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ANNUAL REPORT OF COOPERATIVE INTERREGIONAL
RESEARCH PROJECT NO. 4
IR-4
JANUARY 1 TO DECEMBER 31, 1986

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

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

3. ADMINISTRATION (PRINCIPAL LEADERS):

Interregional Administrative Advisory Committee (AA):	Represents
Dr. N.P. Thompson, University of Florida, Chairman	Southern Region
Dr. D.J. Burns, Rutgers University (TO OCT 86)	Northeastern Region
Dr. J.P. Jordan, CSRS Administrator	USDA-CSRS
Dr. T.B. Kinney, ARS Administrator	USDA-ARS
Dr. R.H. Kupelian, IR-4 National Director	National
Dr. J.P. Mahlstede, Iowa State University	Northcentral Region
Dr. D.E. Rolston, University of California (TO APR 86)	Western Region
Dr. G.W. Ware, Jr. University of Arizona (FROM APR 86)	Western Region
Dr. R.E. Wyse, Rutgers University (FROM OCT 86)	Northeastern Region

Technical Committee (TC):	
Dr. W.B. Wheeler, University of Florida, Chairman (Southern IR-4 Regional Laboratory Director)	Southern Region
Dr. J.B. Bourke, Cornell University/Geneva (TO NOV 86) (Northeastern IR-4 Regional Laboratory Director)	Northeastern Region
Dr. K.P. Dorschner, USDA-CSRS	USDA-CSRS (Pesticides)
Dr. R.H. Kupelian, Rutgers University, Executive Secretary (National Director, IR-4 Project)	National
Dr. Fumio Matsumura, Michigan State University (Northcentral IR-4 Regional Laboratory Director)	Northcentral Region
Dr. P.H. Schwartz, Jr. USDA-ARS/Beltsville (Staff Scientist, Pesticide Assessment Staff)	USDA-ARS
Dr. J.N. Seiber, University of California (Western IR-4 Regional Laboratory Director)	Western Region
Dr. T.D. Spittler, Cornell University/Geneva (FROM NOV 86) (Northeastern IR-4 Regional Laboratory Director)	Northeastern Region
Dr. H.S. Teague, USDA-CSRS	USDA-CSRS (Animal Drugs)
Dr. N.P. Thompson, University of Florida	Administrative Advisor

4. CONSULTANTS COMMITTEE:
Mr. D.M. Baker, Jr., EPA Liaison to IR-4, Chairman
Dr. V.F. Boyd, EPA-OPP-HED-RCB Liaison
Dr. W.J. Brunton, AHI Representative
Dr. D.A. Espeseth, USDA-APHIS Advisor
Dr. K.R. Hill, USDA-ARS, Analytical Chemistry Lab., AEQI, Director
Mr. H.L. Jamerson, EPA-OPP-RD, Minor Uses Officer
Mr. D.L. Olson, NACA Representative (FROM 1 DEC 86)
Dr. R.E. Ridsdale, NACA Representative (TO 30 NOV 86)
Mr. D.R. Stubbs, EPA-OPP-RD
Dr. J.R. van Diepen, PPA Representative
Dr. E.E. Viera, FDA Liaison to IR-4

7. Continued

On 13 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 Technical Committee Representative; and (V) a Secretary at IR-4 HQ. Additionally, the Center for Veterinary Medicine (FDA-CVM) designated their Dr. Viera to function as a FDA liaison to IR-4 and established in 1983 a Minor Use of Animal Drugs Joint Standing Committee. The task of this committee is to review/revise the Minor Use Guidelines as appropriate; to discuss, evaluate and make recommendations of issues related to the Minor Use Drug Program and to review protocols and final data. The membership and specific responsibilities of this FDA-CVM Committee are as follows:

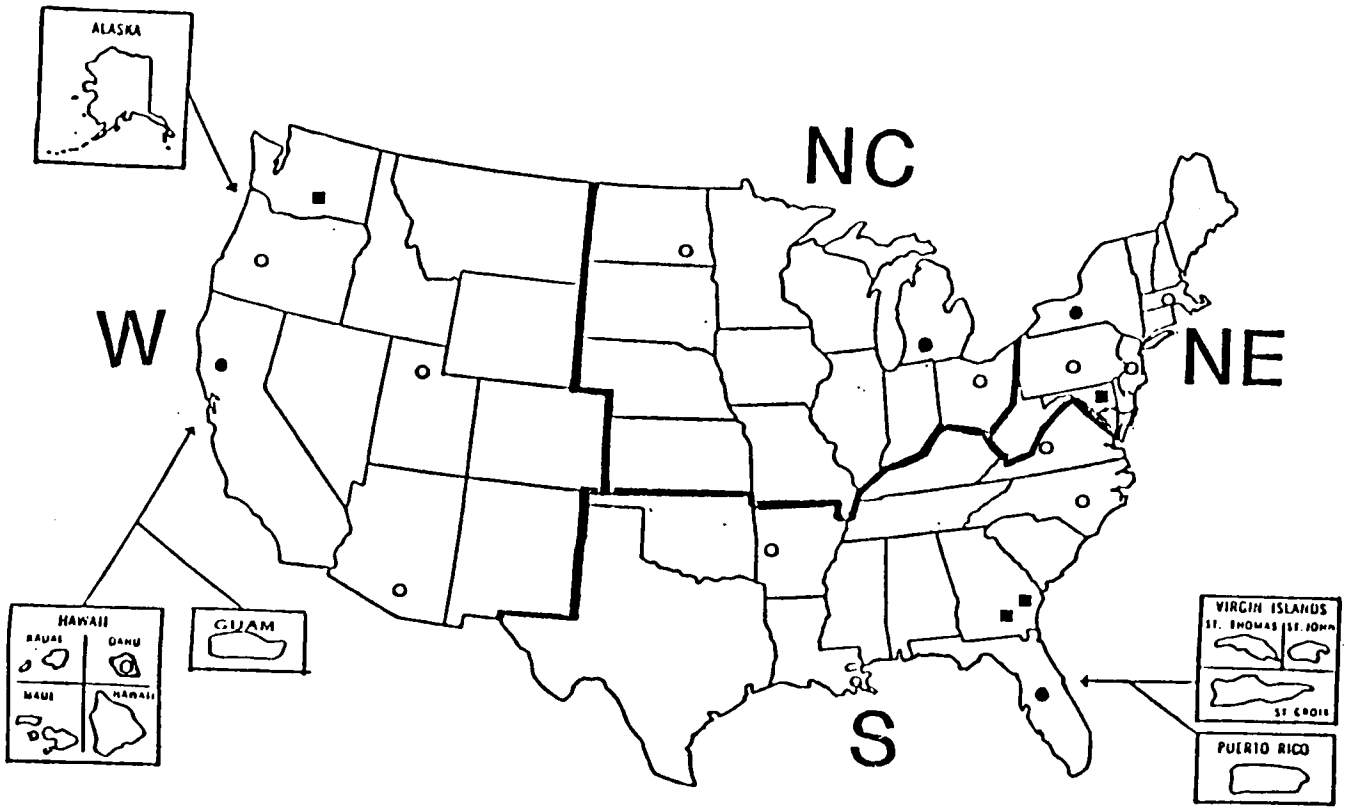
Dr. Thomas V. Raines, Chairman, Avian
Dr. Nelson S. Chou, Aquaculture
Dr. Melba M. Smith, Fur Bearing Animals and Honey Bees
Dr. Naba Das, Ruminants
Dr. John R. Quast, Target Animal Safety
Dr. Robert E. Osterberg, Toxicity (Human Safety)
Dr. Robert C. Livingston, Chemistry (Human Safety)
Dr. Emilio E. Viera, FDA Liaison to IR-4

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

7. Continued

MINOR USES PROJECT RESIDUE LABORATORIES



RESIDUE LABORATORIES

- ● IR-4 REGIONAL
- o IR-4 SATELLITE
- ■ USDA/ARS

NORTHEASTERN REGION

- ● Cornell University, Geneva NY
  - o Universiy of Masachusetts
  - o Pennsylvania State University
  - o Rutgers University, New Brunswick, NJ
- ■ USDA/ARS, Beltsville, MD

SOUTHERN REGION

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

NORTHCENTRAL REGION

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

WESTERN REGION

- ● University of California, Davis, CA
  - o Oregon State University
  - o Utah State University
  - o University of Hawaii
  - o University of Arizonia
- ■ USDA/ARS, Yakima, WA

8A. Continued

(3) INSECTICIDES, MITICIDES, MOLLUSCICIDES AND RODENTICIDES:

Acephate/asparagus, lupine, pecan - Amitraz/bees - Azinphos methyl/pomegranate, figs - B.T. Israelensis/mushroom - Carbaryl/avocado, dill, loquat, yam - Chlorpyrifos/asparagus, bean (snap), broccoli, cabbage, hops, onion (green), pineapple - Diazinon/banana (plantain), yam - Dimethoate/Brussels sprout, lupine (grain), squash - Disulfoton/Chinese cabbage (tight), mustard greens - Endosulfan/blackberry, raspberry - Esfenvalerate/bean (mung), beet, Chinese broccoli, Chinese cabbage (non-tight), cucumber, kale, strawberry, sweet potato - Ethoprop/hops - Fensulfothion/beet, spinach - Fenvalerate/Chinese broccoli, Chinese cabbage (non-tight), okra - Hexakis/avocado, blueberry, corn (sweet), marigold, tomato - Magnesium Phosphide/sweet potato - Malathion/small grains - Methamidophos/bok choy, Chinese mustard, sesame - Methomyl/bok choy, cranberry, lupine, Chinese mustard, pasture grasses, sesame, yam - Methiocarb/ginseng, pepper (bell) - Mevinphos/bok choy, Chinese mustard - Oxydemetonmethyl/bok choy, Chinese cabbage, collard, mustard greens, kale, kohlrabi, Swiss chard - Parathion/celeriac, leek, small grains - Permethrin/basil, cucumber, greens (collard & mustard), kale, mint, onion (dry bulb), pigeon pea, pepper (non-bell), squash (summer), tarragon, watermelon - Phosmet/crabapple - Propargite/clover, cucumber, pepper (bell), tomato - Zinc Phosphide/alfalfa, artichoke, wheat

8B. Continued

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. Additional areas that we must continue to address under research and development (R&D) are:

1) Good Laboratory Practice (GLP) - Proposed EPA GLP guidelines for residue and environmental chemistry data will be published in 6/87. IR-4 will update its R&D forms and field and laboratory guides to comply with the new guidelines. Additionally, the IR-4 laboratory procedures will be reviewed for compliance purposes.

2) Endangered Species - EPA is required to consult with the USDI, Office of Endangered Species (OES), whenever information is available which indicates endangered species may be affected by a clearance action. OES would issue a biological opinion on the endangered species in an area. The opinion may result in the restriction or prohibition of a pesticide use in the range of the affected species.

3) Inert Ingredients - Recently EPA has had increased concerns about certain inert ingredients in pesticide formulations. The EPA Office of Pesticide Program Director has noted that EPA will impose essentially the same data requirements on a group of 55 inerts of toxicological concern as are imposed on active ingredients. EPA will issue an interim policy which will not allow expansion of any new uses for formulations that have one or more of the 55 inert chemicals.

4) Groundwater - Requests that exhibit pesticides with potential groundwater concerns will be reviewed under the additional criteria of soil type, amount of rainfall and depth of the groundwater table in the area(s) covered by the request before any research is consummated.

8. Continued

(E) ANIMAL DRUG RESEARCH AND DEVELOPMENT

Since January 1983, 139 drug requests have been submitted to IR-4 HQ. Six have been approved and 18 drug requests are in the research stage. Ninety-seven drug requests are in various stages of evaluation and 18 cannot be cleared because of significant data gaps. The 18 research projects which were established in cooperation with 10 universities, USDI-Fish & Wildlife Service, USDA-Agricultural Research Service and 10 pharmaceutical companies are as follows:

ADR #	SPECIES	DISEASE	DRUG NEEDED	COOPERATING INSTITUTIONS
17	Goats	Gastrointestinal Worms	Ivermectin	University of Nebraska & Merck & Company, Inc.
18	Salmonid fishes	Bacterial Gill Disease	Chloramine-T	USDI,Fish & Wildlife Serv. & 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 (Michigan) & Bayvet Laboratories
33	Dairy Goats	Bacterial Infections	Amoxicillin Trihydrate	University of California & Beecham Laboratories
36	Dairy Goats	Bacterial Enteritis	Ampicillin (injection)	University of California & Bristol Laboratories
59	Dairy Goats	Bacterial Pneumonia	Sulfamethazine	University of California & Norden Laboratories
66	Dairy Goats	Mastitis	Novobiocin & Procaine Penicillin	University of California & The Upjohn Company
74	Sheep	Bacterial Pneumonia	Sulfamethazine	University of Idaho & Norden Laboratories
87	Sheep	Bacterial Pneumonia	Amoxicillin Trihydrate	University of Idaho & Beecham Laboratories
88	Sheep	Bacterial Pneumonia	Ampicillin	University of Idaho & Bristol Laboratories
112	Goats	Fascioliasis	Chlorsulon	University of Florida & Merck & Company, Inc.
122	Rabbits	Coccidiosis	Lasalocid	University of Arkansas & Hoffman-LaRoche, Inc.

8E. Continued

The IR-4 Annual Animal Drug Coordination meeting was held at the Holiday Inn Crowne Plaza, Rockville, Maryland on 9-10 SEP 86. The first day was devoted to a review of priority procedures for the 1987 IR-4 Animal Drug Research Program, present budget allocation and future program funding. On the second day, the Animal Drug Coordinators and HQ scientists met with officials from the Center for Veterinary Medicine (CVM) to discuss the following items with the CVM staff: (1) clearing human safety protocols, (2) duties of the Animal Drug Regional Coordinators regarding the Bioresearch Monitoring Program (GLP), (3) Production Drugs, (4) Experimental Design Protocols on efficacy and animal safety and (5) development of needed drugs for aquatic species. Dr. Gerald B. Guest, Director of CVM, addressed the attendees and expressed full support for the IR-4 Project.

The 4th IR-4/FDA Workshop for Minor Use of Animal Drugs scheduled tentatively for September 1986, was postponed until 1987 because of the Gramm-Rudman cuts in the budget for FDA. FDA has allocated funds in the amount of $35,000 annually in '83, '84 and '85 for this event. We anticipate that Workshop Number 4 can be held in 1987.

The USDA-CSRS has provided a grant of $25,000 to IR-4 HQ, to maintain 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 88 food, 250 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 efficacy. Eighty-one percent (81%) of the states participated in the 1986 research program.

9. 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 safe drug, pesticide and biorational 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 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.

Addendum 1
Pesticide Registrations on Ornamentals Supported by IR-4 Data
January 1986 to December 1986

Chemical (formulation)	Ornamental uses or species registered
Fluazifop-butyl (FUSILADE 4E) (FUSILADE 2000)	Control of grass weeds as an over-the-top application in a wide variety of field and container grown shrubs, shade trees and flowers including: Alder, aucuba, azalea, barberry, boxwood, bradford pear, bearberry, calendula, cherry ornamental, crab-apple, crape myrtle, false cypress, firethorn, gardenia, geranium, honey-locust, hosta, hydrangea, iris, juniper, liriope, magnolia, maple, marigold, oregon grape, petunia, pachysandra, photinia, podocarpus, red bud, russian olive, rose, sedum, spiraea, sweetgum, syringa, willow, zinnia.
Triadimefon (BAYLETON)	Control of powdery mildew and/or rust on: Aspen, calendula, cineraria, cottonwood, crassula, daisy, fern, gerbera, kalanchoe, poplar, pyracantha, sedum, snapdragon, ornamental sunflowers.
Diazinon, Microencapsulated (KNOX OUT 2FM)	Control of insects in greenhouses on African violets, ageratum, alyssum, azalea, begonia, birds nest fern, calendula, camellia, chrysanthemum, coleus, croton, daisy, geranium, impatiens, ivy, maranta, marigold, orchid, petunia, podocarpus, primrose, salvia, sansevieria, snapdragon, velvet plant, wandering jew and wax plant.
Napropamide (DEVRINOL 50 WP, 5G)	Control of weeds, in ageratum, aster, aucuba, birch, camellia, cotoneaster, crape myrtle, chrysanthemum, dahlia, daisy, dogwood, forsythia, gardenia, geranium, gladiolus, heather, honeysuckle, leucothe, narcissus, osmanthus, petunia, plantain lily (hosta), pin oak, raphiolepsis and zinnia (consult label for use directions on field grown and container grown ornamentals).

ADDENDUM 2
1986 IR-4 ANNUAL REPORT
Definition of Abbreviations in this Report

AA - Administrative Advisor
AEQI - Agricultural Environmental Quality Institute
AHI - Animal Health Institute
APDB - Antiparasitic & Physiologic Drugs Branch
APHIS - Animal & Plant Health Inspection Service
ARS - Agricultural Research Service
CSRS - Cooperative State Research Service
CVM - Center for Veterinary Medicine
EIS - Environmental Impact Statement
EPA - Environmental Protection Agency
FDA - Food and Drug Administration
GLP - Good Laboratory Practice
HED - Hazard Evaluation Division
IPM - Integrated Pest Management
IR-4 - Interregional Research Project No. 4
NACA - National Agricultural Chemical Association
NADE - Office of New Animal Drug Evaluation
OES - Office of Endangered Species
OPP - Office of Pesticide Programs
PPA - Pesticide Producers Association
RCB - Residue Chemistry Branch
RD - Registration Division
RSERB - Registration Support & Emergency Response Branch
SAES - State Agricultural Experiment Station
TC - Technical Committee
TDFA - Division of Therapeutic Drugs for Food Animals
USDA - United States Department of Agriculture
USDI - United States Department of Interior
Vet. - Veterinary