A NATIONAL AGRICULTURAL PROJECT:

Clearances of Safe Animal Drugs, Bioregistration
(Microbials and Biochemicals), and
Pesticides for Minor or Specialty Uses.
ANNUAL REPORT OF COOPERATIVE INTERREGIONAL RESEARCH PROJECT NO. 4
IR-4
JANUARY 1 TO DECEMBER 31, 1987

1. PROJECT: IR-4 - A National Agricultural Project: Clearances of Safe Animal Drugs, Biorational (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):
Dr. N.P. Thompson, University of Florida, Chair
Dr. J.P. Jordan, CSRS Administrator
Dr. K.M. Kerr, The Ohio State University (FROM JUL 87)
Dr. T.B. Kinney, ARS Administrator
Dr. R.H. Kupelian, IR-4 National Director
Dr. J.P. Mahlstedt, Iowa State University (TO JUN 87)
Dr. G.W. Ware, Jr., University of Arizona
Dr. R.E. Wyse, Rutgers University

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

Technical Committee (TC):
Dr. W.B. Wheeler, University of Florida, Chair
(Southern IR-4 Regional Laboratory Director)
Dr. J.B. Bourke, USDA-CSRS
Dr. R.M. Hollingsworth, Michigan State University (FROM OCT 87)
(Northcentral IR-4 Regional Laboratory Director)
Dr. R.H. Kupelian, Rutgers University, Executive Secretary
(National Director, IR-4 Project)
Dr. Fumio Matsumura, Michigan State University (TO SEP 87)
(Northcentral IR-4 Regional Laboratory Director)
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. T.D. Spittler, Cornell University/Geneva
(Northeastern IR-4 Regional Laboratory Director)
Dr. H.S. Teague, USDA-CSRS
Dr. N.P. Thompson, University of Florida

Represents
Southern Region
USDA-CSRS (Pesticides)
Northcentral Region
National
Northcentral Region
USDA-ARS
Western Region
Northeastern 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-RCB Liaison
Dr. W.J. Brunton, AHI Representative
Dr. D.A. Espeseth, USDA-APHIS Advisor
Dr. M.F. Kovacs, Jr., EPA-OPP-HED-RCB Liaison
Dr. K.R. Hill, USDA-ARS, Analytical Chemistry Lab., AEQI, Director
Mr. H.L. Jamerson, EPA-OPP-RD, Minor Use Officer
Mr. D.L. Olson, NACA Representative (TO JUL 87)
Mr. N. Somma, NACA Representative (FROM AUG 87)
Mr. D.R. Stubbs, EPA-OPP-RD
Dr. E.E. Viera, FDA Liaison to IR-4
5. COOPERATING REGULATORY AGENCIES:

Environmental Protection Agency (EPA):
Dr. J.A. Moore, EPA-Pesticides & Toxic Substances, Assistant Administrator
Mr. D.D. Camp, EPA-OPP, Office Director
Mr. E.F. Tinswort, EPA-OPP-RD, Division Director
Ms. F.S. Bishop, EPA-OPP-RD-RSERB, Branch Chief
Dr. C.L. Trichilo, EPA-OPP-HED-RCB, 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, Vet. 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):
Mr. B.W. Hawkins, USDA-APHIS, Administrator
Dr. D.A. Espeseth, USDA-APHIS, Senior Staff Veterinarian

6. 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. J.E. Elson, Associate Coordinator
Dr. W.L. Biehn, Associate Coordinator
Dr. J.J. Baron, Assistant Coordinator
Mr. D.M. Baker, Jr., EPA Liaison
Dr. E.E. Viera, FDA Liaison
Dr. J.A. Farnham, Animal Drug Consultant
Dr. S.E. Katz, Animal Drug EIS Consultant
Mr. R.R. Libby, Pesticide 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
Miss C.L. Guise, Secretary
Miss D.M. Ritter, Secretary
Mrs. J. Streisand, Secretary

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

IR-4's field research personnel includes (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.

<table>
<thead>
<tr>
<th>NAME</th>
<th>STATE</th>
<th>TELEPHONE</th>
<th>SPECIALTY AREA</th>
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<th>STATE</th>
<th>TELEPHONE</th>
<th>SPECIALTY AREA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mr. John H. Martini</td>
<td>Pesticide Coor.</td>
<td>(315) 787-2283</td>
<td>Chemistry</td>
<td>Dr. Charles W. Hauser</td>
<td>Pesticide Coor.</td>
<td>(904) 392-8119</td>
<td>Plant Path.</td>
</tr>
<tr>
<td>Dr. John G. Babish</td>
<td>Animal Drug Coor.</td>
<td>(607) 256-6541</td>
<td>Drug&amp;Foreign</td>
<td>Dr. Steve P. Sundlof</td>
<td>Animal Drug Coor.</td>
<td>(904) 392-8141</td>
<td>Veterinary</td>
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<td>Compound Met.</td>
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<tr>
<td>Dr. Richard A. Ashley</td>
<td>CT</td>
<td>(203) 486-3435</td>
<td>Plant Sci.</td>
<td>Dr. Michael Williams</td>
<td>AL</td>
<td>(501) 575-3955</td>
<td>Weed Science</td>
</tr>
<tr>
<td>Mr. Max R. Graustein</td>
<td></td>
<td>(302) 742-8788</td>
<td>Entomology</td>
<td>Dr. Terry L. Levy</td>
<td>AR</td>
<td>(501) 575-3955</td>
<td>Weed Science</td>
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<tr>
<td>Mr. Grady McDonald</td>
<td>NC</td>
<td>(202) 822-7372</td>
<td>Horticulture</td>
<td>Dr. O. Norman Nesheim</td>
<td>FL</td>
<td>(904) 392-4772</td>
<td>Entomology/Tox.</td>
</tr>
<tr>
<td>Mr. Edwin Pletsch</td>
<td>ME</td>
<td>(207) 581-7930</td>
<td>Entomology</td>
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<tr>
<td>Dr. James J. Lindskog</td>
<td>ND</td>
<td>(301) 742-8788</td>
<td>Entomology</td>
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<tr>
<td>Dr. Prasanta Showak</td>
<td>MA</td>
<td>(413) 565-2353</td>
<td>Weed Science</td>
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<tr>
<td>Dr. James Bowman</td>
<td>KY</td>
<td>(603) 862-1159</td>
<td>Entomology</td>
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<tr>
<td>Dr. Jerry Ghidlo</td>
<td>NJ</td>
<td>(609) 455-3100</td>
<td>Entomology</td>
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<tr>
<td>Dr. John H. Martin</td>
<td>NY (Geneva)</td>
<td>(315) 787-2281</td>
<td>(See above)</td>
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<tr>
<td>Dr. Donald A. Rutz</td>
<td>NY (Ithaca)</td>
<td>(607) 255-3283</td>
<td>Entomology</td>
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<tr>
<td>Dr. Ralph O. Musa</td>
<td>PA</td>
<td>(814) 863-4435</td>
<td>Entomology</td>
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<tr>
<td>Dr. A. R. Gottlieb</td>
<td>VA</td>
<td>(802) 656-2630</td>
<td>Plant Path.</td>
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<tr>
<td>Dr. Joe E. Weaver</td>
<td>WV</td>
<td>(304) 293-6023</td>
<td>Entomology</td>
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<tr>
<td>Dr. Ralph E. Webb</td>
<td>ND, USDA-ARS</td>
<td>(301) 741-2269</td>
<td>Entomology</td>
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<tr>
<td>Dr. James C. Locke</td>
<td>ND, USDA-ARS</td>
<td>(301) 741-2269</td>
<td>Entomology/</td>
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<tr>
<td>Mr. J. Ray Frank</td>
<td>ND, USDA-ARS</td>
<td>(301) 741-2269</td>
<td>Plant Path.</td>
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<tr>
<td>Dr. Kenneth R. Hill</td>
<td>ND, USDA-ARS</td>
<td>(301) 741-2269</td>
<td>Residue Chem.</td>
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<tr>
<td>Dr. Robert M. Hollingworth</td>
<td>Reg. Lab. Dir.</td>
<td>(517) 353-9430</td>
<td>Entomology</td>
<td>Dr. Robert L. Hauser</td>
<td>Reg. Lab. Dir.</td>
<td>(916) 752-1142</td>
<td>Chemistry</td>
</tr>
<tr>
<td>Dr. Satoru Miyasak</td>
<td>Pesticide Coor.</td>
<td>(517) 353-9497</td>
<td>Plant Analysis &amp;</td>
<td>Mr. Harold G. Adkins</td>
<td>Pesticide Coor.</td>
<td>(916) 752-1142</td>
<td>Plant Path.</td>
</tr>
<tr>
<td>Dr. R.K. Ringer</td>
<td>Animal Drug Coor.</td>
<td>(517) 353-8414</td>
<td>Entomology &amp;</td>
<td>Mr. Harold G. Adkins</td>
<td>Animal Drug Coor.</td>
<td>(916) 752-1142</td>
<td>Veterinary</td>
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<td>Entomology &amp;</td>
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<tr>
<td>Dr. David E. Foster</td>
<td>IA</td>
<td>(515) 294-1101</td>
<td>Entomology</td>
<td>Dr. Jeff Conn</td>
<td>IA</td>
<td>(907) 479-7614</td>
<td>Weed Science</td>
</tr>
<tr>
<td>Dr. David J. Williams</td>
<td>MD</td>
<td>(217) 333-2126</td>
<td>Entomology</td>
<td>Dr. Paul B. Baker</td>
<td>IA</td>
<td>(907) 479-7614</td>
<td>Weed Science</td>
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<tr>
<td>Dr. Richard X. Latin</td>
<td>IN</td>
<td>(317) 494-4639</td>
<td>Plant Path</td>
<td>Dr. Ralf F. Coleman</td>
<td>IN</td>
<td>(907) 479-7614</td>
<td>Weed Science</td>
</tr>
<tr>
<td>Dr. Don Cress</td>
<td>KS</td>
<td>(913) 532-5891</td>
<td>Entomology</td>
<td>Dr. Michael R. Coleman</td>
<td>IN</td>
<td>(907) 479-7614</td>
<td>Weed Science</td>
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<tr>
<td>Dr. Satoru Miyasak</td>
<td>WI</td>
<td>(517) 353-9497</td>
<td>Plant Path</td>
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<tr>
<td>Dr. Leonard B. Hertz</td>
<td>MD</td>
<td>(612) 624-3665</td>
<td>Horticulture</td>
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<tr>
<td>Dr. John D. Halewaja</td>
<td>ND</td>
<td>(702) 377-7971</td>
<td>Weed Science</td>
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<tr>
<td>Dr. Roger Gold</td>
<td>NE</td>
<td>(612) 472-1446</td>
<td>Entomology</td>
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<tr>
<td>Dr. Alec Waldrum</td>
<td>OH</td>
<td>(614) 292-7541</td>
<td>Entomology &amp;</td>
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<tr>
<td>Mr. Leon J. Wrage</td>
<td>SD</td>
<td>(605) 688-5121</td>
<td>Plant Path</td>
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<tr>
<td>Dr. Chuck Koval</td>
<td>WI</td>
<td>(608) 262-6608</td>
<td>Entomology</td>
<td>Dr. Howard Deer</td>
<td>WI</td>
<td>(801) 750-1600</td>
<td>Pesticides</td>
</tr>
<tr>
<td>Dr. T. L. Ladd</td>
<td>OH, USDA-ARS</td>
<td>(216) 263-3898</td>
<td>Entomology</td>
<td>Mr. Richard C. Maxwell</td>
<td>WA</td>
<td>(509) 355-2995</td>
<td>Plant Path.</td>
</tr>
<tr>
<td>Dr. Charles Krause</td>
<td>OH, USDA-ARS</td>
<td>(614) 363-1129</td>
<td>Plant Path/</td>
<td>Mr. Everett Spackman</td>
<td>WA</td>
<td>(509) 766-4261</td>
<td>Plant Path.</td>
</tr>
<tr>
<td>Dr. Loud M. Wask</td>
<td>IL, USDA-ARS</td>
<td>(217) 333-1277</td>
<td>Entomology</td>
<td>Dr. Robert G. Linderman</td>
<td>OR, USDA-ARS</td>
<td>(503) 757-4544</td>
<td>Plant Path/Phys. Tox.</td>
</tr>
<tr>
<td>Dr. William M. Doane</td>
<td>IL, USDA-ARS</td>
<td>(309) 685-4011</td>
<td>Physical Chem.</td>
<td>Mr. Eric Halfhill</td>
<td>WA, USDA-ARS</td>
<td>(509) 575-5982</td>
<td>Entomology</td>
</tr>
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<td></td>
<td></td>
<td>Mr. Leslie M. McDonough</td>
<td>WA, USDA-ARS</td>
<td>(509) 575-5982</td>
<td>Entomology/Tox.</td>
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<td>Dr. Rick Boydton</td>
<td>WA, USDA-ARS</td>
<td>(509) 786-2226</td>
<td>Weed Science</td>
</tr>
</tbody>
</table>

**Northeastern Region**

**Southern Region**

**Northcentral Region**

**Western Region**

**Revised 1/21/88**
8. PROGRESS OF WORK AND PRINCIPAL ACCOMPLISHMENTS:

(A) FOOD USE RESEARCH PROJECTS:

There are currently 3671 total IR-4 food-use requests, an increase of 507 over the 3164 requests reported last year. Of these, 1085 are characterized as researchable projects. During 1987, the four IR-4 Regions and USDA-ARS scheduled research on 229 food-use projects, from which residue samples for 116 projects went to state and USDA-ARS cooperating laboratories and samples for 53 projects went to chemical company laboratories. With the completion of 1987 and prior research projects, data requirements will be fulfilled for an additional 126 minor use needs. Research protocols for 428 requests were prepared or revised and the following pesticides/commodities were researched in 1987:

(1) FUNGICIDES AND NEMATICIDES:

Anilazine/watercress - Benomyl/cauliflower, endive, grape, mint, parsley, pistachio, potato, sorghum (grain), spinach, sunflower, sweet potato, sweet sop - Captan/lettuce, onion (green) - Carbboxin/cantaloup, eggplant, pepper (bell), tomato - Chlorothalonil/Chinese broccoli, eggplant, kohlrabi, pepper (non-bell) - Copper Hydroxide/dill, ginseng - Copper Sulfate/sweet sop - DCNA/bean (snap), leaf-cutting bee - Fenamiphos/acerola, bean (snap), beet, blueberry, bok choy, cantaloup, kiwifruit, onion (dry bulb), pea (green), pepper (bell), southern pea, squash, strawberry, watermelon - Ipromione/bok choy, broccoli raab, cabbage, cherry, Chinese broccoli, Chinese cabbage (tight), Chinese mustard, collard, endive, kale, kohlrabi, leek, mint, nectarine, parsley, peach, pepper (bell), plum, radish, safflower - Mancozeb/mango - Metalaxyl/kiwifruit, tanier - Triforine/cantaloup, cucumber, okra, pumpkin, squash (summer)

(2) HERBICIDES AND PLANT GROWTH REGULATORS:

Acifluorfen/perennial peanut, strawberry - Ametryn/cassava, tanier - Bensulide/asparagus - Bentazon/perennial peanut - 2,4-D/blueberry, cranberry, raspberry - DCFA/daikon, ethylcollar, kale - Diquat/cassava, eggplant, pepper (bell), pepper (non-bell), tanier, tomato - Fluazifop/avocado, basil, Chinese cabbage (non-tight), collard, eggplant, mango, parsley, perennial peanut, pigeon pea, rhubarb, safflower, tyfon - Gibberellic Acid/watercress - Glyphosate/asparagus, broccoli, celery, cranberry, garlic, greens (mustard), leek, mango, onion (dry), onion (green), spinach, turnip (root & top) - Metolachlor/broccoli, cabbage, carrot, cauliflower, celery, leek, pepper (non-bell), pigeon pea, radish - Metribuzin/Bermudagrass - Oxyfluorfen/broccoli, cabbage, cantaloup, cauliflower, clover (ladino, red), cucumber, horseradish, pepper (bell), squash, strawberry, tomato, watermelon - Paraquat/broccoli, cucumber, pumpkin - Prometryn/coriander - Pronamide/Brussels sprout, cabbage, cauliflower, collard, coriander, cranberry, kale, parsley, Swiss chard - Pyrazon/Swiss chard - Sethoxydim/basil, buckwheat, celery, parsley, perennial peanut - Simazine/Brussels sprout, cauliflower, collard, kohlrabi, mango - Sodium Chlorate/bean (mung) - Tertbutyl/watermelon - Tertbutryn/ sugarcane - Thiobencarb/bok choy, parsley
8A. Continued

(3) INSECTICIDES, MITICIDES, MOLLUSCICIDES AND RODENTICIDES:

Amitraz/honey bee – Bacillus thuringiensis/pigeon pea, pineapple – Calcium Cyanide/honey bee – Carbaryl/ginseng, mango, yam – Carbofuran/clover – Chlorpyrifos/bean (snap), cranberry, millet, onion (green), raspberry – Cypermethrin/clover – Cyromazine/bok choy, calves (beef & dairy) – Diazinon/banana, cranberry, pistachio, plantain, sugarcane – Dithane/asparagus, bok choy, Brussels sprout, kohlrabi, squash, strawberry, tanier – Dusulfoton/bok choy, greens (mustard) – Epsom/sulfate/bean (mung), beet, Chinese broccoli, Chinese cabbage (non-tight), clover (sweet), collard, endive, greens (mustard), greens (turnip), kale, mango, onion (dry), onion (green), pigeon pea, strawberry, sweet potato – Formetanate Hydrochloride/peach – Hexakis/tomato, watermelon – Methidathion/ carambola, kiwifruit, longan, sweetsop, tanier – Methomyl/broccoli raab, greens (rape), kohlrabi – Oxamyl/pepper (non-bell) – Permethrin/cardoon, carrot, Chinese cabbage (non-tight), cucumber, radicchio, squash, tomato – Propargite/cucumber, pepper (bell) – Thiodicarb/endive, escarole

In summary, the IR-4 Project sponsored research on over 90 individual commodities in 1987.

The Fourth IR-4/EPA National Food-Use Workshop* was held in Northbrook, IL on September 22-23, 1987. Ninety-five representatives from SAES, USDA-ARS, EPA, the pesticide chemical industry and commodity producers attended the meeting. Special effort was made at this workshop to include commodity producers. Consequently, there were 14 representatives from various commodity groups, including B&W Quality Growers, J.R. Brooks & Sons, California Prune, Raisin and Walnut Marketing Board, Campbell Soup Company, Del Monte, A. Duda & Sons, Florida Fruit and Vegetable Association, Gerber Foods, McCormick, Michigan Blueberry Growers Association, and Zellwin Farms. The success of this meeting was due in large measure to the participation of these producers of minor and specialty crops who have first hand knowledge of pest problems and pesticide needs in the various commodity areas.

Four hundred and twenty-one pesticide clearance requests which require national (multi-regional) data for registration were reviewed by the three working groups (Entomology, Plant Pathology and Weed Science). They identified 174 of these requests as high priority. Seventy-four requests were designated as medium priority and the remainder were categorized as either low priority or could be deleted as a researchable project after contacting the requester.

In October, the IR-4 State & Federal Liaison Representatives in the Regional Committees selected the active research projects for 1988. They reviewed and prioritized the national (multi-regional) researchable projects and the researchable projects for LDI crops for their region. Since tolerances and labels are possible for LDI crops on the basis of regional or even state data, no one knows better what these priority needs are than the scientists who comprise the Regional Committees. Each region struck a balance in funding between projects requiring national data and projects requiring only geographically representative data. The research program was finalized at the National Research Planning Meeting (NRPM) which was held at IR-4 Headquarters

* This workshop was funded by a grant from EPA.
8A. Continued

in December. At the NRPM, the IR-4 Headquarters Pesticide Program Scientists, the IR-4 Pesticide Regional Coordinators, the IR-4 Regional Laboratory Supervisors, the USDA-ARS Staff Scientist and the USDA-ARS Laboratory Supervisors formulated a cooperative research program to establish field research and designate laboratories to analyze residue samples.

(B) DEVELOPMENT AND REGULATORY SUCCESSES:

IR-4 HQ prepared 48 tolerance and crop definition petitions in calendar year 1987. Thirty-nine petitions were submitted to EPA and nine petitions are still under review by the manufacturers (eventual label registrants) prior to EPA submission. Additionally, four 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 low dietary intake (LDI) crops for which tolerances can be established with geographically representative data. In line with this policy, the following clearances which have the (R) designation are tolerances with regional registrations. During 1987, IR-4 petition submissions resulted in pesticide actions representing 96 pesticide/commodity tolerances including one crop definition. These are reviewed in detail below:

(1) FUNGICIDES (8 tolerances):
Benomyl/pistachio (R), watercress (R) - Fosetyl Al/asparagus (R) - Iprodione/carrot, ginseng (fresh & dry) - Oxytetracycline/pear, pear (Oriental)

(2) HERBICIDES (19 tolerances):
Fluazifop/sweet potato, tabasco pepper (R), yam - Metolachlor/tabsaco pepper (R) - Metribuzin/carrot - Oxyfluorfen/broccoli, cabbage, cauliflower, Chinese broccoli, Chinese cabbage (tight), guava (R) - Paraquat/cassava (R), pigeon pea (R), tanier (R), tyfon (R), yam (R) - Sethoxydim/flaxseed, straw and meal

(3) INSECTICIDES AND MITICIDES (47 tolerances):
Chlorpyrifos/blueberry, date (R), leek (R) - Fenvalerate/blueberry, broccoli raab, caneberry (blackberry, boysenberry, dewberry, loganberry, raspberry, youngberry and varieties of these), currant, elderberry, gooseberry, hanover salad, huckleberry, okra (R), turnip (root & top) - Magnesium Phosphide/sweet potato, yam - Malathion/Brassica leafy vegetables, chayote (fruit & root), non-Brassica leafy vegetables - Permethrin/brccoli raab (R), collard (R), hanover salad (R), turnip (root & top) (R) - Phosmet/pistachio (R)

(4) CROP DEFINITION (22 tolerances):
Nectarine = Peach

Additionally, one crop definition and four tolerances were proposed. These proposals will become clearances in 1988.
SB. Continued

Certain tolerances requested by IR-4 have not been established because EPA through its Pesticide Re-registration Program has indicated that the existing data bases are not adequate to support the tolerances at this time; e.g. metabolism, toxicology and environmental fate studies. These data gaps, especially for those products that were registered before 1982, have surfaced because of the current guidelines which must be addressed for all products under re-registration. Further, certain re-registration standards require additional residue data for established uses, including minor uses. In many cases, these new studies are being addressed by the manufacturers, but some of the studies may take up to five years to complete. However, due to the cost of re-registration, some of the older products or uses are being voluntarily cancelled by the manufacturers. This has resulted in additional pest management voids for many crops, especially minor crops.

IR-4 continues to have a meaningful dialogue with EPA's Residue Chemistry and Toxicology Branches concerning current residue and toxicology data requirements for various pesticide uses. 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 were published on 28 DEC 87. IR-4 has initiated revision of its R&D forms and field and laboratory guides to comply with the draft guidelines. Additionally, the IR-4 laboratory procedures have been reviewed for compliance purposes.

2) Endangered Species - EPA regularly consults with the USDI-U.S. Fish and Wildlife Service to determine whether the use of a particular pesticide will jeopardize an endangered or threatened species. If jeopardy exists, EPA will take action to eliminate or otherwise modify the use of the pesticide to preclude jeopardy. County range maps have been developed by the U.S. Fish and Wildlife Service which identify the general locations of the affected endangered species. EPA will utilize the maps to restrict or prohibit the use of certain pesticides in the range of the jeopardized species.

3) Inert Ingredients - EPA has increased its concerns about certain inert ingredients in pesticide formulations. EPA published (22 APR 87, Federal Register) a list (List 1) of 57 inert ingredients which are of toxicological concern. Registrants who retain an inert of toxicological concern in their products will be subject to data call-in under FIFRA. EPA may require as much data as would be required for an active ingredient. This notice also has a list (List 2) of 67 inert ingredients which are considered potentially toxic inerts which have a high priority for testing. The inert ingredients on this list are being tested and some could be moved to List 1, if data so indicate, becoming subject to the restrictions of that category.

4) Groundwater - Requests that include 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.
(C) ORNAMENTAL RESEARCH AND DEVELOPMENT:

During the 10 1/2 years the IR-4 Ornamentals Program has been in existence (APR 77 - NOV 87), IR-4 has undertaken 11,138 ornamental research trials. In 1987, the IR-4 Project funded 671 ornamental research trials, and IR-4 HQ prepared registration packages for 15 pesticides (1 fungicide, 10 herbicides, 2 insecticides, 1 nematicide and 1 PGR) which were submitted to potential registrants. During 1987, IR-4 data were used to support 327 ornamental pesticide registrations. Since 1977, the total number of label registrations on ornamentals is 2,603 or an average of about 20 clearances per month. Ornamental registrations that were supported by IR-4 data in 1987 include:

<table>
<thead>
<tr>
<th>PESTICIDE</th>
<th>ORNAMENTAL USES OR SPECIES REGISTERED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abamectin (AVID\textsuperscript{0.15EC})</td>
<td>Control of leafminers and twospotted spider mites on flower crops, foliage plants and other non-woody ornamental plants including: ageratum, alocasia, alyssum, anthurium, asplenium, aster, calendula, chrysanthemum, English daisy, Shasta daisy, dahlia, dianthus, dieffenbachia, dusty miller, ficus, gypsophila, hydrangea, lobelia, marigold, nepthytis, pansy, periwinkle, petunia, poinsettia, primrose, salvia, schefflera, snapdragon, syngonium, spathiphyllum, verbena, and zinnia.</td>
</tr>
<tr>
<td>Dimethoate (DIMETHOATE 267)</td>
<td>Control of thrips on anthurium (HI only).</td>
</tr>
<tr>
<td>Etridiazole (TERRAZOLE\textsuperscript{5G})</td>
<td>Control of damping-off and root rot diseases caused by Pythium and Phytophthora at the time of seeding or transplanting in nurseries and greenhouses on plants including: carnation, coleus, dianthus, foxglove, larkspur and pansy.</td>
</tr>
<tr>
<td>Etridiazole (TERRAZOLE\textsuperscript{35WP})</td>
<td>Control of damping-off, root and stem diseases caused by Pythium and Phytophthora on plants including: caladium, carnation, gerbera, gypsophila, juniper, statice and yew.</td>
</tr>
<tr>
<td>Fosetyl AL (ALIETTE\textsuperscript{80W})</td>
<td>Control of Phytophthora and Pythium as a foliar spray on aglaonema, azalea, boxwood, juniper, and rhododendron (field and greenhouse).</td>
</tr>
</tbody>
</table>
### PESTICIDE

| Glyphosate (ROUNDUP®) | Control of weeds around a wide variety of shade trees, ornamentals and shrubs as a directed spray including: African violet, alder, apricot (ornamental), arborvitae, arctotheca, Areca palm, artemesia, ash, aster, azalea, baccharis, bayberry, beech, birch, Bishop pine, boxwood, capeweed, carnation, cherry (ornamental), Christmas tree, chrysanthemum, cotoneaster, crabapple, crape myrtle, dieffenbachia, dogwood, Douglas fir, dracena, Easter lily, elm, English ivy, euonymous, false cypress, fatshedera, ficus, fir, firethorn, forsythia, Fraser fir, gardenia, geranium, gladiolus, golden rain tree, hackberry, hawthorn, hedera, hemlock, hickory, holly, honey locust, hyporicum, jack pine, Japanese spurge, japonica, jasmine, juniper, lantana, lavender cotton, ligustrum, lilac, linden, liriope, locust, loquat, magnolia, mahonia, maple, mountain ash, mountain laurel, myoporum, nandina, Norfolk Island pine, oak, orchid, pachysandra, palm, peach (ornamental), pear (ornamental), pennisetum, peony, periwinkle, petunia, philodendron, photinia, pine, pittosporum, plane tree, plum (ornamental), podocarpus, poinsettia, poplar, potentilla, potnos, privet, pyracantha, quince (ornamental), red bud, red maple, rhododendron, rose, salvia, schefflera, Scotch pine, sedum, snapdragon, spruce, St. Johnswort, star jasmine, viburnum, walnut (ornamental), weigela, white birch, willow, yellow birch and yew. |
| Iprodione (CHICO®26019) | Control of various diseases as a foliar or drench application in container, field-grown and greenhouse-grown ornamentals including: ajuga, andromeda, apherandra, artemesia, azalea, bee balm, calendula, carnation, cineraria, cumbine, coral bells, crape myrtle, cyclamen, deutzia, dianthus, dogwood, episcia, gazania, gloxinia, hawthorn, holly, hydrangea, juniper, pachysandra, peach (ornamental), periwinkle, phlox, pine, pittosporum, poinsettia, poppy, primrose, privet, protea, pyracantha and violet. |
| Mancozeb (MANZATE®200) | Control of various diseases in field, nursery or greenhouse grown ornamentals including: aglaonema, almond, andromeda (pieris), Areca palm, baby's breath (gypsophila), birch, boxwood, cotoneaster, crassula, croton, daisy, dusty miller, horsechestnut, ivy, lavender cotton, liriope, mahonia (Oregon grape), maranta, nephthytis, osmanthus, peach (ornamental), peperomia, periwinkle, petunia, piggyback plant, pilea, Norfolk Island pine, pittosporum, plane tree, plum (ornamental), primrose, privet, protea, redwood, sand cherry, sansevieria, strawflower, velvet plant, willow, yucca, and zebra plant (aphelandra). |
### PESTICIDE

<table>
<thead>
<tr>
<th>PESTICIDE</th>
<th>ORNAMENTAL USES OR SPECIES REGISTERED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metolachlor</td>
<td>Control of many annual grasses, certain broadleaf weeds and yellow nutsedge in field and liner grown ornamentals including: (Same species as labeled for DUAL® plus heavenly bamboo, jasmine, photinia, pine, podocarpus, and spruce).</td>
</tr>
<tr>
<td>(PENNANT®5G)</td>
<td></td>
</tr>
<tr>
<td>Oxyfluorfen +</td>
<td>Control of weeds in container and field grown ornamentals including: abelia, andromeda, bog rosemary, dogwood, mahonia, nandina, pine, pyracantha, spirea, and ternstroemia.</td>
</tr>
<tr>
<td>Oryzalin (ROUT®)</td>
<td></td>
</tr>
</tbody>
</table>

A special Ornamentals Steering Committee meeting was held on September 24-25, 1987 to prioritize the researchable requests for pesticides on ornamentals. This core group representing the disciplines of entomology, plant pathology, nematology and weed science, met to evaluate the many ornamental requests which have not been prioritized since the last Ornamentals Workshop in 1984. In addition to the 22 invited scientists there were 12 other participants representing IR-4 Headquarters, the IR-4 regions, the ornamentals industry and USDA-CSRS. A grant from EPA provided partial funding for this meeting.

**(D) BIORATIONAL RESEARCH AND DEVELOPMENT:**

The IR-4 Biorational Program was established to help develop biological (microbial and biochemical) control agents for economically important pests. September, 1987 marks the completion of five years of the IR-4 Biorational Program.

In 1987, IR-4, in conjunction with Dr. L. Falcon of the University of California at Berkeley, wrote a petition proposing a temporary exemption from the requirements of a tolerance for the codling moth granulosis virus (CMGV) on apples, pears, plums and walnuts. The CMGV will be produced at the University of California. Based on the data contained in this petition, Dr. L. Falcon obtained an Experimental Use Permit (EUP) for the use of CMGV in apple, pear, plum and walnut production. The EUP, which was approved by EPA in September 1987, is for a period of two years.

In 1987, IR-4 in conjunction with Drs. T. Dennehy and W. Roelofs of the New York Agricultural Experiment Station, wrote a petition proposing a temporary exemption from the requirements of a tolerance for the biochemical pesticide, grape berry moth pheromone dispensers (GB-ROPE), containing the active ingredients (Z)-9 dodeceny acetate and (Z)-11 tetradecenyl acetate, as part of an Experimental Use Permit (EUP). Under the proposed EUP program, the grape berry moth pheromone dispensers (GB-ROPE) would be evaluated for the control of the grape berry moth on up to 100 acres of grapes in New York from 1987 to 1989. The above petition was submitted to EPA in July, 1987.
8. Continued

(E) ANIMAL DRUG RESEARCH AND DEVELOPMENT:

Since 1983, 161 animal drug requests have been submitted to IR-4 Headquarters. One hundred twenty-three animal drug requests are in various stages of evaluation, 12 are ongoing research projects and 18 cannot be cleared because of significant data gaps. Eight clearances have been published in the Federal Register for the following:

<table>
<thead>
<tr>
<th>ADR NO.</th>
<th>SPECIES</th>
<th>DISEASE CLAIM</th>
<th>DRUG</th>
<th>COOPERATING INSTITUTIONS</th>
<th>PUBLICATION DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Goat</td>
<td>Coccidiosis</td>
<td>Monensin</td>
<td>Texas A &amp; M Univ./Eli Lilly Co.</td>
<td>12/19/86</td>
</tr>
<tr>
<td>2</td>
<td>Pheasant</td>
<td>Coccidiosis</td>
<td>Amprolium</td>
<td>Pennsylvania State Univ./Merck &amp; Co.</td>
<td>12/24/84</td>
</tr>
<tr>
<td>4</td>
<td>Catfish</td>
<td>Enteric Septicemia</td>
<td>Sulfadimethoxine &amp; Ormetoprim</td>
<td>Mississippi State Univ./Hoffmann-LaRoche</td>
<td>4/16/86</td>
</tr>
<tr>
<td>5</td>
<td>Pheasant</td>
<td>Gapeworm</td>
<td>Thiabendazole</td>
<td>Pennsylvania State Univ./Merck &amp; Co.</td>
<td>2/22/84</td>
</tr>
<tr>
<td>11</td>
<td>Reindeer</td>
<td>Warbles</td>
<td>Ivermectin</td>
<td>University of Alaska/Merck &amp; Co.</td>
<td>12/24/84</td>
</tr>
<tr>
<td>15</td>
<td>Lobster</td>
<td>Gaffkemia</td>
<td>Oxytetracycline</td>
<td>University of Maine/Pfizer &amp; Co.</td>
<td>1/13/86</td>
</tr>
<tr>
<td>111</td>
<td>Goat</td>
<td>Coccidiosis</td>
<td>Deccoquinate</td>
<td>Washington State Univ./Rhône-Poulenc Inc.</td>
<td>2/18/87</td>
</tr>
<tr>
<td>114</td>
<td>Quail</td>
<td>Coccidiosis</td>
<td>Monensin</td>
<td>USDA-Agricultural Research Service/Eli Lilly Co.</td>
<td>4/13/87</td>
</tr>
</tbody>
</table>
Public Master Files for the following five projects are currently under review by FDA-Center for Veterinary Medicine (CVM):

<table>
<thead>
<tr>
<th>ADR NO.</th>
<th>SPECIES</th>
<th>DISEASE CLAIM</th>
<th>DRUG</th>
<th>REGION</th>
<th>COOPERATING INSTITUTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>17</td>
<td>Goat</td>
<td>Gastrointestinal parasites</td>
<td>Ivermectin</td>
<td>NCR</td>
<td>University of Nebraska/Merck &amp; Co.</td>
</tr>
<tr>
<td>30</td>
<td>Quail</td>
<td>Ulcerative enteritis</td>
<td>Bacitracin M.D.</td>
<td>SOR</td>
<td>University of Florida/A.L. Labs</td>
</tr>
<tr>
<td>115</td>
<td>Quail</td>
<td>Coccidiosis</td>
<td>Salinomycin</td>
<td>NER</td>
<td>USDA-Agricultural Research Service/ A.H. Robbins Co.</td>
</tr>
<tr>
<td>125</td>
<td>American Bison</td>
<td>Hypodermosis</td>
<td>Ivermectin</td>
<td>NCR</td>
<td>Michigan State University/Merck &amp; Co.</td>
</tr>
<tr>
<td>127</td>
<td>Bighorn Sheep</td>
<td>Lungworms</td>
<td>Fenbendazole</td>
<td>WSR/HQ</td>
<td>Washington State University/Hoechst- Roussel Agri-Vet Co.</td>
</tr>
</tbody>
</table>

The research for the following five projects is completed and data will be filed with FDA-CVM in early 1988:

<table>
<thead>
<tr>
<th>ADR NO.</th>
<th>SPECIES</th>
<th>DISEASE CLAIM</th>
<th>DRUG</th>
<th>REGION</th>
<th>COOPERATING INSTITUTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>33</td>
<td>Goat</td>
<td>Bacterial Pneumonia</td>
<td>Amoxicillin</td>
<td>WSR</td>
<td>University of California/Beecham Labs</td>
</tr>
<tr>
<td>59</td>
<td>Goat</td>
<td>Bacterial Pneumonia</td>
<td>Sulfamethazine</td>
<td>WSR</td>
<td>University of California/Norden Labs</td>
</tr>
<tr>
<td>74</td>
<td>Sheep</td>
<td>Bacterial Pneumonia</td>
<td>Sulfamethazine</td>
<td>WSR</td>
<td>University of Idaho/Norden Labs</td>
</tr>
<tr>
<td>87</td>
<td>Sheep</td>
<td>Bacterial Pneumonia</td>
<td>Amoxicillin</td>
<td>WSR</td>
<td>University of Idaho/Beecham Labs</td>
</tr>
<tr>
<td>122</td>
<td>Rabbit</td>
<td>Coccidiosis</td>
<td>Lasalocid</td>
<td>SOR</td>
<td>University of Arkansas/Hoffman-LaRoche</td>
</tr>
</tbody>
</table>
The following 12 ongoing research projects were established in cooperation with seven universities, USDI-Fish and Wildlife Service, USDA-Agricultural Research Service and ten pharmaceutical companies:

<table>
<thead>
<tr>
<th>ADR NO</th>
<th>SPECIES</th>
<th>DISEASE CLAIM</th>
<th>DRUG</th>
<th>REGION</th>
<th>COOPERATING INSTITUTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>18</td>
<td>Salmonids</td>
<td>Bacterial gill disease</td>
<td>Chloramine-T</td>
<td>NER/NCR/HQ</td>
<td>USDI-Fish and Wildlife Service/ Wisconsin Pharmacal Co.</td>
</tr>
<tr>
<td>31</td>
<td>Merganser Duck</td>
<td>Schistosomiasis</td>
<td>Praziquantel</td>
<td>NCR</td>
<td>Hope College/Bayvet Labs.</td>
</tr>
<tr>
<td>43</td>
<td>Goat</td>
<td>Bacterial pneumonia</td>
<td>Oxytetracycline</td>
<td>WSR</td>
<td>University of Idaho/Pfizer &amp; Co.</td>
</tr>
<tr>
<td>66</td>
<td>Dairy Goat</td>
<td>Mastitis</td>
<td>Novobiocin &amp; Procaine Penicillin G</td>
<td>WSR</td>
<td>University of California/Upjohn Co.</td>
</tr>
<tr>
<td>83</td>
<td>Sheep</td>
<td>Bacterial pneumonia</td>
<td>Oxytetracycline</td>
<td>WSR</td>
<td>University of Idaho/Pfizer &amp; Co.</td>
</tr>
<tr>
<td>112</td>
<td>Goat</td>
<td>Liver fluke</td>
<td>Clorsulon</td>
<td>SOR</td>
<td>University of Florida/Merck &amp; Co.</td>
</tr>
<tr>
<td>124</td>
<td>Goat</td>
<td>Gastrointestinal parasites</td>
<td>Fenbendazole</td>
<td>NCR</td>
<td>University of Nebraska/Hoechst-Roussel Agri-Vet. Co.</td>
</tr>
<tr>
<td>128</td>
<td>Swine</td>
<td>Coccidiosis</td>
<td>Amprolium</td>
<td>SOR</td>
<td>Auburn University/Merck &amp; Co.</td>
</tr>
<tr>
<td>134</td>
<td>Goat</td>
<td>Gastrointestinal parasites</td>
<td>Levamisole</td>
<td>NER</td>
<td>University of Massachusetts/ Pittman-Moore, Inc.</td>
</tr>
<tr>
<td>135</td>
<td>Salmonids</td>
<td>Bacterial kidney disease (BKD)</td>
<td>Erythromycin</td>
<td>WSR</td>
<td>University of Idaho/Ceva Labs.</td>
</tr>
<tr>
<td>137</td>
<td>Chukar Partridge</td>
<td>Coccidiosis</td>
<td>Sulfadimethoxine &amp; Ormetoprim</td>
<td>NER</td>
<td>USDA-Agricultural Research Service/ Hoffman-LaRoche</td>
</tr>
<tr>
<td>138</td>
<td>American Alligator</td>
<td>Bacterial infections</td>
<td>Virginiamycin</td>
<td>SOR</td>
<td>University of Florida/SmithKline Animal Health Products</td>
</tr>
</tbody>
</table>
8E. Continued

The Fourth IR-4/FDA National Workshop for Minor Uses of New Animal Drugs* was held in Rockville, MD on September 15-16, 1987. There was a pre-workshop symposium sponsored by The Center for Veterinary Medicine (CVM) on September 14. The objective of the CVM's symposium was to review the progress that has been made by the minor use cooperative agreements supported by CVM. The primary objective of these cooperative agreements was to generate basic metabolism and pharmacokinetic data that might be useful in extrapolating information between animal species.

One hundred and seventy scientists from academia, CVM, USDI-Fish and Wildlife Service, USDA-Cooperative State Research Service, USDA-Agricultural Research Service, the pharmaceutical industry and animal producer associations met to: (1) define prevalent diseases and drug needs for minor species and minor uses, (2) set priorities for drugs that should be developed for prevalent diseases in minor species, and (3) report on the combined efforts of the IR-4 Project and CVM to clear new animal drugs for minor species.

The Fourth IR-4/FDA National Workshop was organized into five working sessions:

1. Symposium on the Utility of Interspecies Extrapolation in the Approval Process
2. Avian Session
3. Aquaculture Session
4. Ruminant Session
5. Symposium on Fur Bearing Animals, Rabbit and Honey Bee Diseases.

It was the consensus of the groups that additional IR-4/FDA Workshops will be necessary to maintain the current close working relationship.

* This workshop was funded by a grant from FDA.
8. Continued

(F) COORDINATION WITH FEDERAL AND STATE AGENCIES:

USDA-Agricultural Research Service and USD-I-Fish and Wildlife Service scientists cooperated with SAES scientists on 82 food, 281 ornamental and two 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 increased production efficacy. Seventy-eight percent of the states/territories participated in the 1987 research program.

9. USEFULNESS OF FINDINGS:

Without the field and laboratory research conducted by the SAES and USDA-ARS 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 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, which includes the development of biological (microbial and biochemical) control agents, also supports the organic or sustainable farming systems.

10. WORK PLANNED FOR NEXT YEAR:

Since IR-4 is mission oriented with its focus on food and environmental safety, and crop and animal protection, we 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 15% and 20%, 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:


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

December 31, 1987

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

Approved:

Date
1/16/88
S.J. Kleinschuster, Dean and Executive Director
NJAES, Cook College, Rutgers - The State
University of New Jersey

Date
1/20/88
W.B. Wheeler, Chair, Technical Committee
Professor, Food Science and Human Nutrition
University of Florida

Date
1/20/88
N.P. Thompson, Chair, Administrative Advisors
Associate Dean for Research
University of Florida

Attachment:
Glossary of Abbreviations used in this Report
1987 IR-4 ANNUAL REPORT
Glossary of Abbreviations used in this Report

AA - Administrative Advisor
AABD - Antimicrobial and Antiparasitic Drugs Branch
ADR - Animal Drug Request
AEQI - Agricultural and Environmental Quality Institute
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
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
FIFRA - The Federal Insecticide, Fungicide, and Rodenticide Act, as amended
GLP - Good Laboratory Practice
HED - Hazard Evaluation Division
HQ - Headquarters
IPM - Integrated Pest Management
IR-4 - Interregional Research Project Number 4
LDI - Low Dietary Intake
NACA - National Agricultural Chemical 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
RCB - Residue Chemistry Branch
RD - Registration Division
R&D - Research and Development
RSERB - Registration Support and Emergency Response Branch
SAES - State Agricultural Experiment Station
SAR - Southern Region
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
WSR - Western Region