Encyclopedia of Agrochemicals 3/1/01

Chapter: Minor Use Pesticides – Registration (IR-4 Program) ● Dynamic Project ●

Introduction

Minor crops are defined as any crop grown on 300,000 acres or less. This includes most vegetables, fruit, nuts, herbs, spices, nursery and landscape plants and flowers. Almost all food crops are minor crops except for the large acreage crops like corn, soybeans, wheat, oats, rice and cotton. Minor crops account for over 40 billion dollars in annual sales, which is about forty percent of the total agricultural sales for the United States (US). Despite the high value of minor crops, there is frequently insufficient financial incentive for the agrochemical industry to invest in registering crop protection tools for these crops. Development, testing, registration and personnel time are huge expenses for the registrant of a pest control product. To maximize the return on investment, most pest control products are targeted on major acreage crops where there is potential for large sales. This, coupled with potential liability issues from crop injury, often leads to an unfavorable risk-reward relationship for registrants. Minor crops and minor uses on major crops often end up with few pest control tools despite their high value and importance.

Lack of available pest control products for minor food crops is not new. The Directors of state agricultural experiment stations (SAES) recognized the problem in 1963. Working with the US Department of Agriculture (USDA), they organized the Interregional Research Project No. 4, commonly known as IR-4. IR-4 is a cooperative government and industry effort by the USDA's Agricultural Research Service (ARS) and Cooperative State Research, Education, and Extension Service (CSREES), the land grant university system, the US Environmental Protection Agency (EPA), the agrochemical industry, commodity groups and growers. The IR-4 Mission is

to provide pest management solutions (chemical and biological) to growers of fruits, vegetables and other minor crops. In line with the mission, people who benefit from IR-4 are minor crop growers, food processors, and consumers.

IR-4's success in providing pest management solutions can be measured by the large number of minor crop pest control clearances established or retained as a result of IR-4's efforts. An IR-4 clearance is defined as a pest control agent and commodity combination that supports a registration. Registration of a specific use is the responsibility of the agrochemical manufacturer, who is the seller of the product. Over 5,500 food-use clearances, over 8,800 ornamental clearances and over 200 biopesticide clearances have been established since 1963. This quantity is over 40% of the total number of clearances granted by EPA. As the Food Quality Protection Act (FQPA) threatens to restrict or eliminate many long-standing pest control products, IR-4 is focusing on "reduced risk", safer chemistry and biopesticides to ensure that producers of minor crops have an adequate toolbox of pest control products. (1)

History and Milestones

The Early Years

As early as the late 1950's, the SAES Directors, university extension personnel, and USDA recognized the need for developing mechanisms for clearing chemicals for use on minor crops and for minor uses of chemicals on certain major crops. This was because the agricultural chemical companies did not have sufficient financial incentives to invest resources in registering crop protection tools for low acreage/high value crops. In 1962, the SAES Directors were extremely concerned that there were numerous minor crop pest management voids and minor

crop grower's needs were not being met. In fact, in order to determine the scope of the problem, a survey of states was conducted and a list of 548 desired clearances was surfaced. The SAES Directors requested the USDA's help in solving the above mentioned minor use problem. The IR-4 Project was established, July 1, 1963 as an interregional (national) research project with the title; Evaluation of Current Data and Needed Research to Determine Tolerance Limits of Chemicals for Minor Uses on Agricultural Products. Because of the interest and concern expressed by New Jersey, the coordination of the program and its national headquarters were placed on the campus of Cook College/New Jersey Agricultural Experiment Station (NJAES). The NJAES titled the project: The Clearance of Chemicals as a Public Service. There were synergies in placing the program in New Jersey because NJAES was involved in other major research projects designed to contribute new knowledge concerning the fate of agricultural chemicals in the environment and New Jersey was the headquarters of many of the agricultural chemical companies.

Several government agencies and industry groups endorsed the principle of the IR-4 Project and expressed a willingness to cooperate in any appropriate manner. They included the Food and Drug Administration (FDA), the USDA Pesticide Regulation Division (USDA-PRD, one of the precursors to the Office of Pesticide Programs at EPA) and the National Agricultural Chemicals Association (NACA now called American Crop Protection Association or ACPA).

The IR-4 Program started with an infrastructure consisting of a Technical Committee, Administrative Advisers, State Liaison Representatives (SLR's), and a National Project Leader. The Technical Committee of IR-4 including Administrative Advisers was charged with

coordination and management of the program. This committee's membership consisted primarily of persons designated by the four regional associations of Experiment Station Directors and representatives of USDA.

In order to get the program off to a strong start, the Technical Committee chose an eminently qualified, able, and experienced leader. Dr. Charles C. Compton was selected as the first National Project Leader. He was a well-known entomologist with experience in the university system and the agrochemical industry.

Each SAES Director was asked to designate a SLR for the IR-4 Project from their respective state. The SLR's were expected to convey needs and supply information on clearances needed as well as use and residue data which were needed to meet minimum FDA and USDA-PRD requirements for clearances.

The early years of the project were truly a cooperative program because IR-4's only direct funding source was $25,000 from the CSRS, USDA agency to cover the salaries of Dr. Compton and his assistant, Professor George Markle. There were no direct sources for funding research. However, several regional USDA research programs provided data to assist IR-4 in meeting its mission. The following were some of the key programs that contributed data:

Northcentral Project 19	Fundamental problems associated with the accumulation of pesticide chemicals in soils
Northcentral Project 33	Pesticide residues in or on food, feed, and forage crops

North East Project 36	Pesticides in or on raw agricultural commodities
Southern Project 22	Pesticide residues in plant and animal products and soils
Western Project 45	Pesticide residues – their nature, distribution, and persistence in plants, animals, and soils

The importance of the IR-4 Project to the minor crop community was shown very early in the history of the program. After the April 13, 1966 proposal by USDA to cancel all "No-Residue/Zero Tolerance" registrations within a five year period, IR-4 received numerous requests to help save the "older" chemical uses, which were not being defended by the respective registrants. Companies could not afford the expense required for the development of acceptable analytical methods, animal toxicology, performance and environmental impact data for use on major crops let alone minor crops. IR-4's strategy was to serve as a facilitator between interested parties. If the chemical could be saved on a major crop, it would be possible to also defend its uses on minor crops.

An example of this strategy was sodium TCA, a herbicide that had long been used in sugar beet and sugarcane plantings to control grass weeds. A meeting was held at Michigan State University, East Lansing, Michigan which was attended by the major sugar beet processors, representatives of the Beet Sugar Development Foundation and SAES herbicide specialists. The procedures required to obtain all necessary data for tolerances and labels were outlined in detail. The Michigan Agricultural Experiment Station's Specialist in weed control supervised the sugar beet plot trials which included applications of the herbicide in representative growing areas at various rates of application and the harvesting of the beets at designated intervals. The Beet

Sugar Development Foundation, Fort Collins, Colorado arranged to develop an acceptable analytical method for sodium TCA in sugar beet tops, roots, juice, molasses, dried pulp and refined sugar. IR-4 made arrangements with Hazleton Laboratories for conducting a 90-day feeding study on dogs to determine the no effect level for the active ingredient. The Beet Sugar Development Foundation financed the residue analytical work and toxicology studies along with additional contributions from industry at a cost of about $50,000. This project was an example of close cooperation between IR-4, the processor, a grower association, farmers and state experiment station personnel. IR-4 prepared the petition that resulted in the establishment of chemical tolerances in or on the raw agricultural commodities sugar beet roots and sugarcane. On the basis of IR-4 participation in the clearance of this herbicide, the "No Residue/Zero Tolerance" labels were extended by USDA's PRD. IR-4 also submitted petitions for other chemicals in this general category with cooperation and financing by similar alliances.

The 1970's

The 1970's resulted in tremendous change in the program. In 1975, USDA allocated funds to support the establishment of the Regional Leader Laboratories. For the first time, IR-4 was provided funding to directly develop data. IR-4 was able to hire Field Coordinators to manage the field research and establish analytical laboratories to analyze resulting residue samples. The funds were appropriated under the oversight of Public Law 89-106, Special Research Grants. Dr. John Mahlstede, Iowa State University, Associate Director and IR-4 Administrative Adviser, was instrumental in obtaining these funds for IR-4.

In 1976, USDA-ARS, noting the need for additional resources for the IR-4 Program, established their minor use program. This USDA-ARS activity was slated to work in close cooperation with existing efforts at the state level. In fact, it was designed to supplement state research, not replace it. The initial USDA-ARS minor use program consisted of a coordinator at the Beltsville MD research station and field research cooperators at Beltsville and Frederick, Maryland; Delaware and Wooster, Ohio; Yakima and Prosser, Washington; Corvallis, Oregon; Weslaco, Texas; and Tifton, Georgia.

In 1977, the IR-4's program title was changed to; A National Program for Clearances of Pesticides for Minor or Specialty Uses. Along with this program title change, the IR-4 Program expanded its research objectives to include developing data to cover the pest management voids in nursery and floral crops, forest seedlings, turf grass, Christmas trees and woody nursery stock. This objective, collectively called the Ornamentals Program, required only crop safety and/or product performance information. Since these are not food crops, no tolerance is required.

Most experts agree that one of the most significant solutions to the minor use problem was the establishment of crop groups. In order to make the efforts of residue data more valuable, IR-4 has also been involved in the development of crop groups. The federal crop grouping regulations (40 CFR 180.41) enable the establishment of residue tolerances for a group of crops based on residue data for certain key crops, normally major crops, that are representatives of the group. The first documentation of this concept was contained in a publication by IR-4 entitled, *Food and Feed Crops of the United States*, NJAES Bulletin 828, IR Bulletin No. 1, 255 pages,

June 1971 by Magness, Markle and Compton.(2) The significant contributions made by this publication are detailed in the Crop Grouping and Subgrouping part of the Research Section.

The 1970's also saw an expansion of IR-4 Project Headquarters from the original two people to a 10-person program by the end of the decade. Dr. Compton retired in 1977 and was replace by Dr. Robert Kupelian.

The 1980's

The 1980's for IR-4 can be characterized as the decade of turmoil which was mainly due to poor funding support. For several years, the IR-4 budget requests from the President to Congress did not include any support for IR-4. This was because the program was lumped with other programs considered non-essential. Fortunately, Congress saw fit to keep IR-4 going and funded the program during their appropriation deliberations.

In 1982, IR-4 once again expanded its objectives by adding research on biological based pest control agents in order to work on early stage biopesticide tests, including toxicology. This was a formal change to IR-4's objectives because IR-4 had been working on these materials in the advanced stages of registration prior to 1982. In fact, prior to the formal establishment of IR-4's biological objective, IR-4 was responsible for the exemption from the requirement of a tolerance for *Bacillus thuringiensis* (BT) on all crops. This allowed the broad introduction of this key biopesticide into commercial agricultural production. There was not much funding for the IR-4 biological based pest control agents program (first titled Biorational Program which was later changed to the IR-4 Biopesticide Program) during this time. The majority of the effort was

to provide assistance to USDA and the SAES scientists to help with the regulatory process. Funding came from outside sources. For example, the State of California provided significant funding to IR-4 to pay for studies required for registration of the biopesticide Codling Moth Granulosis Virus.

During the time when the biorational objective was added to the IR-4 Project Statement, there was also the addition of the IR-4 Animal Drug Program. Following the same logic as the support for minor use pest control tools on food crops, there was a need for regulatory clearance of drugs for minor animal species.

Along with the above mentioned additions to IR-4 objectives, the official title for IR-4 changed twice in the 1980's. In the early 1980's, the title was changed to; A National Agricultural Program: Clearances of Chemicals and Biologicals for Minor or Special Uses. This charter update incorporated the additional aspects of the Project including the Biorational and Animal Drug programs. The title was again changed in 1988 to; A National Agricultural Program to Clear Pest Control Agents and Animal Drugs for Minor Uses.

A significant modification of the US pesticide laws was promulgated in December 1988 that changed the focus of the IR-4 Program. This law, commonly called FIFRA 88, included the 1988 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). FIFRA 88 required the accelerated development, submission and review of current state-of-the-art data to support continued registration of pest control tools that were originally registered prior to November, 1984. This law put tremendous data development burdens on the agricultural

chemical registrants. It was feared that many minor uses would not be defended due to the cost of developing the data to meet the new data guidelines. Because of this fear of the loss of minor uses, IR-4 developed a strategy to defend as many as 1000 uses considered vulnerable to cancellation. Along with the plan of action, IR-4 was able to obtain additional resources from Congress to develop the necessary data. Almost two-thirds of IR-4's resources were tied up in developing new data to support existing uses.

Shortly after FIFRA 88 was enacted, EPA established new regulations that also significantly affected the IR-4 Project. In these regulations, the Agency required that all data developed in support of registrations be conducted under prescribed procedures following Good Laboratory Practice (GLP) guidelines. These guidelines were not new to toxicology laboratories which had been operating under them for approximately ten years. The guidelines forced significant changes at the field and analytical laboratory level. Procedures that were considered routine were no longer acceptable. For example, most scientists used pencils to collect and record data in the field because of the concern that ink pens would run if a notebook got wet. The GLP's required that pens must be used and pencils were no longer acceptable. In addition to the cost of GLP research (GLP regulations were estimated to result in an approximately 40% increase in research costs), the paperwork associated with the GLP's resulted in many of the established IR-4 field cooperators wanting to "retire" from IR-4 work. This loss of field cooperators forced IR-4 to rethink who does the field work and resulted in establishment of numerous field research farms at strategic locations throughout the US. With the field research farms or centers, IR-4 could fund full time technical personnel to work exclusively on IR-4

studies. These people were trained in GLP compliance and were not subject to the tenure track pressures of junior faculty.

The 1990's

Strategic planning has been an important function of the IR-4 program since the late 1980's. The 1989 Strategic Plan set goals to respond to FIFRA 88 as well as expanding both the biopesticide and ornamentals programs. It also called for the establishment of strategically located field research centers to conduct food use residue studies, expanded capability of the existing IR-4 residue laboratories, expanding the network of cooperating SAES analytical laboratories and conducting all residue projects under GLP's. The Animal Drug Program became a separate program under USDA-CSREES in 1993.

The decade of the 1990's saw all of these goals come to fruition. The program set a goal of reregistering 1,000 FIFRA 88 uses and ended up with accomplishing about 700 of the uses because of limited resources and the need to work on new reduced risk products. The Biopesticide (Biologicals) Program was expanded greatly from its initial objective to support USDA and land grant university researchers in the EPA regulatory process to a funded competitive grants program and a full time Biopesticide Manager. Since 1995, 115 biopesticide projects have been funded. The Biopesticide Manager and other Headquarter Staff have helped registrants obtain biopesticide clearances which have exceeded 200 during the period.

The Ornamentals Program also received additional support during the final decade of the 20th Century. The efficacy and crop tolerance or phytotoxicity trials are conducted about equally

with land grant university researchers and ARS scientists supported by funding from CSREES and ARS. The Ornamentals Program conducts workshops to prioritize research projects and discuss the best means of conducting the field research. The program has been highly successful in recent years in obtaining ornamental clearances as evidenced by over 500 clearances in 1999 and over 1,100 in 2000.

The Headquarters Quality Assurance Unit (QAU) was established in 1993. The Headquarters QAU staff subsequently expanded to its current level of three while each region added a Regional QA Coordinator with some having assistants. As of 2000, the program had a total of 10 QA staff who assure compliance by monitoring both the laboratory and field phases of the program as well as conducting facility inspections. Measures of the QAU program's successes include over 30 EPA inspections without any negative citations and all residue petitions accepted by the EPA.

The laboratory network has been strengthened greatly during this period with increased staffing at the four regional and three ARS laboratories along with the establishment of seven satellite laboratories to conduct additional residue analyses. The regional laboratories have also added analytical equipment to meet the challenge of more sophisticated analyses with detection capabilities at parts per billion levels.

The 1995-2002 Strategic Plan reinforced the major goals emphasized in the 1989 Strategic Plan while a 1996 update stressed a shift toward "safer" pest control products and chemistries while expanding the Biopesticide Program coinciding with the completion of the

FIFRA 88 registration initiative. The 2001 to 2005 Strategic Plan discussed in greater detail in a later section reinforced the safer or Reduced Risk chemistry strategy as the best means of addressing the challenges of the Food Quality Protection Act (FQPA) of 1996. FQPA posed an additional 10X safety factor for children, aggregate risks (dietary exposures including water, and exposure from all non-occupational sources) and cumulative risks (from same mechanism of toxicity chemicals). FQPA required that nearly all of the 10,000 chemical tolerances in effect in 1996 be reassessed by 2006. The ultimate impact of FQPA on minor crop growers is uncertain, but it is clear from early EPA and registrant actions that some crop protection tools will be eliminated or their use severely restricted. Therefore, it is critical that the 2001 to 2005 Strategic Plan be fully implemented to provide minor crop growers with replacement crop protection tools.

The IR-4 Commodity Liaison Committee (CLC), formed in 1991, provides the program with guidance on how best to serve minor crop growers, provides input on overall strategies, and provides the annual program with priorities on projects to conduct. The CLC strives to keep their Congressional representatives informed about the valuable work done by IR-4 and the need for increased federal funding to support that work.

Organizational Structure

IR-4 continues to operate as a unique partnership between the land grant university system and the USDA (ARS and CSREES) to accomplish its goal to provide crop protection solutions for minor crop growers. The Headquarters staff is located at Rutgers University in New Jersey, the USDA-ARS management is located at Beltsville, Maryland and the four

regional staffs are located at the University of California/Davis, University of Florida/ Gainesville, Michigan State University/East Lansing and Cornell University/Geneva, New York (Table 1). All of these units operate independently under the umbrella of the Project Management Committee or PMC (previously called the Technical Committee). The PMC consists of the Headquarters Executive Director and Associate Director of Administration, who serves as Secretary, the four Regional Directors, the ARS IR-4 Coordinator, the Chair of the Administrative Advisers (one for each of the four regions in addition to the USDA/CSREES and USDA/ARS Administrators), the USDA-CSREES IR-4 National Program Leader and the Chair of the Commodity Liaison Committee. The Administrative Adviser Chair, CLC Chair, Secretary and the USDA-CSREES representative positions are non-voting. A Chair for the PMC is elected from the voting members and is usually one of the Regional Directors or the ARS IR-4 Coordinator. The PMC meets three to four times a year to review the status of ongoing programs, develop policy and procedures, set operational budgets, develop strategic plans, and insure that the program's overall goals are being met (3).

The CLC continues to serve as a bridge between IR-4 and the growers of minor crops to assure that the program continues to focus on significant pest management problems. They serve as an important stakeholder group to provide guidance and advice on ways in which the program can best serve their needs as minor crop producers. The CLC encourages its members, other commodity organizations and minor crop growers to submit Project (Pesticide) Clearance Requests (PCR) to define pest control problems needing IR-4 support. The CLC also communicates the IR-4 mission to the agricultural community and provides grower level visibility on minor crop issues. Another important CLC role is to support federal IR-4 funding

and budget support initiatives and to help secure other sources of extramural funding from its members to maintain a viable food and ornamentals research and registration program.

Headquarters provides the overall program coordination with the various internal and external partners through selected leadership positions as follow:

IR-4 Headquarters (HQ) titles and functions:

Executive Director/Headquarters Management

Associate Director/Headquarters Management and program support

Assistant Director/Headquarters Management and New Technology Team

Associate Director of Administration/Funding, contracts, expenses and support staff

Registration Manager/Study Director management and planning

Coordinators/Study Directors

Research Assistant/Coordination

Quality Assurance Manager and staff/Quality Assurance Program

Ornamentals Manager/Ornamentals Program

IR-4 Liaison to Office of Pesticide Programs (OPP)/Adviser to OPP on minor crop issues

Each Regional Director is responsible for the staff and programs in their region managed by Regional Field (RFC), Laboratory (RLC) and Quality Assurance (RQAC) Coordinators. The RFC's are responsible for assigning the field residue trials for projects conducted in their regions from the final project prioritization in coordination with the Assistant Director to ensure the studies are conducted in the appropriate EPA geoclimatic zones. The RFC's work with Field

Research Directors in the land grant universities to finalize trial locations, oversee their implementation and review the Field Data Books (FDB's) from those trials for quality control issues before sending them to the RQAC's. The RQAC's not only perform GLP reviews of FDB's, but they also perform in-life audits of field and laboratory portions of the studies and review the Analytical Summary Reports provided by the chemists who report to the RLC and conduct all of the extraction, purification and quantification of possible chemical residues in the harvested minor crops.

The ARS IR-4 Coordinator manages a similar program as carried out in the Regions except he is responsible for making both the field and residue assignments.

With an average of 150 residue projects a year and an average of 600 field trials plus over 600 ornamental efficacy and crop tolerance trials and 30 plus Biopesticide Program projects, it is a unique management challenge to coordinate the various projects and trials between numerous field and laboratory locations. However, the program has done a fine job in accomplishing its goal of minor crop clearances as evidenced by the results highlighted in the Accomplishments Section.

The current funding supports the four Regional Laboratories, seven satellite laboratories and 18 Field Research Centers in the land grant system and three laboratories and 11 Field Research locations in the ARS system. IR-4 has been recognized for its approach to clearing safe pest control materials over the years with funding increases. (4)

IR-4's Research Supporting Transition

IR-4's goal is to facilitate new registrations of pest control tools for minor crops. However, during the late 1980's and early 1990's, IR-4 was very instrumental in developing new magnitude of residue data on existing products in order to maintain minor use registrations as part of the FIFRA 88 reregistration program. In fact, IR-4's efforts supported about 700 minor uses on minor food crops.

The push to develop defensive data to support existing uses was winding down in 1995. At the same time, IR-4 was becoming aware of the tremendous number of new pest control materials that were being developed. Many of these new chemicals were considered as reduced risk alternatives to existing chemistry. They had characteristics that were desirable to consumers and the environment such as low toxicity, short life in the environment, and very specific for certain pests, that is, they did not affect non-target plants or animals. Prior to the passage of FQPA, IR-4 recognized the advantage of working on this new, reduced risk chemistry and integrated 25 studies into the 1995 research program (approx. 20% of the total research program). This effort was the beginning of the IR-4 Reduced Risk Strategic Initiative.

In 2000, over 80% of IR-4's research effort involved new pest control technology which was typically considered reduced risk chemistry. This huge shift from a "defensive" program to embracing new technology in a few short years was a direct result of the focus IR-4 placed on advocating this new technology. This was accomplished through a two pronged approach consisting of partnering with the agricultural chemical companies and education of the minor crop stakeholders. IR-4 recognized that without access to the new technology it could not assist

the minor crop growers. IR-4 solicited industry's willingness to work together on new product development strategies that, for the first time, included the minor crops in their development plans. The foundation for this close working relationship was the crop groups. With studies on a few key crops, many other minor crops were eligible for registration. The other aspect of IR-4's push on new technology was the educational facet. It became clear that with reduced staffs in many of the companies due to mergers, that federal and state research/extension scientists were not always given the ability to test the new materials. IR-4 instituted a mechanism through publication of ***New Pest Control Products/Transition Solutions List*** (1) to inform the public about the virtues of the new technology to assist in the transition away from FQPA vulnerable crop protection tools.

Research

As noted previously, IR-4's primary mission is to provide growers of minor crops with pest management solutions. The processes to accomplish this task have evolved as IR-4 has expanded in size and complexity. Some of the key steps are described in further detail below.

Identification of Pest Management Voids

Most requests for assistance to IR-4 come from federal and state researchers/extension scientists involved in minor crop pest management. IR-4 also receives requests directly from growers and/or organizations representing a commodity. The only group of IR-4 stakeholders prohibited in submitting requests are representatives of agricultural chemical companies.

A request for assistance consists of the completion and submission of a simple one-page Project Clearance Request (PCR) form. Completed forms can now be submitted electronically via the IR-4 web site at www.cook.rutgers.edu/~ir4. This form seeks some basic information, such as the crop, the proposed pest management tactic, the target pest(s) in question, the proposed use of the pest management tool including the application rate and timing, the interval from last treatment to harvest and why the pest control material is needed. The form also inquires if any preliminary data are available. Preliminary data are very important because they are often needed to convince the agricultural chemical companies that the proposed use is safe when used on the crop and it effectively controls the target pests. In many instances, the completed PCR forms are sent from the requester directly to IR-4 Headquarters or one of the four regional offices for further processing. However, requesters can send the completed PCR forms to their local IR-4 SLR. One of the functions of the IR-4 SLR is to encourage the submission of requests for assistance from their state to document the pest management needs.

Upon receipt of the completed PCR, the proposed use is screened by IR-4 personnel for validity. The basic query includes questions such as, is the proposed use already registered?, will the agricultural chemical company which holds the US registrations for the chemical be willing to cooperate with IR-4 to obtain the regulatory clearance of the pest control tool?, and are there any regulatory impediments known that may delay or result in denial of the registration? To answer some of these questions, IR-4 formally submits a questionnaire to the appropriate agricultural chemical company to determine if they are willing to expand the registration to

include the IR-4 suggested use once IR-4 develops the appropriate data[1]. If so, the proposed use is regarded as "Researchable" and is considered in the research project priorization procedures.

Establishment of Research Priorities

Unfortunately, IR-4 does not have sufficient resources to conduct research on all proposed researchable projects. In fact, for every research project IR-4 funds, there are approximately five projects delayed pending additional resources. Because of this shortfall, IR-4 strives to work on the most important projects.

The Food Use and Ornamentals Workshops are the cornerstone of the IR-4 priorization process. These are open forums where over 200 minor crop growers, commodity organization representatives, agricultural chemical company representatives, and federal and state research/extension scientists attend and participate. At the workshops, every potential project is discussed in detail and its importance is considered on such factors as the availability and efficacy of alternatives, pest damage potential, performance of the proposed chemical, and its integrated pest management program (IPM) compatibility. From the workshop participants, three tiers of priorities projects are identified. Priority A's, the highest tier, are the most important projects. Because of their importance, IR-4 will begin research work at the next practical experimental start date. All efforts will be made to submit results of Priority A research to EPA within 30 months of protocol approval. The next tier projects, Priority B, are also important, but funding may not be available. IR-4 will use its resources in the most efficient

[1] For food crops, IR-4 develops data which determines the amount of chemical remaining on the crop at harvest. This is called a Magnitude of the Residue study. For non-food crops, IR-4 develops crop safety and/or product performance data.

manner to complete as many of these projects as soon as possible, given funding restraints. The final tier projects, Priority C, are considered of less importance than Priority A and Priority B projects. IR-4 will conduct research on these projects only after all Priority A and Priority B projects are conducted, which usually is unlikely.

Though IR-4 follows the priorities set at the workshops very closely, there are occasions when the EPA or the cooperating agricultural chemical company will recommend that IR-4 delay initiation of research for a specific chemical. IR-4 usually heeds this advice and delays or cancels research pending satisfactory handling of the outstanding issue(s).

Studies

For food crops, the EPA has published specific guidelines on conducting magnitude of residue research studies which require a certain number of field trials to be conducted in specific geographic regions of the country. These guidelines are based on the acreage of the crop along with the potential of dietary exposure, plus the major production regions for the crop. In addition, the EPA requires that this research be conducted and documented following exacting procedures outlined in the GLP guidelines. These GLP guidelines mandate that a Study Director is assigned and serves as the single point of control for the research at the field and laboratory sites. The GLP's also require that all research work is monitored by an independent QAU which is specifically required to notify the Study Director and the Study Director's management when there are any perceived as non-compliance issues.

All IR-4 research on food crops is conducted following very specific research directions outlined in a research protocol. This protocol contains directions for the receipt and handling of the test chemical, the application of the test chemical on the target crop, the harvesting of the mature crop at the appropriate harvest time, the collection of representative crop samples and handling of these samples after harvest, the transfer of the crop samples to the analytical laboratory, and the analysis of crop and other supporting residue samples.

In order to best meet the above requirements and to complete the research, IR-4 has established 25 field research centers at strategic locations throughout the United States. In addition, IR-4 has a network of four regional, three ARS and seven satellite analytical laboratories that determine the amount of chemical remaining on the crop. All these field centers and analytical laboratories operate under GLP.

For non-food crops, the GLP guidelines are not required. In these studies, general protocol use directions are issued and the research cooperators apply the test chemical to the ornamental crops and monitor for pest control and/or an indication that the test chemical caused damage to the plants.

All data from IR-4 sponsored studies are transferred from the field sites and/or analytical laboratories to the IR-4 Headquarters. Before it is transferred, it is subjected to both quality control and quality assurance audits. These quality checks have helped ensure that IR-4 has achieved some of the lowest number of review cycles of any data submitter to EPA. Once at IR-

4 Headquarters, the Study Directors critically review the data and reformat it into a style required for submission and review by the cooperating agricultural chemical company and the EPA .

In order to better service the needs of the minor crop growers and to be a more credible partner with the agricultural chemical companies, IR-4 instituted a 30-month timeline policy in 1999. The policy applies to the highest priority projects (Priority A) and basically says that IR-4 will complete research and submit the results of the study to EPA within 30 months of when the research protocol was approved.

Obtaining Regulatory Clearance

The first step in obtaining the regulatory clearance for a proposed IR-4 food use is for IR-4 to submit the data to the EPA. Upon receipt, EPA Registration Division personnel perform a preliminary review for completeness of the data and start discussions with scientists in the Health Effects Division (HED) to schedule a comprehensive review of the IR-4 and supporting data from the agricultural chemical company. The data are reviewed and if they show that clearance of the use would not expose consumers or the environment to unreasonable adverse effects, the EPA publishes a tolerance as a Final Rule in the Federal Register. This tolerance is the maximum residue limit (MRL) of the agricultural chemical in or on the crop that is considered safe and legally acceptable.

For non-food crops, the process is much simpler because a tolerance is not required. The cooperating company can add the ornamental crop(s) to their registration once it feels comfortable that the use is safe to the crop and effective on the pest.

The ultimate goal of IR-4's efforts is to facilitate new registrations of safe and effective pest control tools. However, to register the uses for both food and non-food crops, it is the responsibility of the cooperating agricultural chemical companies. In most cases, there is no problem and the use is registered as proposed. However, there are some occasions when the cooperating registrant will require that additional crop safety and/or product performance data be developed. There are also occasions when the cooperating agricultural chemical company requires that additional safeguards against crop damage liability be integrated into the label.

Crop Groupings and Subgroups/*Food and Feed Crops of the United States*

As noted in the history section, IR-4 has been very involved in the development of crop group lists that have helped to improve the regulations over the years. Regulatory crop groupings were one of the best avenues to extend research funds and provide the necessary data to establish safe tolerance levels or maximum residue limits (MRL) for groups of related crops.

Instead of developing residue data on every food or feed crop for every chemical use, data could be developed on a smaller set of representative crops and then be extrapolated to a larger number of related crops. This efficient method of developing research data saved valuable industry and IR-4 research time and money, and regulatory review costs. At the same time, IR-4's researchers, Study Directors, and EPA developed standardized protocols for these representative crops that were well represented in our food inventory using pre-designated field sites, number of sites, and recognized seed sources and cultural practices to cover many minor and unique crops. The development of data on representative crops permitted EPA to develop an

enhanced database with less variables, thereby improving decision-making in reviewing petitions. This standardization continues to show results.

The first edition (1971) *Food and Feed Crops of the United States* by Magness, Markle and Compton (a.k.a. The "Greenbook") outlined the general plant grouping scheme which is used today with the focus on the types of edible plant parts, e.g. fruit, seed, roots, etc.; and use , e.g. vegetable, feed, etc. Included in the tailoring of these crop groups and definitions were botanical relationships, growth characteristics, etc. The first edition included over 300 crops divided into large crop groups, e.g. vegetables, tree fruits, tree nuts, oil crops, spices, grasses, non-grass feed, grains, etc. Within these large crop groups, the specific crops were subdivided or subgrouped by like parts, e.g. root and tuber, fruit, leaves, pods, etc. The first edition was used in the development of the international FAO/WHO Codex Alimentarius crop groups listings or classifications in 1978 and by US EPA for their early crop grouping scheme in 1983. In the 1995 updated EPA regulatory crop grouping scheme, Table 2 (5), IR-4 also played a key role in the development of the grouping and subgrouping concept. IR-4 developed justifications to add new crops and help develop subgroupings which are smaller and more closely related groups of commodities with their own representative commodity(s).

The second edition (1998) of *Food and Feed Crops of the United States* by Markle, Baron and Schneider (6), continues to improve the regulatory environment with more standardization included in a scientific base. It is a complete source of food and feed information which serves as a significant part of the current regulatory guidelines for food safety. It includes many minor crops and their grouping with larger consumption representative crops.

Food and feed crop harmonization provides a standardization in preferred or principal commodity names and common crop names used in the trade. Additionally, the common and principal vernaculars are supported by their scientific names and synonyms. The EPA has utilized these principal vernaculars and other common names in their "Food and Feed Crops Vocabulary" database which is on the world wide web (www.epa.gov/pesticides/foodfeed/) and is used by the regulatory agencies in standardizing commodity names for tolerance purposes. The second edition included over 1,000 scientific crop names. The authors' crop classification includes 10 primary or large crop groups, e.g. vegetables, fruits, tree nuts, etc., and 31 principal crop groups, e.g. root and tuber, citrus, berries, herbs, etc. An example of the primary crop groups would be the vegetables. The primary vegetable group is further divided into 11 principal groups, e.g., root and tuber, leafy, bulb, brassica, etc. for better representation. The vegetables compose a third of the proposed crop groups.

Accomplishments

Since the program started in 1963, it has been responsible for residue data and other petitions to support over 5,500 food use clearances, more than 8,800 ornamental or non-food crop clearances and supported research on biopesticides which has resulted in over 200 biopesticide clearances (Table 3). This is a tremendous accomplishment when measured against the level of funding and the efforts of the crop protection industry. The IR-4 supported clearances account for approximately 40% of all food use approvals granted by the EPA and with over 50% of the Agency's ornamental approvals.

As noted in the 1990's discussion, the FQPA triggered a new set of health based standards which in the early stages of implementation severely impacted the IR-4 success rate in the food crop clearance program, and to a lesser extent the ornamentals clearance program. IR-4's pre-FQPA 12-year (1984-1996) average was 100 clearances per year. The first year following FQPA (1997) resulted in one minor crop IR-4 clearance which was similar to the experiences from the crop protection industry. The ornamental clearances were impacted less in 1997 and returned to normal levels in 1998. The food crop clearances started to rebound in 1998 and completely recovered by 1999 due to a number of proactive partnership initiatives between IR-4 and the EPA as follow:

- EPA/IR-4 Technical Working Group. Quarterly meetings have been held since early 1999 to address regulatory issues and develop procedures to improve regulatory review.
- IR-4 Workplan. IR-4 has provided the EPA with a rolling three year workplan with possible petition submission schedules to allow the Agency to select those petitions of greatest FQPA impact and more efficient scheduling for review using multiple petitions for an active ingredient where possible to save risk assessment review resources.
- Petition Summaries. An improved data evaluation record for each study report was implemented by IR-4 Study Directors on petition submissions, which saved the EPA one to two months review time because it followed EPA's general review format. All the key data are summarized into a standardized format or tables for review purposes and it is called the Herndon Tables after the EPA-HED chemist who proposed it.
- Blanket Tolerances for Selected Reduced Risk Products. Working with registrants with new, reduced risk chemistries, like Dow AgroSciences with spinosad and Zeneca (Syngenta) with

azoxystrobin, and the EPA, IR-4 negotiated reduced residue data requirements on certain minor crops using the crop grouping concept documented in *Food and Feed Crops of the United States* which resulted in over $1,000,000 savings in field and laboratory expenses. This initiative resulted in 165 new minor crop uses for spinosad in January 2000. Also the reduced risk product, glyphosate, was cleared on 207 new crops in September 2000.

- IR-4 Liaison to OPP. An IR-4 position was created in the Office of Pesticide Programs to advise the Director and senior management staff about minor crop issues and facilitate input into the EPA's Minor Use Team.

As a result of these partnership initiatives with the EPA, there were a record number of food crop clearances granted by the Agency on behalf of IR-4 petitions in 1999 and 2000. An unplanned contribution, but one that should be noted as an accomplishment, was the number of Section 18's, which are special FIFRA waivers that permit growers to utilize pesticides for critical plant pest problems, granted to states for emergency pest control situations using IR-4 data as the supporting residue information with the EPA. In 1998 and 1999, the number of Section 18's averaged over 50 with many states covered by the uses approved.

Strategic Plans/Vision for IR-4's Future

IR-4 has tried to take a proactive approach during its existence to address the challenges facing minor crop agriculture by developing strategic plans and action plans. FIFRA 88 triggered a strategy and action plan to support 1,000 priority minor use needs that would not be reregistered by the crop protection industry. This program eventually led to about 700 reregistered minor uses. However, by 1995 it was clear to the PMC (Technical Committee at

that time) that the industry had a number of new, safer chemistries and biopesticides in the development pipeline, which held good promise leading to the decision that the FIFRA 88 effort should be concluded (4).

The PMC was quite visionary in their shift in emphasis from older, FIFRA 88 chemistries needing reregistration, to the newer IPM compatible products as borne out by the impacts of the FQPA. However, by 1999, a number of factors led the PMC to review and reevaluate the program's goals and strategies. Some of these factors were the uncertainty about how FQPA would be implemented, the rapid consolidation of the crop protection industry, global market competitiveness in the minor crops, increased use of microbials, pheromones and biochemicals in IPM programs, organic farming and resistance management, perception that the industry new product pipeline was starting to slow, especially for minor crop herbicides, and the need to work toward global minor crop tolerances based on residue and trade barrier issues. Input was gained through a two day planning workshop attended by about 150 stakeholders in October 1999 to insure that concerns from the land grant university system, USDA, EPA, crop protection industry and most importantly, minor crop grower and commodity organization customers were being addressed. The result was a document entitled "A Strategy for Meeting the Challenge of Pest Management on Minor Crops 2001-2005" which was issued in early 2000. It produced an updated Mission Statement (see Introduction Section), emphasized the important impact FQPA was having on minor crop pest control options, reinforced the reduced risk/safer chemistry strategy, and reemphasized the importance of the Biopesticide and Ornamental Programs. Some of the key initiatives for 2001-2005 outlined in the plan were as follow:

- Highest priority was placed on food use and ornamental crop protection solutions in response to FQPA.
- Continue emphasis on new, reduced risk chemistries by accelerating their registration and making them available for minor crop growers. Part of this initiative involved partnering with the industry at an early stage and a 30-month completion schedule (discussed in Research Section).
- Methyl Bromide Alternatives research for minor crop needs.
- Selected efficacy studies when required to supplement existing industry product tolerance for minor crop labeling and to obtain registrants' support on minor crop PCR's for priority projects.
- Upgrading equipment and facilities at Regional Laboratories, Field Research Centers and ARS Units.
- Strengthen SLR network to improve grower contacts and inputs for project needs.

Conclusion

Since 1963, the IR-4 program has accomplished its mission to provide pest management solutions to growers of fruits, vegetables and other minor crops as evidenced by over 5,500 food crop, 8,800 ornamental (non-food) crop and 200 biopesticide clearances granted by the EPA as a result of IR-4 initiatives. The program has evolved through the years to adapt to legislative and agricultural industry changes and challenges. FIFRA 88 initiated an extensive effort to register many minor uses for products that would not be defended by the crop protection industry due to insufficient economic incentives. However, the exciting new, low use rate, safer, environmentally compatible chemistries in the 1990's coupled with the FQPA resulted in a

complete shift by IR-4 from product defense to new crop protection tools (both chemical and biological) for minor crop growers. Partnership initiatives with the crop protection industry, land grant universities, EPA, USDA-ARS and CSREES, growers and commodity organizations broadened stakeholders input and improved customer focus. As we enter the 21st century, the 2001 to 2005 Strategic Plan and the action items outlined in it should place IR-4 in a leadership role for the future of minor crop agriculture.

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Suggested Readings

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Table 1

IR-4 Minor Use Program

OBJECTIVES

- To register new crop protection chemicals on food and ornamental crops and to assist in maintaining existing product registrations
- To further the development and registration of biopesticides and biochemicals for minor uses

ORGANIZATION

- Headquarters staff at Rutgers University/New Jersey Agricultural Experiment Station: 25 Coordinator (Study Directors), Quality Assurance, Registration, Biopesticide, Special Project, Database and Administrative Support Staff
- Regional Laboratories at Michigan State University, Cornell University-Geneva, University of Florida and University of California-Davis
- Satellite Laboratories - 10 (7 Land Grant plus 3 USDA-ARS)
- Field Research Centers (25 including 11 USDA-ARS)
- Support from Federal and State Liaison Reps and the Commodity Liaison Committee(farmers and commodity organizations)
- Project Management Committee
  4 Regional Directors, ARS and CSREES Representatives, CLC Chair, Administrative Advisory Committee Chair and IR-4 Executive Director and Executive Secretary
- Administrative Advisory Committee
  Provides liaison between State Agriculture and Extension Service Directors, ARS and CSREES
- USDA-ARS
  Minor Use office headquartered at Beltsville, MD with own budget and lab (3) and field (11)facilities at strategic locations
  Cooperates closely with IR-4 Program

Table 2

The following is an example of one of the nineteen (19) EPA approved crop groups and subgroups from 40 CFR 180.41, see reference 5 for the complete list or Food and Feed Crops of the United States, reference 6.

Crop Group 1

(1) Crop Group 1: Root and Tuber Vegetables Group.
(i) Representative commodities. Carrot, potato, radish, and sugar beet.
(ii) Table. The following Table 1 lists all the commodities included in Crop Group 1 and identifies the related crop subgroups.

Table 1--Crop Group 1: Root and Tuber Vegetables

Commodities	Related crop subgroups
Arracacha (Arracacia xanthorrhiza).....	1-C, 1-D
Arrowroot (Maranta arundinacea).....	1-C, 1-D
Artichoke, Chinese (Stachys affinis).....	1-C, 1-D
Artichoke, Jerusalem (Helianthus tuberosus)....	1-C, 1-D
Beet, garden (Beta vulgaris).....	1-A, 1-B
Beet, sugar (Beta vulgaris).....	1-A
[[Page 26636]]	
Burdock, edible (Arctium lappa).....	1-A, 1-B
Canna, edible (Queensland arrowroot) (Canna indica).....	1-C, 1-D
Carrot (Daucus carota).....	1-A, 1-B
Cassava, bitter and sweet (Manihot esculenta)..	1-C, 1-D
Celeriac (celery root) (Apium graveolens var. rapaceum).....	1-A, 1-B
Chayote (root) (Sechium edule).....	1-C, 1-D
Chervil, turnip-rooted (Chaerophyllum bulbosum).....	1-A, 1-B
Chicory (Cichorium intybus).....	1-A, 1-B
Chufa (Cyperus esculentus).....	1-C, 1-D
Dasheen (taro) (Colocasia esculenta).....	1-C, 1-D
Ginger (Zingiber officinale).....	1-C, 1-D
Ginseng (Panax quinquefolius).....	1-A, 1-B
Horseradish (Armoracia rusticana).....	1-A, 1-B
Leren (Calathea allouia).....	1-C, 1-D
Parsley, turnip-rooted (Petroselinum crispum var. tuberosum).....	1-A, 1-B
Parsnip (Pastinaca sativa).....	1-A, 1-B
Potato (Solanum tuberosum).....	1-C
Radish (Raphanus sativus).....	1-A, 1-B
Radish, oriental (daikon) (Raphanus sativus subvar. longipinnatus).....	1-A, 1-B
Rutabaga (Brassica campestris var. napobrassica).....	1-A, 1-B
Salsify (oyster plant) (Tragopogon porrifolius).....	1-A, 1-B
Salsify, black (Scorzonera hispanica).....	1-A, 1-B
Salsify, Spanish (Scolymus hispanicus).....	1-A, 1-B

Table 2-2

Skirret (Sium sisarum).....	1-A, 1-B
Sweet potato (Ipomoea batatas).....	1-C, 1-D
Tanier (cocoyam) (Xanthosoma sagittifolium)....	1-C, 1-D
Turmeric (Curcuma longa).....	1-C, 1-D
Turnip (Brassica rapa var. rapa).....	1-A, 1-B
Yam bean (jicama, manoic pea) (Pachyrhizus spp.).....	1-C, 1-D
Yam, true (Dioscorea spp.).....	1-C, 1-D

(iii) Table. The following Table 2 identifies the crop subgroups for Crop Group 1, specifies the representative commodity(ies) for each subgroup, and lists all the commodities included in each subgroup.

Table 2--Crop Group 1 Subgroup Listing

Representative commodities	Commodities
Crop Subgroup 1-A. Root vegetables subgroup.	
Carrot, radish, and sugar beet.	Beet, garden; beet, sugar; burdock, edible; carrot; celeriac; chervil, turnip-rooted; chicory; ginseng; horseradish; parsley, turnip-rooted; parsnip; radish; radish, oriental; rutabaga; salsify; salsify, black; salsify, Spanish; skirret; turnip.
Crop Subgroup 1-B. Root vegetables (except sugar beet) subgroup.	
Carrot and radish.....	Beet, garden; burdock, edible; carrot; celeriac; chervil, turnip-rooted; chicory; ginseng; horseradish; parsley, turnip -rooted; parsnip; radish; radish, oriental; rutabaga; salsify; salsify, black; salsify, Spanish; skirret; turnip.
Crop Subgroup 1-C. Tuberous and corm vegetables subgroup.	
Potato.....	Arracacha; arrowroot; artichoke, Chinese; artichoke, Jerusalem; canna, edible; cassava, bitter and sweet; chayote (root); chufa; dasheen; ginger; leren; potato; sweet potato; tanier; turmeric; yam bean; yam, true.
Crop Subgroup 1-D. Tuberous and corm vegetables (except potato) subgroup.	
Sweet potato.	Arracacha; arrowroot; artichoke, Chinese; artichoke, Jerusalem; canna, edible; cassava, bitter and sweet; chayote (root); chufa; dasheen; ginger; leren; sweet potato; tanier; turmeric; yam bean; yam, true.

Also, IR-4 plans to add more crops to this group and others, e.g. Kava to Crop Group 1.

Table 3

IR-4 Minor Use Program

ACCOMPLISHMENTS

1963-2000

- **5,500+ Food Use Clearances (511 in 2000)**
- **8,800+ Ornamental Crop Clearances since 1977 (1,155 in 2000)**
- **200+ Biopesticide Clearances since 1982 (56 in 2000)**

1988 FIFRA Response

- **Reregistered about 700 minor uses on food crops**
- **Reregistered over 2000 ornamental uses**
- **Obtained 10 biopesticide tolerance exemptions on 56 crops**

FQPA Response

- **1997** — **45 reduced risk projects out of 150 total projects involving 524 trials**
- **1998** — **78 reduced risk projects out of 163 total projects involving 609 field trials. 14 biopesticide projects supported**
- **1999** — **82 Reduced Risk projects out of 149 total projects involving 566 field trials. 29 biopesticide projects supported**
- **2000** — **104 Reduced Risk projects out of 131 total projects involving 725 field trials. 37 biopesticide projects supported**