THE IR-4 PROJECT OVER 50 YEARS OF SUSTAINED SUCCESS

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Keywords: IR-4, Specialty crops, Minor uses, Off-label uses, Sustainability, Environmental agriculture, Reduced risk pesticides, Biopesticides, MRLs


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Introduction

Many food crops we consume, e.g. fruits, vegetables, nuts, herbs, and spices as well as non-food crops such as landscape plants and flowers are considered specialty crops. Specialty crops are grown on limited acreage and often have a high economic value; collectively estimated at $67 billion annually in 2007 (Clark). The pests that damage crops do not discriminate between major crops (corn, soybean, cotton, wheat/small grains, etc.) and specialty crops. Crop protection technology is often needed to prevent significant damage to crop quality and yield. The agrochemical industry often lacks the financial incentives to expand registration for their products to specialty crops. This is due to limited sales, high crop damage liability concerns and the significant expense to develop the data to support a registration of a crop protection product on a specialty crop. The same situation exists for minor uses on major crops. The lack of crop protection products for specialty crops and minor uses on major crops is referred to as the "Minor Use Problem" and was the basis for the IR-4 Project being formed in 1963 as a means to solve this problem for US growers.

The IR-4 Project operates as a unique partnership between the U.S. Department of Agriculture (USDA) – both the National Institute of Food and Agriculture (NIFA) (formerly called the Cooperative State Research Education and Extension Service or CSREES), and the Agricultural Research Service (ARS), the State Agricultural Experiment Stations (SAES), the U.S. Environmental Protection Agency (EPA), the agrochemical industry, commodity groups, and growers. In recent years, additional partnerships have been formed with USDA- Foreign Agricultural Service (FAS) which supports international specialty crop export activities, Animal Plant Health Inspection Service (APHIS) to work on selected invasive species, and the Department of Defense's Deployed Warfighter Protection Program (DWFP) to provide regulatory support for public health pesticides.

The Mission Statement for the IR-4 Project is simply to: "*Facilitate Regulatory Approval of Sustainable Pest Management Technology for Specialty Crops and Specialty Uses to Promote Public Wellbeing*". Stakeholders gain numerous benefits from the IR-4 Project's efforts, including: Growers pest management solutions for traditional and organic farmers that maintain productivity and competiveness; Food Processors a dependable, safe and economic food source; Consumers a safe, wholesome, affordable, varied, and nutritional food supply.

From a humble beginning in 1963 with only two staff members and a $25,000 budget to today a staff of 125 full time equivalent members and a budget of over $36 million ($18.9 million direct support and $18 million indirect/in-kind support), the IR-4 Project has made a major impact on U.S. agriculture by providing over 46,000 specialty crop registrations.

The early years

In the late 1950s, as a national system for the registration of pesticides continued to develop, the SAES Directors, university extension agents, and USDA recognized the need to develop processes for registering agrochemicals for use on specialty crops and for minor uses on major crops. The project concept began in early 1960 when the University of California proposed to the National Agricultural Chemical Association (NACA) the need for registration of chemicals on minor crops. NACA supported this suggestion and asked the Director of the California Agricultural Experiment station to determine if the State Agricultural Experiment Stations could participate in this type of work (Markle, Baron & Holm 2002). The Western Agricultural Experiment Station Directors approved this idea and solicited the cooperation of other regional associations. The Experiment Station Committee on Policy (ESCOP) agreed with the principle of the program and requested a feasibility study. The study found that most states had a similar problem and that not only was the project feasible but highly necessary to meet a host of needs for growers.

In 1962, the SAES Directors became extremely concerned about the legal availability of pest management tools for specialty crop growers. A list of 548 urgently needed pest control product uses was developed. The SAES Directors requested the USDA's help to solve this Minor Use Problem and as a result the IR-4 Project was established on July 1, 1963 as an Interregional Research Project Number 4 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

DOI: 10.1564/v27_feb_04

concern expressed by the State of New Jersey, the National Headquarters and overall program coordination were placed with Rutgers University/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 the NJAES was involved in other major agrochemical projects on the fate of these chemicals on the environment and, at that time, New Jersey was the home for the headquarters of many agrochemical companies.

Several government agencies and industry groups endorsed the principal of the IR-4 Project and expressed interest in cooperation. They included the Food and Drug Administration, (FDA), the USDA-ARS's Pesticide Regulation Division (the precursors to the EPA's Office of Pesticide Programs), and the National Agricultural Chemicals Association (now called Crop Life America or CLA).

The importance of the IR-4 Project was demonstrated early in its history when on April 13, 1966, USDA proposed to cancel all "No-Residue/Zero Residue" registrations within a five year period. IR-4 received numerous requests to help save the "older" agrochemical uses that were not being defended by registrants due to the expenses involved. IR-4 developed and facilitated a strategy with interested parties to defend uses on specialty crops where the chemical was already being defended by registrants on major crops. By the end of 1967, IR-4 obtained extensions for 38 pesticides on 129 crops.

Leadership and organizational structure

Since its inception, the IR-4 Program has operated under the guidelines for regional research as developed by the Cooperative State Research Service (CSRS) and subsequent successors. The project leadership consisted of two committees: an Administrative Advisory Committee consisting of a member from each of the four USDA agricultural regions; and a Technical Committee consisting of a voting member representative from each participating region and appointed by the director of the SAES, an Administrative Advisor, and a CSRS representative. Subsequently, the IR-4 National Director and the Agricultural Research Service representative were added to the committee as voting members. The Technical Committee was abolished in 1997 and the Project Management Committee (PMC) was formed to take its place with similar responsibilities.

The Project Management Committee (PMC) serves as the Board of Directors for the IR-4 Project. The PMC meets three times a year to develop policies and procedures, to set operational budgets within funding limitation, to review the status of ongoing programs, and to insure the program's overall goals are being met. The PMC members consist of the IR-4 Project Executive Director (formally called National Director), the four Regional Directors, the ARS Minor Use Program Director, the IR-4 Administrative Advisors (one for each of the four regions), the USDA/ARS Administrator, the USDA-NIFA Director), the USDA-NIFA IR-4 National Program Leader, and the Commodity Liaison Committee (CLC) Chair. The IR-4 Executive Director, the four Regional Directors, the ARS Minor Use Program Director and the CLC Chair are voting members. The Chair for the PMC is elected from the voting members. A full roster of PMC/Technical Committee members is documented in the IR-4 Project Management Committee/Technical Committee Representatives list found in Table 1.

Photograph from 1966 IR-4 technical committee meeting.

Five individuals have served as the uppermost administrative head of the IR-4 Project and are responsible to the PMC for overall coordination of the program. The Technical Committee chose Dr. Charles C. Compton, a well-known entomologist with experience in the university system and the agrochemical industry, as the first National Project Leader. The other inaugural employee was George Markle, who first served as Compton's assistant, and later became Associate Director and Co-Director.

During the 1970s the IR-4 Project Headquarters expanded from the initial staff of two to a 10-person program by the end of the decade. Dr. Compton retired in 1977 and was one of the early recipients of the IR-4 Hall of Fame Award for his many contributions. Compton was followed by Dr. Robert Kupelian, a chemist with experience in the agrochemical industry.

Dr. Kupelian's tenure as the as the National Director spanned from 1978 to 1990. Kupelian was instrumental in the establishment of the National Animal Drug Program, which was initially dovetailed with the IR-4 Program. After Kupelian's departure, Professor George Markle and Richard (Dick) Guest served as Co-Directors until Guest was named National Director in 1990. Dr. Guest was instrumental in leading IR-4's response to FIFRA 88 and developing a strategy to respond to new regulatory demands of the Food Quality Protection Act of 1996 (FQPA) and encouraged IR-4's efforts to promote work with reduced risk pesticides. Guest retired in 1998. Both Dick Guest and George Markle have been inducted into the IR-4 Hall of Fame.

Dr. Robert (Bob) Holm was hired in 1998 as the Executive Director of the IR-4 Program as an encore to a long career in research and development management roles in the crop protection industry. He was instrumental in forging many partnership initiatives with the EPA and the agrochemical companies, including transitioning IR-4 efforts to reduced risk chemicals. After serving as the national leader for IR-4 for eight years, Dr. Holm retired in 2006. Bob Holm received the Agrow Lifetime Achievement Award based on his many contributions to agriculture, especially his IR-4 contributions. He was also inducted into the IR-4 Hall of Fame in 2006.

Following Holm as IR-4 Executive Director is Jerry Baron. Dr. Baron joined IR-4 in 1986 and has worked in numerous

Table 1. IR-4 Project Management Committee/Technical Committee Representatives*.

Northeast Region	
Administrative Advisor:	Brad Hillman, Dan Rossi, Mark Robson, Bruce Carlton, Rod Sharp, Darrell Lund, Roger Wyse, David Brown, R. M. Hermann, G.F. Walton, W.C. Kebbard, Ordway Starnes
Regional Director:	Dan Rossi, David Soderlund, Richard Durst, Terry Spittler, John Burke, B.R. Wilson, Baily Pepper
North Central Region	
Administrative Advisor:	Doug Buhler, Gary Lemme, Kirklyn Kerr, Eldon Ortman, Roger Wyse, John Mahlstede, J. Collenbach,
Regional Director:	John Wise, Robert Hollingworth, F. Matsumura, R. Ruppel, R. J. Sauer, P.A. Daum. J.E. Fahey, R.L. Janes, P.H. Woodley
Southern Region	
Administrative Advisor:	Jackie Burns, Mary Duryea, Neal Thompson, Vernon Perry, Howard Wilkowske,
Regional Director:	Marty Marshall, Cheng Wei, Willis Wheeler, Neal Thompson William Eden, C.H. Van Middelem
Western Region	
Administrative Advisor:	Mary Delany, Mike Parrella, Andre Lauchli, George Ware, I Thompson, L. Rasmusssen, W.M. Dugger, D. Rolston, K.W, Hill, A.M. Boyce
Regional Director:	Matt Hengel, Ron Tjeerdema, Marion Miller-Sears, T. Shibamoto, Jim Seiber, W.W. Kilgore, Virgil Freed
ARS	
Administrative Advisor:	Sally Schneider[I], Nancy Ragsdale[I], Richard Parry[I], Ralph Ross[I], E. Knipling, Terry Kinney, T.W. Edminister ([I]represent ARS Administrator)
Program Director:	Paul Schwartz, Kenneth Walker
IR-4 Executive Director:	Jerry Baron, Robert Holm, Richard Guest, George Markle, Robert Kupelian, Charles Compton
NIFA/CSREES/CSRS:	Rob Hedberg, Monte Johnson, James Parochetti, H. Teague, Kenneth Dorschner, Robert Riley, R. J. Sauer
Commodity Liaison Committee Chair:	Rich Bonanno, Rocky Lundy, Jere Downing, Larry Elworth

*Incumbent listed first followed by most recent

roles within IR-4 during his tenure. He was instrumental in expanding and supporting IR-4's international activities and establishing IR-4's Public Health Pesticide Registration objective.

The IR-4 National/Executive Director supervises a professional scientific staff at IR-4 Headquarters. The IR-4 Project Headquarters staff provides overall program coordination with the four regions, the USDA-ARS, the EPA, the crop protection industry, Commodity Liaison Committee and numerous other internal and external partners.

The IR-4 Project Regional offices and Regional "Leader" Laboratories were established in 1975 to provide IR-4 with field and laboratory research capacity. The U.S. is divided into four regions with the IR-4 Regional Offices/Laboratories being located in and associated with the host Land-Grant Institutions. From 1975 to 2015 the Northeast Region was at NY SAES in Geneva, NY. Starting in 2015, the Northeast Region relocated to Rutgers University: New Brunswick, NJ. Other IR-4 Regional Offices are North Central Region - Michigan State University; East Lansing, MI; Southern Region - University of Florida; Gainesville, FL and Western Region - University of California; Davis, CA.

All of these units operate independently, receiving separate portions of the IR-4 grant from USDA-NIFA and under the leadership of a Regional Director (PMC member). Each Regional Director is responsible for the staff, budget, and programs in their region managed by Regional Field Coordinators (RFCs), Regional Laboratory Coordinators (RLCs), and Regional Quality Assurance Coordinators (RQACs). The roster of key regional research coordinators since the IR-4 analytical laboratories and regional offices were opened is documented in Table 2.

All regions have an analytical laboratory with the exception of the Northeast Region, which was closed in 2009 after the PMC made a decision to shut down one laboratory as the capacity to analyze residue samples exceeded IR-4's ability to produce new residue samples in its field trials. Savings from the laboratory phase-out were reinvested in the upgrading of equipment at the remaining three laboratories.

The RFCs are responsible for working with stakeholders to identify needs and for assigning field residue trials at IR-4 Field Research Centers located within their regions for research projects that were prioritized the previous year by stakeholders at the annual Food Use Workshop from stakeholder submitted Project Clearance Requests or PCRs. The final residue trial locations are coordinated with IR-4 Headquarters staff to ensure the studies are conducted in the appropriate EPA geo-climatic zones according to EPA guidelines. The actual field residue trials are conducted by the Field Research Directors (FRDs) at research farm locations around the country.

The USDA Agriculture Research Service (ARS) Minor Use Program has its own funding and it works in close coordination with the Headquarters and Regions to conduct specialty crop residue and product performance at its dedicated sites. USDA-ARS also cooperates with ornamental efficacy trials. The program has been led by Dr. Paul Schwartz since 1976 who has provided leadership and continuity not only to the

Table 2. IR-4 Historical Key Regional Research Coordination Personnel*.

Northeast Region	
Regional Field Coordinator:	Marylee Ross, Edith Lurvey, John Martini, Paul Baker, Chand Watve
Regional Lab Coordinator:	Wlodzimierz Borejsza-Wysocki, Chris Lam, Pim Larson-Kovach, Terry Spittler
Regional Quality Assurance:	Jane Forder, Michelle Humiston, Barbara Anderson, Denise Snook,
North Central Region	
Regional Field Coordinator:	Satoru Miyazaki, T. Dudek
Regional Lab Coordinator:	Sue Enhardt, Wayne Jiang, Dick Leavitt
Regional Quality Assurance:	Zhongxiao Chen, Chris Vandervoort
Southern Region	
Regional Field Coordinator:	Michelle Samuel-Foo, Charlie Meister
Regional Lab Coordinator:	Wlodzimierz Borejsza-Wysocki, Jau Yoh, Promode Bardalaye, Neal Thompson
Regional Quality Assurance:	Kathleen Knight, Sam Fernando
Western Region	
Regional Field Coordinator:	Rebecca Sisco, Margaret Reiff, Ron Hampton, Rick Melnicoe, Harold Alford
Regional Lab Coordinator:	Matt Hengel, Chuck Mourer, Jim Stokes, Tom Archer
Regional Quality Assurance:	Martin Beran, Jim McFarland
ARS	
Georgia Lab	Tom Hendrick, Don Wauchope, William Rhode
Washington Lab	Todd Wixon, Ron Sell, Les McDonough
Maryland Lab	Emile Pfeil, Al Herner, Ken Hill

*Incumbent listed first followed by most recent

ARS part of the program but also the entire program through his role in the IR-4 Technical Committee/Project Management Committee where he has served multiple terms as the Chair.

The IR-4 network includes a State Liaison Representative (SLR) in every state and US territory. The SLRs are chosen by the state/territory SAES Director. This individual is asked to provide support for their state specialty crop growers by conveying their needs to the IR-4 Program. A key responsibility of SLRs is to encourage the submission of PCRs to document the pest management needs of their specialty crop growers.

A key external stakeholder group, named the Commodity Liaison Committee or CLC, was formed in 1991 to provide the program with guidance on how best to serve the specialty crop growers they represented. The CLC serves as a bridge between the specialty crop growers it represents and IR-4 to assure that the program continues to focus on the most important pest management problems. The CLC serves as an important stakeholder group to provide guidance and advice on ways in which the program can best serve the needs of specialty crop growers. Additionally, the CLC encourages its members, other commodity organizations and specialty crop growers to submit PCRs to define pest control problems needing IR-4 support. The CLC also communicates the IR-4 mission to the broad agriculture community and provides grower level visibility on specialty crop issues. Another important role of the CLC is to support federal IR-4 funding and budget support initiatives to maintain a viable research and registration program. The historical listing of IR-4 Commodity Liaison Committee members is found in Table 3.

The first Chair of the CLC was Larry Elworth who represented Pennsylvania's apple industry. The next CLC Chair was Jere Downing of the Cranberry Institute followed by Rocky Lundy, Executive Director of the Mint Industry Research Council. Lundy was passionate in keeping IR-4 on the appropriate path to help specialty crop growers find solutions for their pest management problems. His efforts with the PMC helped facilitate an unprecedented expansion within the IR-4 Project. Equally important, Rocky often led fierce budget battles like the one in FY 2005 that resulted in a $1.7 million increase after an unexpected 11th hour cut of $1.1 million in the FY 2004 budget. In 2012, Rich Bonanno, a vegetable and flower grower from Massachusetts took over the leadership of the CLC. Dr. Bonanno coordinated specialty crop growers' response to the USDA's proposed consolidation of IR-4 with five Integrated Pest Management programs to form a new program called Crop Protection. Through his efforts, many in the specialty crop community including CLC members, members of the Minor Crop Farmers Alliance, individual growers and allied industries contacted government officials and encouraged them to remove IR-4 from this consolidation plan.

Funding

Government funding and support for the IR-4 Project started with the initial investment of $25,000 by the SAES in 1963. The funding source for this investment was "off the top" funds from Hatch Act or Regional Research Funds (RRF) accounts. These resources were provided to Rutgers University to cover the salaries of Dr. Compton and Professor Markle. The culture of fully utilizing "in-kind" contributions and partnerships was established at the very beginning of IR-4.

Funding for IR-4 through RRF increased to over $100,000 annually by 1975. During this time, the Project had proven its value and realistic efforts were being made to expand resources. In 1975, Congress appropriated funds under Public

Table 3. IR-4 Commodity Liaison Committee members, 1991–2015.

Aerts, M	Florida Fresh Fruit and Vegetable Assoc.	2001–
Ahrens. D	Twin Gardens Farms	1992–1995
Allman, G	Mint Industry Research Council	1991–1992
Arney, M	National Watermelon Board	2005–
Balling, S	Del Monte	1993–2000
Baumann, K	WI Ginseng	2008
Berger, L	California Specialty Crops Council	2008
Bledsoe, M	Village Farms	2008–
Bonanno. R	Pleasant Valley Garden	1992–
Botts, D	Florida Fresh Fruit and Vegetable Assoc.	1991–2000
Buurma, B	Buurma Farms	2005–
Cranney, J	California Citrus Quality	2009–
Davenport, T	National Grape Cooperative	2006–2010
Downing, J	Cranberry Institute	1991–1998
Elworth, L	PA Apple Marketing	1991–1994
Ewart, W	CA Citrus	1991–2009
Flood, B	Del Monte	2001–
Freeman, R	American Farm Bureau	2005–2009
George, A	US Hops	1991–
Giclas, H	Western Growers	2005–
Humfield, T	Cranberry Institute	2013–
Jewett, V	United Fresh Fruit & Vegetable	1993–1996
Lundy, R	Mint Industry Research Council	1992–2013
Maurer, E	Crop Life America	2003–
McCloud, S	Almond Board	1991
Melban, K	CA Pepper	2005–2007
Monterroso, A	Brooks Tropicals	2013–
Montoian, R	CA Grape & Tree Fruit	1991
Murphy, L	Society of America Florists	1991–1993
Nuxoll, D	Western Growers	2013
Obenauf, G	CA Prune, Raisin, Walnut	1991–1995
Olszack, R	Grower	1991–2010
Pitts, M	Cranberry Institute	2002–2004
Phelps, L	American Mushroom Institute	2009–
Prewett, R	TX Vegetable Assoc.	1994–
Ratto, R	Specialty Crop Grower	1993–
Rawlins, S	American Farm Bureau	1992–2001
Regelbrugge, C	American Nursery and Landscape Assoc.	1992–2004
Romang, R	Ginseng industry	
Salisbury, S	Mint Industry Research Council	2013–
Schlegel, P	American Farm Bureau Federation	2013
Schmale, L	Society of America Florists	1993–
Schreiber, A	Agriculture Development Group	2009
Scholz, T	USA Dry Pea & Lentil	2005–
Sharp, J	CA Strawberry	2001–2003
Simerly, R	National Onion Association	2014–
Sorbello, M	NY Potato	1991–2000
Spencer, B	AZ Citrus	1999–2002
Tanner, B	National Watermelon Association	2006–
Teffeau, M	American Nursery and Landscape Assoc.	2005–2013
Traino, P	NJ Vegetable	1991–1998
Trinka, D	MBG Marketing	1997–
Tristao, D.	JG Boswell	2014–
Zellers, R	MI Vegetable	1991–1996
Zuleger, D	WI Potato & Vegetable Assoc.	1995–2002
Wegmeyer, T	American Farm Bureau	2010–2013

Commodity liaison committee educational session in congress.

Law 89-106-Special Research Grants (SRG) to USDA-Cooperative State Research Service (now known as the National Institute of Food and Agriculture-NIFA) to support the establishment of Regional Leader Laboratories (Regional Offices) which provided, for the first time, the opportunity for IR-4 to develop residue data directly. John Mahelstede, Associate Director at Iowa State University and IR-4 Administrative Advisor from the Northcentral Region, was instrumental in obtaining these dedicated funds for these research operations.

In 1976, ARS allocated $410,000 from its budget to initiate a minor use pesticide program. These funds were obtained through the efforts of Drs. Waldemar Klassen, Paul Schwartz and Warren Shaw of the ARS National Program Staff. The majority of funds were given to ARS personnel at field sites and chemists at analytical laboratories to participate in IR-4 managed residue studies.

The crop protection industry also provides unrestricted grants that IR-4 can use where most needed, such as contracted field sites that often cost more than research at SAES sites, contracted laboratories, and report writing efforts as well as funding for other key programs and to support workshops. IR-4 was able to use the external unrestricted funding from the crop protection industry to continue key programs.

Starting in 2012, IR-4 faced some significant challenges with respect to funding and governmental reorganization. Adequate funding remains the most critical current and future challenge for IR-4. In February 2012, USDA released a proposal to consolidate the IR-4 Project with several Integrated Pest Management (IPM) programs. President Obama's Fiscal Year 2013 funding plan called for the transfer of funds traditionally provided for IR-4 activities and five IPM programs to a new consolidated program called Crop Protection. Many specialty crop growers and others in the minor use community had critical concerns about the impact of including IR-4 in this IPM consolidation plan. The CLC gained support of nearly 100 commodity/stakeholder groups supporting the continued independence of IR-4. Broad grassroots support informed Congress and USDA of the need to keep IR-4 as a stand-alone program and IR-4 was removed from this consolidated Crop Protection Program.

A significant funding cut occurred in 2013 in association with Budget Control Act of 2012. Here, IR-4 funds were reduced by 7.6%. These cuts forced IR-4 to reduce the number of new research projects that were designed to solve grower problems. Additionally, completion of some research projects was delayed, essential travel was reduced, planned laboratory equipment purchases were delayed and some personnel positions were not replaced. Complicating the funding cuts were large increases in operating expenses.

With the diversification of IR-4's research activities, there have been new sources of funding. The Department of Defense, under a cooperative agreement with USDA-ARS, funds the IR-4 Public Health Pesticide Program at approximately $250,000 annually. The USDA-Foreign Agriculture Service has funded much of IR-4's international efforts. More recently, the Standards Trade and Development Facilities grants program (funded by the World Trade Organization) has provided resources for international capacity building activities, where IR-4 is playing a major coordination and training role. The newest funding source is from USDA-APHIS which has provided resources to do research work on invasive pests. A comprehensive accounting of IR-4 funding since the beginning is found in the Total IR-4 Project Funding History – 1963 to 2015, see Table 4.

The above funding discussion refers to the direct funds IR-4 receives from government and other sources. There are significant additional contributions of "in-kind" funding from many sources. It is estimated that for every direct dollar allocated to IR-4 there is AT-LEAST one additional dollar of in-kind support from contributions by SAES, the US EPA, crop protection industry, Canada and commodity associations.

Strategic planning

The 1989 Strategic Plan was the IR-4 Project's first attempt to use the strategic planning process to address current challenges such as FIFRA 88 and longer term issues which included the expansion of both the Ornamentals and Biopesticide Programs. The Ornamentals Program received additional funding under this plan as did the Biopesticide Program. The plan also called for the establishment of strategically located field research centers to conduct food use residue trials according to Good Laboratory Practice (GLP) regulations, as well as expanding the capacity of the existing SAES residue laboratories.

The 1995 to 2002 Strategic Plan reinforced the 1989 Strategic Plan's major goals while it stressed a major shift in the program's emphasis from completing the re-registration of older agrochemical product uses to "safer/reduced risk" pest control products while expanding the Biopesticide Program at the same time.

The 2001 to 2005 Strategic Plan continued to emphasize the importance of responding to the FQPA by targeting safer or reduced risk chemistries and biological pest control approaches. This was critical because specialty crop growers were faced with losing many of their older chemistries due to concerns about their acute and chronic toxicity, especially to farm workers and pesticide applicators as well as environmental fate and impact on non-target organisms.

The fourth IR-4 Strategic Plan covered the years of 2006 to 2008 and was limited to only three years to synchronize future strategic plans with the USDA Project Review Process. This strategic plan expanded the scope of the original three core programs (Food Use, Ornamentals and Biopesticides) to include an initiative to pursue global harmonization of specialty crop residue levels (Maximum Residue Levels or MRLs). This new initiative was deemed important because domestic growers of specialty crops were looking to enhance export markets. However, pesticide tolerances in the U.S. were often different from international standards and these differing standards restricted U.S. export to many foreign countries and, therefore, served as a trade barrier.

The fifth IR-4 Strategic Plan (2009-2014) was developed largely by stakeholder suggestions during the 2008 Strategic Planning Conference. This included:

Facilitate Identification of Pest Management Solutions to Answer Priority Grower Needs (Food Program)

Harmonization of Maximum Residue Levels to Remove Pesticides as a Trade Barrier (Food Program)

Invasive Species Management (Food and Ornamental Horticulture Programs)

Registration Assistance for Products for Organic Markets (Biopesticide and Organic Support Program)

Facilitate the registration of chemistries that manage arthropod pests of medical concern (Public Health Program)

In July 2014, the PMC approved IR-4's newest Strategic Plan, ***IR-4 Project Vision 2020***. Besides reinforcing the initiatives in the previous strategic plans, the blueprint calls for efforts to improve efficiencies, enhance "grass roots" priority setting and outreach, and explore new sources of funds.

Food program

Since its inception in 1963, the IR-4 Project's main emphasis has been to support the regulatory approval of crop protection chemicals for specialty food crops and minor uses on major food crops. The IR-4 Project has conducted residue studies and submitted over 3500 tolerance petitions to regulatory authorities that have support over 16,000 uses of pest control products on specialty food crops. These registrations have helped growers avoid economic losses due to numerous arthropod pests, plant diseases and weeds.

Through IR-4 efforts and data, US grown specialty crops remain some of the safest in the world. The EPA will only allow use of plant protection products that have gone through a rigorous risk assessment, with strict adherence to modern safety standards for humans and the environment.

The EPA and IR-4 have worked closely together to support specialty crops and minor uses. The EPA had dedicated personnel to assist IR-4 directly. Some of the minor use support personnel in the early years of the EPA include, C.L. Smith, Wade Fowler, Henry Korp, Clinton Fletcher and Don Stubbs. EPA even assigned one of their regulatory scientists, Drew Baker, to IR-4 Headquarters in 1976. His duty was to provide advice to IR-4 research managers on studies and to do a pre-screen of regulatory submissions to ensure that all necessary information was clearly available.

In 1982, Hoyt Jamerson was selected as the EPA Minor Use Officer. His unwavering willingness to work with IR-4

Table 4. Total IR-4 Project Funding History (x $1,000).

FY	RRF	SRG	ARS	Animal Drug	Global	APHIS	PHP	Industry	Misc	Total
63-74	592									$592
75	$105	$250								$355
76	$110	$560	$410							$1,080
77	$135	$1,200	$910							$2,245
78	$135	$1,200	$910							$2,245
79	$150	$1,164	$910							$2,224
80	$158	$1,164	$910							$2,232
81	$176	$1,213	$910							$2,298
82	$200	$1,440	$910	$240					$35	$2,775
83	$227	$1,440	$1,100	$240					$70	$3,024
84	$254	$1,440	$1,100	$240					$58	$3,031
85	$289	$1,440	$1,100	$240					$70	$3,129
86	$320	$1,369	$1,100	$279						$2,935
87	$318	$1,369	$1,100	$229					$70	$3,003
88	$337	$1,369	$1,100	$229				$9	$35	$2,996
89	$352	$1,369	$1,100	$229					$35	$3,002
90	$347	$1,975	$1,100	$226				$10	$71	$3,601
91	$433	$3,000	$1,100	$450				$12	$40	$4,603
92	$456	$3,500	$2,100	$429				$92	$70	$6,218
93	$482	$3,500	$2,100	$429				$97		$6,180
94	$490	$6,373	$2,100					$291		$9,254
95	$490	$5,711	$2,100					$160	$50	$8,510
96	$482	$5,711	$2,100					$460	$10	$8,764
97	$514	$5,711	$2,100					$481	$10	$8,816
98	$482	$8,911	$2,100					$594		$12,087
99	$501	$8,990	$2,100					$303		$11,894
00	$482	$8,990	$2,100					$355	$60	$11,987
01	$482	$8,990	$3,100					$786	$288	$13,646
02	$481	$10,485	$3,600					$443	$63	$15,072
03	$481	$10,743	$3,800					$1,040	$94	$16,158
04	$481	$9,549	$4,000					$1,577	$189	$15,796
05	$481	$11,142	$4,000					$1,623	$244	$17,490
06	$481	$10,667	$4,000					$1,156	$359	$16,663
07	$481	$10,667	$4,000					$1,485	$257	$16,890
08	$481	$11,367	$4,000		$29			$1,618	$563	$18,058
09	$481	$12,000	$4,000		$241		$250	$1,453	$234	$18,569
10	$481	$12,180	$4,000		$331		$250	$1,022	$328	$18,342
11	$481	$12,180	$4,000		$409	$155	$250	$1,022	$365	$18,862
12	$481	$11,913	$3,900		$124	$567	$250	$1,149	$278	$18,663
13	$444	$11,006	$3,570		$242	$591	$250	$1,299	$180	$17,452
14	$481	$11,913	$3,200		$350	$462	$250	$1,520		$18,176
15	$481	$11,913	$3,200		$600	$195	$225	$1,200		$17,814
TOTAL	$16,198	$246,262	$91,040	$445	$2,323	$1,970	$1,725	$21,229	$4,835	$386,027

to resolve regulatory issues when needed regarding petition submissions was valuable in obtaining regulatory clearances. Jamerson was the first EPA employee presented with the IR-4 Hall of Fame Award when he retired to acknowledge his many contributions to the overall accomplishments to the food use program.

The 1988 Amendments to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA 88) triggered a significant need for IR-4 to defend critical older chemistry uses on specialty crops. FIFRA 88 required the accelerated development of agrochemical residue data and their submission to the EPA using current (at that time) state-of-the-art analytical equipment and procedures to support the continued registration of pest control tools that were originally registered before November, 1984. This law placed tremendous data development burdens on the agrochemical industry registrants. IR-4 grower and commodity group stakeholders feared that many specialty crop and minor uses would not be defended by the registrants through this process due to the cost of developing the required new data to meet the tougher new guidelines.

IR-4 developed a strategy to defend as many as 1,000 uses considered vulnerable to cancellation due to re-registration data requirements. The US Congress provided IR-4 with increased funds to develop the necessary data. With the new

resources, IR-4 was able to expand and develop the necessary data to defend and maintain registrations of 700 important minor uses.

In 1989, EPA's Office of Compliance extended the Good Laboratory Practice (GLP) regulations to include field studies. IR-4 was now required to operate under the GLP regulations. This resulted in some fundamental changes in IR-4 research operations including dedicated units for IR-4 research, standard processes in many aspects of research, the establishment of the Quality Assurance Unit (QAU), enhanced recordkeeping and identifiable study directors at IR-4 Headquarters who serve as single point of study control. In 1993, IR-4 upgraded its GLP process with the hiring of specialized QAU staff. Much of the credit for IR-4 GLP compliance measures goes to Tammy (White) Barkalow who was the first formal QAU employee and currently oversees this unit. The success of the QAU program may be measured in the over 150 EPA GLP inspections where no negative citations have been recorded to date.

During this same time (1989), IR-4 enhanced its involvement with the National Agriculture Chemicals Association (NACA-since renamed CropLife America or CLA). IR-4 was asked to participate and serve on industry wide workgroups to help shape research practices. Drs. Baron and Schwartz were the primary authors of the initial crop zone maps or data regions for the US and working with NACA members were instrumental in determining the number of trials needed per crop in each region to establish a residue tolerance. Baron also led in the development of a standardized Field Data Notebook that still is the template of data collected in residue studies. IR-4 continues to maintain a presence on appropriate CropLife America committees and workgroups.

In the mid-1990s, IR-4 became aware of the crop protection industry's shift in research and discovery strategies to newer chemistries that had desirable characteristics for consumers and the environment such as low toxicity, short environmental life, and high specificity for the targeted pests with little impact on non-target plants and animals. Because of this exciting new trend, IR-4 started focusing its efforts on this lower risk approach which later became known as the IR-4 Reduced Risk Chemistry Initiative.

In 1996, Congress passed Amendments to FIFRA and the Federal Food, Drug and Cosmetic Act. These Amendments were collectively called the Food Quality Protection Act (FQPA). These Amendments set a completely new and much higher standard for the reregistration of older agrochemicals and registration of new crop protection tools. In addition to the new safety standards, there were some incentives in the FQPA language to encourage specialty crop registrations. The FQPA extended the exclusive 10-year data protection period for a registrant under FIFRA when specialty crops were added to product labels. For every three minor uses registered (within seven years of the initial registration) up to one additional year could be added to data protection rights for a maximum of three additional years of protection. This provision to extend the exclusive marketing period has become a huge incentive for industry to register minor uses and to work with IR-4 to develop specialty crop uses for their new chemistries. Many registrants are now taking advantage of this incentive and it has also been written into Canadian law as well as European Union law.

The early years of FQPA implementation were not easy for the EPA or IR-4. IR-4 went from 82 food crop clearances in 1996 to only one food crop clearance in 1997. This was due to the Agency's efforts to interpret and implement the FQPA passed by Congress in 1996. In the fall of 1998, Mr. Jim Jones, then Director of the Registration Division, attended the IR-4 Food Use Workshop and worked with Bob Holm to form the EPA/IR-4 Technical Working Group (TWG) which started meeting in 1999 with Mr. Jamerson and Dr. Daniel Kunkel as Co-Chairs. Jamerson was instrumental in that role until his retirement in 2004 when Ms. Barbara Madden assumed this role as Minor Use Officer and TWG Co-Chair.

Some of the initiatives implemented through these TWG meetings in association with the EPA's Chemical Scientific Advisory Committee (ChemSAC) included the following:

Petition Summary templates allowing IR-4 and industry to submit a standardized format of summary documents that facilitate an easier and more efficient review by EPA.

"Super Crop Groups" – IR-4 proposed and EPA accepted comprehensive data extrapolations across multiple crop groups for certain Reduced Risk products such as spinosad and azoxystrobin. This action saved IR-4 over $1 million in laboratory and field trial expenses and resulted in hundreds of new uses without generating any additional residue data.

Screen Potential Research where EPA has agreed to prescreened potential chemicals prior to the Food Use Workshop in an attempt to help IR-4 focus on the chemicals with the clearest path towards registration. Chemicals classified as "Red Light" are not considered in the workshop, while "Yellow Light" materials are given higher scrutiny and "Green Lights' proceed without concern.

Petition Bundling: The EPA worked with IR-4 to bundle or submit as many petitions on an individual active ingredient as possible and feasible in order to utilize the Agencies resources for risk assessments and crop grouping opportunities most efficiently.

Reduced Risk Classification for Minor Crops: The EPA streamlined a format which IR-4 could use to propose studies to the Agency in a Reduced Risk Classification for minor/specialty crops.

Work Share Program with California: The California Department of Pesticide Regulation (CDPR) has its own state regulatory review process to ensure crop protection chemistries meet the standards set by state mandated guidelines. IR-4 helped facilitate this "Workshare Program" between the EPA and CDPR in 2000 where the CDPR does regulatory reviews of selected IR-4 petitions important to California specialty crop growers with the EPA granting the Federal registration, thus saving the EPA valuable resources.

Education tours for EPA scientists: IR-4 arranges a field tour of specialty crop agriculture for EPA staff each year to help them to understand better how pesticides are used by growers and to make them more aware of how important these products are for production agriculture.

IR-4's Methyl Bromide Alternatives (MBA) initiative started in 1998 and lasted to 2006 in association with the phase out of this important soil fumigant. This initiative was critically important to certain specialty crop production systems including growers of tomato, strawberry, pepper, cucurbit crops and ornamentals. IR-4 research, which was

managed by Dr. Jack Norton and funded primarily through contributions from cooperating agrochemical companies, entailed field evaluations in CA and FL of alternative systems for strawberry and tomato production systems. In 2003, the program was expanded to peppers, eggplant, cucurbit vegetables, cut flowers, turf and ornamental bulb crops. The data developed by IR-4 helped commodity groups obtain critical use exemptions (CUEs) to enable the continued use of methyl bromide until economical and technically viable alternatives could be registered. More importantly, IR-4 facilitated the support of an alternative product (dazomet) for the use on strawberries and tomatoes as a soil treatment and another product (propylene oxide/carbon dioxide) for postharvest use on stored spices, nutmeats, in-shell nuts, cocoa and cocoa beans. IR-4 helped in the registration process for furfural, a new product in the U.S. sold as MULTI GUARD PROTECT, for soil use and expanded the use of propylene oxide by label amendments to include dry fruits.

Since 2000, 70 to 80% of IR-4's research effort has involved new pest control technologies which are considered reduced or lower risk. IR-4 recognized that older chemistries were being greatly restricted or removed from the market entirely and made a strategic decision to focus on new products with lower risk. IR-4 worked closely with the crop protection industry to include IR-4 data supporting specialty crops with their initial registration submissions. IR-4 also instituted a publication entitled "New Pest Control Products/Transition Solution List" (http://www.ir4.rutgers.edu/FoodUse/NewProducts.cfm) to inform all stakeholders and the general public about the options and virtues of the new technologies available to assist in the transition away from the FQPA vulnerable products.

In January 2004, Congress passed The Pesticide Registration Improvement Act (PRIA-Fee for Service). This law has been reauthorized three times, most recently in 2012. PRIA ushered in a number of new challenges not only for the EPA but also for IR-4. There were many procedural changes that not only required the agricultural chemical industry to pay millions of dollars for the EPA to review their submission, some of which had been "backlogged" at EPA for several years, but also required significant alterations in the way IR-4 made submissions. To ensure that IR-4's petitions were being handled properly, EPA requested that IR-4 follow new procedures that included fee waiver letters, as well as Notices of Filing and for registration packages to be submitted on behalf of the registrants. As a result IR-4 has realized significant benefits from PRIA with the main benefit being a more predictable timetable for EPA decisions. IR-4 is also provided with a PRIA fee exemption on all tolerance submissions.

IR-4's submissions fall under PRIA time lines; a 15 month EPA review period for most submissions in which a new use is added to an existing registered pesticide. There is a 10-month timeline if the submission is considered by the EPA to be a Reduced Risk use. Because of these time lines, the EPA has challenged IR-4 to increase efficiency by bundling as many uses as possible for each chemical into a single petition and routinely to make no more than one submission for each active ingredient in a given year.

Crop grouping

An early initiative for IR-4 which was started in 1971 by Compton and Markle involved the concept of Crop Groups. This was the development of a model that allowed extrapolation of residue data from a few representative crops to many other crops in the same group. This allowed establishment of residue tolerances for the entire group of crops based on the residue values from certain key crops that were similar. This really amplifies the impact of each IR-4 study. On average, IR-4 can gain as many as five or more crop uses for each study conducted.

The first edition of "***Food and Feed Crops of the United States***" (Magness, Markle & Compton 1971) outlined the general crop grouping scheme with a focus on the type of edible plant parts (i.e. fruit, seed, roots, etc.) and their uses (vegetable, feed, etc.). The first edition included over 300 crops divided into large general groups; vegetables, tree fruits, tree nuts, oil crops, spices, grasses, non-grass feed, grains, etc. Within these large groups, the specific crops were subdivided or subgrouped by like parts such as root and tuber, fruit, leaves, pods, etc. The first edition was used as the basis for the international FAO/WHO Codex Alimentarius crop groups' classifications in 1978 and by the EPA in 1983 and again in 1995 for their early crop grouping scheme.

The second edition of "***Food and Feed Crops of the United States***" (Markle, Baron & Schneider 1998) continued to improve the regulatory processes with more standardization included in the scientific base. It serves as a complete source of food and feed information and the basis of a significant part of the current food safety regulatory guidelines with many specialty crops being grouped with larger consumption representative crops which are used for the crop grouping residue studies. The second edition contains over 1,000 scientific crop names along with their common and principal vernacular names and synonyms. This edition classified crops in 10 primary or large crop groups (i.e. vegetables, fruits, etc.) and 31 principal crop groups (i.e. root and tubers, citrus, berries, etc.).

The last decade has seen dramatic changes in the crop grouping approach driven mainly by the rapid development of global food crop markets and import/export activities. In 2002, IR-4 sponsored an International Crop Grouping Symposium in Arlington, VA. The report of this Symposium (CGS) proposed an expansion of the scheme in place by adding a significant number of new crops and groupings. In 2003, the IR-4/EPA Crop Grouping Working Group, under the guidance of Dr. Hong Chen and more recently, Mr. William Barney, was formed to make the proposal part of federal regulation. To assist this effort and make it more global in nature, the International Crop Grouping Consulting Committee (ICGCC) was established in 2004, representing specialty crop, regulatory, and agrochemical experts from about 40 countries. This international effort has significantly helped to promote harmonization of the U.S., Canadian, and Codex crop classification systems.

In 2007, the EPA and the Canadian Pest Management Regulatory Authority (PMRA) codified changes in the Bulb Vegetables, Berries & Small Fruit groups. They also established a new Edible Fungi group. Three years later in 2010,

the North American regulatory authorities modified the Fruiting Vegetables, Citrus Fruit, Pome Fruit groups and established the Oil Seed group to harmonize regulation in the two countries. Most recently, in 2012, there were publications and codification of modifications to the Stone Fruit and Tree Nuts groups. In addition to the above, the EPA and PMRA have accepted, but not yet codified, modifications to the Leafy Vegetables, Stalk, Stem & Leafy Petiole, Brassica Head & Stem groups. The formal approval is expected in the near future and a final group of updates to cucurbit, cereals and the few other remaining crops will follow as the final update.

Without crop groupings and representative crops from each group for residue analyses, as was the reality during the first decade of IR-4's existence, the old paradigm of conducting a residue study for each specialty crop would still be in place. This would have resulted in less than 20% of the current specialty crop clearances over the past 40 years and probably only 10% with the new crop grouping initiatives. For each study IR-4 conducts, an additional 5 commodities can be added to product labels, and after the update is complete, it is expected that each study may support up to 10 crops.

In April 2012, the Codex Committee on Pesticide Residues adopted crop groups similar to the North American based approach for all of the Fruit type crops. Not only did they accept the expansion of the groups but they also approved the concept of representative crops and data extrapolation. The acceptance of representative crops is the critical component of the savings from using the crop groups.

In addition to the codified crop groups, IR-4, on a case-by-case basis for certain situations, has also proposed broader extrapolations of the crop group approach to help growers.

International harmonization

IR-4's involvement with efforts to remove pesticide residues as a barrier for exports for US-grown specialty crops has been growing in importance over the last 20 years. Now using IR-4 data to support exports has become a common aspect of IR-4's efforts and is an expanded use of the data generated by IR-4.

In the mid-1990s, Health Canada's Pest Management Regulatory Agency (PMRA) sent a representative, Douglas Rothwell, to attend IR-4 Food Use Workshops to explore opportunities for partnership projects. Canadian specialty crop growers were also represented by the Canadian Horticultural Council and were somewhat frustrated by not having access to the new, reduced risk chemistries being made available to U.S. specialty crop growers. This also led to significant trade issues due to a lack of MRLs for the new crop protection tools in Canada, which could restrict U.S. grower exports to Canada. To address these issues, PMRA and the Canadian Horticultural Council started conducting joint residue field programs with IR-4 in 1996. Over the next 5 years, a total of 6 joint residue trials were conducted in Canada and the first joint U.S. and Canadian residue petition for fenhexamid on caneberries was submitted to PMRA by Dr. Johannes Corley in 2001 for a joint review with the EPA.

During the period from 2000 to 2002, Drs. Holm, Baron and Kunkel were invited to Canada on numerous occasions to consult with PMRA and Agriculture and Agri-Food Canada (AAFC and Canada's equivalent to the USDA) on setting up a minor crop support program similar to IR-4's in Canada. The Canadian government made a major funding commitment in 2002 to AAFC to set up the Pest Management Centre (CN-PMC) along with 10 Field Research Centers to conduct the field portion of GLP residue trials and residue analysis. This allowed the CN-PMC Team to conduct 52 joint residue trials on 20 joint studies in 2003, compared to 6 trials during the entire period from 1996 to 2001, and resulted in much greater capacity for both the U.S. and Canadian efforts to address joint pest control needs. CN-PMC continues to cooperate with IR-4, contributing in joint data development activities. In 2012, CN-PMC expanded their activities and started to assume the responsibilities for Study Director and Sponsor for some of the joint studies.

During that same period, the EPA and PMRA developed standard operating procedures for conducting joint reviews of these minor use submissions, which save the regulatory agencies significant time and effort. By establishing a common MRL on a specialty crop from a particular crop protection products use, trade irritants between the two countries can be prevented before they have the potential to become a major problem for specialty crop growers on each side of the border. The U.S./Canadian specialty crop partnership has yielded valuable results for all stakeholders involved.

To further this cooperative work, IR-4 worked with the EPA and Canadian authorities to implement the pesticide related areas in President Obama's initiative with Canada's Prime Minister Harper known as the Regulatory Cooperation Council (RCC). Here IR-4 has been working with partners in Canada (Pest Management Centre of Agriculture and Ag-Food Canada) to develop even more harmonized processes and data generation that will allow the US and Canadian regulatory authorities to share resources to review data to eliminate trade barriers and technology gaps between the two countries further.

Much credit for the close coordination between the CN-PMC and IR-4 can be given to Shirley Archambault, who worked in that capacity for the Canadian Horticultural Council and for the past 10 years has served as the IR-4 Coordinator for the CN-PMC. Archambault also represents Canada at U.S. crop protection industry partnership meetings. In 2009, Manjeet Sethi joined the CN-PMC as Executive Director. Under his leadership, the programs have been expanded to include more work with IR-4 and the productivity of the organization has increased.

IR-4 also regularly participates in global organizations that involve pesticide issues and commodities in trade and makes submissions to the Joint Meeting on Pesticide Residues (JMPR) which are used by the Codex Committee on Pesticide Residues to establish Codex Maximum Residue Levels for international trade.

IR-4 provides support by assisting the EPA, as part of the US delegations to both the CCPR and Organization for Economic Co-operation and Development (OECD) as well as the Working Group on Pesticides and the NAFTA Technical Working Group on Pesticides. IR-4 also plays a key role on the OECD Expert Group on Minor Uses, where a number of guidance documents have been prepared and released over the past few years with regard to minor use issues. Additionally, IR-4 assists other countries, both developed and less developed, as they begin to establish minor use programs

and have signed MOUs with Canada, New Zealand, Brazil, Costa Rica, and Colombia. The knowledge and expertise of IR-4 is often sought and is highly valuable to these countries as their minor use programs evolve and develop.

IR-4's international involvement is highlighted with the leadership role it played in the first and second Global Minor Use Summits. Both Summits were held at the United Nations Food and Agriculture Organization (FAO) Headquarters in Rome, Italy and co-organized by the FAO, USDA, EPA, and IR-4. The first Summit was held in December 2007 and Chaired by Jerry Baron. The second Summit was held in February 2012 and Chaired by Dan Kunkel. Over 250 delegates attended the Summits representing over 50 industrialized and developing countries. The First Summit outcome was Five Action items and the second Summit resulted in a five year work plan that categorized items into short, medium and long term timeframes to support and address minor use issues.

Starting in 2012, IR-4, in cooperation with the USDA-Foreign Agriculture Service (FAS), has been conducting capacity building training programs in Southeast Asia, Africa and Central/South America. These programs cover all aspects of the conduct of Good Laboratory Practices in magnitude of the residue studies including pesticide applications, laboratory analysis, data package development and Standard Operating Procedures. The goal of this work is to develop research partners in this region who can cooperate on specific research studies when US priorities match the Asian priorities. Funds for these activities are being provided by the Standards Trade Development Facilities through the World Trade Organization. The Summits served as a spring board for minor use activities including collaborations and cooperation of many partners around the world. This work continues to expand and most recently moved to a new level of cooperative research during the First Global Minor Use Workshop (September 2015), where nearly 200 participates from over 30 countries identified minor use needs and selected cooperative research projects to address growers' needs. In late 2015, USDA provided a "seed" grant to establish and sustain a Global Minor Use Fund to support its continued efforts by international specialty crop community to develop cooperative, international research programs.

Ornamental horticulture program

In early to mid-1970, awareness was growing for the need to register materials for non-food uses (foliage and flowering plants in the greenhouse and out of doors; bedding plants; woody ornamentals; shade trees; and turf) because of the 1972 amendments to FIFRA. These specialty crops were also underserved, and growers and landscape maintenance personnel needed an adequate supply of registered tools in order to manage pests, diseases and weeds. The ornamentals industry approached T. W. Edminster (then Administrator of ARS) with the request that ARS assist with data development to register ornamental uses. Edminster provided $500,000 of ARS funds and directed ARS's National Program Leader for Entomology, Dr. Paul Schwartz, to develop cooperative research with IR-4 to obtain ornamental registrations.

To serve this segment of specialty crop agriculture, the IR-4 Project in 1977 added a new research objective that involved developing data to answer pest management voids in nursery and floral crops, forest seedlings, turf grass, and Christmas trees. This objective became what is now known as the Ornamentals Horticulture Program. This aspect of IR-4 involves the development and collection of crop safety and/or product performance/efficacy data to add new ornamental species and/or pests on existing product registrations.

From left to right are Jerry Baron, Chuck Powell, Richard Lindquist, J. Ray Frank, Paul Schwartz and Cristi Palmer.

The first IR-4 /USDA-ARS Ornamental Workshop was held in April 1977 in St Louis, MO. The needs of the industry were condensed into 5621 distinct project requests. The Second Workshop was held later that year in December in Dallas, TX and prioritized these requests. Ray Frank, Dick Lindquist and Chuck Powell led the prioritization with legendary marathon sessions lasting late in the evenings (Figure 3).

The first IR-4 supported registrations were for new uses of Banrot (etridiazole and thiophanate-methyl), glyphosate, and Ronstar (oxadiazon) which were approved in 1978. In 1981, a special project was initiated to determine which products were efficacious and should be labeled to control black vine weevil. Six products were tested on 20 ornamental species.

In the early years of the Ornamental Program, it was managed part-time by several scientists at IR-4 Headquarters, including Dr. Joe Elson, Dr. William Biehn and Dr. Dan Kunkel. In 1993, J. Ray Frank assumed responsibilities for managing the IR-4 Ornamental Program. Heavy emphasis was placed on developing crop safety data to aid in adding new crops to existing labels.

Dr. Bob Herrick became Ornamentals Manager in 2004 and succeeded in bringing about two key changes: renaming the program Ornamental Horticulture Program and enabling dedicated funding for ornamental horticulture research projects. Dr. Cristi Palmer was hired in 2005 to replace Bob Herrick as Program Manager. She introduced a grower and extension survey to augment the project request process as a means to gauge industry pest management needs without focusing on specific active ingredients. The workshop format was revised so that participants discussed and prioritized current pest, disease, and weed management needs first and then discussed solutions for those needs. The status of EPA registrations became the basis for setting priority levels of products included in research programs. About the same time,

IR-4 expanded into invasive species research by accepting an invitation to participate in the Technical Advisory Committee of the USDA Interagency Task Force for Q-Biotype Whitefly (*Bemisia tabaci*) (Q-TAC).

The Ornamental Horticulture Workshops started meeting every other year in 2009. Workshop participants hear presentations on ongoing projects and potential uses for existing and new products from university research and extension agents, ARS scientists, and agrochemical industry representatives. The growers, researchers and extension agents (but not agrochemical representatives) establish high priority projects for the following two year period in the weed science, plant pathology and entomology disciplines. About 50% of the work is efficacy testing to add new pests to existing registrations and the other 50% of the work is crop safety testing.

The non-food specialty crops make up over 15% of the total sales value of all production crops and 36% of all specialty crop sales. According to the 2007 Census of Agriculture, the total sales value of non-food specialty crops was $13.7 billion (Clark 2009). To date, the IR-4 Ornamental Horticulture Program has delivered to the industry more than 16,000 crop uses with over 100 registrations. Lin Schmale of the Society of American Florists has noted:

"***IR-4 is an invaluable resource for greenhouse and nursery growers – not just in helping make sure they have access to the chemical and biocontrol tools they need to control pests and diseases, but also to support research that helps them use those tools wisely. Specialty crop growers are definitely getting double and triple benefits from the IR-4 program; because the program listens to the industry … you hear our voices!"***

Biopesticide and organic support program

In 1982, the IR-4 Project objectives were expanded to add research on biological-based pest control agents at an early stage in their development. Previous involvement by IR-4 on these materials was at an advanced registration stage. This expansion of mission led to the formation of the Biorational Program, which was later named the Biopesticide Program. The name was changed in 2008 to Biopesticide and Organic Support Program as recognition of the growing organic industry which to a large extent, relies on biopesticides for their pest control needs.

IR-4's objective is to develop product performance data and provide regulatory guidance to support the registration of microbials, viruses, biochemicals, plant incorporated protectants and other relevant technology to support new registrations in conventional and organic agriculture. IR-4 accomplishes this through regulatory support for technology discovered/developed by public sector scientists and small businesses and through funding product performance research to assist with registration. Additionally, with a grant in 2007 from EPA Region 2, IR-4 developed a Biopesticide and Organic Product Label Database which provides an online mechanism to search the latest biopesticide registrations by crop, by pest and by state.

Dr. William Biehn was IR-4's first Biopesticide Program Manager. Upon his retirement in 1999, Dr. Michael Braverman assumed the management responsibilities. Some of the notable accomplishments of this program include:

- Registration of a AGRIPHAGE for the control of bacterial canker in commercial greenhouse tomato production;
- Registration of nine products, including hop beta acid, thymol, euclyptol, camphor, formic acid, menthol, amitraz, coumaphos to control mites in honeybees;
- Registration of a biofungicide (Regalia) extracted from giant knotweed (*Reynoutria sachalinensis*) which controls powdery mildew and other diseases which was awarded the "Best New Biopesticide" award from Agrow in 2012; and
- Registration of AF 36 to control aflatoxin (a potent natural carcinogen).

Estimating the value of the Biopesticide and Organic Support Program presented some challenges because biopesticide use is often associated with integrated pest management practices, organic farming, and use on specialty food and non-food crops. The Michigan State Center for Economic Analysis researchers point out there is no current comprehensive cost/benefit studies of biopesticides in agriculture (Miller & Leschewski 2012). However, they were able to estimate an annual GDP impact of $155 million which appears to be a solid return on the estimated annual expenditure of $1.5 million (both direct and in-kind funding).

Animal drug program

In 1982, IR-4 was given the responsibility to develop the necessary information and data needed to facilitate the regulatory clearances by the Food and Drug Administration's Center for Veterinary Medicine (FDA/CMV) for drugs to be used to treat illnesses in minor food animal species. The need for this objective was articulated several years earlier when FDA initiated an extensive study of the minor use of animal drugs where they identified many gaps in the availability of drugs to manage the principal diseases on these minor animal species. The gap existed because the cost of generating the necessary data to support a modification to the claims for an existing approved drug is significant and time consuming.

IR-4's involvement in animal drugs was short-lived. A USDA Peer Review Panel recommended in 1990, that the animal drug program become separate from IR-4. This recommendation was implemented in 1993 when a new USDA Program NRSP-7, was established as the stand-alone Minor Use Animal Drug Program.

Public health pesticide program (PHP)

The PHP Program is IR-4's newest initiative and was started in 2009 to assist in the development and registration of pest management technology that protects the public from mosquitoes, ticks, sand-fleas and other arthropod vectors that transmit diseases such as malaria, Dengue fever, West Nile virus and Lyme disease. This initiative has been funded through a cooperative agreement by USDA-ARS and the Department of Defense's Deployed Warfighter Protection Program (DWFP). The program has been led from the beginning by Dr. Karl Malamud-Roam and is built on IR-4's traditional expertise in supporting small market pest management efforts and link-

ing key researchers, commercial partners and regulators in the development of new public health pest control tools.

PHP Program successes were noted as early as 2011 with the first federal and state Experimental Use Permits for a series of experiments conducted by the U.S. Navy, Rutgers University and the University of Florida using the reduced risk insecticide, pyriproxyfen, to manage Asian tiger mosquitoes (*Aedes albopictus*) in New Jersey and Florida urban areas. Also that year, a GLP residue study led to the submission to the EPA of a petition for all-crop tolerances from application of the mosquito adulticide, ethofenprox, which was a high priority product for vector control programs. IR-4 also initiated a comprehensive, public database specifically dedicated to public health pesticides.

Crop protection industry

The IR-4 Program could not exist without the cooperation of the crop protection industry which provides IR-4 access to its chemistries and biopesticides for solving specialty crop growers' pest problems. The partnership has evolved greatly; initially the companies only allowed IR-4 access to products that were already registered on major crops. IR-4 would develop the appropriate data (usually guideline residue data) to extend uses to new specialty crops.

A major change in how IR-4 interacts with the companies occurred in the mid-1990s when IR-4 started working with the companies on specialty crop uses for new crop protection products in advance of their first US registrations. This change was largely due to some of the data extension protection incentives mentioned earlier which are provided by the US government for companies to extend their products to specialty crops. For the first time, IR-4's data to support specialty crop uses, were bundled with the company's initial submissions.

Another major changed occurred in mid-2000 when the companies became increasingly concerned about international MRLs and the impact of pesticide residues being an artificial trade barrier. Without corresponding MRLs in importing countries, US growers could not export certain treated produce. To solve this problem proactively, IR-4 began working with companies to ensure there are adequate MRLs to allow full trade.

Over the years, IR-4 has participated in numerous unique cooperative research projects which benefit the specialty crop growers. For example, in 2004 DuPont introduced IR-4 to chlorantraniliprole, one of their new products that was still in development. This product had superior efficacy on lepidopteran insect species with wide safety margins for humans and the environment. IR-4 determined that chlorantraniliprole would be a good fit on specialty crops. With IR-4's encouragement, DuPont disclosed information on chlorantraniliprole at the 2004 IR-4 Food Use Workshop to interested researchers, extension personnel and progressive specialty crop growers. This was DuPont's first public disclosure of this new active ingredient. Several entomologists were impressed with the product and consensus was developed to support registrations for peaches and grapes. Canada was also interested in this new product and a joint research project was started to complete a North American registration strategy.

Chlorantraniliprole was the first truly global joint review of a pest control product and included regulatory agencies from the US, Canada, Ireland, the United Kingdom, Australia, and New Zealand. After approval by the reviewing countries, the same data were used to establish Codex Maximum Residue Limits (MRLs) and in a very short period of time the product was registered in more than 60 countries. This successful cooperative work has been repeated a number of times since with newer, safer products with the result of providing quicker access to specialty crop growers.

Not only do companies provide IR-4 access to their new products but they also provide direct and in-kind resources. Specifically, they provide staff to serve as IR-4 liaisons who review PCRs, protocols and final petition submissions, attend the IR-4 Food Use and Ornamental Workshops, and set up and actively participate, along with other company product development, regulatory and business staff, in annual technical review and partnership meetings with IR-4 staff. Companies also provide analytical standards and methods of analysis, and in some years have served as the analytical labs for IR-4 studies.

The organizations that represent the conventional pesticide and biopesticide companies (CropLife America and Biopesticide Industry Alliance) provide IR-4 an opportunity to participate in many broad industry initiatives. IR-4 is an active observer on many industry committees and workgroups. These organizations look to IR-4 to be an important participant and contributor in many important processes that influence policy.

Communications and public relations

IR-4's communications programs have evolved over the years to keep up with the ever changing technology. For many years, the then familiar green IR-4 Newsletter under the editorial direction of George Markle was published quarterly and consisted of a comprehensive report on program activities. When Professor Markle retired, the PMC recognized that a full time professional was needed to carry on the program and initiate new approaches. Sandy Perry was hired as the National Outreach Specialist located with the Northcentral Region. Perry retired in 2003 and Sherrilynn Novack was hired as the IR-4 Publications Communications Coordinator located at Headquarters to facilitate more efficient coordination of the communications program throughout the program. Novack brought the idea of "branding" to IR-4's communication programs in much the same way companies do to generate recognition for their products or service. The revamped Communications Program of the past ten years with the enhanced newsletter and IR-4's website (http:\\ir4.rutgers.edu 2014), has contributed greatly to how the IR-4 Program has increased its recognition and stature both internally with key stakeholders and externally with consumers and the general public.

Value and impact

There have been several efforts, over the years, to put a dollar figure on the economic impact of the IR-4 Program to the U.S. economy. This is an extremely difficult value to ascertain.

One measure of the success of this program, other than the large effort over the past decade by IR-4 to provide reduced risk alternatives to specialty crop growers, is to look at the decline in use of the pre-FQPA chemistries and the increased use of reduced risk chemistries. The California Department of Pesticide Regulation (CDPR) has studied these trends for over 10 years. From 1994 to 2006, they observed an overall decline of about 50% of the use of OP and 70% use of carbamate insecticides. The use of B2 (carcinogen classification) fungicides showed a lower decrease of 10 to 20%. However, reduced risk insecticide and fungicide chemistries showed a steady increase during this period and are now considered a central element to fruit and vegetable pest management programs. It was estimated that about 50% of the reduced risk products registered during this period were the result of the IR-4 Program. By all measures, IR-4's efforts with reduced risk chemistries has been an important factor in helping U.S. specialty crop growers not only to provide domestic consumers, but also global consumers, with the world's safest food (Vircey & Hollingworth 2009).

For many years, IR-4 collected anecdotal stories from commodity organizations to estimate the impact of IR-4's work. Starting in 1998, IR-4 collated the loss avoidance values that the EPA collected in association with Section 18 Emergency Exemption requests. This "snapshot" would be able to provide an indication of how much economic damage a specific pest cost in a specific state. Because there were so many Section 18s on-going at that time, the loss avoidance values were extremely impressive. Over $20.7 billion has been recorded over the last 15 years in total.

The most recent and by far the most comprehensive study detailing IR-4's contributions was published by the Michigan State University Center for Economic Analysis (Miller & Leschewski 2012). They studied the impact of IR-4's output on associated employment, labor income and Gross Domestic Product (GDP). When well-established methods of measuring direct and secondary economic impacts are used to gauge the contributions of the IR-4 Project and its three primary programs, including the Food Crops, Ornamental, and Biological and Organic Support Programs in terms of sales, employment and gross domestic product, the results are significant. Each program results in real economic benefits to growers and the economy as a whole. Specifically, growers benefit in higher yields with higher quality output, consumers benefit by greater selection and quality with lower costs to food and ornamental crops, and the industry benefits through better global competitiveness of U.S. output. Including all secondary impacts, the IR-4 Project is anticipated to support research and industry sales sufficient to support 104,650 U.S. jobs and increases annual gross domestic product by $7.2 billion.

IR-4 Hall of Fame/other awards

The IR-4 Hall of Fame award is the highest honor bestowed upon an individual by the IR-4 Project. Typically Hall of Fame honorees have gone well above and beyond the call of duty to serve the mission of the IR-4 Project and to make remarkable contributions to advance the program. Only 30 individuals have been inducted into the IR-4 Hall of Fame. The members of the IR-4 Hall of Fame, along with their role in the success of the IR-4 Project are listed in Table 5.

In 2008, IR-4 established the National Excellence Award to recognize the highest level of meritorious service. This award is only given out once every three to four years to a limited number of highly deserving candidates. To date, IR-4 has only awarded five individuals with the National Excellence Award. The honorees are Robin Adkins, IR-4 Southern Region; Dr. Nancy Ragsdale, USDA-ARS; Marylee Ross, University of Maryland; Roger Batts, North Carolina State University; and Rebecca (Becky) Sisco, IR-4 Western Region.

IR-4 Headquarters established a new award in 2010, the SOAR award to recognize excellence in four criteria; **S**ervice, **O**utreach, **A**ltruism, and **R**esearch. This award is given on an annual basis to an individual who excels in at least three of the four criteria. To date, six individuals, Dr. John Ahrens, Connecticut Agriculture Experiment Station; Lori Berger, California Specialty Crop Council; Daniel Botts, Florida Fruit and Vegetable Growers Association/Minor Crop Farmers Alliance; Mike Benzen, North Carolina State University, Dr. Mary Hausbeck, Michigan State University and Dr. Robin Bellinder, Cornell University, have received this award.

The future

IR-4 continues to perform its mandated duties promptly and with tremendous efficiency. IR-4 has provided hundreds of commodities with their primary pest management tools and stands ready to develop new data to support the regulatory clearance of new pest management tactics that will be needed to address the ever changing challenges of pest management. However, the environment in which we live today is much different than in 1963. We fully expect many more changes in the coming years. IR-4, as an organization, must continue to evolve in order to meet the needs of the primary stakeholders.

We predict that new conventional chemical pesticides and biopesticides will still be developed by the private sector to protect crops from devastating pests. The continued discovery of new damaging invasive pest species, an increasing world population, and shifts in pest distribution due to climate change will all point to an increased need for pest management in specialty crops in the years to come. The next generation of innovative pest management technologies will be even lower risk than the current generation of products that are classified by the EPA as Reduced Risk. Pest management will continue to evolve to a broad systems approach to manage pests, resistance of pests to pesticides and to manage residues on the finished food product. Crop protection technologies will be used in a truly prescriptive manner. The need for IR-4 to develop residue data will remain a priority for many crops.

There will be increasing need for IR-4 to develop data showing the efficacy of a pest management tactic on specific target pests. We anticipate that IR-4 will be asked to take the lead on developing pest management systems approach for certain ultra-small area specialty crops.

The use of biotechnology derived pest management will become increasingly accepted by the public. Additionally, alternative pest management technologies will be discovered that will be regulated by the EPA, FDA, USDA and other national and international authorities. There will always be

Table 5. IR-4 Hall of Fame Members.

Name	Award Year	Role
Charles Compton	1987	National Director
Edward Swift	1987	CA State Liaison
Harold Alford	1989	Field Coordinator -West
Thomas Archer	1989	Laboratory Coordinator-West
John Mahlstede	1989	Administrative Advisor
Howard Wilkowske	1989	Administrative Advisor
Virgil Freed	1990	Technical Committee
Baily Pepper	1990	Technical Committee
John Bourke	1991	Region Director-Northeast
Duane Coyier	1991	USDA-ARS Liaison
Robert Menges	1993	ARS Field Research
TJ (Jack) Sheets	1993	Satellite Laboratory Director
Ken Dorschner	1994	CSREES Representative
Willis Wheeler	1997	Region Director-South
Gene Carpenter	1998	State Liaison Representative
Richard Guest	1999	National Director
Robert Libby	2000	National Research Coordinator
Patricia Sarica	2002	Assistant Director
Taka Shibamoto	2002	Region Director-West
George Markle	2003	Co-National Director
Neal Thompson	2003	Administrative Advisor
J. Ray Frank	2003	Ornamental Program Manager
Hoyt Jamerson	2003	EPA Minor Use Officer
Robert (Bob) Holm	2006	Executive Director
Chuck Mouer	2008	Laboratory Coordinator-West
Marion Miller	2013	Director-West Region
Lois Rossi	2014	EPA-Registration Division Director
Bob Hollingworth	2015	Director-North Central Region
Diane Infante	2015	Data Specialist
Mary Duryea	2015	Administrative Advisor-Southern Region

a financial threshold where private industry can no longer invest resources to develop the necessary data or collect information to support the use authorization. IR-4 will stand ready to help the "minor use" community to gain access to new pest management technologies. Furthermore, public institutions will develop technologies that will require regulatory support. IR-4 will often be viewed as a regulatory consultant for the USDA and the land grant institutions to help get their discoveries through the necessary regulatory process to make these technologies more desirable for licensing to investors.

IR-4 will continue to cooperate with international organizations to identify pest management needs for specialty crops and cooperate with their development. We expect that all future pest management technologies will be targeted for global registration. This will be the result of continued globalization through trade and a sharing of resources due to continued budget retractions. IR-4 will lead in the establishment of a not-for-profit foundation that will coordinate the development of global data packages for new technologies on specialty crops.

Management of pests that vector human or animal diseases will become of increasing importance in developed countries. Changes in climate and habitat will allow pests that vector these diseases to survive and thrive. Public investment to develop or reposition pest management technologies to manage the vectors of key diseases is likely. The IR-4 Project will be able to utilize its expertise to assist in this area.

Finally, imports of goods from global trading partners will serve as an entry of invasive pests into the United States. Invasive species containment and management will be of increased importance. Because of IR-4's regulatory expertise and infrastructure, governmental partners will solicit IR-4 for involvement in developing of pest management solutions.

As with the last 50 years, it is expected that the mission of IR-4 will continue to be relevant, evolve and to continue to address the needs of US specialty crop growers.

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Dr. Jerry J. Baron is the Executive Director of the IR-4 Project, a cooperative program in the United States of the state agricultural experimental stations, US Department of Agriculture, growers/commodity organizations, the crop protection industry and the US Environmental Protection Agency. Dr. Baron is responsible for the day to day operations of the IR-4 Project with an operation budget of approximately $18 million US dollars and 125 full time scientists. He was formally President of the Northeastern Weed Science Society in 2008-2009 and was elected as Fellow of this organization in January 2015. He was Chair of the Organization Committee of the first Global Minor Use Summit. He currently serves on the editorial board of *Outlooks of Pest Management* and Board of Directors of the IPM Voice.

Daniel Kunkel is the IR-4 Project Associate Director for Food and International Programs where he provides overall management of the IR-4 Food Use Program which consists of a regulatory team of study directors, research

planning, and the Quality Assurance program. The Food Program develops regulatory data for the registration of Pesticides on Specialty crops. Coordinates data submission to Codex (JMPR) and other international authorities to support US trade and provides support for the Global Residue Date Generation projects (funded through STDF). Serves as a US delegation member for the NAFTA Technical Working group on Pesticides, CODEX Committee on Pesticide Residues and with OECD as a member of the Expert Working Group on Minor Uses. Served as the Program Chair for the Second Global Minor Use Summit and for the first Global Minor Use Priority Setting Workshop. Earned a Ph.D. from Cornell University and a Master's Degree from Southern Illinois University.

Robert (Bob) Holm retired in 2006 after 30 years in the crop protection industry in research and development management positions at Diamond Shamrock Corporation, Mobil Crop Chemical. Rhone-Poulenc and Valent USA Corporation. He served as Executive Director of the IR-4 Program the previous 8 years before retirement where he helped in the FQPA transition to safer, Reduced Risk chemistries and biopesticides and closer cooperation with the crop protection industry and the EPA. After retirement, he consulted for the crop protection industry and served as Membership Chair and Vice-Chair the Board of Directors for the Biopesticide Industry Alliance. He has been accepted into the IR-4 Hall of Fame and received the Agro and BCPA Lifetime Achievement Award. He earned his M.S. and Ph.D. degrees in Plant Physiology and Biochemistry from Purdue University.

Similar articles that appeared in *Outlooks on Pest Management* include – 2002 **13(5)** 185; 2006 **17(4)** 185; 2009 **20(5)** 229; 2010 **21(3)** 132; 2014 **25(3)** 230