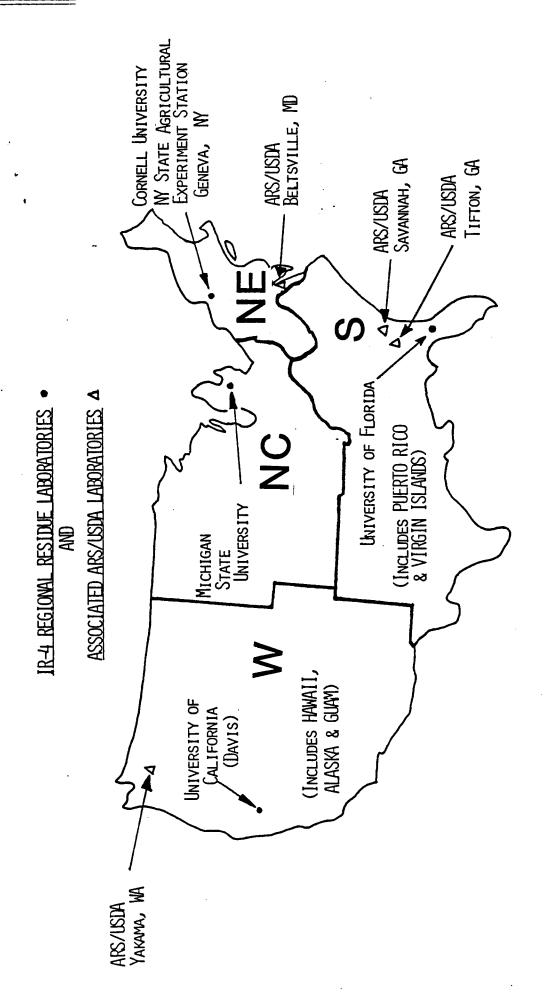
Dr. Roger Gerrits, USDA/ARS (201) 344-3066 Specialty Area: Reproductive Physiology

#### 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 below. Regional Coordinators are physically located at their respective regional laboratories.

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	SPECIALTY AREA		392-1978Biochemistry 392-1978Plant Pathology 392-1841Veterinary	Toxicology 392-1978Res. Chemistry 826-4850Entomology	575-3955Weed Science	542-1765Entomology	258-5955Entomology 388-1464Plant Parhology	325-2085Entomology	/3/-3391Weed Science 624-5531 Friendloom/Plr	Pathology	767-9705Chemistry	656-3111Entomology	845-7028Entomology	961-6543Plant Pathology	//8-U246Fest Management 556-2210Entomology	386-3372Nematology	386-3514Residue Chemistry		17	752-1142Chemistry	/52-7010Entomology 752-1142Environ. Veterinary	Toxicology	752-1142Chemistry 778-7614	621-1151Entomology		Weed Science	734-2575Entomology	885-6595Entomology	994-3517Agronomy	646-3225Entomology	Parasitology	Ag. Chem. 6. Toxicology	Pest. & Toxic	Substances 335-2995Entomology	766-4261Entomology	575-5982Entomology 575-5970Pest. Chemistry	
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	SIMIE	Southern Region	Willis B. WheelerRegional Lab. Director(904) Charles W. MeisterPesticide Coordinator(904) Steve F. SundlofAnimal Drug Coordinator(904)	Promode BardalayeSupervisory Chemist(904)	Terry L. Lavy(501) Sam S. FlukerFL(904)	Chate M Charles(404)	Lowell L. Black	William W. Neel	0. Norman NeshelmOK(419)		Mr. Katael Montalvo-ZapataPR(809) Dr. William DuRose	Mas Nancy TaylorTN	Dr. Rodney L. HollowayTX(409)	Michael J. WeaverVAVA(703)	James M. SchalkSC, USDA-ARS(803)	Dr. Alva W. JohnsonGA, USDA-ARS(912) Dr. Norman Glaze	Dr. Donald Wauchope		western kegion	ames SeiberRegional Lab. Director(9	Arthur L. CraignillAnimal Drug Coordinator(916)		Jeff ConnAK.	David N. ByrneAZ(602)	Marcia G. Alford(916)		CLAICH DJOTK	Gene P. Carpenter1D(208)	Ichael J. Jackson(4	Esting Huddleston(505) Harry G. Smith		James M. Witt0R0R	Mr. Howard DeerUTUTUT	Richard C. MaxwellWA(509)	Everett SpackmanWY(307)	Dr. Eric HalfhillWA, USDA-ARS(509) 575-5982Entomology Dr. Leslie M. McDonoughWA, USDA-ARS(509) 575-5970Pest. Chem	
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	SPECIALTY AREA		787-2281Chemistry 787-2327Entomology 256-6541Drug & Foreign	Compound Metabolism 787-2283Chemistry 486-3435Plant Science	451-2526Entomology 282-7372Horticulture	581-7980Entomology	/42-0/06Entomology 295-2212Entomology	862-1159Entomology	787-2327Entomology	256-7723Entomology	863-4435Entomology 792-2348 Horrical Fare	656-2630Plant Pathology	293-6023Entomology	344-2269Entomology	Plant Pathology	663-7132Weed Science 344-2495Residue Chemistry			353-9430Entomology	//rest. Analysis & Encomology	355-8414Avian & Fur-bearing	353-6377Analytical Chem.	294-1101Entomology	333-1967Horriculture	532-5891Encomology	353-9497(See above)	882-7511Exc. Floriculturist	237-7971Weed Science	4/2-1440Entomology	(Chem. Control)	21Agronomy, Weed 6. Plant Science	262-3226Entomology	882-4942Entomology 363-1129Plant Pathology/	Nematology	333-12//Weed Science 685-4011Physical Chem.		
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18485	SIAIE	Northeastern Region	John B. BourkeRegional Lab. Director(315) Paul B. BakerPesticide Coordinator(315) John B. BabishAnimal Drug Coordinator(607)	Terry SpittlerSupervisory Chemist(315)	Mark K. GrausteinDE(302) Grady McDonaldDG(202)	James F. Dill	Charles F. BrodelMA(517)	James Bowman(603)	BakerNY(Geneva)(315)	TauberNY(Ithaca)(607)	Kalph U. MummaRARA(814)				. (+00)	Mr. J. Ray FrankMD, USDA-ARS(301) 66 Dr. Kenneth R. H111MD. USDA-ARS(301) 34		North Central Region	Fumio MatsumuraRegional Lab. Director(517) 35	Satoru Miyazakiresticide Coordinator(J1/) JJJ-949/fest. Analysis 6 Entomology	R.K. RingerAnimal Drug Coordinator(517) 355-	Richard LeavittSupervisory Chemist(517) 353-			Don CressKSKS(913) 532-						Leon J. WrageSDSD(605) 688-5121	John Wedberg(608) 26		or they	Dr. Loyd M. WaxML, USDA-ARS(217) 333-1277Meed Science Dr. William M. DoaneIL, USDA-ARS(309) 685-4011Physical Che		

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#### 3. PROGRESS OF WORK AND PRINCIPAL ACCOMPLISHMENTS:

#### (A) FOOD USE RESEARCH PROJECTS:

There are currently 2694 total IR-4 food-use requests, an increase over the 2564 requests reported last year. Of these, 643 are characterized as researchable projects. During 1984, the four regions and USDA-ARS scheduled research on 209 food-use projects, from which residue samples went to 19 state and USDA-ARS cooperating laboratories and 10 chemical company laboratories. With the completion of 1984 and prior research projects, data requirements will be fulfilled for an additional 162 minor use needs. Research protocols for 421 requests were prepared or revised and the following pesticides/commodities were researched in 1984:

#### (1) BIORATIONALS:

Codling moth granulosis virus (CMGV)/apple, pear, walnut - Cephalosporium lecanni/tomato.

# (2) FUNGICIDES AND NEMATICIDES:

Benomyl/onion, potato, spinach, watercress - Captafol/peach - Carboxin/cantaloupe, pepper, tomato - Chlorothalonil/asparagus, broccoli, caneberry, Chinese mustard, horseradish, pepper - Ethoprop/broccoli - Fenamiphos/beet, cabbage, celery, eggplant, onion, pepper, snap beans, tomato - Iprodione/broccoli, cabbage, cauliflower, Chinese cabbage, kale, leek, watercress - Mancozeb/asparagus, broccoli, Chinese cabbage, Chinese mustard, Chinese radish, ginseng, leek, parsley, radish - Methyl bromide/asparagus, onion - Oxamyl/strawberry - PCNB/carrot, mustard greens - Thiabendazole/lettuce, sweet potato, yams - Triforine/asparagus, cantaloupe, cucumber.

#### (3) HERBICIDES AND PLANT GROWTH REGULATORS:

Acifluorfen/tomato - Atrazine/blueberry - Bentazon/pea - Diclofop-methyl/annual canary grass - Diethatyl-ethyl/broccoli, cabbage, carrot, cauliflower, collards, kale, mustard greens, Swiss chard - Diquat/cucurbits - Diuron/cherry, rhubarb - Ethephon/bananas - Fluazifop-butyl/asparagus, bean, blueberry, broccoli, cabbage, cauliflower, Chinese cabbage, collards, cranberry, mustard greens, okra, parsley, pea, pepper, pumpkin, radish, rhubarb, safflower, spinach, sweet potato, tomato, turnip - Glyphosate/Japanese millet, onion - Metolachlor/cabbage, carrot, Chinese cabbage, Chinese radish, mustard greens, onion, pepper, strawberry, sweet sorghum, tomato - Napropamide/watercress - Oryzalin/asparagus - Oxyfluorfen/asparagus, banana, broccoli, cabbage, guava, macadamia, mustard greens, papaya - Paraquat/Japanese millet, sweet corn, tyfon - Prometryn/dill, parsley - Propachlor/rutabaga - Pyrazon/Swiss chard - Sethoxydim/asparagus, broccoli, blueberry, buckwheat, carrot, Chinese cabbage, cranberry, endive, eggplant, mustard greens, okra, parsley, pumpkin, radish, rhubarb, sweet potato, spinach, safflower, turnip, watermelon - Simazine/mango - 2,4-D/soybeans - 2,4-DB/small grains.

## (4) INSECTICIDES AND MITICIDES:

Acephate/guar, pea - Aldicarb/lentil, pea - Carbaryl/cabbage, date, potato - Carbofuran/asparagus, clover, eggplant - Chlorpyrifos/asparagus, collards, cucumber, leek, snap beans - Cyhexatin/avocados - Diazinon/asparagus, Chinese radish - Dimethoate/asparagus, mung bean - Disulfoton/celery, mustard greens, turnips - Fenvalerate/cattle, celery, Chinese broccoli, Chinese cabbage, mung bean, okra - Hexakis/avocado, blueberry, caneberry, tomato - Malathion/oat hay - Methamidophos/asparagus, Chinese radish, squash - Mevinphos/endive - Oxamyl/cabbage, parsley, spinach - Oxydemetonmethyl/carrot, Swiss chard - Methyl parathion/Chinese broccoli, Chinese cabbage, Chinese mustard - Permethrin/blueberry, cranberry, raspberry, watermelon - Propargite/avocado, sweet corn, tomato - Resmethrin/cantaloupe, cucumber, pepper, pumpkin, squash, Swiss chard, tomato, snap bean, watermelon.

#### (5) RODENTICIDES:

Strychnine/alfalfa, grains, pasture - Zinc phosphide/artichoke, corn, wheat

# (B) DEVELOPMENT AND REGULATORY SUCCESSES:

IR-4 HQ prepared 65 tolerance petitions in calendar year 1984. Forty-nine (49) tolerance petitions were written and submitted to EPA and 16 petitions are still under review by the manufacturers (eventual label registrants) prior to EPA submission. Additionally, 6 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 1984, IR-4 petition submissions resulted in pesticide clearances representing 120 tolerances. These are reviewed in detail below:

(1) FUNGICIDES AND NEMATICIDES (6 tolerances)

Benomyl/Brussels sprouts, Chinese cabbage, dandelion, turnip greens - Fenamiphos/asparagus, raspberries.

(2) HERBICIDES AND PLANT GROWTH REGULATORS (10 tolerances)

Bromoxynil/mint hay - DCPA/radish roots and tops - Dinoseb/pasture grass & hay - Ethephon/pumpkins - Norflurazon/blackberries, blueberries, raspberries - Paraquat/acerola.

(3) INSECTICIDES (23 tolerances)

Acephate/macadamia nuts - Chlorpyrifos/asparagus, mushrooms - Diazinon/Brassica leafy vegetables - Diflubenzuron/pasturegrass - Dimethoate/lentils - Fenbutatin-oxide/eggplants - Methyl parathion/Brassica leafy vegetables - Mevinphos/watercress - Oxamyl/pumpkins - Oxydemetonmethyl/apricots - Permethrin/asparagus, bell peppers, eggplant, rangegrass.

(4) CROP GROUPINGS (81 tolerances)

EPA established several crop definition extensions at the request of IR-4. These are: (a) to define caneberries by listing species and their varieties to be included in the group; (b) to include pumpkins in the squash group; (c) to define tangerines as mandarins or mandarin oranges, tangelos, tangors and other hybrids of tangerines with other citrus; (d) to include Chinese broccoli within the definition of broccoli; (e) to include Chinese cabbage (tight-heading varieties) within the definition of cabbage; (f) to include Florence fennel within the definition of celery, and (g) to include triticale within the definition of wheat.

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 Code of Federal Regulations 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. As a direct result of the establishment of the previously mentioned crop definition extensions, the following 14 research projects which represent 81 separate tolerances have been cleared and the uses can be registered: all pesticides with wheat tolerances/triticale - chlorothalonil/Chinese broccoli, Chinese cabbage - DCPA/Chinese broccoli - Disulfoton/Chinese cabbage - Fenamiphos/Chinese cabbage - Fenvalerate/Chinese broccoli, Chinese cabbage - Methamidophos/Chinese cabbage - Methomyl/Chinese broccoli - Mevinphos/Chinese cabbage - Oxydemetonmethyl/Chinese cabbage - Permethrin/Chinese cabbage - NAA/tangors.

#### (C) ORNAMENTAL RESEARCH AND DEVELOPMENT:

During the 7 1/2 years the IR-4 Ornamentals Program has been in existence (APR 77 - NOV 84), IR-4 has undertaken 9,234 ornamental research trials. During the year, 732 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 26 insecticides, 22 fungicides and 25 herbicides. During 1984, IR-4 supplied data in support of 206 ornamental pesticide registrations, bringing the total number of label registrations on ornamentals to 1860 or an average of 21 clearances per month. Pesticides for which new or expanded labeling on ornamental crops were obtained during 1984 include: Dual®, Dual® + Princep®, Poast®, Bayleton®, Ornalin®, Pounce®, SBP-1382®, and Vydate®.

The seventh IR-4 Ornamentals Workshop which was hosted by EPA was held in Arlington, VA on 5-6 SEP 84 at the Crystal City Mall. Seventy state, federal and industry scientists participated in the workshop in an advisory capacity. The workshop participants reviewed and prioritized existing pesticide clearance requests on ornamentals, identified new ornamental pesticide clearance needs, and assisted in the preparation of research protocols for ornamental research projects. The workshop participants selected 1265 priority research projects involving over 50 pesticides. These priority projects are eligible for IR-4 funding through the IR-4 Regional Laboratory Program. The workshop was made possible by a grant from EPA to IR-4 HQ at Rutgers University.

# BLACK VINE WEEVIL COOPERATIVE IR-4/CSRS/ARS/SAES PROJECT

The black vine weevil, Otiorhynchus sulcatus (F.), is a serious insect pest of commercial nursery stock, causing economic losses through adult leaf feeding and larval root feeding, of both field grown and containerized nursery stock. Distribution of the black vine weevil (BVW) is largely confined to localized areas within the northern U.S. and Canada. Since females are flightless, the principle method of distribution is by interstate or intrastate movement of infested balled or containerized nursery stock.

Whereas distribution of BVW populations from infested to uninfested areas was diminished by the use of soil applications of chlordane for control of larval populations, the cancellation of chlordane and heptachlor by EPA effective 31 DEC 79 precluded continued use of these materials in compliance with state nursery certification regulations. In that there were no efficacious insecticides registered to control the larval forms of the BVW, a special research program was administered by IR-4 HQ to develop necessary efficacy and phytotoxicity data for registration of one or more alternative insecticides for control of the BVW larvae. USDA-ARS grant funds were utilized to sponsor research at five SAES laboratories and one USDA-ARS laboratory to evaluate five insecticides on 20 container and field-grown woody ornamental species.

In containerized nursery stock, bendiocarb W.P. and carbofuran flowable provided good larval BVW control with no adverse effects at practical use rates. In field-grown production, granular treatments of oxamyl and carbofuran resulted in adequate control with no phytotoxicity.

Carbofuran 4F is presently labelled in OH and MI for BVW control in container production and in CA and OR for both field and container production. As a result of the above IR-4 sponsored research, Mallinckrodt submitted a national label to EPA for approval of bendiocarb (DYCAR®) for soil application to control BVW larvae on a wide variety of nursery plants based on IR-4 data.

# (D) BIORATIONAL RESEARCH AND DEVELOPMENT:

September, 1984 marks the completion of two years of the IR-4 Biorationals Program. The following biorational pest control projects were funded in 1984:

Codling Moth Granulosis Virus (CMGV)/apple, pear, walnut; <u>Beauveria bassiana</u> on ornamentals for control of the black vine weevil and turf for control of the chinch bug; <u>Cephalosporium lecanni</u> (Vertalec® strain)/chrysanthemum and tomatoes for the control of aphids; <u>Cephalosporium lecanni</u> (Mycotal® strain)/poinsettia and bedding plants for the control of whiteflies.

In March, 1984, IR-4 HQ wrote a petition proposing a temporary exemption from the requirements of a tolerance for Codling Moth Granulosis Virus (CMGV). Based on the data contained in this petition, MicroGeneSys Inc. of West Haven, CT obtained an Experimental Use Permit (EUP) for the use of CMGV in apple, pear and walnut production on 14 JUN 84. The EUP is for a period of two years.

# (E) ANIMAL DRUG RESEARCH AND DEVELOPMENT:

Since January 1983, 115 drug requests have been submitted to IR-4 HQ. Twenty-nine drug requests are in the research stage. Eighty-six drug requests are in various stages of evaluation and protocol development. The 29 research projects which were established in cooperation with 14 universities, USDI-Fish & Wildlife Service, USDA-Agricultural Research Service and 13 pharmaceutical companies are as follows:

ADR NUMBER	LIVESTOCK	DISTASE	DRUG NEEDED	COOPERATING INSTITUTIONS
1	Angora goats	Coccidiosis	Monensin	Texas A&M University & Eli Lilly Company
2	Pheasants	Coccidiosis	Amprolium	Penn State University Merck & Company, Inc.
3	Feedlot-lambs	Coccidiosis	Monensin	Texas A&M University & Eli Lilly Company
- 4	Catfish	Aeromonas hydrophila/ Edwardsiella ictaluri	Sulfadimothoxine plus Ormetoprim	Mississippi State University & Hoffmann-LaRoche, Inc.
5	Pheasants	Gapeworms .	Thiabendazole	Penn State University & Merck & Company, Inc.
7	Rabbits	Coccidiosis	To be determined	University of Arkansas
8.	Goats	Liver flukes	Albendazole	Washington State University & Smith Kline Animal Health Products
9	Ducks .	P. anatipestifer	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	Purdue University
13 .	Cattle	Acute Bovine Pulmonary Emphysema & Edema	Monensin	Washington State University & Eli Lilly Company

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

ADR NUMBER	LIVESTOCK	DISEASE	DRUG NEEDED	COOPERATING INSTITUTIONS
14	Feedlot-lambs	Coccidiosis	Decoquinate	Washington State University & 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 Service & Wisconsin Pharmacal Co.
19	Alligators	Bacterial diseases	Oxytetracycline	University of Florida & The Pfizer Company
. 31	Wild Ducks	Schistosomiasis	Praziquantel	Hope College (Michigan) & Bayvet Laboratories
32	Dairy Goat kids	Bacterial enteritis	Ampicillin (Bolus)	University of California & Beecham Laboratories
33	Dairy Goats	Bacterial infections	Amoxicillin Trihydrate	University of California & Beecham Laboratories
42	Dairy Goats	Bacterial infections	Oxytetracycline	University of California & Pfizer & Company
61	Dairy Goats	Bacterial infections	Tylosin (Injection)	University of California & Eli Lilly Company
63	Dairy Goats	Mastitis	Benzathine Cloxacillin	University of California & Bristol Laboratories
74	Sheep	Bacterial Pneumonia	Sulfamethazine	University of Idaho & Norden Laboratories
66	Dairy Goats	Mastitis	Novobiocin & Procaine Penicillin	University of California & The Upjohn Company
113	Quail	Coccidiosis	Amprolium	ARS & Merck & Co.
114	Quail	Coccidiosis	Monensin	ARS & Eli Lilly Co.
115	Quail	Coccidiosis	Salinomycin	ARS & A.H. Robbins Co.
111	Goats	Coccidiosis	Decoquinate	Washington State University & Rhone-Poulenc Co.

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

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 <u>Federal Register</u> on 25 JUL 84. The next two clearance submissions 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 <u>Federal Register</u> on 24 DEC 84.

The IR-4 Regional Animal Drug Coordinators and HQ scientists met on 16-17~AUG~84 in Jackson, MS to review the candidate research projects and to review priority procedures for the 1985~IR-4~Drug~Research~Program.

The second IR-4/FDA Workshop was held at the Sheraton Potomac Inn, Rockville, Maryland on 21-22 AUG 84. One hundred and twenty-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 discussion was 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 third IR-4/FDA Workshop is needed. The workshop was made possible by a grant from FDA to IR-4 HQ at Rutgers University.

The Center for Veterinary Medicine has provided a grant of \$24,850 to IR-4 HQ, Rutgers University to engage 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 AGENCIES:

Agricultural Research Service (ARS) scientists cooperated with SAES scientists on 81 food, 301 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. Eighty-eight percent (88%) of the states participated in the 1984 research projects.

#### 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 and wholesome commodities. The clearances for 1984 will provide protection for commodities valued at more than 3 billion dollars. 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 10% 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 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) <u>C-Notes</u> (Biannually)
- c) SEEER (Biannually)
- d) Burt, M.E., G.M. Markle and R.H. Kupelian. 1984. The Clearance of Herbicides For Minor Uses. Abstracts 1984 Meeting of the Weed Science Society of America.
- e) Markle, G.M., M.E. Burt and R.H. Kupelian. 1984. The Clearance of Insecticides For Specialty Crops. Abstracts of the 56th Annual Meeting of the Eastern Branch, Entomological Society of America.
- f) Biehn, W.L., R.T. Guest and R.H. Kupelian. 1984. IR-4 Programs for Minor Use Pesticide Registration. IN Proceedings of the 4th Annual Industry Conference on the Leafminer.

December 31, 1984

Approved:

Con 18, 1985

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'Date

R.H. Kupelian, National Director

P.H. Schwartz, Chairman, Technical Committee

J.P. Mahlstede, Chairman, Administrative Advisors

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