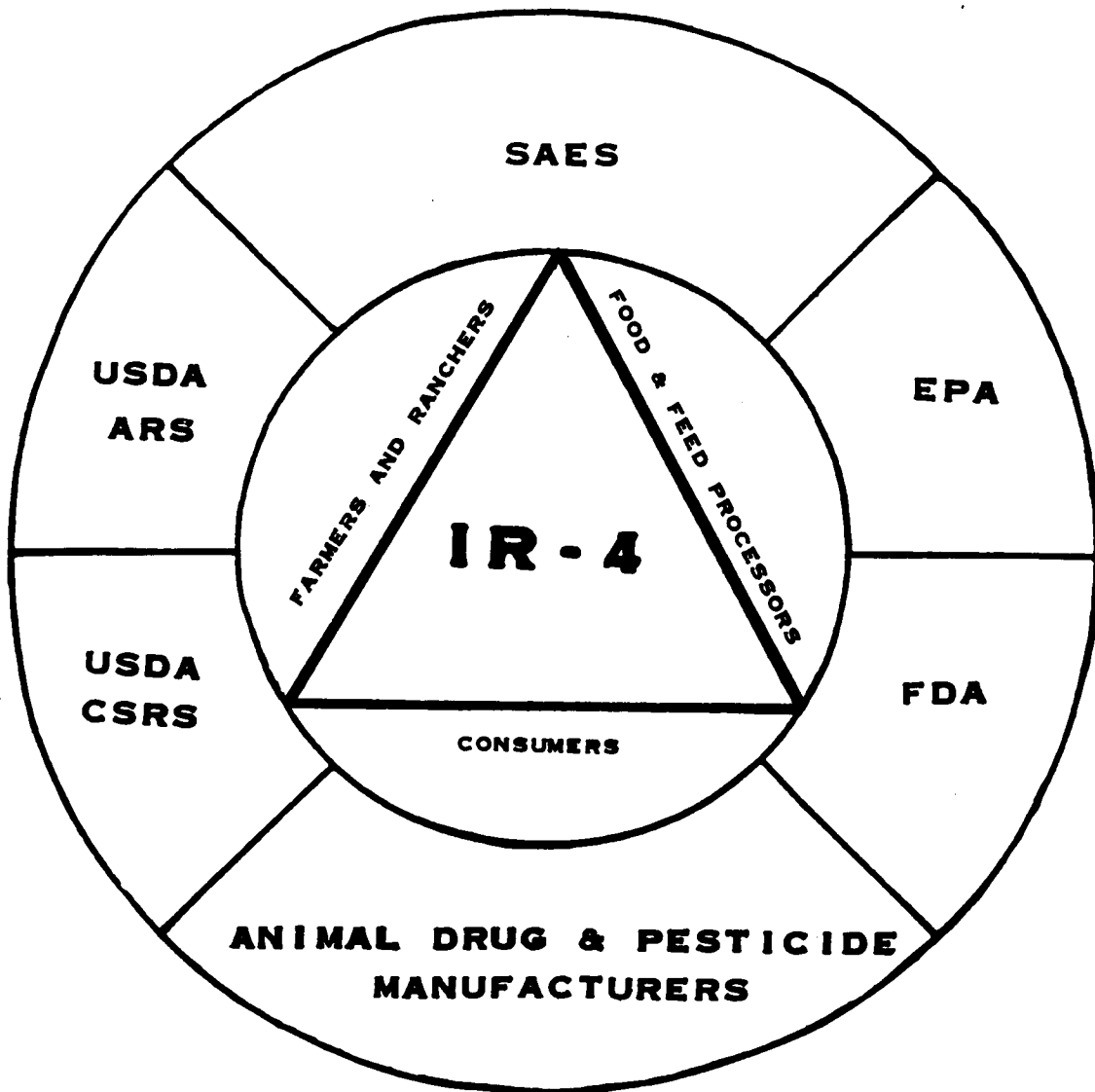


INTERREGIONAL RESEARCH PROJECT NO. 4 1988 ANNUAL REPORT



**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, 1988

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

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

3. ADMINISTRATION (PRINCIPAL LEADERS):

Interregional Administrative Advisory Committee:

Dr. N.P. Thompson, University of Florida, Chair
Dr. J.P. Jordan, CSRS Administrator
Dr. K.M. Kerr, The Ohio State University
Dr. R.D. Plowman, ARS Administrator
Dr. G.W. Ware, Jr., University of Arizona
Dr. R.E. Wyse, Rutgers University

Represents

Southern Region
USDA-CSRS
Northcentral Region
USDA-ARS
Western Region
Northeastern Region

Technical Committee:

Dr. W.B. Wheeler, University of Florida, Chair
(Southern IR-4 Regional Laboratory Director)
Dr. J.B. Bourke, Cornell University/Geneva
(Northeastern IR-4 Regional Laboratory Director)
Dr. R.M. Hollingworth, Michigan State University
(Northcentral IR-4 Regional Laboratory Director)
Dr. R.H. Kupelian, Rutgers University
(National Director, IR-4 Project) (On Sabbatical 1 DEC 88)
Dr. J.V. Parochetti, USDA-CSRS
Dr. P.H. Schwartz, Jr., USDA-ARS/Beltsville
(Staff Scientist, Pesticide Assessment Staff)
Dr. J.N. Seiber, University of California
(Western IR-4 Regional Laboratory Director)
Dr. H.S. Teague, USDA-CSRS
Dr. N.P. Thompson, University of Florida

Southern Region
Northeastern Region
Northcentral Region
National
USDA-CSRS (Pesticides)
USDA-ARS
Western Region
USDA-CSRS (Animal Drugs)
Administrative Advisors

4. CONSULTANTS COMMITTEE:

Mr. D.M. Baker, Jr., EPA Liaison to IR-4, Chair
Dr. V.F. Boyd, EPA-OPP-HED-DEB Liaison
Dr. W.J. Brunton, AHI Representative
Dr. D.A. Espeseth, USDA-APHIS Advisor
Dr. M.F. Kovacs, Jr., EPA-OPP-HED-DEB Liaison
Dr. K.R. Hill, USDA-ARS, Beltsville Analytical Chemistry Lab., Director
Mr. H.L. Jamerson, EPA-OPP-RD, Minor Use Officer
Mr. N. Somma, NACA Representative
Mr. D.R. Stubbs, EPA-OPP-RD
Dr. E.E. Viera, FDA Liaison to IR-4

5. COOPERATING REGULATORY AGENCIES:

Environmental Protection Agency (EPA):

Mr. D.D. Camp, EPA-OPP, Office Director
Mr. E.F. Tinsworth, EPA-OPP-RD, Division Director
Ms. F.S. Bishop, EPA-OPP-RD-RSB, Branch Chief
Dr. C.L. Trichilo, EPA-OPP-HED-DEB, Branch Chief

Food and Drug Administration (FDA):

Dr. G.B. Guest, FDA-CVM, Director
Dr. R.H. Teske, FDA-CVM, Deputy Director
Dr. R.B. Talbot, FDA-CVM-NADE, Director
Dr. D.A. Gable, FDA-CVM-TDFA, Director
Dr. R.C. Livingston, FDA-CVM-DMRCH, Director
Dr. T.V. Raines, FDA-CVM-APDB, Veterinary Medical Officer
Dr. R.E. Osterberg, FDA-CVM-AADB, Branch Chief

United States Department of Interior (USDI)/Fish and Wildlife Service:

Dr. F.P. Meyer, National Fishery Research Laboratory, Director
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, Senior Staff Veterinarian

6. NATIONAL HEADQUARTERS: (201) 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.H. Kupelian, National Director (On Sabbatical 1 DEC 88)	Dr. S.E. Katz, Animal Drug EIS Consultant
Prof. G.M. Markle, National Coordinator and Recording Secretary to the Project	Mr. R.R. Libby, Pesticide Consultant
Dr. R.T. Guest, National Coordinator	Mr. L.E. Mitchell, Pesticide Consultant
Dr. J.E. Elson, Associate Coordinator	Mr. P.L. Pontoriero, Pesticide Consultant
Dr. W.L. Biehn, Associate Coordinator	Mrs. P.A. Sarica, Administrative Assistant
Dr. J.J. Baron, Associate Coordinator	Mrs. D.K. Infante, Information Specialist
Mr. D.M. Baker, Jr., EPA Liaison	Miss C.L. Guise, Secretary
	Mrs. J.R. Streisand, Secretary
	Mrs. J.J. Boyle, 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 Regional Laboratory Supervisor 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 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 the Virgin Islands. The 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.

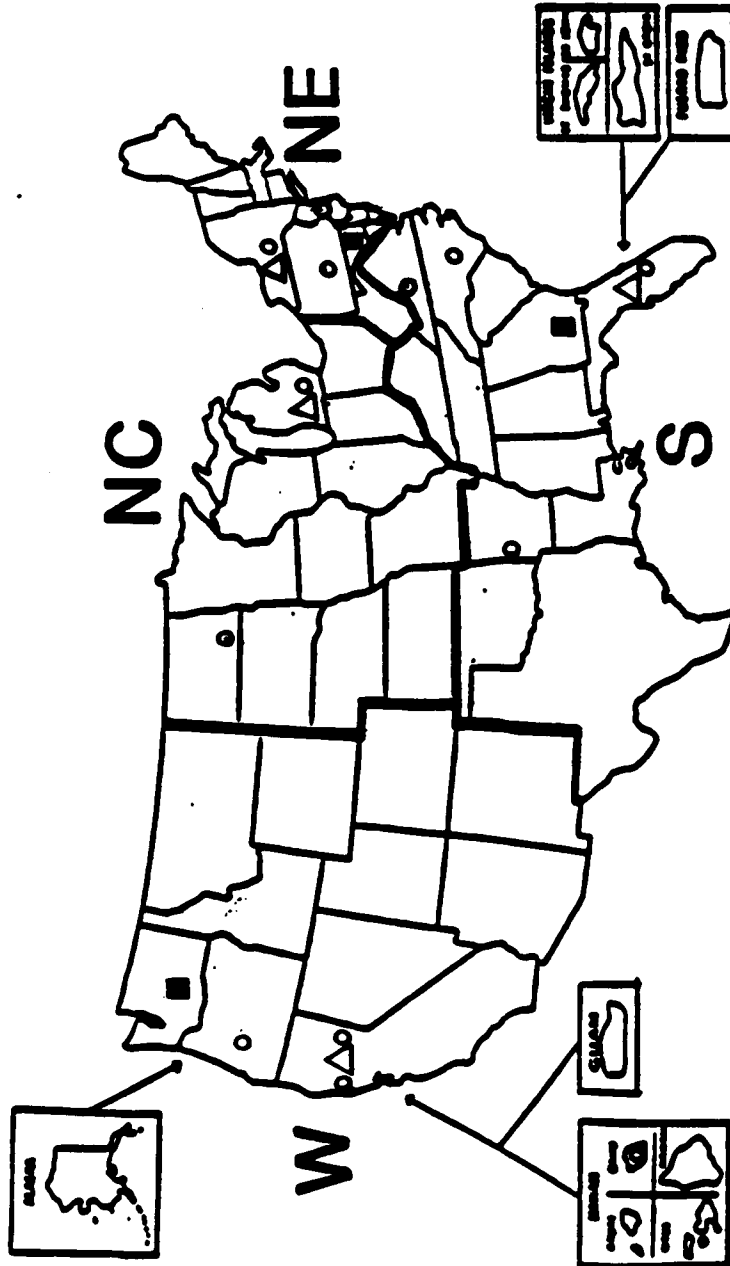
7. Continued

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.

NAME	STATE/TITLE	TELEPHONE	SPECIALTY AREA	NAME	STATE/TITLE	TELEPHONE	SPECIALTY AREA
Northeastern Region							
Dr. John B. Bourke	Reg. Lab. Dir.	(315) 787-2281	Chemistry	Dr. Willis B. Wheeler	Reg. Lab. Dir.	(904) 392-1991	Biochemistry
Mr. John H. Martini	Pesticide Coord.	(315) 787-2308	Chemistry	Dr. Charles W. Meister	Pesticide Coord.	(904) 392-1979	Plant Path.
Dr. John G. Babish	Animal Drug Coord.	(607) 253-3514	Drug/Foreign Compound Met.	Dr. Steve F. Sundlof	Animal Drug Coord.	(904) 392-1841	Veterinary Toxicology
Dr. Terry D. Spittler	Supervisory Chem.	(315) 787-2283	Chemistry	Dr. Lori O. Lim	Supervisory Chem.	(904) 392-1978	Metabolism & Toxicology
Dr. Richard A. Ashley	CT.	(203) 486-3435	Plant Sci.	Dr. Michael Williams	AL.	(205) 826-5006	Entomology
Mr. Mark R. Graustein	DE.	(302) 451-2526	Entomology	Dr. Terry L. Lavy	AR.	(501) 575-3955	Weed Science
Mr. Grady McDonald	DC.	(202) 282-7372	Horticulture	Dr. Charles W. Meister	FL.	(904) 392-1979	(See Above)
Mr. Edwin Flissey	ME.	(207) 581-7930	Entomology	Dr. Burton R. Evans	GA.	(404) 542-3685	Entomology
Dr. James J. Linduska	MD.	(301) 742-8788	Entomology	Dr. Chris M. Christensen	KY.	(606) 257-5955	Entomology
Dr. Prasanta Showmik	MA.	(413) 545-2353	Weed Science	Dr. Lowell L. Black	LA.	(504) 388-1464	Plant Path.
Dr. James Bowman	NH.	(603) 862-1159	Entomology	Dr. James M. McGuire	NC.	(601) 325-3138	Plant Path.
Dr. Jerry Ghidoui	NJ.	(609) 455-3100	Entomology	Dr. T. Jack Sheets	NC.	(919) 717-3191	Weed Science
Mr. John H. Martini	NY (Geneva)	(315) 787-2308	(See above)	Dr. James T. Criswell	OK.	(405) 744-5331	Entomology
Dr. Donald A. Ruti	NY (Ithaca)	(607) 255-3283	Entomology	Miss Nilsa M. Acin	PR.	(809) 767-9705	Chemistry
Dr. Ralph O. Kuma	PA.	(814) 863-4435	Entomology	Dr. Robert G. Bellinger	SC.	(803) 656-5042	Chemistry
Dr. David B. Wallace	RI. (ON LEAVE)	(401) 792-2900	Plant Path.	Dr. Carroll J. Southards	TN.	(615) 974-7135	Nematology
Dr. A.R. Gotlieb	VT.	(802) 656-2630	Plant Path.	Dr. Rodney L. Holloway	TX.	(409) 845-3849	Entomology
Dr. Joe E. Weaver	WV.	(304) 293-6023	Entomology	Dr. Michael J. Weaver	VA.	(703) 961-6543	Plant Path.
Dr. Ralph E. Webb	MD, USDA-ARS.	(301) 344-4562	Entomology	Mr. Walter Knausenberger	Virgin Islands.	(809) 778-0246	Pest Mgt.
Dr. James C. Locke	MD, USDA-ARS.	(301) 344-2413	Nematology/Plant Path.	Dr. James M. Schalk	SC, USDA-ARS.	(803) 556-0840	Entomology
Mr. J. Ray Frank	MD, USDA-ARS.	(301) 663-7132	Weed Science	Dr. Alva W. Johnson	GA, USDA-ARS.	(912) 386-3372	Nematology
Dr. Kenneth R. Hill	MD, USDA-ARS.	(301) 344-2495	Residue Chem.	Dr. Norman Glaze	GA, USDA-ARS.	(912) 386-3908	Plant Phy
Dr. R.K. Ringer	Animal Drug Coord.	(517) 355-8414	Avian/Fur-bearing Physiology/Tox.	Dr. Donald Wauchope	GA, USDA-ARS.	(912) 386-3514	Residue Chem.
Northcentral Region							
Dr. Robert M. Hollingworth	Reg. Lab. Dir.	(517) 353-9430	Entomology	Dr. James Seiber	Reg. Lab. Dir.	(916) 752-4528	Chemistry
Dr. Satoru Miyazaki	Pesticide Coord.	(517) 353-9497	Pest Analysis & Entomology	Mr. Harold G. Alford	Pesticide Coord.	(916) 752-2833	Entomology
Dr. R.K. Ringer	Animal Drug Coord.	(517) 355-8414	Avian/Fur-bearing Physiology/Tox.	Dr. Arthur L. Craigmill	Animal Drug Coord.	(916) 752-2936	Env. Veterinary Toxicology
Dr. Richard Leavitt	Supervisory Chem.	(517) 353-6377	Analytical Chem.	Mr. William Gauer	Supervisory Chem.	(916) 752-4742	Chemistry
Ms. Wendy Winterstein	IA.	(515) 294-1101	Entomology	Dr. Jeff Conn.	AK.	(907) 479-7614	Weed Science
Dr. David J. Williams	IL.	(217) 333-2126	Horticulture	Dr. Paul B. Baker	AZ.	(602) 621-4012	Entomology
Dr. Richard X. Latin	IN.	(317) 494-4639	Plant Path.	Mr. Harold G. Alford	CA.	(916) 752-7010	(See above)
Dr. Don Cress	KS.	(913) 532-5891	Entomology	Dr. Bert L. Bohmert	CO.	(303) 491-5237	Ag. Chemistry & Weed Science
Dr. Satoru Miyazaki	MI.	(517) 353-9497	(See above)	Guam.
Dr. Leonard B. Hertz	MN.	(612) 624-3665	Horticulture	Dr. Michael Kavate	HI.	(808) 948-6007	Biochemistry
Dr. Christopher Starbuck	MO.	(314) 882-7511	Horticulture	Dr. Gene P. Carpenter	ID.	(208) 885-7541	Entomology
Dr. John D. Nalewaja	ND.	(701) 237-8158	Weed Science	Dr. Gregory D. Johnson	MT.	(406) 994-3318	Entomology
Dr. Shripat G. Kamble	NE.	(402) 472-6857	Entomology	Dr. Michael English	NM.	(505) 646-2546	Entomology
Dr. Acie Waldron	OH.	(614) 292-7541	Entomology (Chem. Control)	Dr. Wayne Johnson	NV.	(702) 784-6911	Horticulture
Mr. Leon J. Wraage	SD.	(605) 688-5121	Agronomy, Weed & Plant Sci.	Dr. James M. Witt	OR.	(503) 754-2564	Ag. Chem. & Toxicology
Dr. Chuck Koval	WI.	(608) 262-4608	Entomology	Dr. Howard Deer	UT.	(801) 750-1600	Pesticides
Dr. T.L. Ladd	OH, USDA-ARS.	(216) 263-3898	Entomology	Mr. Richard C. Maxwell	WA.	(509) 335-2995	Entomology
Dr. Charles Krause	OH, USDA-ARS.	(614) 363-1129	Plant Path/ Nematology	Mr. Everett Spackman	WY.	(307) 766-4261	Entomology
Dr. Loyd M. Wax	IL, USDA-ARS.	(217) 333-9653	Weed Science	Dr. Robert G. Linderman	OR, USDA-ARS.	(503) 757-4544	Nematology/Plant Path.
Dr. William M. Doane	IL, USDA-ARS.	(309) 685-4011	Physical Chem.	Dr. Eric Halfhill	WA, USDA, ARS.	(509) 575-5982	Pest Chemistry
				Dr. Leslie M. McDonough	WA, USDA-ARS.	(509) 575-5970	Pest Chemistry
				Dr. Rick Boydston	WA, USDA-ARS.	(509) 786-2226	Weed Science

MINOR USES PROJECT RESIDUE LABORATORIES



RESIDUE LABORATORIES

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

NORTHEASTERN REGION

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

SOUTHERN REGION

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

NORTHCENTRAL REGION

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

WESTERN REGION

- △ University of California, Davis, CA
- University of California, Berkeley, CA
- University of California, Davis, CA (School of Veterinary Medicine)
- University of Hawaii
- Oregon State University
- USDA/ARS, Yakima, WA

8. PROGRESS OF WORK AND PRINCIPAL ACCOMPLISHMENTS:

(A) FOOD USE RESEARCH PROJECTS:

There are currently 3920 total IR-4 food-use requests, an increase of 249 over the 3671 requests reported last year. Of these, 1162 are characterized as researchable projects. During 1988, the four IR-4 Regions and USDA-ARS scheduled research on 171 food-use projects, from which residue samples for 86 projects went to state and USDA-ARS cooperating laboratories and samples for 45 projects went to chemical company laboratories. With the completion of 1988 and prior research projects, data requirements will be fulfilled for an additional 112 minor use needs. Research protocols for 428 requests were prepared or revised and the following pesticides/commodities were researched in 1988:

(1) FUNGICIDES AND NEMATOCIDES:

Anilazine/watercress - Benomyl/atemoya, carambola, collard, cranberry, greens (mustard), kale, mint, pepper (non-bell), potato, sorghum (grain) - Captan/date - Carboxin/cantaloupe, eggplant, pepper (bell, non-bell) - Chlorothalonil/blueberry, mango, papaya, passion fruit, pepper (bell, non-bell) - Fenamiphos/bean (lima, snap), kiwifruit, pea (green, southern), pepper (bell, non-bell), watermelon - Folpet/avocado - Fosetyl Al/cranberry, macadamia nut - Iprodione/blueberry, broccoli raab, cantaloupe, Chinese broccoli, Chinese cabbage (bok choy, napa), collard, cucumber, daikon, eggplant, greens (mustard), radish, safflower - Metalaxyl/blackberry, boysenberry, cranberry, kiwifruit - Methyl Bromide/okra, onion (dry bulb) - Nitrapyrin/pepper (bell, non-bell) - PCNB/chive - Thiabendazole/sweet potato - Triadimefon/artichoke - Triforine/cucumber, mango - Vinclozolin/blueberry

(2) HERBICIDES AND PLANT GROWTH REGULATORS:

Chlorimuron Ethyl/cranberry - Clomazone/broccoli, cabbage, cucumber, greens (mustard), pepper (bell, non-bell), winter squash - Clopyralid/mint - Diquat/pepper (bell), tomato - Fluazifop/asparagus, basil, canola, cauliflower, Chinese cabbage, chive, collard, dill, greens (mustard), horseradish, kale, leek, lettuce (leaf), marjoram, parsley, pepper (non-bell), rhubarb, tyfon - Fomesafen/bean (snap) - Metolachlor/blueberry, broccoli, carrot, cauliflower, Chinese broccoli, Chinese cabbage (bok choy, napa), leek, onion (dry bulb), pea (pigeon), raspberry - Metribuzin/Bermuda grass, pea (pigeon) - Napropamide/basil, Chinese broccoli, Chinese cabbage (bok choy), chive, rosemary, savory (summer) - Oxyfluorfen/blackberry, cacao, cantaloupe, Chinese broccoli, Chinese cabbage (bok choy), chive, clover, cucumber, garlic, leek, raspberry, strawberry, squash (summer), taro (dry, wet) - Paraquat/bean (snap), cucumber - Pendimethalin/marigold - Prometryn/celery - Pronamide/cranberry, kale, raspberry - Sethoxydim/asparagus, canola, Chinese broccoli, Chinese cabbage (bok choy), Chinese mustard, collard, endive, kale, lupine (sweet white), safflower - Simazine/mango - Terbacil/cranberry - Thiobencarb/Chinese cabbage (bok choy), collard, turnip - Tridiphane/sweet corn - Trifluralin/crambe - 2,4-D/blueberry, cranberry - 2,4-DB/barley, triticale

8A. Continued

(3) INSECTICIDES, MITTICIDES, MOLLUSCICIDES AND RODENTICIDES:

Bacillus thuringiensis/basil, chive, coriander, dill, leek, marjoram, rosemary - Carbaryl/leek - Chlorpyrifos/bean (snap), broccoli, cabbage, cauliflower, crambe, cranberry, millet, onion (green), pea (southern) - Cypermethrin/clover - Cyromazine/cattle, Chinese cabbage (napa) - Diazinon/cranberry, pepino, squash (summer) - Dimethoate/strawberry - Esfenvalerate/asparagus, carambola, cardoon, Chinese cabbage (bok choy), collard, endive, greens (mustard), lettuce (leaf), mango, okra, onion (green), quinoa - Fluvalinate/cucumber - Hexakis/avocado, corn (sweet), raspberry, tomato, watermelon - Malathion/sweetsop - Methidathion/atemoya, cherimoya - Methomyl/cranberry - Permethrin/carrot, squash (summer) - Propargite/eggplant, pistachio, raspberry - Zinc Phosphide/blueberry

In summary, the IR-4 Project sponsored research on over 90 individual commodities in 1988.

In October and November, the IR-4 State & Federal Liaison Representatives in the Regional Committees selected the active research projects for 1989. They reviewed and prioritized the national (multi-regional) researchable projects and the researchable projects for low dietary intake (LDI) crops for their region. Tolerances and labels are possible for LDI crops on the basis of regional or even state data. Each region struck a balance in funding between projects requiring national data and projects requiring only regional representative data. The 1989 research program was finalized at the National Research Planning Meeting (NRFPM) which was held at IR-4 Headquarters on 29 NOV - 1 DEC. At the NRFPM, the IR-4 Headquarters Pesticide Program Scientists, the IR-4 Pesticide Regional Coordinators, the IR-4 Regional Supervisory Laboratory Chemists, the USDA-ARS Staff Scientist and the USDA-ARS Supervisory 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 HQ prepared 50 tolerance, reregistration and crop definition petitions in calendar year 1988. Forty-one petitions were submitted to EPA and 9 petitions are still under review by the manufacturers (eventual label registrants) prior to EPA submission. Additionally, 11 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.

EPA published the Minor Use Policy in the 2 APR 86 Federal Register. This policy includes a list of LDI crops for which tolerances can be established with regional representative data. In line with this policy, the following clearances, which have the (R) designation, are tolerances with regional registrations. During 1988, IR-4 HQ petition submissions resulted in pesticide actions representing 66 pesticide/commodity tolerances including six crop definitions. These are reviewed in detail below:

(1) FUNGICIDES AND NEMATOCIDES (6 tolerances):

Fenamiphos/kiwifruit (R), non-bell pepper (R) - Metalaxyl/papaya (R) - PCNB/collard (R), kale (R), mustard greens (R)

8B. Continued

- (2) HERBICIDES (14 tolerances):
Clomazone/pumpkin, succulent pea - Fluazifop/asparagus (R),
endive (R), rhubarb (R), spinach - Glyphosate/atemoya,
carambola, sugar apple - Oxyfluorfen/macadamia nut (R) -
Pendimethalin/garlic (R) - Pronamide/winter pea (R) -
Sethoxydim/artichoke (R), lentil
- (3) INSECTICIDES AND MITICIDES (27 tolerances):
Carbaryl/dill (R) - Diazinon/Chinese radish (R) - Diflubenzuron/
range grass (R), walnut - Methidathion/citrus - Menthol/beeswax &
honey - Methomyl/Brassica leafy vegetables, leek - Parathion/
lentil - Permethrin/avocado (R), cucurbits, dry onion, garlic,
papaya (R) - Phosmet/crab apple (R)
- (4) CROP DEFINITIONS (19 tolerances):
Blackberries = boysenberry, dewberry, marionberry, olallieberry,
and varieties and/or hybrids of these; Caneberries = blackberry,
loganberry, red and black raspberries, youngberry, and varieties
and/or hybrids of these; Green Onion = green shallot or green
eschalot, Japanese bunching onion, leek, spring onion or scallion;
Lentil = pea; Onion = dry bulb onion, garlic and green onion;
Oregano = marjoram

Additionally, 24 tolerances were proposed. These proposals will become clearances in 1989.

IR-4 continues to have a meaningful dialogue with EPA's Health Effects Division concerning current residue and toxicology data requirements for various pesticide uses. Because of these discussions, we have been able to better select projects for research. However, certain tolerances requested by IR-4 are not established by EPA because existing data bases are not adequate to support the tolerances at this time, e.g., metabolism, toxicology and environmental fate studies. These data gaps have surfaced because of the current guidelines which must be addressed for all products under pesticide reregistration.

Congress passed and President Reagan signed into law during 1988, an amendment to the Federal Insecticide, Fungicide and Rodenticide Act that addressed reregistration of pesticides. The data bases for pesticides originally registered before 1984 will have to be updated to meet current requirements within the next nine years or the chemical will be removed from commerce.

Certain reregistration documents require additional residue data for established or registered uses, including minor uses, as well as, new toxicology, metabolism and environmental fate studies. With the rapid reregistration of pesticides, IR-4 fears that many pesticides will be voluntarily cancelled by the manufacturers. In addition, there are strong indications that many minor uses will be lost, resulting in additional pest management voids.

8B. Continued

IR-4 HQ has initiated a new publication, IR-4 Red Alert, which addresses the reregistration status of pesticides. In developing the IR-4 Red Alert, IR-4 first surveys the major manufacturers to determine what are their plans regarding the reregistration of the product in question. The IR-4 Red Alert is a compendium of what uses will not be defended during reregistration. Based on the feedback from the states, as initiated by the IR-4 Red Alert, IR-4 can better prioritize which registered minor uses are still needed and what efforts by IR-4 are necessary to maintain the uses.

During 1988, IR-4 has critically evaluated its field and laboratory procedures in regards to the proposed EPA Good Laboratory Practice (GLP) guidelines. New procedures will be integrated into our 1989 research program to include state of the art project tracking, written standard operating procedures for all research locations, review of field and laboratory research by qualified quality assurance units and centralized archives of raw data. New reporting and tracking forms have been developed and will be introduced. These changes will allow IR-4 to continue to submit reliable residue chemistry data to EPA. Additional procedural modifications to meet EPA mandated GLP's will be completed as necessary to continue to insure the quality and integrity of IR-4 data.

Potential crop damage liability, by the pesticide manufacturer, continues to hinder registration of certain pesticides on minor crops. Third-party registration procedures have been suggested as a mechanism to overcome the crop damage liability issue. In 1988, progress was made in obtaining the first large scale third party registration. Residue chemistry data was submitted to EPA by IR-4, requesting a tolerance for the herbicide metolachlor on cabbage. Once the tolerance is established, third party registration groups in Florida and New York will be able to finalize their first label.

(C) ORNAMENTAL RESEARCH AND DEVELOPMENT:

During the 11 1/2 years the IR-4 Ornamentals Program has been in existence (APR 77 - NOV 88), IR-4 has undertaken 11,628 ornamental research trials. In 1988, the IR-4 Project funded 490 ornamental research trials, and IR-4 HQ prepared registration packages for 29 pesticides (5 fungicides, 8 herbicides, 15 insecticides and 1 PGR) which were submitted to potential registrants. During 1988, IR-4 data were used to support 153 ornamental pesticide registrations. Since 1977, the total number of label registrations on ornamentals is 2,756 or an average of about 20 clearances per month. Ornamental registrations that were supported by IR-4 data in 1988 include:

PESTICIDE

ORNAMENTAL USES OR SPECIES REGISTERED

Acephate
(ORITHENE^R)

To control various insects on dahlia, lily, pachysandra, peony and sedum.

Chlormequat
(CYCOCEL^R)

To induce early flowering of seed geranium grown under greenhouse conditions; to reduce shoot growth and improve flowering of hibiscus grown under greenhouse conditions.

8C. Continued

PESTICIDE	ORNAMENTAL USES OR SPECIES REGISTERED
Diflubenzuron (DIMILIN ^R)	To control beet armyworm on field and greenhouse grown chrysanthemum.
Fosetyl Al (ALLETTE ^R)	To control diseases caused by <u>Pythium</u> and <u>Phytophthora</u> on field nursery or greenhouse grown ornamentals or on ornamentals grown for indoor or outdoor landscaping as a foliar or drench application to plants including: andromeda, aphelandra, arborvitae, aucuba, birch, blueberry (ornamental), camellia, ceanothus, dieffenbachia, dogwood, Fraser fir, laurel, philodendron, pine and yew.
Metalaxyl (SUBDUE ^R)	To control damping off and stem & root rot diseases caused by <u>Pythium</u> and <u>Phytophthora</u> in container, field, and greenhouse grown anthurium, artemisia, columbine, daisy, delphinium, dianthus, ficus, foxglove, gaillardia, petunia, phlox, primrose, sempervivum and yew.
Metolachlor (PENNANT ^R) (liquid & 5G)	To control annual grass and some broadleaf weeds in the production of ash, birch, Douglas fir, hemlock and leatherleaf fern.
Oryzalin (SURFLAN ^R)	To control certain grass and broadleaf weeds in iris and narcissus production.
Oxyfluorfen (GOAL ^R)	To control weeds in seed beds of Monterey pine.
PCNB (TERRACLOR ^R)	To control stem rots (<u>Rhizoctonia</u>) of aphelandra, boxwood, dahlia, dieffenbachia, dracena, English ivy, ficus, fittonia, geranium, gynura, holly, hoyo, juniper, kalanchoe, marigold, peperomia, petunia, pine, portulaca, pothos, rhododendron, salvia, schefflera, synconium, tradescantia, vinca and zinnia.
Pronamide (KERB ^R)	To control winter annual and perennial grasses and certain broadleaf weeds in birch, hemlock and honeylocust.
Sethoxydim (POAST ^R)	To control certain annual and perennial weeds in lily production.
Simazine (PRINCEP ^R)	As a tank mix with metolachlor on field and liner grown <u>Rhododendron</u> spp. as a preemergence application to control various weeds.
Trifluralin (TREFLAN ^R)	To control annual grass and broadleaf weeds in rose production.

(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, 1988 marks the completion of six years of the IR-4 Biorationals Program.

In 1988, IR-4 funded research on the following biorational projects:

- 1) Testing of Xanthomonas campestris for control of annual bluegrass in turf.
- 2) Safety testing to support the registration of the Codling Moth Granulosis Virus (CMGV).

In May 1988, EPA granted an Experimental Use Permit (EUP) and temporary exemption from the requirements of a tolerance for the use of grape berry moth pheromone dispensers (GB-ROPE) in grape production, based on a petition prepared by IR-4 in conjunction with Drs. T. Dennehy and W. Roelofs of the New York State Agricultural Experiment Station. The EUP is for a period of two years.

(E) ANIMAL DRUG RESEARCH AND DEVELOPMENT

The IR-4 Animal Drug Committee met on three separate occasions in 1988. The first two meetings were held in Rockville, MD and were convened under the joint auspices of the IR-4 and FDA minor species committees. At the meetings, funding priorities for animal drug projects were established for the upcoming fiscal year. The FDA Minor Species Committee provided information and guidance in selecting projects which met the minor species guidelines. The FDA also offered analytical assistance in conducting tissue residue studies. This commitment by the FDA should greatly benefit the IR-4 Animal Drug Program because of the technical difficulty and expense often involved in residue analysis.

The third meeting of the IR-4 Animal Drug Committee was held in Gainesville, Florida. In addition to the routine business meeting, the committee members toured two commercially profitable alligator farms.

8E. Continued

Since 1983, 169 animal drug requests (ADR) have been submitted to IR-4 HQ. Of the 169, five are under review as Public Master Files (PMF) with FDA-Center for Veterinary Medicine (CVM), five are complete and the data will be filed with FDA-CVM, 15 are ongoing research projects and nine have been cleared. The nine clearances, listed below, have been published in the Federal Register.

<u>ADR NO.</u>	<u>SPECIES</u>	<u>DISEASE CLAIM</u>	<u>DRUG</u>	<u>COOPERATING INSTITUTIONS</u>	<u>PUBLICATION DATE</u>
1	Goat	Coccidiosis	Monensin	Texas A & M Univ./ Eli Lilly Co.	12/19/86
2	Pheasant	Coccidiosis	Amprolium	Pennsylvania State Univ./ Merck & Co.	12/24/84
4	Catfish	Enteric Septicemia	Sulfadimethoxine & Ormetoprim	Mississippi State Univ./ Hoffmann-LaRoche	4/16/86
5	Pheasant	Gapeworm	Thiabendazole	Pennsylvania State Univ./ Merck & Co.	2/22/84
11	Reindeer	Warbles	Ivermectin	University of Alaska/ Merck & Co.	12/24/84
15	Lobster	Gaffkemia	Oxytetracycline	University of Maine/ Pfizer, Inc.	1/13/86
30	Quail	Ulcerative Enteritis	Bacitracin M.D.	University of Florida/ A.L. Labs.	2/22/88
111	Goat	Coccidiosis	Decoquinat	Washington State Univ./ Rhone-Poulenc, Inc.	2/18/87
114	Quail	Coccidiosis	Monensin	USDA-Agricultural Research Service/Eli Lilly Co.	4/13/87

8E. Continued

Public Master Files for the following five projects are currently under review by FDA-CVM:

<u>ADR NO.</u>	<u>SPECIES</u>	<u>DISEASE CLAIM</u>	<u>DRUG</u>	<u>REGION</u>	<u>COOPERATING INSTITUTIONS</u>
17	Goat	Gastrointestinal parasites	Ivermectin	NCR	University of Nebraska/Merck & Co.
74	Sheep	Bacterial Pneumonia	Sulfamethazine S.R.	WSR	University of Idaho/Norden Labs.
115	Quail	Coccidiosis	Salinomycin	NER	USDA-Agricultural Research Service/ A.H. Robins Co.
125	American Bison	Hypodermosis	Ivermectin	NCR	Michigan State University/Merck & Co.
127	Bighorn Sheep	Lungworms	Fenbendazole	WSR	Washington State University/Hoechst-Roussel Agri-Vet Co.

The research for the following five projects is complete and data will be filed with FDA-CVM:

33	Goat	Bacterial Pneumonia	Amoxicillin	WSR	University of California/Beecham Labs.
43	Goat	Bacterial Pneumonia	Oxytetracycline LA-200	WSR	University of Idaho/Pfizer, Inc.
83	Sheep	Bacterial Pneumonia	Oxytetracycline LA-200	WSR	University of Idaho/Pfizer, Inc.
87	Sheep	Bacterial Pneumonia	Amoxicillin	WSR	University of Idaho/Beecham Labs.
122	Rabbit	Coccidiosis	Lasalocid	SOR	University of Arkansas/Hoffmann-LaRoche

8E. Continued

The following 15 ongoing research projects were established in cooperation with 11 universities, USDI-Fish and Wildlife Service, USDA-Agricultural Research Service and 12 pharmaceutical companies:

<u>ADR NO.</u>	<u>SPECIES</u>	<u>DISEASE CLAIM</u>	<u>DRUG</u>	<u>REGION</u>	<u>COOPERATING INSTITUTIONS</u>
14	Sheep	Coccidiosis	Decoquinat	NER	Cornell University/Rhone-Poulenc, Inc.
18	Salmonids	Bacterial gill disease	Chloramine-T	NER/NCR	USDI-Fish and Wildlife Service/ Wisconsin Pharmacal Co.
31	Merganser Duck	Schistosomiasis	Praziquantel	NCR	Hope College/Bayvet Labs.
66	Dairy Goat	Mastitis	Novobiocin & Procaine Penicillin	WSR	University of California/Upjohn Co.
112	Goat	Liver fluke	Clorsulon	SOR	University of Florida/Merck & Co.
124	Goat	Gastrointestinal parasites	Fenbendazole	NCR	University of Nebraska/Hoechst-Roussel Agri-Vet Co.
128	Swine	Coccidiosis	Amprolium	SOR	Auburn University/Merck & Co.
134	Goat	Gastrointestinal parasites	Levamisole	NER	University of Massachusetts/ Pitman-Moore, Inc.
135	Salmonids	Bacterial kidney disease (BKD)	Erythromycin	WSR	University of Idaho/Ceva Labs.
137	Chukar Partridge	Coccidiosis	Sulfadimethoxine & Ormetoprim	NER	USDA-Agricultural Research Service/ Hoffmann-LaRoche
138	American Alligator	Bacterial infections	Virginiamycin	SOR	University of Florida/SmithKline Animal Health Products
144	Lactating Goat	Gastrointestinal parasites	Morantel Tartrate	SOR	University of Tennessee/Pfizer, Inc.
160	Striped Bass	Protozoan parasites	Formalin	SOR	University of Georgia/Natchez Co.
161	Striped Bass	Bacterial infections	Oxytetracycline	SOR	University of Georgia/Pfizer, Inc.
169	Marine Penaeid Shrimp	Bacterial infections	Formalin	WSR	University of Arizona/Natchez Co.

8. Continued

(F) COORDINATION WITH FEDERAL AND STATE AGENCIES:

USDA-Agricultural Research Service and USDI-Fish and Wildlife Service scientists cooperated with IR-4/SAES scientists on 67 food, 229 ornamental and 3 animal drug specialty-use 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-six percent of the states participated in the 1988 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 are the backbone of integrated pest management (IPM) systems. The biorational research, which includes the development of biological (microbial and biochemical) control agents, also supports the organic or sustainable farming system.

10. WORK PLANNED FOR NEXT YEAR:

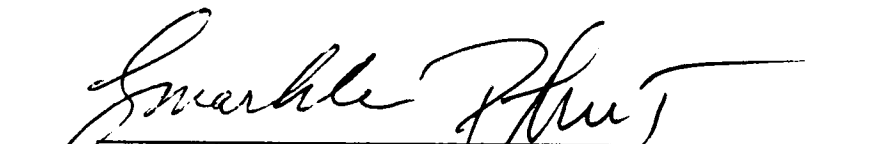
Since IR-4 is mission oriented with its focus on food and environmental safety, as well as, crop and animal protection, we will continue to develop data required by EPA and FDA for the establishment of minor use tolerances, including IPM materials, and animal drug approvals, as necessary, appropriate 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 are not adequate to address more than 15% 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 15% and 10%, respectively, of the researchable projects on the books. The research program in ornamentals has been severely reduced and only 50% 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 and animal drug 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.

11. PUBLICATIONS:

- A. Baron, J.J. 1988. Good Laboratory Practices: A Public Institution Viewpoint. Proc. 6th Annual WSSNC Mtg., Raleigh, NC, pp 27-33.
- B. Baron, J.J., G.M. Markle, and R.H. Kupelian. 1988. IR-4 Helps Growers. American Fruit Grower, Vol. 108, pp 52-56.
- C. Biehn, W.L. 1988. The Future of Pesticides. Greenhouse Grower, February, pp 32-33.
- D. Elson, J.E. 1988. IR-4: Clearing the Way for the New Pesticides. SAF - Business News for the Floral Industry, Vol. 5, No. 4, July, p 28.
- E. Markle, G.M., J.J. Baron, W.L. Biehn, and R.H. Kupelian. 1988. Reregistration Update - 88:1. IR-4 Red Alert, IR-4 Headquarters, Rutgers University, New Brunswick, NJ, pp 6.
- F. Markle, G.M., J.J. Baron, P.L. Pontoriero, and R.H. Kupelian. 1988. Reregistration Update - 88:2. IR-4 Red Alert, IR-4 Headquarters, Rutgers University, New Brunswick, NJ, pp 6.
- G. Markle, G.M. (Editor). IR-4 Newsletter (Quarterly).

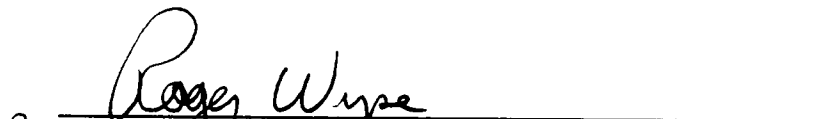
December 31, 1988



R.H. Kupelian, National Director
IR-4, Cook College, Rutgers - The State
University of New Jersey


Approved:

1/11/89
Date



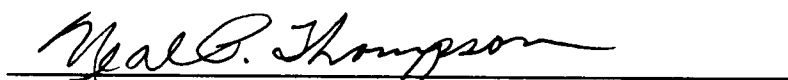
S.J. Kleinschuster, Dean and Executive Director
NJAES, Cook College, Rutgers - The State
University of New Jersey

1/19/89
Date



W.B. Wheeler, Chair, Technical Committee
Professor, Food Science and Human Nutrition
University of Florida

1/19/89
Date



N.P. Thompson, Chair, Administrative Advisors
Associate Dean for Research
University of Florida

Attachment:

Glossary of Abbreviations used in this Report

1988 IR-4 ANNUAL REPORT
Glossary of Abbreviations used in this Report

AADB - Antimicrobial and Antiparasitic Drugs Branch
ADR - Animal Drug Request
AHI - Animal Health Institute
APDB - Antiparasitic and Physiologic Drugs Branch
APHIS - Animal and Plant Health Inspection Service
ARS - Agricultural Research Service
BKD - Bacterial Kidney Disease
CMGV - Codling Moth Granulosis Virus
CSRS - Cooperative State Research Service
CVM - Center for Veterinary Medicine
DEB - Dietary Exposure Branch
DMRCH - Division of Drug Manufacturing and Residue Chemistry
EIS - Environmental Impact Statement
EPA - Environmental Protection Agency
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
NADE - Office of New Animal Drug Evaluation
NCR - Northcentral Region
NER - Northeastern Region
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
SAF - Society of American Florists
SOR - Southern Region
TDFA - Division of Therapeutic Drugs for Food Animals
USDA - United States Department of Agriculture
USDI - United States Department of Interior
WSR - Western Region