

IR-4 PROJECT: VISION 2020



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IR-4 Project: Vision 2020

Introduction/Background

Since 1963, the IR-4 Project (IR-4) has been the primary entity in the United States to facilitate registrations of conventional pesticides and biopesticides on specialty food crops (fruits, vegetables, nuts, herbs, spices) and non-food ornamental horticulture crops (greenhouse flowers, nursery, landscape plants, and Christmas trees). These registrations are necessary to prevent damage to the crops we eat or the plants that enhance our environment. The crop protection industry focuses their product development efforts on large acreage crops with significant sales and adequate return on investment. Specialty crops are low acreage and potential sales are limited, often not enough to provide an adequate return to the registrant.

The IR-4 Project often serves as an intermediary between the crop protection industry and specialty crop farmers to facilitate the regulatory approvals that meet the pest management needs of these producers/farmers. In this capacity, IR-4 develops research data to support US Environmental Protection Agency (EPA) registrations and cooperates in the registration of pest management tools for minor uses on major crops. Additionally, IR-4 effectively and efficiently gains many added uses through extrapolation and crop grouping.

The IR-4 Project operates as a unique partnership between the Federal government (USDA, EPA, and Department of Defense), the land-grant universities/State Agricultural Experiment Stations (SAES), farmers/commodity associations, food processors, the crop protection/pest management industry and international partners (e.g. Pest Management Centre of Agriculture and Agri-Food Canada). The IR-4 Commodity Liaison Committee (CLC) provides IR-4 with a direct link to specialty crop farmers/commodity associations. The CLC provides stakeholder guidance and suggestions on policy. See the IR-4 Project website (<http://ir4.rutgers.edu>) for a detailed overview of the IR-4 Project.

The IR-4 Project has made a substantial impact on U.S. agriculture over the past 50 years. Its research data has been used to garner nearly 16,000 food crop registrations and an additional 160 product registrations impacting nearly 31,000 ornamental crop uses.

A recent study from Michigan State's Center for Economic Analysis concluded that IR-4 contributes an estimated \$7.2 billion to U.S. Gross Domestic Product and the Program supports nearly 105,600 jobs¹. Without IR-4 intervention, it is anticipated that many specialty

¹ Miller, S.R. and A. Leschewski (2011). Economic Impacts of the IR-4 Project and IR-4 Project Programs. East Lansing, MI: Michigan State University's Center for Economic Analysis.

crops would enter the food supply with illegal pesticide residues and in many crops there would be significant crop losses which would make these healthy foods extremely expensive and in some cases, unavailable for consumers.

To ensure that the IR-4 Project remains relevant to its stakeholders and worthy of a government funding, the IR-4 Project Management Committee conducts an extensive process that includes, updating of the Project's strategic plan, a formal review by outside experts to substantiate the value of IR-4 activities, and if appropriate, reauthorization of the Project by USDA/State Agricultural Experiment Station Directors. This process is conducted every five years; the last expert panel issued a report in 2009; a copy of the expert panel's report and IR-4's response is in Appendix 1.

The IR-4 2009-2014 Strategic Plan expanded the Project's mission to become more actively involved in three areas:

- **Assist U.S. specialty crop farmers to compete in international** trade by aiding in the harmonization of pesticide use and country-specific Maximum Residue Levels (MRLs), which often differ between the US and its global trading partners.
- **Research to mitigate invasive species** which cause economic and environmental hardships as well as disrupts Integrated Pest Management (IPM) systems and strategies.
- **Initiate a public health pesticide program** to protect US Armed Forces and the public from arthropod pests that transmit disease to humans.

See Appendix 2 for accomplishments under the IR-4 2009-2014 Strategic Plan.

Many acknowledge that with the rapidly expanding global population, climate changes and other major issues, the challenge of production and distribution of adequate food will become more acute. Not only must farmers produce more food, science is challenged to improve food quality, shelf life of products, and reduce storage losses to pests, including post-harvest diseases. IR-4 is a proven, publically funded, science based entity that can assist with these challenges now and in the future.

As IR-4 moves into the next five-year strategic planning timeframe, a strategic planning survey was conducted from September to November 2013 to solicit input on future directions from the specialty crop/specialty use community. Over 550 stakeholders responded and their anonymous comments, ideas and suggestions influenced the development of this **IR-4 Project Vision 2020**. A summary of their survey responses is included in Appendix 3.

The Need for IR-4

The IR-4 Strategic Planning Survey asked participants a series of questions including, “**Do you believe the need for existing services provided by the IR-4 Project will increase, decrease or stay the same over the next five years?**” The majority of respondents (65.5%) replied that the need for IR-4 will increase².

Survey participants were asked to identify the transformational forces that are driving the increased need for IR-4. Factors resulting in increased need for IR-4; responses include:

- **New pest pressure** – It is anticipated that crop damage from invasive species and emerging pests will become a greater challenge to crop production. New public health pests have also been introduced in the U.S. in recent years. Pest management technology, supported through IR-4’s efforts, is needed to manage these newly emerging pests.
- **Pest Resistance to Pesticides** – There is a rapid increase in the number of weeds, insects and plant diseases that are becoming resistant to existing pesticide products. IR-4 is needed to secure new registrations for specialty crops and vector control with new technology that must be part of the strategy to maintain efficacy of existing products as well as replacing those products that are unable to manage resistant pests.
- **Increased Need for Product Performance Data** – Traditionally much of the crop safety and product performance testing has been conducted by public sector scientists associated with the land-grant universities. Many of the scientists who conduct this research have retired and this traditional duty has been downplayed during the hiring of new scientists. At the same time, the crop protection companies have become increasingly cautious about supporting registrations without having adequate efficacy and crop safety data. Furthermore, EPA is using product performance data in the development of “Public Interest Findings”. The gap between the need for data and the ability to conduct the necessary research is increasing rapidly. Many are looking at the IR-4 Project to use its existing scientific expertise and infrastructure to fill this gap by sponsoring efficacy and crop safety trials on specialty crops and serving as the critical source of impartial Product Performance data.
- **Residue Studies are becoming more complex** - IR-4 residue studies continue to increase in size and complexity. As regulatory schemes evolve there is an increased need for data showing decline in residues over time from multiple locations. Additionally there are needs for data representing broader geographic locations to meet stricter field trial separation standards, the use of different types of adjuvants, and a broader array of delivery systems as well as analysis of multiple metabolites of the test pesticide.
- **Internationalization of IR-4 Data Development** – Specialty crop producers want access to international markets but pesticide residues can be a barrier to trade. To help overcome this obstacle, IR-4 can design and conduct studies to meet both domestic and international standards. In many studies, IR-4 will need to establish additional field trials beyond the sites required by U.S. guidelines.

² The response by program area was: Food Program (69%), Ornamental Horticulture Program (56%), Biopesticide and Organic Support Program (72%) and Public Health Pesticide Program (65%).

- **Emerging Science and Regulatory Issues** - As science and regulatory knowledge advances, it is anticipated that new issues will emerge that will require IR-4's assistance. The most recent example of this is the protection of European honeybees; the impact of pesticides on honeybees and other pollinators of specialty crops is of increasing concern. Some of the emerging issues will require crop-specific, and potentially cost prohibitive solutions and could limit registrations on certain specialty crops and specialty uses. Assistance from IR-4 to develop the required crop specific data or secure the registration of alternative pest management technologies is of critical importance.

Other areas that respondents identified as forces to drive the future need for IR-4 included:

- More work is needed to develop insect and disease management programs that use combinations or rotations of multiple active ingredients, including biopesticides. Such programs have value for both resistance management and improved environmental health.
- The ongoing development of new and better technology, including biopesticides, biotechnology (e.g. genetically modified specialty crops, RNAi) will require IR-4's assistance to complete registrations.
- Consumer demand for locally grown, pick your own or organically grown specialty crops is increasing. Farmers need IPM compatible, conventional chemical pesticides and/or biopesticides to manage pests in these production systems.

The IR-4 Project has a long and proven record of developing required data that supports the EPA registrations for specialty crops and other minor use products. Ninety-two percent of the survey respondents noted that IR-4 delivers an indispensable service for specialty crop agriculture.

The unique infrastructure within the IR-4 Project includes strategically located field research sites, fully capable analytical laboratories, and a highly trained and experienced staff that develops and submits IR-4 research data through the complex regulatory process. IR-4 seamlessly manages and coordinates research and regulatory affairs. With adequate funding, the IR-4 Project is fully capable of helping specialty crop growers and other minor use stakeholders in obtaining the best available pest management technology they need for them to manage pests and successfully grow high quality products.

IR-4 Project Vision

The IR-4 Project aspires to remain a responsive and efficient organization that supports the farmer/growers, food processors and consumers of specialty crops (e. g. fruits, vegetables, nuts, herbs, trees, shrubs flowers, etc.) by facilitating the U.S. regulatory approval and international acceptance of chemical and biologically-based pest management technologies. This allows producers/processors to provide a consistent supply of nutritious foods essential to good health as well as aiding in the production of ornamental horticulture crops that enhance the environment. IR-4 activities also assist in agriculture profitability.

The IR-4 Project effectively and efficiently assists with obtaining regulatory approvals for small market uses of pest management technology, such as specialty uses of pesticide products on major crops (e.g., corn, soybean, cotton, grains). Other specialty uses include the management of invasive species; approval of biotechnology for specialty crops and use of pest management technology to manage arthropod pests that pose a public health risk. IR-4 concentrates its efforts in the cooperative registration process of pest management technology that respects human health and the environment when the need for such regulatory approval is in the public interest.

Mission Statement

Facilitate regulatory approval of sustainable pest management technology for specialty crops and specialty uses to promote public wellbeing.

Project Values & Culture

- **Exceptional Service to Customers/Stakeholders** – Prompt and dependable response to all requests for assistance as well as providing deliverables in a reasonable time.
- **Inclusiveness** - Encourages the participation of all stakeholders in the identification of pest research needs and establishment of research priorities.
- **Development of innovative solutions** - including the creative development of strategies to bridge data gaps.
- **Effective collaboration** - Partner with numerous groups including commodity associations, land-grant universities, USDA, pest management industry, EPA, Canada's Pest Management Centre³ (PMC) and other domestic and international government agencies to accomplish tasks.

³ IR-4 has expanded its infrastructure capability by partnering with the Agriculture and Ag-Food Pest Management Centre. For example, IR-4 has access to field and lab research sites associated with the Canadian minor use pesticide program to support joint projects in order to meet regulatory data requirements.

- **Transparency, Accountability and Stewardship** - Share information with interested parties to enable a better understanding and trust that government funds appropriated to IR-4 are being used in a fiscally-sound and efficient manner.
- **Maintain a Highly Competent Staff** – IR-4 will continue to hire, nurture and retain talented and hardworking team members to achieve its goals.

Plant Health Objectives

Food Program

- **Facilitate the domestic registration of conventional chemical pesticides to manage pests on specialty food crops as well as specialty uses on major food crops.**

Steps

- A. Solicit new requests for assistance to help specialty crop farmers/specialty use stakeholders with their pest management needs, including uses of pesticide products in an integrated pest management program and/or pesticide resistance management systems.
- B. Manage an open and transparent research priority setting process.
- C. Screen potential pest management products for efficacy in managing priority pest problems, as well as tools in integrated pest management programs and/or pesticide resistance management systems.
- D. Conduct and submit to EPA Magnitude of the Residue Studies to facilitate registration of conventional chemicals. Conduct Magnitude of the Residue Studies with biopesticides and other pest management technology if required for registration.
- E. When appropriate, develop data documenting changes in pesticide residues on specialty crops through washing, handling and other activities after harvest. Data may be used in refining the dietary exposure risk assessments.
- F. Perform product performance (crop safety and/or efficacy) field trials to provide specific data needed by the product registrants in making decisions to market their products on specialty crops and specialty uses.
- G. Develop specific extrapolation proposals and models (Crop Groups/Subgroups) that allow data developed on a few representative crops to be used to support registration on multiple crops within a group.
- H. Share program results through current and new outreach avenues.

- **Where appropriate, assist in the establishment of international Maximum Residue Levels (MRLs) of pesticides in specialty food crops to remove pesticide residues as a barrier of trade.**

Steps

- A. Provide existing IR-4 data to international regulatory authorities and other organizations to establish MRLs that facilitate U.S. exports of treated produce.
- B. When priorities align, work with domestic and international government/non-government programs on cooperative research projects.
- C. Develop residue data required by international regulatory authorities to establishing needed MRLs needed to export domestic specialty crops/uses.
- D. When appropriate, develop data documenting reductions in pesticide residues on specialty crops/uses through washing, handling and other activities after harvest. These decline data may to be used to develop models of potential pesticide residue in specialty crops targeted for export.
- E. Share program results through current and new outreach avenues.

Ornamental Horticulture Program

Develop data that supports appropriate use of pest management technology (conventional chemistry, microbials, plant extracts, etc.) and cultural practices to manage pests on ornamental horticulture plants.

Steps

- A. Solicit, via a grower survey and/or other mechanisms, a comprehensive list of pest management voids for the ornamental horticulture industry.
- B. Manage an open and transparent research priority setting process.
- C. Perform efficacy and crop safety trials with pest management technologies that facilitate label development and registration and to support appropriate use.
- D. Share program results through current and new outreach avenues.

Biopesticide and Organic Support Program

Develop product performance/value data and provide regulatory guidance to support new registrations of biopesticides for the management of pests in conventional and organic agriculture.

Steps

- A. Solicit, via a stakeholder survey and/or other mechanisms, a comprehensive list of pest management voids and potential biopesticide/organic products that could provide a biopesticide solution.
- B. Manage a recurring open and transparent research priority setting process on a regular basis.

- C. Conduct Efficacy/Crop Safety research trials on the highest priority projects that include potential biopesticide/organic solutions alone and when appropriate, in combination with conventional chemical pesticides.
- D. Assist public sector scientists, institutions and small businesses with the EPA registration of biopesticides when IR-4 involvement is in the public interest.
- E. Assist public sector scientists, institutions and small businesses with the government approval of novel technology (e.g. plant incorporated protectants, RNAi) for pest management.
- F. Develop data to promote adoption of biopesticides.
- G. Share program results through current and new outreach avenues.

Human/Animal Vector Management Objective

Provide assistance in the development and registration of biopesticides, conventional chemical pesticides and other pest management technology for use in controlling arthropod pests that transmit disease to humans and minor animal species.

Steps

- A. Solicit input and develop priorities from Department of Defense, Center for Disease Control and Prevention and other stakeholders on potential products that can manage arthropod pests that transmit diseases to human and minor animal species.
- B. Perform Efficacy/Crop Safety trials and other studies with biopesticides, conventional chemical pesticides and other pest management technology that provides necessary data and/or information for the registrants to make a specific decision on registering their products for managing pests that transmit disease to humans or minor animal species.
- C. Assist others with the registration of biopesticides, conventional chemical pesticides and other pest management technology when IR-4 involvement is in the public interest.
- D. Develop and maintain a comprehensive catalogue of existing and potential public health pesticides.
- E. Share program results through current and new outreach avenues.

Turning Ideas into Actions

Improving efficiencies

The organizational structure of the IR-4 Program has been consistent over the last 50 years. There are four regional offices (Northeastern, North Central, Southern, and Western) and IR-4 Headquarters connected to State Agricultural Experimental Stations/land grant university system who receive funds to conduct field work, perform laboratory residue analysis or to manage studies. USDA-ARS has a complementary Minor Use Program which conducts similar research activities at several USDA-ARS research stations that are fully integrated with research performed at the land grant universities. Under this structure, the IR-4 Project is essentially six independently-funded operational units cooperating together to address grower needs. Much of the time, the culture of good will and collaboration allow

successful completion of the mission. However, there are times when potential efficiencies are lost due to the existing organizational structure.

In an effort to improve efficiency, IR-4 seeks an independent examination of its organizational structure, tactical approaches and document/data management systems by an expert panel. This panel will be asked to make recommendations on how IR-4 operational efficiencies can be improved and whether the Project should be restructured. If restructure is recommended, the panel is charged with making suggestion(s) on a structure to best meet the needs of specialty crop stakeholders. These recommendations will be submitted to the IR-4 Project Management Committee for full consideration.

Enhancing “Grass Roots” Priority Setting and Outreach

IR-4 has an existing network of State Liaison Representatives (SLR), one for each of the 50 states, Puerto Rico, Guam and the District of Columbia. In many states, the IR-4 SLR responsibilities are an added duty assignment to someone within that state’s land-grant institution who is familiar with pest management of horticulture crops. Due to IR-4’s budget challenges and other responsibilities the SLR “assets” have not been fully utilized in many states/territories. Furthermore, many SLR’s have not been given clear direction on IR-4’s expectations of their activities

IR-4 SLRs will be asked to conduct/hold state based workshops or collaborate on multi-state workshops targeting specialty crop farmers, extension personnel, researchers and industry. The purpose of these workshops is to identify outstanding pest management voids in all program areas, update the stakeholders on IR-4 activities and build better communication links.

The need for reinvestment in IR-4’s Plant Health Objective activities

The federal investment from USDA (NIFA & ARS) and the SAES in the IR-4 Plant Health programs (Food, Ornamental Horticulture, and Biopesticides & Organic Support) has been reduced from \$16.48 million in 2009 to \$15.96 million in 2014. This financial reduction underscores the more substantial loss of “buying power” from five years of moderate inflation.

The funding cuts and loss of “buying power” has forced IR-4 to reduce the number of Food, Ornamental Horticulture and Biopesticide research studies and not respond to important needs of specialty crop agriculture. In 2009, the Food Program funded research that responded to 109 priority “Requests for Assistance” (PR’s) identified by stakeholders at the IR-4 priority setting workshop. By 2014, IR-4 only had resources to fund research for 75 new priority PR’s. IR-4 is currently carrying a backlog of 362 unanswered pest control product needs in the Food Program. Of these, 131 were identified as high priority at IR-4’s September 2013 priority setting workshop.

The funding challenges resulted in targeted reduction of in some Project positions and closure of several IR-4 analytical laboratories. Additionally the funding cuts resulted in a deferral in making purchases for replacing field and laboratory research equipment essential to IR-4’s Plant Health research. Much of the instruments and equipment in IR-4’s analytical laboratories is at or past their recommended replacement date, making it less reliable and

more prone to failure. In order for IR-4 to maintain state-of-the-art analytical laboratories, equipment must be replaced or upgraded in three to five year cycles.

In addition to the above, the data requirements for residue studies continues to evolve and increase in complexity. Recent trends include the need to develop data on multiple chemical metabolites. There is an increasing need for data showing the decline or degradation of chemical residues over time, both pre-harvest and post-harvest. Sometimes this data is used by EPA if the proposed use meets the threshold for exposure in their risk assessment. In other cases, decline data can be used to help farmers export their specialty crops to other countries where the MRL is different from what EPA has established. Furthermore, EPA is expanding their need for efficacy and crop safety data in association with registration submissions. This data is used in the development of Public Interest Findings documenting the benefits of new registrations.

The Ornamental Horticulture and Biopesticide and Organic Support Programs experienced similar reductions in research activities. In 2009 IR-4 conducted 1,212 ornamental field trials and funded 34 biopesticides research grants. By 2013, the numbers dropped to 715 ornamental horticulture field trials and 23 biopesticide grants.

Another financial factor that IR-4 must address is indirect costs. Indirect costs are real expenses associated with managing a grant and housing a research program. Indirect cost rates are negotiated between universities and the federal government based on actual university expenditures in support of sponsored research. Most USDA grants allow land-grant universities to collect approximately 30% of a grant as indirect costs. The legislation authorizing support for IR-4 by USDA-NIFA explicitly prohibits the payment of indirect costs. The unrecovered indirect costs represent a significant contribution by the participating institutions, that some may not be able to sustain. Some of the land-grant universities hosting IR-4 research units have been innovative in recouping some of these costs. For example, some have transitioned certain indirect costs into allowable direct costs (e.g. IR-4 Headquarters pays rent for its office space). Others are instituting new policies which may limit further IR-4 involvement with that institution. These changes will divert funds from research resulting in even fewer research studies being conducted through IR-4.

IR-4 has built its infrastructure of scientific expertise, facilities and research capacity over the last 50 years. This infrastructure is critical in allowing IR-4 to provide its stakeholders with deliverables that are in the public good. Financial resources are the limiting factor. ***For IR-4 to continue to support specialty crop agriculture and other specialty minor uses in meeting pest management needs, an increased investment in funding for IR-4 is absolutely necessary.***

Enhancement of IR-4's Human/Animal Vector Management Objective

IR-4 has developed and populated public health pesticide database. The purpose of this database was to provide a comprehensive listing of pesticides registered to manage arthropod pests that transmit disease to human/animals as well as a single source of information on potential new products that can be used in this niche. The database is population with regulatory information, product performance data and chemical

characteristics. There is an on-going effort to continue to expand the information captured in the database to make it more useful to stakeholders.

Additional funds (\$75 K) are needed annually to continue to augment and validate the information in the database. The funds will be used for enhanced collection of new product information/intelligence as well as convert the structure to allow for public access to the data via a web based application. This would eliminate the need for IR-4 staff to perform custom searches for stakeholders.

Development

The Crop Protection Industry generously provides IR-4 approximately \$1.25 million dollars annually through unrestricted grants and gifts. These resources have been used to supplement public funding to accomplish IR-4's mission in all existing program areas. Industry funds have been used to pay for additional research, including; field trials, analytical analysis, required processing of apples, grapes, tomatoes, citrus, oil seeds and other commodities into specific crop fractions, and is used in funding biopesticide grants. Industry funds also cover the costs of IR-4's Food and Ornamental Priority Setting Workshops, repair/replacement of critically important research equipment, and shortfalls in IR-4 Headquarters operational expenses such as maintaining the data archives, travel and updating computers.

It is IR-4's goal to double the unrestricted grants and gifts to \$2.5 million annually by 2020. Development funds will be targeted from a variety of sources, including the crop protection industry, grower groups, commodity associations and philanthropic organizations. These new funds will be used to restore IR-4 research capacity and infrastructure.

Strategic Benchmarks for the Plant Health Objectives

With appropriate funding IR-4 will be able to:

- Replace key personnel lost through retirements and resignations.
- IR-4 SLR will be supported with funds to conduct workshops targeting Cooperative Extension and grower participation that identify pest management voids, expand exposure, and measure impact of the program.
- Replace outdated analytical equipment at the three IR-4 Analytical Laboratories.
- Contribute up to 10% of grant funds to host institution as part of indirect cost recovery.
- Food Program
 - On an annual basis, IR-4 will hold a prioritization workshop that enables stakeholders to provide input on most important projects and select those projects as research priorities.
 - IR-4 will conduct up to six studies which includes conventional chemical pesticides, biopesticides, and combinations to determine the most promising product(s) to manage a most critical pest management void.
 - IR-4 will conduct approximately 100 Magnitude of the Residue studies annually and an equal number of studies will be submitted each year to EPA or regulatory authorities to support registrations. Leverage the partnership with Canada's PMC and cooperate with bilateral data generation for joint

submissions on common pest(s) identified by farmers/producers in the United States and Canada. When appropriate, IR-4 will conduct residue trials at enough sites to meet international standards.

- IR-4 will conduct 50 to 60 field trials designed to collect efficacy and/or crop safety data annually.
- IR-4 will complete the development and submission to EPA of the remaining crop grouping expansion proposals.

- Ornamental Horticulture Program
 - Once every two years, IR-4 will host a forum to allow stakeholders to provide input on the most important pest management voids and most important research priorities with decision criteria such as mitigation of resistance development, impact on beneficial organisms, and lack of available alternatives.
 - IR-4 will conduct at least six research projects to screen options for the management of critical pests and to determine whether solutions impact plant quality. Depending on research targets, efficacy protocols will incorporate tank mix combinations or rotations of multiple active ingredients, including conventional chemistry, microbials, plant extracts, and other pest management technology.
 - IR-4 will disseminate results through: project summary reports posted to the website, presentations at scientific and trade meetings, and communications via social media. IR-4 will explore additional digital media or other avenues for grower outreach.

- Biopesticide and Organic Support Program
 - IR-4 will actively engage stakeholders and encourage submission of known pest management voids that can potentially be answered by biopesticide technology and will empower appropriate IR-4 SLRs to conduct statewide workshops to encourage more Cooperative Extension and grower participation.
 - IR-4 will enable stakeholders to provide input on the most important projects and identify those most important projects as research priorities.
 - IR-4 will conduct up to 20 studies at multiple locations with biopesticides, conventional chemical pesticides and combinations will be tested to determine which program(s) exhibit potential to manage critical pests, provide pesticide resistance strategies, or are an important component of an integrated pest management system.
 - IR-4 will assist public sector associates on an as-needed basis, and provide guidance on how to develop data needed to successfully attain deregulation and findings of substantial equivalence of genetically modified organisms.
 - IR-4 will provide funds to conduct approximately five on-farm extension type Biopesticide Demonstration projects to help specialty crop farmers.

Financial resources needed to achieve benchmarks associated with IR-4's Objectives (x \$1,000)

Purpose	USDA-NIFA \$	USDA-ARS \$	Development \$	Total \$
Existing Plant Health Program Funding	\$11,916	\$3,600	\$1,250	\$16,766
Additional Funding Needed for Plant Health Programs				
Restore Program Capacity	\$900	\$1,000	\$1,250	\$3,150
Expanded Efficacy/Crop Safety Testing	\$1,500	\$400	----	\$1,900
Enhanced State-Based priority setting	\$100	----	----	\$100
Funds for Indirect Costs	\$1,442	----	----	\$1,442
Existing Human/Animal Vector Management Funding⁴		\$252		\$252
Additional Funding Needed for Human/Animal Vector Management				
Enhanced Data Management Capabilities	----	\$75	----	\$75
TOTAL (Existing and New)	\$15,858	\$5,327	\$2,500	\$23,685

IR-4 SPONSORED PROGRAMS

The IR-4 Sponsored Program objectives extend the scope and capabilities of the IR-4 Project to benefit the public interest and are often funded by grants and agreements written specifically to address a particular issue or problem. It is also a way for specialty crop farmers/producers and other specialty use stakeholders to gain access to the knowledge base and capabilities of IR-4 when regulatory research/regulatory assistance is not available from the registrant, and the data needs are beyond the scope of the core IR-4 budget or objectives. It is expected that sponsored program stakeholders will contribute full funding to cover requested data development and regulatory activities.

Grower-Funded Research

Due to funding limitations, IR-4 can only take on a limited number of research projects with food and ornamental crops annually. Individual farmers, commodity associations and/or others have volunteered supplemental funding to have their priority project added to IR-4's research program. IR-4 will continue to accept funds to support these commodity driven projects, and develop data required by the registrants and EPA that support the registrations for these important needs.

⁴ USDA-ARS provides funds through a cooperative program in associations with Armed Forces Pest Management Board, Department of Defense

Invasive Species Management

IR-4 will provide leadership in the development of data and other relevant information with biopesticides and conventional chemical pesticides to manage invasive species. IR-4 will collaborate with USDA-APHIS, USDA's Office of Pest Management and Policy (OPMP), Regional Integrated Pest Management Centers and other stakeholders to identify voids in the availability of conventional chemical pesticide and biopesticide registrations for invasive species already present in or likely to establish themselves in the U.S. IR-4 will then facilitate cooperative research, which furthers the development of technologies to manage invasive species for use in integrated management or recovery plans.

International (Global) Capacity Building

IR-4 will conduct educational programs and outreach activities to train research and regulatory personnel in the processes used for the development of regulatory data, and to support the establishment of Maximum Residue Levels and registrations for biopesticides and conventional chemical pesticides. IR-4 will help with the establishment of publically-funded data producing programs through capacity building and cooperate on international data generation.

IR-4 will continue to strengthen the partnership with PMC of AAFC to advance research priorities in order to support the Canada-United States Regulatory Cooperation Council initiative under regulatory coordination to harmonize, when possible, pesticide labels on crops grown in and traded between the United States and Canada.

Import Tolerances

IR-4 will assist U.S. based stakeholders that rely on imported specialty crops as their raw materials through assistance in the establishment of import pesticide tolerances. IR-4, working with U.S. based stakeholders, will utilize its existing priority list of pesticide products used on the relevant crops where an import tolerance is needed. IR-4 will then open dialogue with EPA, the crop protection industry and the representatives of the relevant crops to determine where field trials must be conducted and other information required in the research protocol. IR-4 will find and collaborate with qualified researchers at locations where the residue data must be gathered to perform Magnitude of the Residue studies with IR-4 then providing the residue data to cooperating registrants for submission to EPA for import MRLs.

Pollinator Protection

IR-4 will provide regulatory support and assistance with the registration of biopesticides, conventional chemical pesticides and other pest management technology to manage Varroa mites and other pests of managed honeybees and other pollinators. IR-4 will collaborate with USDA, EPA, the crop protection industry, commodity associations and other stakeholders to identify potential solutions to manage critical pests of pollinators. When necessary, IR-4 research cooperators will perform efficacy/crop safety trials with biopesticides, conventional chemical pesticides and other pest management technology to provide necessary information that allows the registrants to make a specific decision to register their product for a pollinator's

health use. If acceptable, IR-4 will facilitate cooperative research to further the development of technology to manage pests of pollinators. The resulting data will be used to assist with the registration of products to protect the pollinators, including assistance with registration.

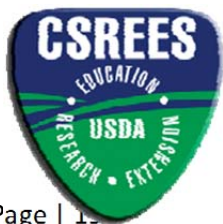
Other Studies

When appropriate and if resources are available, IR-4 will conduct and/or manage other regulatory studies, required by EPA to support the registration of a priority use for a biopesticide, a conventional chemical pesticide or other pest management technology to manage a pest.

Appendix 1:

**Report of CSREES-USDA External Peer Review of
National Research Support Project-4 (NRSP-4) IR-4: A
National Agricultural Program to Provide Registration
Assistance for Specialty Crop and Minor Use Pest
Management IR-4 Headquarters, Princeton, New Jersey
May 19-21, 2009
&
The IR-4 Project's Response to Report**

National Research Support Project-4 (NRSP-4) IR-4



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May 19-21, 2009



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IR-4 Headquarters, Princeton, New Jersey
May 19-21, 2009**

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External Peer Review of NRSP-4 (IR-4)
IR-4 Headquarters, Princeton, New Jersey
May 19-21, 2009

The External Peer Review Panel wishes to thank the Cooperative State Research, Education, and Extension Service and the leaders and staff of the IR-4 Project for their leadership and overall effort in preparing for this review. The following consensus report represents an opinion from the review panel of the current status and recommended future direction of the program.

Acknowledgment

The External Review Panel extends their appreciation to Dr. Jerry Baron, IR-4 Project Executive Director and the entire IR-4 HQ Staff for their efforts in preparing for the review and for their hospitality and graciousness in hosting the panel. Arrangements and accommodations were excellent. The panel appreciated the well developed Background Materials and Information Book, the well prepared and informative presentations, and the thoughtful and open dialogue in response to our numerous questions and discussion sessions. The panel also thanks Dr. Monte Johnson, USDA-CSREES, Dr. Mary Duryea, Administrative Advisor, and Dr. Sally Schneider, USDA-ARS for their guidance and comments regarding the charge and objectives for this review. We also extend our thanks to Dr. Marty Marshall, chair of the IR-4 Project Management Committee, for his attendance at the review and his contributions to the numerous discussions. Finally, appreciation is extended to the numerous internal and external stakeholders who participated in the review and provided useful commentary and ideas for the panel to consider. The obvious multi-agency, multi-disciplinary, and broad-based stakeholder support and cooperation is unique among Federal-funded R&D programs and is worthy of acknowledgment from the panel and other interested parties.

Introduction

The National Research Support Project (NRSP) system, and specifically this project (currently known as the IR-4 Project), was established 46 years ago by the directors of the State Agricultural Experiment Stations to facilitate registrations of pesticides on specialty food crops (fruits, vegetables, nuts, herbs/spices) and minor uses on major crops. Currently the national IR-4 Project (IR-4 Headquarters, the USDA-Agricultural Research Service (ARS) Office of Minor Use Pesticides, the four regional offices, the seven analytical laboratories and the 31 field research centers) employs about 125 full-time staff. Fiscal year 2009 financial support includes: USDA-Cooperative State Research, Education, and Extension Service (CSREES) (\$12 million), USDA-ARS (\$4.01 million), State Agricultural Experiment Stations (SAES) (\$481,182), USDA-FAS (\$250,000) and industry (\$1.66 million). Other funds are provided from an “in-kind” match (SAES and industry) at about a 1:1 ratio. This support is supplemented by in-kind support from the State Agricultural Experiment Stations which is conservatively estimated to be equal to the amount of direct federal support. USDA-ARS established a

companion program in 1976 to provide additional cooperation and program support to the IR-4 Project.

The following information is taken directly from the comprehensive *IR-4 Project Background Materials and Information Book* provided to the Review Panel:

“The mission of the IR-4 Project is to facilitate registration of sustainable pest management technology for specialty crops and minor uses. The IR-4 Project focuses its efforts on providing value and exceptional service to the primary beneficiary of the Project, the growers of specialty crops, fruits, nuts, vegetables, herbs, ornamentals, and other horticultural crops. IR-4’s principal duty is to assist in the cooperative registration process of safe and effective pesticides and other pest management technology, supplementing the efforts of industry in markets where economic factors preclude full industry development. IR-4 concentrates its efforts on lower risk technology that respects humans and the environment. Additionally, IR-4 assists specialty crop growers in eliminating international trade barriers caused by pesticide residues in food crops. IR-4 will also assist other stakeholders by aiding in the cooperative registration of minor uses of pesticides, including: minor uses on major crops, invasive species management, approval of biotechnology for specialty crops and the minor use of pesticides to manage arthropod pests that transmit vector borne diseases posing a public health risk. IR-4 will supplement the efforts of industry and government in the development of these minor uses to ensure success.

“Benefitting from activities of IR-4 are growers, food processors and the general public. The general public benefits by having high quality food and ornamental crops available at reasonable prices. Specialty food crops provide essential nutrition for a balanced diet as well as health promoting activity recommended by nutritionists and health professionals. The non-food ornamental crops enrich the environment and improve the quality of life. Also important are the efforts of IR-4 to provide safe and effective tools to manage medically important arthropods.”

Please also refer to Appendix 1, *Relevant IR-4 Facts*, provided by the IR-4 HQ staff which briefly summarizes the current status and accomplishments of the Project.

The External Review Panel met at IR-4 National Headquarters in Princeton, NJ, on May 19-21, 2009. Their charge was to review the current status of the IR-4 Project and make recommendations for IR-4 staff consideration that would enhance their operations and effectively position the program to best fulfill their mission and identify future opportunities for the program. The panel examined past accomplishments and current organizational structure and operations. Additionally, it commented on future programmatic and management considerations.

Following are the consensus comments and recommendations of the External Peer Review Panel.

IR-4 Project Successes and Key Accomplishments

Since the last program review in 2003, the IR-4 Project has continued its remarkable record of progress in developing pest management solutions for the numerous customers and stakeholders involved in specialty crops and minor uses on major crops. The Review Panel commends IR-4 Project leaders, managers, and staff for continuing their pesticide registration efforts and for addressing program challenges in a manner necessary to optimize operational efficiencies.

Specifically, the following commendations are provided:

A. Productivity and Recognition

- The IR-4 Project has maintained high levels of overall productivity as evidenced by the 700+ food trials, 1200+ ornamental trials, and the continued expansion of the biopesticide program. The number of new registrations that are supported by these trials and the related information developed on product residues (food safety), plant health, and pest efficacy are excellent indicators of continued program success. The panel noted that the average annual number of trials conducted has generally increased since 2003. IR-4 developed data supports approximately 50 percent of the new tolerances established by EPA in a given year which are used in facilitating registrations on food crops. The panel also noted the increased number of studies in support of EPA food tolerances developed by IR-4 data since 2003.
- The panel noted that the high number of tolerance petitions developed by IR-4 that led to registration has also led to the decreased need for Emergency Exemptions.
- The IR-4 Project received an increase in appropriated funding in FY 2009. The panel notes that during austere times, receipt of a funding increase is an exceptional indicator of program success.
- The panel commends the IR-4 Project for conducting the 2007 National Economic Impact of the IR-4 Project study. In particular, it is noted that the project efforts attributed an estimated \$7,675 million in expected direct contributions to the U.S. gross domestic product, which is also expected to support over 113,000 U.S. jobs (2007 estimates). Additionally, the panel commends the IR-4 Project for conducting an economic impact study of the Ornamental Horticulture Project which was estimated to contribute \$1.2 billion to the gross domestic product and approximately 17,000 jobs within the United States
- The IR-4 Project HQ Staff is well trained and dedicated. The staff is well informed and considered subject matter experts. They work well as a team and all are well versed in their disciplines and coordinate with one another when discussing the mission and objectives of the IR-4 Project. The panel noted that

they have excellent knowledge of agriculture, IPM, horticulture/ornamental production practices, residue chemistry, GLP, and the overall process necessary to test and register new pest management products. The panel was impressed with their “can do” attitude and their ability to work “smart and efficiently”. Their ability to leverage available data to seek solutions and efficiencies with cooperators (“push the envelope”) has been invaluable to the success of the project. Particularly impressive are the following examples: a) in collaboration with EPA, developed an expedited approach to extrapolate results of residue field trial data on certain commodities to a wide variety of crops for chemicals with extremely low mammalian toxicity, low application rates, and short half life in the environment (i.e., super crop groups); b) ability to think creatively to reposition the Tifton, GA, location to provide needed data to support Florida tolerance/registration needs.

- The IR-4 Project field staffs (regional offices, residue laboratories, and field research groups) have an excellent reputation and sustained productivity.
- IR-4 is a leader in globalization/international harmonization efforts. This process has been well received by both the national and international regulatory, marketing, and horticultural production communities. Substantial progress has been made in crop grouping.
- Canada has decided to model their minor use/specialty crop program after the IR-4 Project. To date the Canada/U.S. IR-4 collaboration has resulted in 16 joint projects.

B. Customer/Stakeholder Relationships

- The IR-4 Project Staff (both national and regional) is engaged with their customer and stakeholder base and interacts with them on a regular basis.
- The entire IR-4 Project has an open door relationship with industry, the regulatory community, and other partners which has led to numerous successful outcomes while striving for continuous improvement.
- IR-4 continues to maintain excellent cooperation with USDA-CSREES, USDA-ARS, U.S. Environmental Protection Agency (EPA), USDA-Foreign Agricultural Service (FAS), State Agricultural Experiment Stations (SAES), Universities, Canada Pest Management Regulatory Agency (PMRA) and Agriculture and Ag Food Canada (AAFC), registrants, producers, and others.
- The panel commends the IR-4 Project for their excellent communication efforts. The website, newsletter, and other communication tools have been substantially modified since the 2003 Review. All are well done and provide excellent information to IR-4 internal and external stakeholders.

C. Program Structure and Management

- The panel acknowledges the IR-4 Project for addressing the majority of suggestions made in the 2003 Program Review.
- The panel commends the IR-4 Project for the process used to develop their current IR-4 Strategic Plan - - *A Strategic Plan for the IR-4 Project (2009-2014)*.

Input from a large group of stakeholders was a good initial step for developing a process to gather input in the future. The panel also commends the project for their strategic thinking in looking at future needs for the program.

- The panel commends the IR-4 Project for conducting a comprehensive review of the Ornamental Horticulture Program on June 3, 2008, which resulted in a unanimous decision to continue the program and to subcontract with an economist to define the economic impact of the work (completed in Dec. 2008).
- The panel commends IR-4 Project leadership for the difficult decision to downsize the number of regional laboratories from four to three. A good process was developed and followed that may result in more flexibility in utilization of future resources and continued evaluation and alignment with program mission.

Recommendations

A. IR-4 Project Administrative and Strategic Management – the panel recognizes the difficulties in managing a national effort involving numerous institutions and commends the HQ staff and the Project Management Committee for their leadership. The following recommendations are made in an effort to provide guidance to staff to continue to work to position the IR-4 Project as the leader in the specialty crop and minor use pest management solutions arena.

- The panel recommends that the IR-4 Project develop an action plan based on the newly developed Strategic Plan for 2009-2014. The action plan should provide a roadmap on how to accomplish the stated objectives of the project.
- The panel recommends that a business plan be developed as part of the overall action plan (see above). The business plan should consider development of a financial management strategy that would maintain the project during flat budget periods, as well as position the project to take advantage of growth opportunities. Once the business plan is developed, IR-4 leadership should periodically revisit the Strategic Plan to determine if mid-course corrections might be necessary.
- The panel believes it is important for the IR-4 Project to determine and prioritize the core business practices and program objectives that are most important to maintain during difficult financial times. Additionally, they should analyze potential growth areas (see next bullet) as part of the overall prioritization process.
- The panel urges IR-4 Project leadership to carefully evaluate “Mission Creep” in relation to their Strategic Plan and accompanying business plan. Program expansion should be based on a careful evaluation of potential growth areas and within the context of a business strategy. The project would benefit from staff and stakeholder sessions designed to develop the pros and cons for expansion of the project mission. These sessions could determine the benefits (e.g., science capacity and outcomes, knowledge development, enhanced funding, broader stakeholder support, and accomplishment of the core mission) that might result from potential expansions.

- As part of the development of a business plan the panel recommends that IR-4 Project leadership continue to evaluate the capacity of the remaining regional residue laboratories and the ARS residue facilities. A cost/benefit study would be helpful to determine appropriate current and predicted needs for the IR-4 Project.
- The panel recommends that IR-4 Project leadership, both at HQ and at the regional level continue to evaluate field study site distribution needs and related capacity issues. They also recommend that close coordination with the ARS IR-4 program continue so as to optimize available resources.
- The panel noted the continuing difficulties the IR-4 Project has had in regards to timely distribution of appropriated funds. Receipt of funds occurring approximately 6 to 9 months after the start of the Federal Government fiscal year due to delays in appropriation bill passage has complicated maintenance of existing field and laboratory projects, as well as impeded the timely initiation of new projects. Although events surrounding the appropriation cycle are out of the control of IR-4 Project management, it remains necessary to seek alternative solutions to aid cooperating project coordinators. The panel suggests that IR-4 Project leadership in cooperation with USDA-CSREES leadership work together to seek solutions that could minimize some of the concerns. Solutions could include approving projects to receive funds for a minimum of two-years to eliminate carry over issues, or seek new authorizations to change the manner in which funds are received by the project (five-year authorization at an established funding level rather than single year appropriations). Close communication and continuing dialogue on possible resolutions between IR-4 and cooperating universities is also encouraged.
- Explanations of the above cited funding concerns are complicated and difficult for many stakeholders and interested parties to adequately understand. The panel suggests that IR-4 Project stakeholders (e.g., Commodity Liaison Committee) work closely with IR-4 leadership to develop a one-page summary document that describes the current funding process and suggests potential options for resolution of the problem. This document would be beneficial for stakeholder education and enhanced communication.
- The panel recommends that the IR-4 Project develop a transparent process to better track and analyze existing and potential uses of industry unrestricted funds. As part of the recommended Business Plan, these funds should be identified for possible uses including emergency/contingency needs and matches for special grants.
- The panel recommends the continued evaluation of the role of state liaisons within the IR-4 Project. It was noted that one state, Missouri, did not have a current liaison. Within the Southern Region, some states have separated their liaisons into separate positions for food crops and ornamentals. We encourage IR-4 to evaluate this concept and determine if it worthy of implementation in other key production states.

B. IR-4 Project Personnel Management – the panel believes that the strength of any organization is based on the productivity and skills of their personnel. It is imperative that organizations properly evaluate their personnel needs and position themselves to address potential changes that might affect program delivery effectiveness. The following recommendations provide suggestions to address a critical program continuity need.

- The panel recommends that all organizational levels of the IR-4 Project review their current personnel structures and discuss and implement succession planning activities as appropriate. We also encourage establishment of career ladders as opportunities arise.
- Traditional succession planning may be difficult to achieve within the IR-4 Project structure. We encourage IR-4 staff to develop a mentoring program for early and mid-career staff to provide opportunities to better understand how the project functions as well as operational considerations at the host institutions of project employees. The project is also encouraged to conduct cross-training as appropriate.
- The panel recommends that the IR-4 Project employ summer interns as opportunities arise.
- The panel encourages IR-4 Project leadership to work closely with university department chairs and heads and related university administrators to seek professional status of IR-4 staff on their respective campuses. We would also encourage consideration of sabbatical opportunities.

C. IR-4 Project Program Management and Leadership – the panel is encouraged by the continued progress the project has made in developing data used to petition the EPA to establish tolerances for potential registrations and collaborations on specialty crop and minor use pest management solutions. Leadership in global harmonization efforts has positioned the IR-4 Project to play a key role in international activities. The following recommendations are made to provide IR-4 with ideas to maintain the high level of productivity and leadership in specialty crop and minor use pest management arenas.

- The panel concurs that the use of “specialty crop and minor use pest management” in its mission statement is appropriate. We recommend that the IR-4 Project evaluate their mission statement periodically as part of their strategic planning and program review process.
- The panel recommends that the IR-4 Project continue to evaluate how the project incorporates management of exotic and invasive pests into their program. Coordination with EPA, APHIS, and the state agricultural departments and experiment stations is encouraged.
- Global Harmonization (MRLs and crop grouping) is critical for production of specialty crops. The panel recommends that the IR-4 Project continue to support efforts and provide international leadership on MRL harmonization and crop grouping.

- The panel heard from various stakeholders that lumping crops into crop groups has had, and will continue to have, export ramifications regarding receipt of labels from the registrant. We recommend that IR-4 Project staff provide advanced notification to affected stakeholders for timely assessment of possible registrations. We note the addition the IR-4 staff made to the Project Clearance Request (PCR) form (a tab to indicate if export is involved with a potential material) which will improve the process.
- The panel recommends that the IR-4 Project outline a process for broader vetting of use patterns with stakeholders during project protocol development (before anything enters into testing). This involves expanded and diligent consideration of proposed use patterns on a national basis. In some cases, this may also include planning for sufficient U.S. trials necessary to support the data requirements of an important international trading partner in the event that additional field trials are necessary to gain an MRL in the foreign market.
- We encourage the continued inclusion of the following (originally developed in the 2003 Review Report and slightly updated with this review) criteria to maximize the benefits of allocated resources and to ensure alignment with IR-4's strategic objectives:
 - role in pesticide resistance management
 - severity of pest problem
 - crops, acreage affected and potential economic impact
 - multi-year Section 18 exemptions
 - awareness of potential risk issues – communicate with EPA as part of the vetting process for projects
 - where possible, make priority selection for project support for a material that could be considered reduced risk and/or fully compatible with sustainable agriculture
 - regional input to prioritization prior to food use and ornamental workshops
 - status of potential trade barriers
- The panel encourages the continued evaluation, as appropriate, of the feasibility of including efficacy and crop safety components within work plans and prioritization activities.
- The panel recommends that IR-4 Project HQ staff develop a value-added metric for the biopesticide program.
- The panel recommends that IR-4 Project leadership develop a scope and related action plan for the Human Health pilot program (public health pest control). The program should be evaluated based on how it fits into the current IR-4 Project mission, as well as the value it adds to the project. We suggest that the program be evaluated prior to the end of the pilot to determine the feasibility of continuing as part of the IR-4 Project. In general, we believe this type of evaluation should be conducted for any new program enhancement or expansion of the existing core capacity of the project.
- The panel encourages the IR-4 Project to continue their active communication and coordination with potential registrants to address issues such as hazard and

risk cup characterization, timely notices of filing, labels, registration materials, etc. If necessary data/information cannot be provided by the registrant in a timely way, we believe it is proper for IR-4 to consider withdrawing its investment and energy toward developing field trial data for the project.

D. IR-4 Project Stakeholder Considerations – over the life of the IR-4 Project, stakeholders, customers, and partners have played a key role in the success and overall programmatic health of the project. Maintaining good relations with stakeholders is paramount to the future of these efforts. Expansion of the current stakeholder base is underway and will pay dividends in the future.

- The panel suggests that current metrics used by the IR-4 Project to measure programmatic success be reviewed and possibly refined to better reflect stakeholder needs. For example, registration of a use on a “label” is viewed as a key measure of success among growers but was not included in documentation reviewed by the panel. The number of specialty/minor uses included on a label should be included in future reports.
- Stakeholders would like to be better informed of issues, registration decisions, etc., involving genetically modified organisms (GMOs)/plant incorporated protectants (PIP) before moving forward on potential projects. The panel encourages IR-4 Project leadership to consider this recommendation and develop a protocol to include these discussions as part of the prioritization process.
- The panel encourages IR-4 Project leadership along with the Project Management Committee to evaluate the structure and review the current mission and charter of the Commodity Liaison Committee to ensure stakeholder equity.
- The panel encourages the IR-4 Project leadership, the Project Management Committee and the Commodity Liaison Committee to seek opportunities to broaden the existing stakeholder base. Interested stakeholders not currently associated with IR-4 should be identified and encouraged to become more involved in the project.
- The panel recommends that the IR-4 Project enhance cooperation with the Regional IPM Centers as appropriate.

E. Opportunities – Opportunities for program expansion, acquisition of additional funds, or hiring of personnel with innovative and unique skills can frequently occur, and sometimes without advance notification. The panel encourages the IR-4 Project to proactively address opportunities and continue leadership in specialty crops and minor use pest management activities and provides the following recommendations to assist this effort.

- The panel suggests that IR-4 Project leadership carefully evaluate their current and future role as the premier resource for specialty crop and minor use pest management and product registration. Is there a role for the IR-4 Project staff as national/international consultants and/or experts in this important field of work?

- As mentioned in earlier recommendations, the panel encourages the IR-4 Project to evaluate and determine if other researchable areas could be included within the program. Opportunities are known to exist in application technology, beneficial organisms/biological control, biotechnology, and in development of innovative methodologies to estimate residue quantities with less testing involved. All opportunities should be evaluated in the context of the IR-4 Project business plan.
- The panel encourages the IR-4 Project to seek opportunities to obtain funds from sources other than traditional CSREES Federal appropriations as long as the funding source and project scope meets existing IR-4 Project goals and objectives. Sources could include Department of Defense (DOD), Department of Energy (DOE), Department of Health and Human Services (DHHS), and the National Science Foundation (NSF).

F. International Opportunities – Trade facilitation is a relatively recent and increasingly important aspect of IR-4’s activities. The work currently focuses on providing residue test results to other developed trading partners so that products exported by our growers are accepted. USAID or FAS may request IR-4’s assistance in establishing residue testing laboratories or minor use efficacy/phytotoxicity trials overseas to enhance food safety and regional/international trade.

Conclusions:

The IR-4 Project continues to be a very good program and is a leader within the specialty crop and minor uses communities for pest management. The project has made substantial strides in administrative and program management since the 2003 review. The current Review Panel applauds their continued success and encourages the needed development of action and business plans necessary to maintain their leadership role. The IR-4 Project has a bright future.

Appendix 1

Relevant IR-4 Facts

- For forty-six years, the IR-4 Project has been assisting in the registration of pesticides for fruits, vegetables, herb/spices, nuts, ornamentals and other specialty crops as well as minor uses on major crops. IR-4 is needed because the cost of the data required by US EPA for registrations far exceeds the potential profits to industry from sales in the low volume specialty crop/minor use markets. IR-4 provides the necessary data to facilitate industry's expansion of registrations.
- IR-4 maintains three core objective programs (Food Crops, Ornamental Horticulture, Biopesticide and Organic Support) plus a new cooperative project: Registration Support for Pesticides Managing Medically Important Arthropods. Under the Food Crops program, there is a task to support the expansion of current crop groups.
- The new Mission Statement of the IR-4 Project is to “facilitate the registration of sustainable pest management technology for specialty crops and minor uses of pesticides”. Under this new mission statement, the core objectives have been enhanced to include:
 - Product performance testing to identify pest management solutions to answer priority grower needs.
 - International harmonization of maximum residue levels to remove pesticides as trade barriers.
 - Invasive species management and registration assistance for products available for organic producers.
- Policy, funding distribution and strategic decisions are made by the IR-4 Project Management Committee. Day to day activities are managed by IR-4 Headquarters, the four regional offices and USDA-ARS Office of Minor Use Pesticides.
- IR-4 employs about 125 FTE who work at either IR-4 Headquarters, one of the four regional offices, USDA-ARS Office of Minor Use Pesticides, one of the seven analytical laboratories or at one of the 31 field research centers.
- Annually, IR-4 conducts about 700 food crop trials that support 100 Magnitude of the Residue Studies, 1,200 ornamental efficacy and/or crop safety trials and funds approximately 40 biopesticide proposals. This activity leads to approximately 1,000 tolerances for crop and chemical combinations on food crops and registrations that impact 3,000 plus ornamental crops annually.
- IR-4 has a presence within almost every state and United States territory through the assignment of State Liaison Representatives.
- Research priorities are established through a “Workshop” process for Food Crops and Ornamental Horticulture and through a “Call for Proposal” process in the Biopesticide and Organic Support Program.

- Most work in the Food Crops Program is conducted following EPA established Good Laboratory Practice regulations. IR-4 has a fully functional Quality Assurance Unit that audits food crop data and reports.
- Fiscal year 2009 financial support includes: USDA –CSREES (\$12 million), USDA-ARS (\$4.01 million), SAES (\$481,182), USDA-FAS (\$250,000) and industry (\$1.66 million). Other funds from the “in-kind” match (SAES and industry) at about 1:1 ratio.
- IR-4 research and regulatory successes contribute \$7.675 billion and \$1.2 billion to the US gross domestic product annually in the food crops and ornamental horticulture areas, respectively.



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October 29, 2009

Dear Dr. Broussard,

On behalf of the IR-4 Project Management Committee, we submit to you our responses to the recommendations provided by CSREES-USDA External Peer Review of the National Research Support Project-4 (NRSP-4)/IR-4 which was held at IR-4 Project Headquarters, May 19-21, 2009. We thank Dr. Laurence Chandler, Team Leader of the Panel and the other Panel members for their efforts before, during and after the External Peer Review. They were extremely well prepared; they asked tough questions and provided excellent recommendations.

The entire IR-4 Project gets great value out of having a panel like this review our activities and strategies. We believe it helps us maintain IR-4 as a successful government sponsored research project.

Below are the Recommendations developed by the NRSP-4 External Review Panel. Immediately following each recommendation is the IR-4 Project's response to their proposal.

A. IR-4 Project Administrative and Strategic Management

- The panel recommends that the IR-4 Project develop an action plan based on the newly developed Strategic Plan for 2009-2014. The action plan should provide a roadmap on how to accomplish the stated objectives of the project. The panel recommends that a business plan be developed as part of the overall action plan. The business plan should consider development of a financial management strategy that would maintain the project during flat budget periods, as well as position the project to take advantage of growth opportunities. Once the business plan is developed, IR-4 leadership should periodically revisit the Strategic Plan to determine if mid-course corrections might be necessary. **Response: IR-4 is in the process of developing an action plan and business plan. Much of this information is required for the proposal to renew NRSP-4 and will be a part of this document that will be submitted later this year to the Directors of the State Agriculture Experiment Stations.**

Major funding for IR-4 is provided by Special Research Grants and Hatch Act funds from USDA-CSREES, in cooperation with the State Agricultural Experiment Stations, and USDA-ARS.

- The panel believes it is important for the IR-4 Project to determine and prioritize the core business practices and program objectives that are most important to maintain during difficult financial times. Additionally, they should analyze potential growth areas (see next bullet) as part of the overall prioritization process. **Response: In difficult financial times IR-4 will protect the traditional functions of the core objectives, that is, Magnitude of the Residue studies on food crops to support pesticide tolerance applications, pesticide efficacy and phytotoxicity testing on ornamental crops and efficacy testing of biopesticides.**
- The panel urges IR-4 Project leadership to carefully evaluate "Mission Creep" in relation to their Strategic Plan and accompanying business plan. Program expansion should be based on a careful evaluation of potential growth areas and within the context of a business strategy. The project would benefit from staff and stakeholder sessions designed to develop the pros and cons for expansion of the project mission. These sessions could determine the benefits (e.g., science capacity and outcomes, knowledge development, enhanced funding, broader stakeholder support, and accomplishment of the core mission) that might result from potential expansions. **Response: IR-4 will consider this recommendation and conduct staff and stakeholder sessions when any potential program expansion or new opportunity is uncovered.**
- As part of the development of a business plan the panel recommends that IR-4 Project leadership continue to evaluate the capacity of the remaining regional residue laboratories and the ARS residue facilities. A cost/benefit study would be helpful to determine appropriate current and predicted needs for the IR-4 Project. **Response: IR-4 has evaluated analytical capacity previously, which resulted in phasing out one of its regional laboratories. IR-4 will continue to evaluate the capacity of its programs, especially the analytical capacity in the future. Because of the transition with the phase out of the Northeast Region laboratory and the partial transfer of resources to enhance personnel and infrastructure. IR-4 will conduct a reassessment of laboratory capacity in 2011.**
- The panel recommends that IR-4 Project leadership, both at HQ and at the regional level continue to evaluate field study site distribution needs and related capacity issues. They also recommend that close coordination with the ARS IR-4 program continue so as to optimize available resources. **Response: On an annual basis, IR-4 does an assessment of the field study site distribution needs for State Agricultural Experiment Station and Agriculture Research Service sites. This occurs at the IR-4 National Research Planning meeting. IR-4 will continue to reevaluate the field site distribution needs and make strategic modifications when necessary.**
- The panel noted the continuing difficulties the IR-4 Project has had in regards to timely distribution of appropriated funds. Receipt of funds occurring approximately 6 to 9 months after the start of the Federal Government fiscal year due to delays in appropriation bill passage has complicated maintenance of existing field and laboratory projects; as well as impeded the timely initiation of new projects. Although events surrounding the appropriation cycle are out of the control of IR-4 Project management, it remains necessary to seek alternative solutions to aid

cooperating project coordinators. The panel suggests that IR-4 Project leadership in cooperation with USDA-CSREES leadership work together to seek solutions that could minimize some of the concerns. Solutions could include approving projects to receive funds for a minimum of two-years to eliminate carry over issues, or seek new authorizations to change the manner in which funds are received by the project (five-year authorization at an established funding level rather than single year appropriations). Close communication and continuing dialogue on possible resolutions between IR-4 and cooperating universities is also encouraged. **Response: The IR-4 Executive Director has met with CSREES/NIFA management in an attempt to expedite resource distribution to the program. As a result, a modified process will be initiated. This was implemented in fiscal year 2010 when the IR-4 Request for Applications (RFA) was released in mid-October 2009. The RFA review process will occur concurrently with the Federal Government's appropriation process. This change could potentially reduce the funding delays by at least 90 days. Other opportunities to minimize the problem are being explored.**

- Explanations of the above cited funding concerns are complicated and difficult for many stakeholders and interested parties to adequately understand. The panel suggests that IR-4 Project stakeholders (e.g., Commodity Liaison Committee) work closely with IR-4 leadership to develop a one-page summary document that describes the current funding process and suggests potential options for resolution of the problem. This document would be beneficial for stakeholder education and enhanced communication. **Response: This is an excellent suggestion and this task is being assigned to the IR-4 Communications Manager for follow-up.**
- The panel recommends that the IR-4 Project develop a transparent process to better track and analyze existing and potential uses of industry unrestricted funds. As part of the recommended Business Plan, these funds should be identified for possible uses including emergency/contingency needs and matches for special grants. **Response: An annual report on the income and expenditures of industry funds will be provided to the PMC, maintaining due respect for confidentiality where the source of funding.**
- The panel recommends the continued evaluation of the role of state liaisons within the IR-4 Project. It was noted that one state, Missouri, did not have a current liaison. Within the Southern Region, some states have separated their liaisons into separate positions for food crops and ornamentals. We encourage IR-4 to evaluate this concept and determine if it is worthy of implementation in other key production states. **Response: Additional other states have established both a food crop and ornamental crop SLR. It is being proposed that an ad hoc panel be established to examine the roles and responsibilities of the IR-4 State Liaison representatives (SLRs). The panel will be asked to develop recommendations on future duties of the SLRs.**

B. IR-4 Project Personnel Management

- The panel recommends that all organizational levels of the IR-4 Project review their current personnel structures and discuss and implement succession planning activities as appropriate.

We also encourage establishment of career ladders as opportunities arise. Response: IR-4 Project Headquarters has recently reorganized and opened up some advancement opportunities for staff. Other units are exploring this possibility.

- Traditional succession planning may be difficult to achieve within the IR-4 Project structure. We encourage IR-4 staff to develop a mentoring program for early and mid-career staff to provide opportunities to better understand how the project functions as well as operational considerations at the host institutions of project employees. The project is also encouraged to conduct cross-training as appropriate. Response: IR-4 Project Headquarters has provided mentors to recently hired junior scientists. With several recent hires at IR-4 Project Headquarters and at the Regions, it is appropriate that IR-4 explore opportunities to renew the past practice of cross training of staff between Headquarters and the Regions.
- The panel recommends that the IR-4 Project employ summer interns as opportunities arise. Response: IR-4 Project Headquarters continues to employ a student intern. Some Regions hire undergraduates and participate in the graduate students and visiting scientists from overseas. Additional opportunities will be explored.
- The panel encourages IR-4 Project leadership to work closely with university department chairs and heads and related university administrators to seek professional status of IR-4 staff on their respective campuses. We would also encourage consideration of sabbatical opportunities. Response: Several IR-4 Project Headquarters professionals are serving as instructors in Rutgers University courses. This is allowing for closer involvement of IR-4 and their faculty associates on the campus. One member has an adjunct appointment with the Rutgers University Center for Vector Biology. This is true at the North Central Region; all three of the project coordinators are classified as Academic Staff and have the option of becoming non-tenure track faculty in Entomology.

C. IR-4 Project Program Management and Leadership

- The panel concurs that the use of "specialty crop and minor use pest management" in its mission statement is appropriate. We recommend that the IR-4 Project evaluate their mission statement periodically as part of their strategic planning and program review process. Response: Will place this recommendation on an agenda of a future Project Management Committee meeting.
- The panel recommends that the IR-4 Project continue to evaluate how the project incorporates management of exotic and invasive pests into their program. Coordination with EPA, APIDS, and the state agricultural departments and experiment stations is encouraged. Response: As a first step, IR-4 Project Headquarters has opened dialogue with USDA-APHIS on IR-4's potential involvement in the management of invasive pests.

- Global Harmonization (MRLs and crop grouping) is critical for production of specialty crops. The panel recommends that the IR-4 Project continue to support efforts and provide international leadership on MRL harmonization and crop grouping. **Response: IR-4 Project Headquarters has reorganized and specifically assigned the Associate Director with the responsibility to lead IR-4's international activities. Additionally, IR-4 Project Headquarters has submitted a grant application to USDA-Foreign Agriculture Service to obtain some additional resources to expand on IR-4 international leadership activities including expansion of submission of IR-4 data for Codex MRL's.**
- The panel heard from various stakeholders that lumping crops into crop groups has had, and will continue to have, export ramifications regarding receipt of labels from the registrant. We recommend that IR-4 Project staff provide advanced notification to affected stakeholders for timely assessment of possible registrations. We note the addition the IR-4 staff made to the Project Clearance Request (PCR) form (a tab to indicate if export is involved with a potential material) which will improve the process. **Response: For many of the commodity organizations that are engaged with IR-4 (e.g. mint, hops, cranberry) an advanced notice process is being implemented. For commodity organizations that are not actively engaged with IR-4, specific active notification systems will have to be developed.**
- The panel recommends that the IR-4 Project outline a process for broader vetting of use patterns with stakeholders during project protocol development (before anything enters into testing). This involves expanded and diligent consideration of proposed use patterns on a national basis. In some cases, this may also include planning for sufficient U.S. trials necessary to support the data requirements of an important international trading partner in the event that additional field trials are necessary to gain an MRL in the foreign market. **Response: IR-4 currently posts proposed protocols on the IR-4 Website and solicits comments from stakeholders for approximately 14 days prior to finalization. IR-4 can increase communication and outreach on the availability of the draft protocols and comment period deadlines. Please note, though comments are received, there are instances when protocols are not modified in response to the comments. In many cases, EPA or company recommendations are forcing a specific use pattern.**
- We encourage the continued inclusion of the following (originally developed in the 2003 Review Report and slightly updated with this review) criteria to maximize the benefits of allocated resources and to ensure alignment with IR-4's strategic objectives:
 - o role in pesticide resistance management
 - o severity of pest problem
 - o crops, acreage affected and potential economic impact
 - o multi-year Section 18 exemptions
 - o awareness of potential risk issues – communicate with EPA as part of the vetting process for projects
 - o where possible, make priority selection for project support for a material that could be considered reduced risk and/or fully compatible with sustainable agriculture

- o regional input to prioritization prior to food use and ornamental workshops
 - o status of potential trade barriers
- Response: Agreed**

- The panel encourages the continued evaluation, as appropriate, of the feasibility of including efficacy and crop safety components within work plans and prioritization activities. **Response: The Assistant Director, Research Planning and Outreach has been given the task to hone in on IR-4 Project efficacy and crop safety activities and develop specific recommendations for potential expansion.**
- The panel recommends that IR-4 Project HQ staff develop a value-added metric for the biopesticide program. **Response: Agreed and IR-4 will open discussions with Michigan State University's Center for Economic Analysis on the feasibility of conducting a study.**
- The panel recommends that IR-4 Project leadership develop a scope and related action plan for the Human Health pilot program (public health pest control). The program should be evaluated based on how it fits into the current IR-4 Project mission, as well as the value it adds to the project. We suggest that the program be evaluated prior to the end of the pilot to determine the feasibility of continuing as part of the IR-4 Project. In general, we believe this type of evaluation should be conducted for any new program enhancement or expansion of the existing core capacity of the project. **Response: The recommended assessment will be undertaken prior to the termination date of the pilot project (July 2013).**
- The panel encourages the IR-4 Project to continue their active communication and coordination with potential registrants to address issues such as hazard and risk cup characterization, timely notices of filing, labels, registration materials, etc. **If necessary data/information cannot be provided by the registrant in a timely way, we believe it is proper for IR-4 to consider withdrawing its investment and energy toward developing field trial data for the project. Response: Agreed and for many companies, IR-4 is expanding its active communications from one annual meeting into multiple face to face meetings.**

D. IR-4 Project Stakeholder Considerations

- The panel suggests that current metrics used by the IR-4 Project to measure programmatic success be reviewed and possibly refined to better reflect stakeholder needs. For example, registration of a use on a "label" is viewed as a key measure of success among growers but was not included in documentation reviewed by the panel. The number of specialty/minor uses included on a label should be included in future reports. **Response: Agreed and IR-4 is developing systems to better track registrations associated with IR-4 activities vs. the current system of tracking tolerances. It is agreed that tolerances may not always be the ultimate measure of success.**
- Stakeholders would like to be better informed of issues, registration decisions, etc., involving genetically modified organisms (GMOs)/plant incorporated protectants (PIP) before moving forward on potential projects. The panel encourages IR-4 Project leadership to consider this recommendation and develop a protocol to include these discussions as part of the prioritization

process. Response: IR-4 has a longstanding policy that was established by the IR-4 Project Management Committee in consultation with the CLC that IR-4 will not initiate registration support involving Plant Incorporated Protectants unless the commodity organization involved with the PIP provides acknowledgement and agreement of the activity. However, many feel this policy needs modification to manage instances where one segment of the commodity is agreeable and another segment is not.

- The panel encourages IR-4 Project leadership along with the Project Management Committee to evaluate the structure and review the current mission and charter of the Commodity Liaison Committee to ensure stakeholder equity. Response: The PMC will evaluate structure and review the mission and charter of the Commodity Liaison Committee.
- The panel encourages the IR-4 Project leadership, the Project Management Committee and the Commodity Liaison Committee to seek opportunities to broaden the existing stakeholder base. Interested stakeholders not currently associated with IR-4 should be identified and encouraged to become more involved in the project. Response: The PMC will evaluate opportunities to broaden the Commodity Liaison Committee.
- The panel recommends that the IR-4 Project enhance cooperation with the Regional IPM Centers as appropriate. Response: Agreed and the Executive Director will attempt to visit these centers to encourage cooperative activities. There is additional involvement between the IR-4 Regional Offices and the Regional IPM Centers. For example, the North Central Region IR-4 office always invites the NC Regional IPM Center Director to our annual advisory meeting and solicits any ideas for collaboration and cooperation.

E. Opportunities

- The panel suggests that IR-4 Project leadership carefully evaluate their current and future role as the premier resource for specialty crop and minor use pest management and product registration. Is there a role for the IR-4 Project staff as national/international consultants and/or experts in this important field of work? Response: IR-4 will continue to provide national and international leadership for specialty crop and minor use pest management and registration. The IR-4 will continue to evaluate these activities for relevance within the IR-4 overall mission, goals and objectives.
- As mentioned in earlier recommendations, the panel encourages the IR-4 Project to evaluate and determine if other researchable areas could be included within the program. Opportunities are known to exist in application technology, beneficial organisms/biological control, biotechnology, and in development of innovative methodologies to estimate residue quantities with less testing involved. All opportunities should be evaluated in the context of the IR-4 Project business plan. Response: As recommended by this panel, IR-4 should consider potential growth areas only after careful evaluation with staff and stakeholder sessions designed to develop the pros and cons for expansion of the project mission.

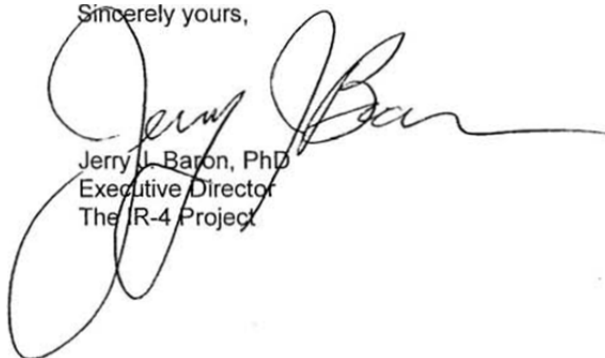
- The panel encourages the IR-4 Project to seek opportunities to obtain funds from sources other than traditional CSREES Federal appropriations as long as the funding source and project scope meets existing IR-4 Project goals and objectives. Sources could include Department of Defense (DOD), Department of Energy (DOE), Department of Health and Human Services (DHHS), and the National Science Foundation (NSF). **Response: Agreed and grant applications are currently pending from sources outside the "traditional" CSREES/NIFA source, which fit the overall goals and objectives of the program.**

F. International Opportunities

- Trade facilitation is a relatively recent and increasingly important aspect of IR-4's activities. The work currently focuses on providing residue test results to other developed trading partners so that products exported by our growers are accepted. USAID or FAS may request IR-4's assistance in establishing residue testing laboratories or minor use efficacy/phytotoxicity trials overseas to enhance food safety and regional/international trade. **Response: Agreed**

In closing we want to thank Dr. Monte Johnson of your team for facilitating the External Peer Review of the IR-4 Project. He did an excellent job. Please let me know if you need additional information or have any questions.

Sincerely yours,

A large, stylized handwritten signature in black ink, appearing to read "Jerry L. Baron".

Jerry L. Baron, PhD
Executive Director
The IR-4 Project

Cc: IR-4 Project Management Committee
L. Chandler, USDA

Appendix 2: Accomplishments under the 2009–2014

Strategic Plan

Food Program - To identify and facilitate registrations/approvals which allow growers to use the newest generation and most effective pest management solutions for high-value specialty food crops and minor uses on a major food crop. Emphasis will be placed on using lower/reduced risk chemicals and encouraging uses compatible with Integrated Pest Management and Resistance Management programs.

Performance measure: If requested funding is obtained, the specific goal is to develop data for submission to US EPA in support of grower needs. The target is data packets that support 1,000 potential new domestic registrations annually, with at least 80% of these registration focusing on lower/reduced risk technologies. Additionally, IR-4 will provide and/or submit 25 data packages to international bodies (eg Codex Committee of Pesticide Residues, European Union, Canada, Japan, Taiwan) annually to support US grower exports.

Progress:

	2009	2010	2011	2012	2013	Mean
Registrations	952	786	382	1085	1032	874 ⁵
Petitions Submissions to EPA	126	55	179	142	85	100
New Research (Field Trials)	553	604	512	523	534	545
International Submissions ⁶	0	0	28	70	20	39 ⁷

Crop Group Modifications Approvals: (2010) Oilseed, Fruiting Vegetable, Citrus Fruit and Pome Fruit Groups. (2012) Stone and Tree Nut Groups

Other: (2012) Global Minor Use Summit 2

Ornamental Horticulture Program - To identify and develop efficacy and phytotoxicity data to support reduced risk pest management solutions for ornamental horticulture crops, with an emphasis on the most effective biological and chemical solutions compatible with Integrated Pest Management and resistance management programs. Data developed will establish or expand the number of ornamental horticulture crops or pests on pesticide labels and enable growers to most effectively utilize these tools by assessing their impact on beneficial organisms and their ability to be used within resistance management programs.

Performance Measure: The specific goal is to provide product performance (efficacy and/or crop safety data) to the crop protection industry and to facilitate establishment or expansion of registrations

⁵ 2009-2013

⁶ Not funded until 2011

⁷ 2011-2013

(new products, new crops and/or new pests) associated with ornamental crops. If requested funding is provided, the data developed by the IR-4 Project will contribute to at least 20 registrations and impact at least 5,000 ornamental species annually.

Progress:

	2009	2010	2011	2012	2013	Mean ⁸
Registrations	9	4	11	3	5	6.4
Species Impacted ⁹	614	2367	2572	644	1535	1552
Data Summaries Submitted	16	21	21	21	19	19
New Research (field trials)	1212	1473	1199	722	715	1064

Invasive Species Research

- (2009-2013) - Gladiolus Rust
- (2010-2014) – Management of Invasive Arthropods
- (2010-2014) - Chrysanthemum White Rust
- (2011–2014) – Boxwood Blight
- (2012-2014) – Impatient Downy Mildew

Biopesticide and Organic Support Program - To support research and provide regulatory support that enhances the development, registration and use of biopesticides in conventional specialty crop production systems and to facilitate the approval of pest management technology for use in certified organic production systems.

Performance Measure: If requested funding is obtained, the specific goal is to fund at least 50 research projects annually that will evaluate and demonstrate the use of biopesticides as well as projects that develop data in support of pest management products for organic crop production.

Progress:

	2009	2010	2011	2012	2013	Mean ¹⁰
Registrations	7	776	5	12	13	163
Proposals funded	34	36	22	19	23	26.8

Registration Support for Pesticides Managing Medically Important Arthropods - To facilitate the registration of pest management products that control arthropod pests responsible for transmitting vector borne diseases and threatening human health.

Progress:

⁸ 2009-2013

⁹ Not funded until 2011

¹⁰ 2009 -2013

- (2011) – IR-4 submits data requesting an “All Crops Tolerance” for etofenprox.
- (2012) –Published on-line inventory of over 600 available and potential pesticides for to manage arthropod pests that transmit diseases to humans and animals
- (2013) – EPA establishment of crop tolerances to allow the an adult mosquitocide, etofenprox to manage mosquitoes near crops.
- (2013) – Provided regulatory support for Attractive Toxic/Targeted Sugar Bait technology

Appendix 3

Summary of Responses from IR-4's 2013 Strategic Planning Survey

How familiar are you with the IR-4 Project?

- 550 responses
- 88% moderately or very familiar

Which Program have you interacted?

- 329 w/Food-Residue
- 306 w/Food-E/CS
- 171 w/Ornamental-E/CS
- 128 w/Biopesticide-Grants
- 100 w/Food-International
- 60 w/Biopesticide-Regulatory support
- 52 w/Public Health Pesticide
- 50 w/Ornamental-Invasive

What role do you interact with IR-4 Project?

- 35% are State/Federal Research/Extension
- 26% are Crop Protection Industry
- 16% are Grower/Commodity Group Representative
- 11% are Consultant
- 10% are IR-4 employee

IR-4 Delivers Indispensable service for Specialty Crop Agriculture or other minor uses

- 69% Strongly Agree
- 23% Agree
- <4% Disagree/Strongly Disagree

Assuming new unrestricted funds are available; please state how important it is for IR-4 to work in the following areas (highest to lowest)

- Increase the IR-4 Food Use Program
- Conduct research to fully integrate biopesticides with chemical pesticides
- Monitor and/or mitigate pest resistant to pesticides
- Increase support for IR-4 Biopesticide and Organic Support Program
- Develop data to assess exposure of pollinators to pesticides
- Develop data to answer the regulatory needs associated with FMSA
- Develop data to help satisfy regulatory requirements for Public Health Pesticides
- Increase Ornamental Horticulture program research
- Increase regulatory support for Biopesticide program

Are there untapped opportunities for synergy between IR- and other government funded groups on pest management?

- *“Work on strengthening ties with IPM. Start paying more attention to organic”*
- *“IR-4 should be an advocate for ag issues with other government programs”*
- *USDA Office of Pest Management and Policy*
- *Sustainable ag groups*

IR-4 is communicating effectively using its website, social media, newsletter, and monthly reports. Please select your level of agreement.

- Agree – 59%
- Strongly Agree – 21%
- Neither Agree or Disagree - 18%
- Disagree/Strongly Disagree – 2%

How can IR-4 Communicate Better?

- *“Through direct contact..... Our stakeholders are busy it is not sufficient to expect that they will voluntarily go to our website or read our newsletters”*
- *“Ensure that communication pieces are created/used are technically accurate and verbally/grammatically correct”*
- *“IR-4 should work more with State Extension Services”*
- *“Social media outreach should be more aggressive”*
- *“Attend grower meetings” / “interact more with commodity organizations”*
- *“use the telephone”*
- *“make the IR-4 website more friendly”*
- *“Implement email tracking tool to notify stakeholder of milestones”*
- *“Use less jargon and language that growers understand”*

Do you agree the benefits of face-to-face meetings with stakeholders outweigh their expense?

- 23% Strongly Agree
- 42% Agree
- 26% Neither agree or disagree
- 8% Disagree/Strongly Disagree

How comfortable are you with video and voice conferencing technologies to replace IR-4 meetings?

- 36% Very Comfortable
- 36% Neither Comfortable nor Uncomfortable
- 17% Very Uncomfortable

How important are the following in helping the talent and expertise of the IR-4 State Liaison Representatives?

- 78% of respondents felt it was important (Somewhat/Very/Extremely) for SLRs to hold state wide IR-4 workshops
- 67% of respondents felt it was important (Somewhat/Very/Extremely) for SLRs to produce a state newsletter
- 88% of respondents felt it was important (Somewhat/Very/Extremely) for SLRs to represent IR-4 at grower meetings
- Comments:
 - *“Maybe involve Extension Area Agents or specialists better to connect with growers”*
 - *“Establish statewide stakeholder boards:”*
 - *“obtain additional feedback from suppliers and consultants; closer to growers”*

IR-4’s involvement with international harmonization of pesticides is important in facilitating increased exports of specialty crops

- 44% Strongly Agree
- 43% Agree
- 10% Neither agree or disagree
- <2% Disagree/Strongly Disagree
- Comment
 - “There seems to be a disconnect between the people submitting petitions and the consideration of international MRL and IR-4 involvement with participating in all of these international activities. Some energy would be better spent working with staff on considering international markets when preparing protocols and petitions”

How do you see IR-4 participating in international activities in the future?

- 82% Yes
- 5% No
- 14% Unclear

Assuming external funds are available, how important is it that IR-4 participate in training and mentoring international scientists and regulators to assist them in establishing their own minor use program?

- 15% Extremely important
- 42% Very important
- 31% Neither important or Unimportant
- 11% Unimportant

The IR-4 Food Use Program has been successful in serving the needs of its stakeholders

- 50% Strongly Agree
- 44% Agree
- 6% Neither agree or disagree
- 0% Disagree/Strongly Disagree

Do you believe the need for existing services provided by the IR-4 Food Use Program will increase, decrease or stay the same over the next five years

- 69 % - Increase
- 26% - Stay the same
- 5% - Decrease

What are the greatest strengths of the IR-4 Food Use Program?

- Service to growers (55%)
- Facilitation cooperation/collaboration/inclusion (26%)
- Its people (19%)

“It has a valuable, well-defined product and its impact is readily measured. The culture of IR-4 is very healthy, and even contagious. Thus, as the projects interacts with other entities, nationally and internationally, the IR-4 GOODS will continue to be spread”

How can IR-4 build upon this strength?

- “Secure multi-year funding so that every year the extensive energy/resources required to deal with budget issues could be more appropriately used”
- “Find ways to make sure the tolerances make it to the user label”
- “Continue to be the best you can be with customer focus as your trademark.. Customers being the growers”

- *“Keep focus on what IR-4 was designed to do, provide specialty crop tolerances and 24Cs”*
- *“Awareness of pesticide resistance issues and how to manage without new tools being developed”*
- *“I have witnessed that as good as IR-4 is, there remains those that do not understand their operation. Still need the simple explanation of what it is and how effective it has been to share with many potential stakeholders and general public”*
- *“Help link USDA-ARS discoveries to commercial development entities”*
- *“The strength of the program is tethered to a softening source of funding. The Project has to now begin to move toward additional sources of funding”*
- *“Start developing a group of interns that are going to be able to continue the work as the core group retires”*
- *“Build stronger relationships at EPA”*
- *“Embrace IPM, no more lip service or pandering to fringe elements of their stakeholder base. Adopt progressive role in contracting resistance management monitoring services that represent another major gap between what manufacturers cannot/will not provide and what stakeholders need to protect their valuable investment in minor use programs”*
- *“Encourage IR-4 Regional coordinators to be active representatives of their regions”*

What part of the IR-4 Food Program needs improvement?

- Priority setting (16%)
“Priority setting is still very much dependent on who is present/involved”.
“Transparency of regional decision prior to annual FUW.... There sometimes (often?) appear to be large discrepancies between commodity group needs and regional decision making”
- None/Not sure (16%)
- Communication/Outreach (13%)
- Resource allocation (12%)
“Some restructuring to deal with decreased funding and overcapacity in certain regions”
- Timelines to registration (11%)
“30 month timeline for approval to submission is too long; should be closer to 20 months”
- Funding (7%)
“there are often times when research centers are not adequately supported, perhaps IR-4 should consider consolidating regions”
- Involvement with industry (4%)
- Mission Creep (2%)
“IR-4 HQ has to be careful in not expanding too far from its core mission”
- Misc. (18%)

Are there aspects of the Food Use Program that have outlived their utility?

- No (66%)
- Not sure (18%)
- Yes (16%)
 - Biopesticide Program could be tailed back (3)
 - National meeting not needed (2)
 - The current regional structure (2)
 - Too Much Administration (2)
 - The paper IR-4 Newsletter
 - Food Use Workshop
 - QA inspections & travel-Use local consultants
 - Overcapacity in EPA Data Region 2
 - Databases could be more user friendly

What do you see is trending in pest management in specialty food crops that IR-4 can lead, or participate in, to better serve the needs of its stakeholders?

- Biopesticides/GMOs (21%)
- International harmonization (17%)
- Resistance Management (13%)
- Invasive Species (12%)
- IPM (11%)
- Efficacy/Crop Safety data needs (10%)
- Pollinator Protection (9%)
- New Uses/New Crop (4%)
- Other (2)

If Funding for IR-4 Food Program were to increase, which activities should be expanded or what new activities should be added?

- Intensify the process of running residue studies to get new products registered (29%)
- More Efficacy/Crop Safety Testing (18%)
“Make the generation of E/CS data more critical to IR-4 business as many registrants will not market uses until comfortable against liability claims is satisfied by proof of concept and/or proof of safety data”
- International-Expand harmonization and international involvement (16%)
- Biopesticides/GMO’s/Organics (10%)
 - Interesting-this many added Biopesticide related comment to question that was specifically targeted to Food Program
- Other (7%)
 - Crop Groups/IPM/Seed Treatment/Animal Health/
- More grower outreach (5%)
- Invasive/critical pests (5%)
- Resistance Management (4%)
- Replace equipment (3%)
- Pollinator Protection (3%)

Other noteworthy comments:

- *“Investigate need of getting involved in the use of antimicrobial products in food preparation or processing areas”*
- *“As the number of applied scientists decrease, we need to increase our support for efficacy and crop safety research. However, if this area is increased, we need to develop a better system for selecting projects”*

What are the threatening forces that will challenge the IR-4 Food Use Program?

- Funding (50%)
- Public Policy (21%)
- IR-4 Independence (6%)
- Available Technology (5%)
- Qualified Personnel (5%)
- Government Regulation (5%)

Comments

- *“Dwindling support within the ARS system for the critical work IR-4 does”*
- *“Being isolated from other IPM Programs”*
- *“Major crops claiming minor status”*
- *“Top heavy in management, inefficient in comparison to private industry. Waste of taxpayer money”*
- *“GMO plants that do not require pesticides”*
- *“Success of Crop Grouping”*

How can these threats be turned into opportunities?

- Communication & Education
- *“Perhaps IR-4 can garner additional support from industry” or “Fee for Service”*
- *“Apply for more grant” But “take care that chasing dollars does not dilute the mission of IR-4 but rather compliments or improves the organization”*
- *“keep answering growers needs”*
- *“Budget cuts could push more cooperative efforts with other countries and make the whole process more efficient”*
- *“The annual funding issue could create an opportunity for IR-4 to consider a wholesale restructuring; the 4-region structure may have outlived its usefulness and could be adjusted to take advantage of the strengths of its human resources, possibly into 3 or even 2 regions, with maybe only 2 labs; the savings from significant restructuring could be substantial, making it a leaner/meaner program that continues to be the envy of, and example for, all other government entities.”*

The IR-4 Ornamental Horticulture Program has been successful in serving the needs of its stakeholders

- Agree- 63%
- Strongly Agree-26%
- Disagree/Strongly Disagree <1%

Do you believe the need for existing services provided by the IR-4 Ornamental Horticulture Program will increase, decrease or stay the same over the next five years

- Increase- 56%
- Stay the same – 37%
- Decrease – 7%

What is the greatest strength of the IR-4 Ornamental Horticulture Program?

- Data development/expanded registrations- 48%
- Facilitating Collaboration – 36%
- Research Funding – 9%
- The people- 7%

How can we build upon the strength over the next 5 years?

- *“Keeping up the momentum; increase interaction with Hort industry”*
- *“Increase funding for ornamental research”*
- *“More researchers participating, greater funds to distribute.”*
- *“Develop a truly integrative program by more research into conventional and biopesticide efficacy, rotation, and non-target impacts”*
- *“Exploration of new chemical molecules”*
- *“Promote regional programs – difficult as faculty numbers fall”*
- *“Improve organization, management and efficiency of program. Also involve grower stakeholders more”*
- *“Continue the existing strategy”*

Since the last strategic plan, the IR-4 Ornamental Horticulture Program has become involved in addressing exotic invasive species. How can IR-4 enhance service to growers related to invasive species?

- Facilitate cooperation between multiple parties- 53%
- Education/Communication – 27%
- Fund research, develop data to support registrations- 20%

“Invasive species are a major threat to all areas of crop, animal and human health. Whole industries and populations are threatened. All efforts must be made to coordinate and build strategies across the Federal and State governments to limit the introduction. IR-4 must be the advocate for ag with other government agencies to educate about the seriousness of the threat and the importance of putting solutions in place prior to crisis”

What part of the Ornamental Horticulture Program needs improvement?

- *“Getting people involved – the grower so the surveys reflect the biggest need and not just what they see the most in their own operation. The efficacy part of the program has vastly improved the worth of the data that IR-4 generates. Being able to show that some products are more specific for pest/pathogen/weed control vs. another product so growers can see good rotation products in very important to help build meaningful platform of solutions for growers”*
- *Getting the industry involved. Every national conference should have a presentation about the importance of IR-4 to the industry, OFA- July, CENTS- January, NEGrows- February, Farwest -August, etc.*
- *“timing of funding-often research is almost completed when the research dollars arrive and getting more difficult to continue to do this”*
- *“Protocols need to be designed to assess efficacy in light of the pest biology rather than a one-size fits all protocol. Much more could be learned with more thoughtful protocols”*

Are there aspects of the Ornamental Horticulture Program that have outlived their utility?

- No (91%)
- Yes (9%)

What do you see is trending in pest management in ornamental crops that IR-4 can lead, or participate in, to better serve the needs of its stakeholders?

- Biopesticides/IPM/Systems approach to manage pests - 48%
 - Managing tools for pesticide resistant pests – 13%
 - Development of efficacy data to help growers make good decisions on which product to use -13%
 - Management of invasive species – 13%
 - New pests/new crops – 10%
- “Take an ornamental production chain approach to managing diseases, pests and environmental safety, starting at seed production and propagation through production, processing and sale. Inclusion of more biopesticides and use of combinations of available products/strategies in efficacy trials and priority projects. Best management or production practices can be developed piece by piece or crop group by crop group to best fulfill pest and disease management needs of the industry and environmental safety needs of the public”*

If ornamental horticulture program funding were to increase...what activities should be expanded?

- More efficacy research – 40%
- Invasive species management – 20%
- Biopesticide integration – 16%
- Develop international partnerships – 10%

What are the threatening forces that will challenge the Ornamental Horticulture Program in the next five years?

- Funding – 60%
- Invasive pests – 13%
- Retirement of scientists – 9%
- Downsizing of ornamental production industry – 5%

How can IR-4 convert the current and future threats into opportunities?

- *“Seek more funds”*
- *“Improve communication with stakeholders through the development of digital tools; request state liaisons and researchers identify IR-4 as funding source for research/data in extension/education program.”*
- *“Bring more industry businesses into the process to widen the support base”*

- *“Exotic pests and phytosanitary issues ... pesticides are still essential for ornamentals. This may be a good approach to continue (or increase) government funding in an effort to both address these issues and maintain the traditional roles of the IR-4 ornamentals program.”*
- *“Establish priorities and continue doing what it has been doing: supporting accurate and objective research. Establish a work force with experts in different areas to advice on course to follow.”*

The IR-4 Biopesticide and Organic Support Program has been successful in serving the needs of its stakeholders

- Agree- 48%
- Strongly Agree-13%
- Disagree/Strongly Disagree 13%

Do you believe the need for existing services provided by the IR-4 Biopesticide and Organic Support Program will increase, decrease or stay the same over the next five years

- Increase- 72%
 - Stay the same – 19%
 - Decrease – 10%
- “More biopesticides coming to market”*
“Need for effective, softer, more biological approaches to managing pests, diseases and weeds will only increase as resistance development and environmental pressures increase”

What is the greatest strength of the IR-4 Biopesticide and Organic Support Program?

- Furthering the registration of biopesticides through data development and/or regulatory support- 62%
- Facilitating collaboration between industry/research community and EPA – 28%
- Much needed support for the Organic industry – 9%

How can we build upon the Biopesticide and Organic Support Program strength?

- *“There is a need of unbiased research data and for developing program approaches with other biopesticides to provide growers with sound options that actual work in defending their crops against pathogens”*
- *“Offer cleaner guidelines for the organic support program, build connections with OMRI and certifiers, get input on the needs of organic growers”*
- *“Continue to provide assistance to small companies or help provide linkages from ARS discoveries to commercialization entities.”*

What part of the Biopesticide and Organic Support Program needs improvement?

- *“If you look at many of the projects that have been funded it seems most of them are for products that go nowhere. If you did a retrospective of funded projects and figured out who many products are being used significantly, I suspect you would find a few winners and a lot of products that just went away or are not being used.”*
- *“Many organic materials are labeled for various specialty crops, but have no efficacy data. If the funding was available, then IR-4 could help with some kind of improved efficacy screening program for organic materials”*
- *“The grant application process is quite laborious, it seems that there is repetition in the forms/information that is required” & “the format of Biopesticide proposal is highly dysfunctional. The format should fall in line with normal scientific writing format of competitive grants”*
- *“the granting program needs to be more transparent, regarding feedback into how priorities were set and award decisions were made”*

Are there aspects of the Biopesticide and Organic Support Program that have outlived their utility?

- *“the database and other items on the web page should be reviewed”*

- *“the biopesticide program should fund/address cutting edge innovations---not the same old tired options which keep getting recycled”*

IR-4 is adequately meeting the needs of organic growers?

- Neither Agree nor Disagree – 45%
- Agree- 31%
- Strongly Agree-4%
- Disagree/Strongly Disagree 19%

What do you see is trending in biopesticides that IR-4 can lead, or participate in, to better serve the needs of its stakeholders?

- *“The desire on the part of more progressive grower to incorporate biopesticides in their IPM Programs”*
- *“Biopesticide industry is growing fast” & “more companies are involved with biopesticides and will need more service from IR-4”*
- *“Integrating pesticides, biopesticides and biological control organisms into meaningful repeatable programs to reduce pesticide use and counter resistance”*
- *“Need for products with safety to pollinators”*
- *“Nanotechnology”*
- *“Need for efficacy data is great. Many products come on the market without good efficacy data. Growers are very interested and supplier eagerly promote these products but Extension has a difficult time know what to recommend so efficacy data is critical”*

If funding for the IR-4 Biopesticide and Organic Support Program were to increase over the next five years, how important is it that the program be expanded in the following areas? (1 to 5 scale with 1= not important at all and 5 = extremely important)

- Biopesticide integration into conventional programs – 4.24
- Utilizing biopesticides for safety to pollinators – 4.03
- Use of biopesticides to reduce conventional pesticide residues on crop – 3.76
- Organic Agriculture- 3.63
- Extend biotechnology program into APHIS deregulation – 3.41

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