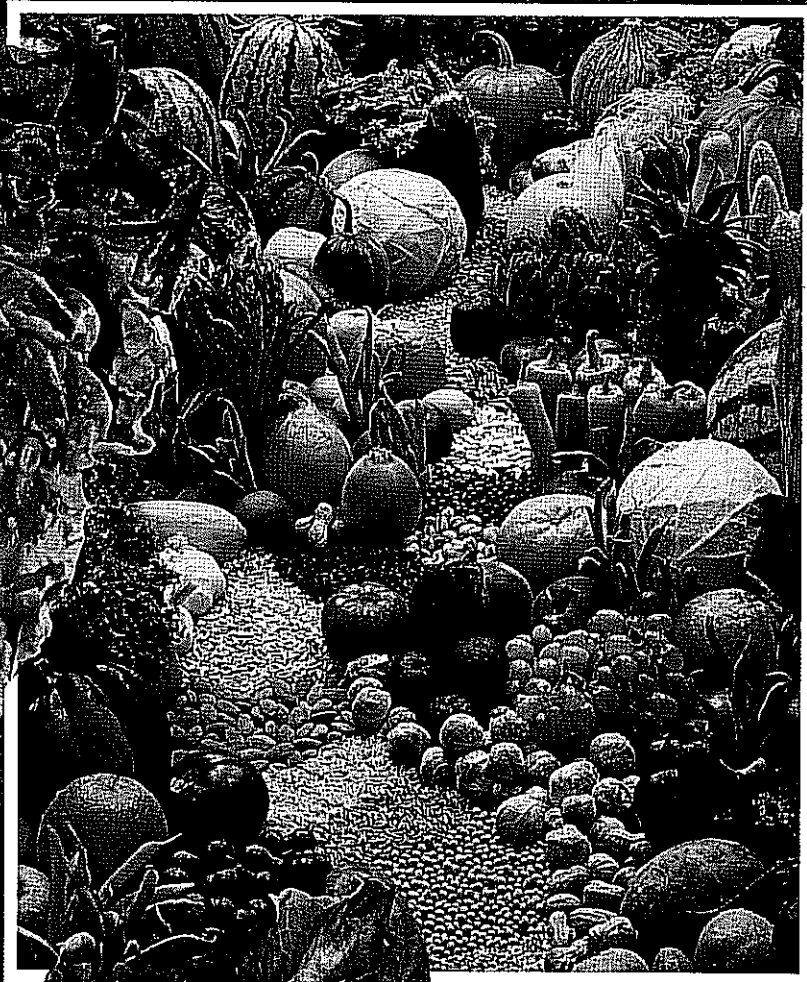


PESTICIDES

MINOR USES/MAJOR ISSUES



COUNCIL FOR AGRICULTURAL SCIENCE AND TECHNOLOGY

COMMENTS FROM CAST 1992-2
JUNE 1992

Council for Agricultural Science and Technology

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Foreword

The CAST National Concerns Committee recommended to the Board of Directors that CAST prepare a report addressing the reregistration of pesticides for minor crops. The topic was approved by the CAST Board of Directors at the February 1991 board meeting.

Dr. Kenneth P. Dorschner, recently retired as Principal Weed Scientist, U.S. Department of Agriculture, Cooperative State Research Service, was selected to serve as chair. A highly qualified group of scientists was chosen and includes persons with expertise in chemistry, entomology, horticulture, nematology, federal pesticide regulation, pest management, toxicology, and weed science.

The authors were responsible for writing the first draft. All authors assisted in revising all subsequent drafts and reviewing the proofs. The CAST Executive and Editorial Review committees reviewed the final draft. The CAST staff provided editorial suggestions and published the document. The chair and authors are responsible for all scientific content in the report.

On behalf of CAST, we thank the authors, who gave of their time and expertise to prepare this report as a contribution of the scientific community to public understanding. We also thank the employers of the

authors, who made the time of the authors available at no cost to CAST. The members of CAST deserve special recognition because the unrestricted contributions they have made in support of the work of CAST have financed the preparation and publication of this report.

This report is being distributed to members of Congress and their staffs, the U.S. Department of Agriculture, Environmental Protection Agency, Food and Drug Administration, Agency for International Development, Office of Technology Assessment, Office of Management and Budget, media personnel, and institutional members of CAST. Individual members of CAST may receive a copy upon request. The report may be republished or reproduced in its entirety without permission. If copied in any manner, credit to the authors and CAST would be appreciated.

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Abbreviations

ADI	Acceptable daily intake
ARS	Agricultural Research Service
CMGV	Codling moth granulosis virus
CSRS	Cooperative State Research Service
EPA	Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act
FIFRA 88	Federal Insecticide, Fungicide and Rodenticide Act as amended in 1988
GLP	Good laboratory practice
IPM	Integrated Pest Management
IR-4	Interregional Research Project No. 4
NACA	National Agricultural Chemical Association
NAPIAP	National Agricultural Pesticide Impact Assessment Program
NPIRS	National Pesticide Information Retrieval System
SAES	State Agricultural Experiment Station
USDA	United States Department of Agriculture

Summary

Vegetables, fruits, nuts, herbs, ornamentals, trees, and turfgrass are often referred to as minor crops because the acreage and volume of production of any one of the many crops in these groups are much below that of corn, soybean, wheat, or any of the other major field crops. Minor crops, as well as major crops, must be protected from insects, weeds, and diseases so as to be economically produced. Specialized pest control needs also exist for major crops in certain situations. Pesticides developed for use on minor crops and to meet the specialized needs for major crops are referred to as minor use pesticides.

Historically, there has always been a problem with the availability of pesticides for minor uses. Registrants traditionally have sought the major markets for their products and labeled those uses that could be justified on the basis of economic returns. The significant time and expense required of registrants to develop the data to support registration of new chemicals and to defend existing uses have left fewer resources for registration of minor uses.

This situation was intensified with enactment of the 1988 amendments to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), which require that all pesticides and their uses registered before November 1984 be reregistered by the end of 1997. Experts now estimate that about 25% of the existing tolerances for pesticide residues on food crops will not be supported by their registrants with new data during the reregistration period. This will have serious implications for growers of minor crops, and even growers of major agronomic crops requiring minor uses of pesticides. This scenario is generally referred to as the minor use pesticide issue.

The intent of this report is to analyze the impacts of the registration and reregistration processes on the availability of pest management tools for minor uses and offer strategies to help resolve this dilemma.

The use of pest control agents is very important for production of fruit and vegetable crops in the United States where consumers demand a high quality product. Estimates show a decline of about 30% in yields with attendant increases of food costs of approximately 50% without the use of pesticides. Further, if U.S. growers are denied appropriate pest control

measures, they will not be competitive in domestic and foreign markets. Some view the competitiveness of agriculture and the agrichemicals industry as being adversely affected by U.S. regulations.

An additional problem occurs as the number of pesticides available for minor uses diminishes. The likelihood for pest resistance to the remaining pesticides used on these commodities increases. Such resistance is best managed through uses of chemicals having diverse mechanisms of toxic action against pests.

Several positive measures have been implemented that address the minor use pesticide registration and reregistration issues. Pesticide registrants who choose to voluntarily cancel uses because of economic considerations may decide to form alliances with interested parties such as grower groups or one of the U.S. Department of Agriculture (USDA) pesticide programs. The USDA and the Environmental Protection Agency (EPA) have recognized the need and implemented a program to alert growers to the consequences of reregistration. Additionally, they have provided a mechanism for communicating their needs to the agrichemical industry and to state and federal agencies. Moreover, growers and grower organizations are recognizing the need to become more involved with the legislative and regulatory processes. And the EPA has adopted regulatory policies that can help reduce the cost of developing data and otherwise facilitate pesticide registrations on minor crops.

Nevertheless, serious impediments to minor use pesticide registration and reregistration exist. They must be addressed expeditiously to meet the 1997 mandated deadline of reregistration. These impediments relate to (1) financial profitability versus liability for registrants of pesticides; (2) facilities, staffing, and stable funding to conduct field and laboratory research to support the 25% of existing food tolerances that are expected to be lost; (3) coordination of state and federal minor crop programs for implementing new technology; and (4) regulatory decisions involving data waivers, surrogate data, good laboratory practices, and guidelines for registering biological pest control agents.

This minor use pesticide dilemma can be addressed most effectively by implementing an innovative minor use strategy for the future that will require the cooperative efforts of all parties in the minor use arena. Such a strategy should include the use of biological pesticides and other pest control techniques in an integrat-

ed system of pest management for minor crops. Development of these systems will require adequate resources for the exploratory, developmental, and technology transfer stages. Without this commitment, the minor use dilemma will continue to escalate to the detriment of U.S. producers and consumers.

1 Background

In October 1988, Congress amended the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA 88). As amended, FIFRA 88 requires that all pesticides and their uses registered before November 1984 be reregistered to comply with present standards by the end of 1997. This legislation has most serious implications for the so-called minor crops: vegetables, fruits, nuts, herbs, spices, ornamentals, flowers, trees, turfgrass, and even for major agronomic crops requiring minor uses of pesticides. Minor crops are of major importance in the United States and there is serious concern that pest management on these crops will suffer.

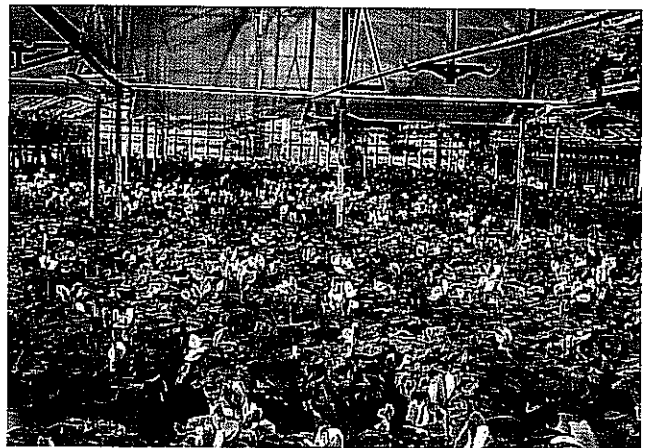
At the time FIFRA 88 was passed, approximately 44,000 registered pesticide products representing 611 active ingredients or groups of related active ingredients (referred to as active ingredient cases) were registered for use in the United States. In this reregistration process, there is an opportunity for registrants to notify the EPA of their intent to comply with current scientific and regulatory standards for registration or, alternatively, to withdraw registration. As of October 1991, the EPA reported that the number of registered products had been reduced to about 20,000, representing 405 active ingredient cases. Most of the lost products reportedly had little or no recent production. Food use chemicals consist of about 232 active ingredient cases and account for 17% of all pesticides registered with the EPA. A serious dilemma arises for minor food crop producers since pesticide tolerances for many of these uses may be revoked by the EPA if the manufacturer or other interested parties are unwilling to provide the data necessary to support them and reregister the uses. This scenario is generally referred to as the minor use pesticide issue.

There are about 10,300 tolerances currently established on raw agricultural commodities and their by-products for pesticide residues. Of these, approximately 2,600 (25%) are established on animals and their by-products and 1,200 (12%) are established on major crops and their by-products including alfalfa, clover, field corn, cotton, grain sorghum, soybean, and wheat. The remaining 63% of the tolerances are established on what are generally considered to be minor crops. They range from almond to zapote and generate roughly 40% of the dollar value of total sales

by all U.S. agricultural producers (Table 1.1). If the by-products, such as fodder, forage, pomace, hulls, etc., are eliminated, there are a total of about 4,300 tolerances of which 90% represent minor crops.

Experts now estimate that 25% of minor use pesticide tolerances will not be supported with data provided by their registrants, leaving about 1,000 tolerances to be supported by other parties or revoked by the EPA. In addition to these tolerances, there are a large number of pesticides registered for use on major crops that have never been registered on minor crops. For some minor crops, these unregistered uses could fill a void where nothing is currently registered. For others, these unregistered uses are more effective and safer or could be used at lower dosage rates than existing registrations for the same use. Most of the uses considered in this report are for minor crops. There also are some pesticide registrations on major crops for uses that are very limited, specific, or sporadic in nature. These are low volume minor uses on major crops. This further illustrates the minor use issue.

The minor use issue is exacerbated by a general lack of communication among growers, registrants, and the EPA. Many minor crop growers feel that they are not fully informed of the ramifications of the reregistration process, and also that registrants are often



Greenhouse grown ornamentals. Photograph courtesy of J. R. Frank, USDA, ARS, Frederick, Maryland.

required to make economic decisions that are not in the growers interests.

In the EPA reregistration process, a list of voluntarily withdrawn or unsupported pesticide products and uses is published in the *Federal Register* and time is allowed for interested parties to respond. This response time gives growers and others a window of opportunity to indicate their willingness to support products or uses that are not supported by the registrants. Often there is insufficient time for growers to evaluate their positions, to notify the EPA and to encourage registrants of critically needed chemicals to generate the data necessary to support the product or use. Growers are very concerned that they will lose these products or uses if they are unable to respond to the EPA or to the registrant in time to meet the short deadlines. In most cases, growers are not prepared to meet the challenges posed by the reregistration process. This is particularly true when the crop is produced in more than one area of the United States and when there are no established commodity or grower groups to address the issues involved. Growers fear a number of the pesticide products or uses they currently require in their pest management and crop production systems will be lost.

Some of the consequences of losing minor use pesticides due to lack of reregistration may be summarized as follows:

- Growers who lose needed pesticides for specific production practices will be at a competitive disadvantage, both foreign and domestic.
- Production of some minor crops will be forced to relocate to avoid pests that lack adequate control methods. Relocation may occur outside the United States.
- Financial hardships may occur, or major adjustments may be required of individual growers who are unable to compete successfully in the marketplace.
- Production costs may increase due to changes in agricultural practices to accommodate changes in pest control tactics with resulting increased costs to consumers.
- Losses due to pests may increase, thereby decreasing the supply and quality of the commodity.
- Prices may rise for certain commodities due to reduced availability.
- Pest resistance will likely increase as a result of fewer choices of pesticides with different modes of action.
- Options for use in Integrated Pest Management (IPM) will be reduced.
- Pesticide usage may increase due to the need to apply less effective materials more frequently and at higher dosages to control pests.

The intent of this report is to focus on the impact of the minor use registration and reregistration processes and offer strategies to help resolve this dilemma.

Table 1.1 Crop sales by states, 1987 (U.S. Department of Agriculture, 1987)

State	Value of minor crops ^a (in \$1,000)	Percent of value of all crops
Alabama	259,447	52
Alaska	7,740	72
Arizona	425,597	47
Arkansas	34,372	3
California	7,357,881	79
Colorado	240,278	31
Connecticut	158,875	96
Delaware	47,989	50
Florida	3,261,154	98
Georgia	697,440	69
Hawaii	497,686	100
Idaho	569,150	52
Illinois	234,627	6
Indiana	137,077	6
Iowa	50,313	1
Kansas	58,908	3
Kentucky	504,433	57
Louisiana	218,716	24
Maine	146,274	93
Maryland	119,890	47
Massachusetts	207,267	96
Michigan	640,830	50
Minnesota	386,085	15
Mississippi	31,254	3
Missouri	87,793	6
Montana	58,875	9
Nebraska	57,992	3
Nevada	22,284	29
New Hampshire	30,990	88
New Jersey	327,859	88
New Mexico	118,737	45
New York	521,008	74
North Carolina	1,057,218	74
North Dakota	194,539	13
Ohio	356,125	20
Oklahoma	127,519	21
Oregon	673,162	64
Pennsylvania	568,522	69
Rhode Island	26,145	98
South Carolina	283,015	63
South Dakota	18,289	2
Tennessee	260,806	37
Texas	732,530	25
Utah	50,980	39
Vermont	16,394	65
Virginia	332,133	71
Washington	1,117,690	66
West Virginia	35,784	73
Wisconsin	396,084	42
Wyoming	41,157	33
United States	23,806,913	40

^aIncludes vegetables, sweet corn, melons, fruits, nuts, berries, tobacco, nursery and greenhouse crops.

2 Current Efforts to Maintain Minor Use Registrations

As the concern over loss of important minor use registrations has grown, the agrichemical industry has become sensitive to the needs of growers of minor crops. Each registrant is making a sincere effort to determine whether or not it can continue to support minor uses for its products either alone, in cooperation with Interregional Research Project No. 4 (IR-4), or by forming alliances with grower groups. Solutions may be possible in instances where the only issue is resources required to conduct a residue study. In other cases, the reason for discontinuing support for a minor use registration may be more complex and less amenable to solution.

IR-4 is the only publicly supported research program in the United States created to register pest control agents for minor uses. It was established in 1963 as part of the State Agricultural Experiment Station (SAES) Regional Research Program. Both the USDA-Cooperative State Research Service (CSRS) and the USDA-Agricultural Research Service (ARS) are active participants in the minor use program. In 1982, objectives to seek clearances for biological agents on agricultural commodities and for therapeutic drugs on minor use animal species were added to the program. IR-4 is part of a national effort to ensure that environmentally safe compounds are used wisely in agriculture.

IR-4 aids the public by helping to maintain a low cost, high quality food supply. It works through producers by developing data to support registrations for pesticides where there is no economic incentive to do so on the part of commercial registrants. The minor use program has been very successful in carrying out this mission. IR-4 has directly supported more than 50% of the pesticide registrations on minor crops since 1970. An important reason for this success is the "grass roots" nature of the program in identifying and prioritizing needs. IR-4 operates through a network of state and federal scientists, called liaison representatives, who interact with farmers, nurserymen, and their respective organizations to identify pesticide registration needs. These needs are prioritized by regional and national committees in an attempt to assure that all crops receive equal consideration.

The passage of FIFRA 88 created additional chal-

lenges for the producers of minor agricultural commodities. The same economic pressures that acted as deterrents for registration of new pesticide uses for minor crops apply also to the reregistration of existing labelled uses. Consequently, the support of important minor use reregistrations was added to the existing minor use registration workload for IR-4. Through national surveys and workshops conducted by IR-4 in cooperation with federal agencies and SAES in 1989, it was estimated that about 1,000 minor use registrations that were important to the agricultural community would be lost to reregistration. IR-4 developed a Strategic Plan to support these uses together with an estimated 2,600 new minor use registrations that would accrue by the conclusion of the 1997 deadline for reregistration. This Strategic Plan called for an increase in the research capacity of the program from 100 completions to 500 completions per year to develop the data required by the EPA to register and reregister 3,600 minor uses; and to expand existing research on biological pesticides for use on minor crops. The cost of achieving this effort was estimated to be \$12 million annually through 1997. However, fewer projects have been completed than originally forecast because of funding shortfalls in FY 1990 and FY 1991. As a result, the current estimate to accomplish a registration/reregistration workload



Cranberry water harvest. Photograph courtesy of Ocean Spray Cranberries, Inc., Lakeville-Middleboro, Massachusetts and Cranberry Institute, East Wareham, Massachusetts.

of 3,360 projects by the end of 1997 means that IR-4 will need to complete 560 projects each year at an annual cost of \$14 million.

The USDA and EPA recognize the need for crop producers to become more aware of the consequences of reregistration and to express their needs in terms of products required to achieve adequate crop protection. As a result, they have joined forces to provide wide distribution of a jointly authored bulletin entitled *Minor Use and Pesticide Reregistration*¹ that discussed reregistration and its possible consequences in terms of reduced availability of pesticides. This publication highlights a joint USDA/EPA/industry program to alert the pesticide user community and others, of notification of voluntary cancellations of registered pesticide labels. With proper knowledge of impending cancellations, it is envisioned that growers will be in a better position to assess their needs and to approach industry, and state and federal agencies to make these needs known. Grower groups are being encouraged to organize and take an active role in the reregistration process by communicating with registrants regarding their crop protection needs and, when necessary, by financially assisting with data development for reregistration or the development of alternatives.

Industry, the EPA, and the USDA have combined forces to develop a Reregistration Notification Network to provide growers with information on impending pesticide cancellations. In addition, the National Agricultural Chemical Association (NACA) member companies have formed a Minor Use Committee to direct decisions on voluntary cancellations to a network consisting of growers, state Extension offices, and federal and state agencies. The USDA through the National Agricultural Pesticide Impact Assessment Program (NAPIAP) is participating in this notification network by distributing cancellation notifications from NACA companies and the EPA to an extensive list of interested parties. Early notification of impending cancellations is intended to provide additional time for user groups affected by the loss of these pesticides to organize, assess the consequences to commodity production, and take action to either influence the registration action or to seek alternatives.

Recognizing the adverse impacts of the voluntary

cancellation by the technical registrants of a large number of registrations for the insecticide, malathion, the Chemical Producers and Distributors Association organized a Malathion Reregistration Coalition to seek alternative measures for maintaining needed uses. Together with IR-4, it appears they will support all needed minor uses of malathion not being supported by the technical registrant.

Farmers and commodity organizations recognize the need to become more proactive in defense of needed pesticide registrations. Increasing numbers of individuals and agricultural organizations are contacting the USDA, the EPA, and their elected representatives in Congress to make known their concerns over adequate pest control alternatives for minor crops. Various organizations and associations, representing commodity producers and processors, have formed alliances to propose legislation intended to aid in the minor use pesticide issue.

One initiative used by growers to maintain registrations is the "third party registration," a mechanism outlined under FIFRA that permits the registration of a pesticide by an entity other than the chemical manufacturer or distributor. It has been used in the past to address liability concerns from a crop perspective. Any interested organization (such as a grower group) may engage in a limited use of a pesticide on a crop by indemnifying, or holding harmless, a chemical company from potential damage to the crop.

A limited number of third party registrations have been obtained since 1976, with many of these involving state labels. The following list represents recent examples of labels now in use in the United States, most of which include some type of waiver of liability or hold-harmless agreement between the new registrant and the manufacturer or formulator:

- California Grape and Tree Fruit League—Pro-Gibb^{®2} on grapes in California.
- Columbia Basin Vegetable Seed Association—Dual^{®3} on seed radish other than Daikon.
- New Mexico Department of Agriculture—Dual[®] on chili peppers.
- Wisconsin Kraut Growers Association—Dual[®] on transplanted cabbage.
- New York State Vegetable Growers Association, Inc.—Dual[®] on transplanted cabbage.

¹U.S. Environmental Protection Agency, U.S. Department of Agriculture. April 1991. *Minor Use and Pesticide Reregistration: How Growers Can Participate*. For more information contact: Registration Division (H7505C), Office of Pesticide Programs, U.S. Environmental Protection Agency, Washington, D.C. 20460.

²Pro-Gibb[®] contains the active ingredient, gibberellic acid, a plant growth regulator manufactured by Abbott Laboratories, Chicago, Illinois.

³Dual[®] contains the active ingredient, metolachlor, in an herbicide manufactured by CIBA-GEIGY, Greensboro, North Carolina.

- Platte Chemical Company/United Agri Products—Curbit^{®4} on cucumbers, melons and watermelons.
- Third Party Registrations, Inc.—Dual[®] on direct seed and transplant cabbage and Bolero^{®5} on lettuce, celery, endive, and escarole.

The number of labels available and their restrictive use patterns are excellent indications that third party labels are useful options. However, the high cost of developing data to support a registration may make this option prohibitively expensive to many grower organizations. Consequently, third party registrations generally are considered viable alternatives but are not viewed as the ultimate answer to the minor crops registration issue.

Congress has made provisions within FIFRA that provide guidance to the EPA for establishing policies for minor uses of pesticides. Since minor uses generally do not provide sufficient economic return to offset the cost of the data development, the EPA has adopted regulatory policies that can help minimize the costs of these data. Some of the more significant minor use policies are as follows:

1. **General Commodity Tolerances.** In 40 CFR 180.1⁶, the EPA defined specific raw agricultural commodities that, for tolerance purposes, are considered to be a single "general" commodity. For example, the general commodity, onions, includes the specific commodities such as dry bulb onions, green onions, shallots, garlic, leeks, and spring onions. Any tolerance obtained for the general category, "onions," automatically covers its specific commodities, and the residue data requirements are limited to those necessary to support the general commodity.
2. **Crop Group Tolerances.** In a manner similar to the general commodities approach, the EPA has defined in 40 CFR 180.34(f) groups of raw agricultural commodities for which group tolerances may be set. Although the commodities in the groups are similar to each other (for example, taxonomically related), they are not sufficiently similar to be considered identical for tolerance purposes.

Crop group tolerances are established for a pesticide based on residue data for certain crops that are representative of the group. Once a crop group tolerance is established, the tolerance applies to all

commodities in the group. The crop group approach allows the EPA to establish tolerances for several related commodities on the basis of less residue data than would be required if each commodity member were considered separately. In addition, the representative commodities are generally more widely grown and provide greater economic incentive than the remaining commodity members.

3. **Policy Statement on Minor Uses of Pesticides.** Pesticides are frequently required for crops grown in very limited areas of the United States or for the control of pests that are an economic problem in limited areas. Included in this policy statement (FR 51, No. 63, Wednesday April 2, 1986) are a number of ways in which registrants may obtain tolerances for minor crops or minor uses. For example, for crops with low dietary intake, EPA will consider the approval of residue data from geographically limited areas, and the policy contains a list of some of the more common agricultural commodities that meet the criteria for low dietary intake. In addition, the policy allows for crops which do not meet the criteria for low dietary intake to be considered on a case by case basis. The associated registrations for these types of uses limit use to the state or region approved by the EPA based on the geographical representation of the residue data.
4. **Surrogate Data.** The EPA may permit the use of surrogate data derived from related commodities to fulfill the data requirements for minor uses. Several examples of the use of surrogate data are as follows:
 - a. Residue data from air and ground application on selected crops may suffice for data required for dilute aerial application to minor crops, provided the use and cultural practices are the same and the use is limited to a dilute ground and aerial spray.
 - b. Residue data that are representative of the major production areas may not be required for national registration of a minor use when studies using the same pattern result in no detectable residues on related commodities.
 - c. Residue data for the parent chemical may be acceptable with limited metabolite data for a minor use, if adequate residue data for the parent compound and metabolites are not of greater toxicological concern than the parent compound.

5. **Low Volume Chemical Data Waiver.** Registrants may request low volume chemical data waivers when the cost of developing the required data exceeds anticipated revenues from all pesticide uses

⁴Curbit[®] contains the active ingredient, ethalfuralin, in an herbicide manufactured by DowElanco, Indianapolis, Indiana.

⁵Bolero[®] contains the active ingredient, thiobencarb, in an herbicide manufactured by Valent USA Corporation, Walnut Creek, California.

⁶This is Title 40 in the Code of Federal Regulations, Section 180.1.

of the chemical. There are two separate steps to the EPA's evaluation of a low volume chemical data waiver. To be eligible for consideration for a data waiver, registrants must first meet the EPA's economic test of a low volume chemical. If the chemical qualifies for consideration as a low volume chemical, the EPA must determine the minimum data set required to support registration based on the potential exposure and risk associated with use of the pesticide. The EPA sometimes takes a tier approach to the data requirements for low volume chemicals; requiring a subset of studies to evaluate the need for additional studies.

Closer coordination between IR-4 and NAPIAP is benefiting minor uses. NAPIAP has a mission to support existing pesticide registrations. With a separate budget and utilizing the expertise of SAES scientists, NAPIAP is able to develop reregistration data, such as toxicology and environmental fate, that are beyond the scope of IR-4. To better coordinate their research efforts, IR-4 and NAPIAP personnel are meeting on a regular basis to explore and solve reregistration needs of mutual interest.

Other activities have taken place at the federal level that address the minor use issue. In April 1990, Cooper Evans, then Special Assistant to the President for Agricultural Affairs, held a "White House Listening Session" on minor uses that was attended by a broad

representation from federal agencies, Congress, commodity representatives, and IR-4. This meeting ultimately resulted in a comprehensive draft report on the "Loss of Safe Pesticides for Minor Crops," which has not been published but is available in draft form.⁷

The 1990 Farm Bill addressed the importance of the minor use issue and included a number of provisions that indicate the need for continued, effective pest control on minor crops. Among these provisions was a call for a pesticide/crop/pest matrix, the study of recovering the cost of pesticide registrations, and the authorized appropriation of continuing funds to carry out the mission of the minor use program. The database of the National Pesticide Information Retrieval System (NPIRS) is being utilized by IR-4 and NAPIAP in a collaborative project to develop a crop/chemical/pest index and matrix that simplifies access to and use of the national pesticide registration database. Information from this index-matrix will be a valuable aid to NAPIAP, IR-4, and others in analyzing current pesticide registrations on minor crops and in evaluating the loss of products due to cancellations.

⁷For a copy of this report, write to IR-4 Headquarters, Rutgers University, New Jersey Agricultural Experiment Station, P. O. Box 231, New Brunswick, New Jersey 08903-0231.

3 Impediments to Minor Use Registration and Reregistration

Many of the problems associated with registering new uses of pesticides on minor crops are applicable to the reregistration of existing pesticide uses for minor crops. These problems involve the complex interactions of pesticide registrants, the user community, and federal and state agencies and departments. The following briefly highlights some of the major impediments to the registration and reregistration of pesticides on minor crops or to minor uses on major crops.

Pesticide registrants are confronted with economic decisions in developing data needed to support registrations of pesticides for minor crops. The question arises as to whether the new use will pay for itself in terms of capital expended for data required for registration by the EPA. Generally, the answer is "no" and other considerations, such as liability and Acceptable Daily Intake (ADI), usually support this decision. In some cases, registrants declare that they would be pleased if no minor uses were on their product labels.

Crop liability is a chronic impediment to minor use pesticide registration. There is an inherently greater economic risk in minor crop production than there is in producing major crops because of the consistent high per-acre value of minor crops. Thus, financial liability is significantly greater. The loss of a single planting of a highly valued minor crop can far exceed the anticipated revenue from the sale of a pesticide. For this reason, and in spite of label disclaimers, registrants are very cautious concerning registrations of pesticides on minor crops. Thus, third party registrations, in the opinion of some registrants, may be vulnerable to litigation if tested in the courts.

Another major impediment confronting registrants is the problem of ADI. The ADI is a guidepost used by the EPA to regulate maximum permissible levels of pesticide residues in the human diet. The established residue tolerance or the anticipated residue level for each crop on which the pesticide is used, together with estimates of the portion of the total crop treated with that pesticide and the amount of that crop eaten by the average consumer, determines the proportion of the ADI "used up" by each registered pesticide use. Thus, a manufacturer of a pesticide with many possible uses often finds that the number of registered uses must be limited to comply with ADI requirements.

Typically, this negatively impacts the producer of minor crops, because pesticide sales on minor crops are less profitable and utilize a disproportionate amount of the ADI that could be allocated to the more profitable major uses.

Unique to the reregistration process is the fact that FIFRA 88 requires that the reregistration of a large number of pesticide uses be compressed into a very short time frame. This means that the required residue data, to support reregistration, must be generated by registrants at a time when in-house and contract resources are stretched to the limit meeting the high priority reregistration needs of major crop uses. This works against support for minor uses, which represent negligible (if any) profitability, and the decision to voluntarily cancel becomes increasingly easy. The net result is that growers of many minor crops are left with few, if any, tools for crop protection.

In general, commodity producers and processors have not been well organized when it comes to influencing minor use legislation. With few exceptions, American farmers have been more concerned with the business of producing and selling crops than in legislation affecting pesticide usage. For the most part, growers and grower groups have not been involved in the registration process. In light of pesticide reregistration and the minor use issue, several coalitions have developed to address various needs. For example, the "Minor Crop Farmer Alliance" is comprised of a number of commodity organizations and food processors. They have worked with the USDA and EPA on policy matters concerning the use of pesticides on minor crops and have drafted legislative proposals to assist Congress in amending FIFRA which will benefit growers of minor commodities without jeopardizing food safety or the environment. Notwithstanding a heightened awareness, many growers and processors may lack the resources, both monetary and human, to carry their message forward.

Through national surveys and workshops conducted by IR-4 in cooperation with federal agencies and SAES in 1989, it was estimated that about 1,000 minor use registrations that were important to the agricultural community would be lost to reregistration. IR-4 agreed to support these uses together with an



IR-4 Regional Analytical Laboratory. Photograph courtesy of J. William, New York Agricultural Experiment Station, Geneva, New York.

estimated 2,600 new minor use registrations that would accrue by the conclusion of the reregistration time-frame. These estimates suggest that 1,500 field trials and 500 laboratory projects would be required each year to achieve this goal. To compensate for work not completed because of shortfalls in funding for FY 1990 and FY 1991, the number of such field trials and laboratory projects done each year will need to increase in each of the remaining reregistration years. In any event, an effort of this magnitude will place a serious strain on the existing capacities of state and federal cooperators who participate in the minor use registration program. This has caused the IR-4 Technical Committee to assess the available resources and develop an IR-4 Strategic Plan for providing the needed data.

During the past year this Strategic Plan and the management structure of IR-4 have been favorably reviewed by a CSRS Peer Review Team and by the General Accounting Office of the U.S. government.

IR-4 funds do not cover all expenses incurred by SAES and USDA-ARS cooperators on minor crop research. This means that state and ARS research funds are required to underwrite a share of the efforts. Moreover, the development of data by SAES and ARS scientists in support of minor uses is viewed by the academic community as "service work" and, as such, is often counter productive to career advancement. Coupled with these disincentives is the added responsibility of federally mandated Good Laboratory Practice (GLP) requirements. Few question the beneficial impacts of conducting field and laboratory research according to GLP, but the fact remains that record keeping and other requirements have increased the costs of minor use data development by at least 25%.

The ARS has been actively involved with the IR-4 minor use program since 1976. Because of the nature of the ARS program, many of these federal scientists are provided with base funding to cooperate in the minor use program. Many scientists in the ARS believe that IR-4 is a worthy effort and that they should receive credit for their activities. In 1980, the Administrator of ARS convened a workshop to resolve the problem of crediting ARS scientists for research-related activities. As a result of this workshop, the research accomplishment rating guide was amended to include credit for IR-4 related activities. The ARS scientists can substitute IR-4 activities for one of their significant research accomplishments, but rarely do so because of the stigma attached to this kind of research.

4 Pesticide Loss Implications

By some estimates, all crop production in the United States would decline 30%^a and food costs would increase by 50%^a or more without the use of agricultural pesticides. The prudent use of agricultural pesticides benefits consumers as well as producers through the availability of a variety of high-quality fruits and vegetables. Certainly the abundance, variety, and quality of produce available to consumers would be reduced.

The average U.S. family spends only about 10% of their disposable income on food. For these families, a substantial increase in the costs of fruits and vegetables would not be popular, but could be absorbed without great hardship. However, some 30 million of the U.S. population spend at least 60% of their disposable income on food. For those of limited means, a substantial increase in the price of fruits and vegetables would impose a further serious economic burden. As fruits and vegetables become less affordable, this segment of the population would consume less at a time when health experts recommend an increased consumption of fresh fruits and vegetables.

The effects on consumption of reduced quality produce is difficult to assess. At present, the American public, for example, does not associate the absence of pesticides with wormy apples. But, if U.S. fruit growers do not use pesticides (including biological pesticides) to control codling moths, for example, virtually every apple tree will produce wormy fruit, just as before the advent of pesticides. Under this scenario a decline in quality, coupled with price increases, will lead to reduced consumption.

Another issue that exists, in addition to reduced quality of agricultural products, is contamination of food with naturally occurring and quite harmful materials. Some agricultural chemicals (fungicides) stop the growth of plant diseases and prevent the formation of various fungal toxins (e.g., mycotoxins) on fresh crops and stored products. In addition, plants

protect themselves against fungi through the production of chemicals (called phytoalexins). Mycotoxins are toxic and some are carcinogenic; phytoalexins are toxic to animals and humans. As a result, the use of fungicides may prevent contamination of food with these very toxic, naturally occurring chemicals.

If U.S. crop producers are denied appropriate pest control measures, for purely economic reasons, they will be uncompetitive in both domestic and foreign markets. Today, minor crop markets are world markets. Production will shift to lowest-cost areas of the world, determined, to a substantial measure, by the availability of pesticides. The threat of crop production (minor or major) moving off-shore should be of serious concern to American consumers. Importation of a substantial proportion of food commodities produced by foreign interests could affect U.S. citizens by causing embargo restrictions of far greater consequence than those of the oil embargo of the early 1970s. Of equal importance, is the loss of control and regulation of pesticides applied by foreign producers. This problem becomes magnified because many of the foreign crop production regions are in warmer climates where insect and disease problems can become acute, resulting in the use of higher pesticide inputs than in the United States. To place this problem into perspective, only about 2% of the fresh and processed agricultural products imported into the United States are inspected at points of entry. This becomes significant because it is difficult to ascertain the nature and extent of pesticide usage on foreign produce.

Loss of minor use pesticides by U.S. producers can seriously affect U.S. competitiveness in agricultural markets. The availability of modern crop protection chemicals has given U.S. producers an advantage over foreign producers. By reducing unit production costs and increasing crop yields, U.S. growers can compete with the lower labor costs in most other countries while maintaining the quality of U.S. products. Similarly, growth in the export of high-value minor crops in recent years has been impressive. Fruits and vegetables are now near the top in dollar value for agricultural exports to our most important markets. However, the situation is changing. Modern chemical pesticide technology is becoming readily available

^aWalker, K. 1970. P. 149. *The Biological Impact of Pesticides in the Environment*. Oregon State University Press, Corvallis, Oregon.

^aAbernathy, J. R. 1981. P. 159. *Handbook of Pest Management in Agriculture*. Vol. 1. CRC Press, Boca Raton, Florida.

around the world, and U.S. producers are facing increasing competition from foreign markets.

The competitiveness of the U.S. agrichemicals industry is being adversely affected by U.S. regulations. The regulatory environment in the United States is a strong incentive for agricultural companies to shift manufacturing and research operations overseas. FIFRA 88 and prospects for new legislation restricting some pesticide exports strengthen this incentive. Growers in other countries are likely to continue to have early access to newer, safer, and more effective products. Given the well developed agrichemicals industry outside the United States, including developing countries such as India and Brazil, it is unlikely that legislation prohibiting the export of unregistered chemicals will be effective in denying foreign producers access to these materials, even for foods exported to the United States.

To remain competitive, food processors must seek the most economical sources of raw and finished products that increasingly come from foreign markets. The projected loss of minor use pesticides further reduces the ability of U.S. growers to compete and favors foreign sources. This represents a serious change. If foreign products are both cheaper and of high quality, the incentive to move processing outside the United States will increase. This shift is, in many respects, similar to the U.S. auto industry. Equally important, processors need reliable and predictable availability of raw materials to ensure that facilities operate efficiently. Pesticides are very important in extending seasons and geographic production areas. By extending the crop harvest and opening other production areas, food processing facilities can be

operated more efficiently. This contributes to keeping food costs down. Without an adequate array of safe and effective pesticides for U.S. crop production, there would be greater costs to U.S. food production operations. These would ultimately be passed on to the consumer as increased food costs.

As the number of pesticides for minor uses dwindles, the likelihood for pest resistance to the remaining pesticides used on these commodities increases. During the last 30 years, development of pest control chemicals has moved strongly toward materials that are highly specific for their target pests. This substantially reduces health and environmental risks, but also increases opportunities for a build-up of resistant pests through the biological process of natural selection. Resistance is best managed through a program that uses a variety of pest control methods and incorporates a number of chemicals that differ in their mechanisms of toxic action against pests.

Our agricultural system supports a large infrastructure and service industry. To successfully service the agricultural market, support industries such as farm machinery, chemicals, fertilizers, transportation, and wholesale and retail merchants need a "critical mass" of agricultural activity. As growers find their profitability reduced or their ability to successfully grow a crop impacted, decisions may be made to withdraw from the area. It is conceivable to envision an effect similar to the "Rust Belt" where steel mill closings severely impacted the local economy. Food processors are already looking elsewhere for production facilities and some relocations are having detrimental effects on jobs and supporting businesses.

5 Minor Use Strategy for the Future

The minor use issue has been debated extensively, and the present critical need for approved pest management tools for minor crops is well documented. Nevertheless, serious problems remain as is evidenced by the impediments to pesticide registration already discussed in this report. These problems can be addressed most expeditiously through development and implementation of a minor use strategy for the future, a strategy that is national in scope and innovative rather than reactionary.

There is an urgent need for participants in the minor use system (i.e., federal and state legislators, regulators, research, extension and marketing specialists, growers and processors, and commodity organizations) to clearly set forth the issues that must be included in a future strategy. The following comments address many of these issues.

Registrants of pesticides often view continued support of minor uses as heavily weighted towards cost and liability with little counter balancing financial reward or incentive. Provision of exclusive use rights to data generated in response to the requirements of FIFRA 88, would provide an economic incentive and would be extremely attractive to registrants. The degree of such exclusive use protection should be linked to the degree of support for minor use registrations.

A variation of this would be to provide exclusive use rights for data provided by task forces or alliances, including alliances with grower groups. In some cases, the exclusive use rights to the data could belong only to a grower group, provided that the basic manufacturer allowed access to the underlying toxicology data when necessary. An additional related incentive is directed to pesticide products still under patent protection by extending the term of patent protection when minor uses are supported and maintained. Often patents have already expired when minor uses are registered, leaving the company without opportunity for compensation.

Resources of registrants are stretched to the limit in dealing with the requirements of FIFRA 88. The chief concern of registrants is to maintain the registrations of their highest priority products and uses. This will not always include support of minor uses.

However, registrants recognize the problems that have been created by the loss of minor uses of their products and remain receptive to working with grower groups to seek solutions to these problems. This may involve sharing of costs with grower groups, contingent on resolution of liability concerns, or responding positively to incentives such as exclusive use of data or patent extensions.

Another issue extremely important to a future strategy relates to regulatory relief. For example, Congress should consider providing greater flexibility by allowing more time before product cancellation. Currently, cancellation occurs 90 days after publication in the *Federal Register* if no one supports the reregistration of that pesticide use. In addition, flexibility could result in modification of existing policies. Some suggestions include: (1) granting a data waiver in certain cases based on data available and knowledge of data in-use situations (surrogate data), (2) bridging data in-use situations or similar circumstances, (3) expanding or revising the crop grouping policy, and (4) extending the time frames for data development.

Third party registrations can, in some instances, address minor uses and reregistration needs and should be included as an important element of a future strategy. Critical to this, however, is the fact that chemical companies must be certain that their liabilities relating to possible crop damage are truly resolved. Waivers of liability have not yet been tested in court. Third party grower groups could fund or share in the cost of the necessary research to obtain a registered pesticide label. It must be recognized, however, that to establish a third party registration, a tolerance for that use must be approved by the EPA. Developing the data necessary to support a tolerance can be a lengthy and costly process.

The lack of a unified commodity organization at the national level has been a hinderance in communicating the need for an effective pest management policy. The recent focus on the minor use issue has indeed stimulated interest in formulating organizations to address the uses of pesticides on minor crops. One such organization, the Minor Crop Farmer Alliance, which is composed of a number of agriculturally oriented groups, is seeking a way to speak with one voice in

representing the needs of producers to Congress and to federal departments and agencies.

Historically, one of the most difficult constituencies from which to gain support is the general public. It is incumbent upon grower organizations, agrichemical companies, federal agencies, and others to educate the public concerning the safe and nutritious food supply produced within our country. Many of these efforts must start in the public schools with programs such as the Council for Agricultural Science and Technology's *Science of Food and Agriculture*, and the USDA's Teacher Research Fellowship and Agriculture in the Classroom programs. Growers need to take a proactive role and become involved in school boards and public education forums. Agricultural awareness events such as Farm/City Week need to be expanded. The message must be taken to the urban areas. Often farmers only talk among themselves or within the boundaries of their own communities. Special tours through agricultural areas should be established with elected officials invited to participate. Only by developing their awareness will the general public perceive agriculture as a resource to be conserved and nurtured.

Notwithstanding the minor use programs, reregistration will be slow and many pesticides will be lost from use. Pest resistance too will continue to reduce the effectiveness of existing products. Unpredicted and uncontrollable pest epidemics are likely to occur. It is critical, therefore, that new technologies be developed. Although it may be expedient to continue to rely on chemical and biological pesticides, a more pragmatic view is that these resources are finite. Wise use of remaining and new products is essential. This means maximizing the use of all biologically-based methods for controlling pests and devising a future strategy for use of them such that selection pressure on pest populations is minimized, thus reducing the selection for genetic resistance.

Among the biologically-based methods there are two scenarios for implementation that need to be emphasized in a minor use strategy for the future. The first scenario is the utilization and augmentation of indigenous and exotic parasites and predators. While the importation of exotic organisms may be an effective long range strategy to control pests, it is best suited for certain, introduced pests. The most prevalent form of biological control will be the management of cropping systems so that beneficial organisms are nurtured and augmented. While research has made, and continues to make, progress in this area, there is a critical shortage of extension specialists trained to deliver this technology. Additionally, Extension Service should make a concerted effort to develop informational materials for training specialists and the public to deliver and use

biological control¹⁰. Extension specialists predict that biological control will be the most important approach to pest control in the next decade.

In the second scenario, products will be developed for the commercial market by industry. These will be microbial products such as the currently available Polyhydrosis viruses of the bollworm/budworm complex and gypsy moth, and the Codling Moth Granulosis Virus (CMGV). These products will have increasing sophistication relative to the kind and degree of bioengineering incorporated into the product. However, the following are common features whether the product is naturally derived or highly genetically engineered:

1. They are fundamentally different from chemical pesticides because they are living organisms applied to a crop for the purpose of inducing an epizootic event.
2. Because of this fundamental difference, these organisms will have to be formulated, applied, and evaluated in a unique manner.
3. Cost of development will be relatively high for the unique and highly targeted market niches, requiring special consideration and/or subsidy in the developmental process.

Since most biological pesticides are subject to registration requirements, they will need the support of the minor use registration process. This must be a high priority issue of a minor use strategy for the future.

A modest approach to this component of a future strategy occurred in 1982 when an objective was added to IR-4 directing IR-4 to obtain data to support the registration of microbial and biochemical pest control agents. This addition appropriately expanded IR-4 pest control activities beyond conventional chemical pesticides. Entry of IR-4 into the biological pesticide arena signaled a new direction for the program. IR-4 activities with conventional pesticides traditionally have been limited to working with chemicals for which the core registration data had previously been developed by a commercial registrant. However, the biologicals objective for IR-4 directed the project to go beyond the traditional role of the program, if necessary, to seek Experimental Use Permits, to petition for temporary exemptions from the requirements of tolerances, and to develop toxicology and human safety data. Although the registration of biologicals for use in agriculture is a desirable objective, the limited funding base for IR-4 and high cost of developing registration data have severely

¹⁰Mahr, Daniel L. 1990. *Implementing Biological Control of Arthropods in North Central States: An Extension Perspective Memo Report*. Department of Entomology, University of Wisconsin, Madison. 38 pp.

restricted the IR-4 biologicals program. Notwithstanding, nine biologicals have been registered through the cooperative efforts of IR-4, SAES, and various commercial registrants, including the milky spore disease for control of Japanese beetles and a pheromone for disrupting the mating behavior of the grape berry moth. Five additional projects are active in various stages of data development.

Although it is generally agreed that IR-4 should become more active in the registration of biological pesticides for minor crops, the appropriate role should be carefully examined and more precisely defined. Clearly, the program has expertise to offer for introduction of biologicals to commercial agriculture. Aside from IR-4, there are only a few publicly supported programs that are able to provide the technical guidance and assistance needed to bring candidate biologicals from the discovery and research stages through registration to commercialization. A technology-transfer role falls within the technical capability of IR-4, provided a mandate and funding are provided. This capability has been demonstrated by the development of efficacy and toxicity data to support a pending exemption from tolerance requirements for the use of CMGV on pears, apples, walnuts, and plums and assembly of residue data to support registration of a pheromone to control the grape berry moth.

IR-4 could become a public sector facilitator for the registration of pest management technologies that require registration under the provisions of FIFRA. This could include collaboration with various public and private agencies and organizations, and research programs that have an interest in developing both conventional and biological pesticides applicable to IPM programs on minor crops. IR-4 would have to achieve greater visibility in this area to undertake this broader role. In any event, a central component of a future strategy for minor use pesticides should be a funding initiative intended to correct a chronic shortage of monies that have constrained IR-4 from achieving its full potential. An appropriate portion of increased funding should be earmarked for biological alternatives to chemicals for use on minor commodities, both food crops and ornamentals.

A minor use strategy for the future needs to foster the development of workshops to assemble and publish information on the utilization of nonchemical control methodologies, including beneficial organisms. This technology requires that extension specialists, commercial crop pest management consultants, and producers know the correct species to use, how to foster or augment the beneficial organisms, and how to evaluate the resulting control in a timely manner. Educational programs of this type are taking place at some institutions.



Grape vines protected from grape berry moth infestation by experimental pheromone. Photograph courtesy of T. H. Dennehy, New York Agricultural Experiment Station, Geneva, New York.

Fostering of effective biological pest control (including the use of biological pesticides) should be a national priority.

The IR-4 Project is a research partnership among federal and state scientists to develop field and laboratory data necessary to support registration of minor use pest control products. However, to accommodate the anticipated large number of field trials in response to the dramatically increased minor use registration and reregistration workload, a concept for establishing "regional field research centers" has been devised. These centers to be strategically located geographically, will accommodate about 75% of the needed field trials, with the remainder of the field trials performed at other SAES or ARS locations or by the private sector. Regional field research centers will alleviate the problems of attracting competent research personnel in the face of increasing demands brought about by GLP requirements and diminished professional credit for carrying out service oriented research. To be successful, regional field research centers will require multi-year commitments of adequate funding. This will permit the employment and training of competent full-time and part-time technical assistants to carry out field procedures and perform record keeping and other associated GLP requirements. Technicians conducting IR-4 field research will work directly under the supervision of one or more scientists who will be directly responsible for the research program. Figure 5.1 indicates the locations where regional field research centers are most needed to satisfy needs for geographically obtained residue data.

IR-4's current estimate of the annual costs of registration and reregistration for needed pesticides on

minor crops and the enhancement of the minor use biological pesticide registration program is \$14 million in 1992 dollars. While this represents a substantial increase in the combined USDA-CSRS and ARS budget of \$6.5 million for 1992, the average cost per completed project is only about \$25,000 compared to \$120,000 to \$250,000 by private industry. This efficiency is due largely to the absence of overhead and the approximate 3 to 1 leveraging of federal funds by the cooperating state and federal minor use research institutions.

The economic disincentives caused by current registration and reregistration data requirements suggest continued problems for the agrichemical industry to support reregistrations and develop new ones. The impending loss of a significant portion of chemical pest management tools and the long lead time to secure alternatives require that an investment in biological pesticides be made now. Funding must be found from federal, state, and private sources.

Funding sources for developing data to register biological pesticides for use on minor crops are fragmented. For example, the IR-4 Project required 10

years to secure data, which resulted in the registration of the CMGV on apples, pears, walnuts, and plums. The research effort on this microbial insecticide received support from the University of California, the California Environmental License Plate Fund, the national and regional IR-4 programs, user-grower contributions, and the Small Business Innovation Research program. Each of these organizations supported the research because of a sincere desire to reduce the use of conventional pesticides wherever possible. Regardless of how noble the effort, however, the fact remains that it required 10 years to develop the registration data for a single biological pesticide through a laborious process of assembling comparatively small research grants. This is not the way to aggressively develop biological replacements for synthetic pesticides. If the goal is to achieve adequate pest control on minor crops through intelligent and carefully applied integrated programs employing a combination of appropriate strategies (including the use of both conventional and biological pesticides), then a coordinated effort that includes adequate public monies must be achieved.

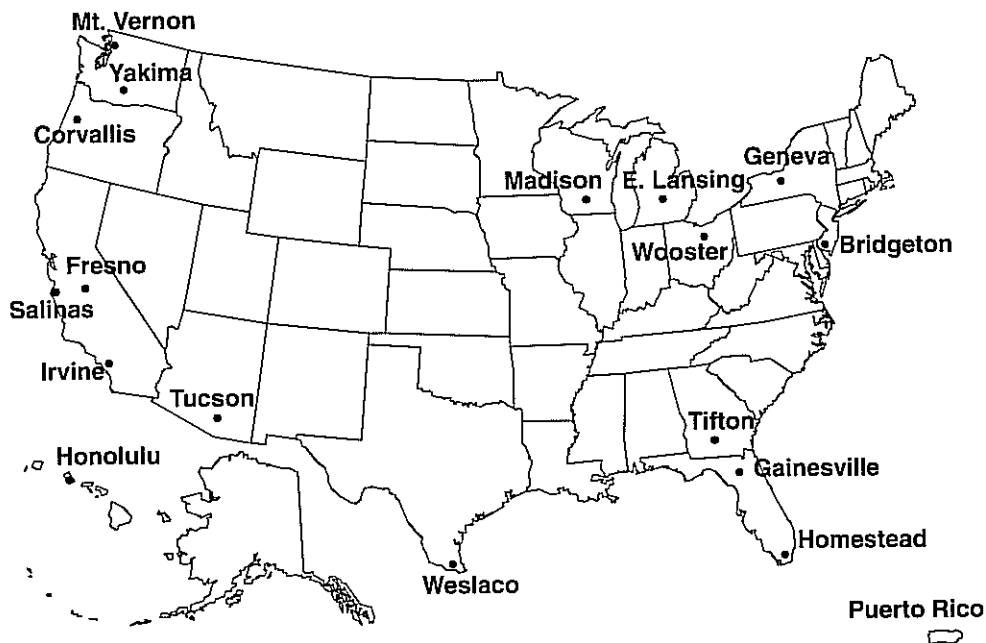


Figure 5.1. Potential IR-4 regional field research centers, state and ARS.

6 Conclusion

Solution of existing and anticipated minor crop/minor use pesticide related issues will require concerted and cooperative efforts by all parties including federal and state legislators and regulators, research, extension and marketing specialists, growers and processors, manufacturers and formulators, and com-

modity groups. Only through the efforts of these parties can the needs of U.S. minor crop producers be adequately addressed. Without such cooperative efforts, minor use issues will continue to escalate to the detriment of U.S. agriculture, minor crop growers, and consumers.

7 Recommendations

Domestic producers of agricultural commodities have an immediate and urgent need for pest control agents for use on minor crops to continue producing an abundant and varied supply of safe and nutritious foods at a reasonable cost and to remain competitive with foreign producers. These needs have increased dramatically as a result of the EPA accelerated reregistration program mandated by FIFRA 88. Furthermore, fundamental changes in the way minor crops are protected from devastation by agricultural pests are mandated by human safety and environmental concerns as expressed by producers and the general public alike. The following recommendations address these issues.

1. **National Focus for Minor Crops.** The USDA needs to improve coordination of federal programs relating to pest management on minor crops. Federal coordination with state programs is needed to rapidly develop and integrate new technology into practical pest management programs.
2. **Additional Funding for Minor Uses.** Multiyear funding is needed to achieve the goals of the IR-4 Project to register new minor use pesticides and support needed reregistrations of existing uses. Appropriate funding should be directed toward establishing and staffing field research centers, upgrading existing analytical facilities, establishing additional satellite laboratories, and expanding the existing program for registering biologicals.
3. **Expanded Research Emphasis.** There must be renewed emphasis on fundamental and applied research for agricultural pest control. Such research should be encouraged through the availability of additional competitive grants funding.
4. **Additional Time for Submission of Residue Data.** The EPA should allow the maximum amount of time consistent with reregistration time frames for the submission of residue data in support of minor uses.
5. **Data Waivers and Surrogate Data.** The EPA should fully utilize existing policy for minor use data waivers. The EPA also should explore additional options for the use of surrogate data from related commodities in support of minor use registration and reregistration.
6. **Good Laboratory Practice Requirements.** Unquestionably, GLP requirements are necessary to assure the creditability of data used in support of pesticide registration. However, policies are needed to ensure that GLP requirements do not unnecessarily discourage the development of data for minor use registration.
7. **Continued Registration of Unsupported Minor Use Registration.** The EPA should delay cancellations of unsupported minor uses, at the request of the registrant, until the Agency is prepared to make a decision on the reregistration of the pesticide active ingredient, provided the EPA is not aware of any unreasonable risks associated with the unsupported uses. This would provide a transitional period to allow IR-4 and other interested parties additional time to develop data for unsupported uses of pesticides that were otherwise being supported for reregistration or to develop alternative pest control methods.
8. **Registration Guidance for Biological and Microbial Pest Control Agents.** The EPA should reaffirm and extend its commitment to facilitate and expedite the registration of biological and microbial pest control agents. The EPA should reassess the testing guideline requirements for biologically-based pesticides to determine that they are practical and reasonable, and to develop clear guidance for potential registrants.
9. **The EPA Minor Use Commitment.** Presently one minor use officer is assigned by the EPA to the Registration Division to handle petitions related to minor crops and minor uses. The EPA must provide an adequate staff to coordinate the review of minor use petitions from all sources and to assist in expediting approvals for biological control

agents. Funds to support this minor use activity within the Agency should be earmarked specifically for this purpose.

10. Incentives for Minor Use Registrations.

Appropriate incentives are needed to encourage private sector registration of minor use pest control products. Among those incentives that are frequently cited are extended patent protection, extended periods of exclusive use of data, and "fast tracking" registrations that include one or more minor uses.

11. Technology Transfer. USDA and state departments of agriculture develop better federal and state mechanisms for the transfer of practical pest control technologies for minor crops from researchers to producers.

12. Recognition of Service Oriented Research.

Deans and directors of SAES need to develop a mechanism to ensure the availability and promotion of professionals who are involved in service oriented research that leads to the practical application of pest control technologies.

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