



A Strategic Plan for the IR-4 Project (2009 -2014)



Facilitating registration of
sustainable pest management
technology for specialty crops
and minor uses.

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Background

For over forty-five years, the IR-4 Project has been the primary resource in the United States for facilitating registrations of conventional pesticides and biopesticides on food crops (fruits, vegetables, nuts, herbs, spices, etcetera,) and non-food ornamental crops (nursery, landscape plants, Christmas trees, flowers, etcetera,). The IR-4 Project also facilitates registrations of pest management tools for minor and low volume uses on major crops. IR-4 is needed because the return on investment of the relatively small markets associated with specialty crops and minor uses is not a priority business objective for the companies involved in developing, registering and marketing pesticides. US Department of Agriculture (USDA) recognized this need and established the IR-4 Project to provide a means for US growers of specialty crops to have legal access to safe and effective pest management tools. The IR-4 Project accomplishes this task by developing the necessary research data to support US Environmental Protection Agency (EPA) registrations.

The IR-4 Project is a cooperative program funded primarily by USDA and the State Agriculture Experiment Stations (SAES). The Project, which began in 1963, with two scientists housed at the New Jersey Agriculture Experiment Station, has grown in both size and mission. In 2008, IR-4 employed about 125 full-time equivalent staff and had a federal appropriation of over \$15.6 million. This direct support is supplemented by in-kind support from SAES; the in-kind contributions from the SAES are conservatively estimated to be equal to the amount of direct federal support. See the IR4 Project website (www.IR4.rutgers.edu) for a detailed overview of the IR-4 Project.

The purpose of this document, *A Strategic Plan for the IR-4 Project (2009-2014)*, is to articulate the mission, vision and objectives of the IR-4 Project. This is the fourth IR-4 Project strategic plan. The first plan, approved in 1989, focused on expanding the efforts of the IR-4 Project to develop new pesticide residue data for specialty crops in the context of the re-registration provisions of the 1988 Amendments to the Federal Insecticide, Fungicide and Rodenticide Act. The second Strategic Plan, approved in 1995 and updated in 1996 and 2000, focused on expanding the efforts of the IR-4 Project to encourage registrations of newer, lower-risk pest management pesticides for specialty crops due to the anticipated loss of older technologies following implementation of the Food Quality Protection Act of 1996. The third Strategic Plan, 2006-2008 expanded the scope of the IR-4 Project's three core programs, Food, Ornamental Horticulture and Biopesticide¹ programs and added initiatives to pursue global harmonization of Maximum Residue Levels (MRLs) for food specialty crops and to generate data to support registration of new herbicides for use in aquatic environments. The 2006 to 2008 plan was limited to three years to synchronize future strategic plans with USDA Project review process. The accomplishments of the 2006 – 2008 Strategic Plan can be found on Page 11 of this document.

This fourth Strategic Plan (2009-2014) incorporates expanded and new initiatives recommended as part of the IR-4 Project's Strategic Planning Conference, December, 2008 in Arlington, Virginia. The Conference was attended by 111 IR-4 Project stakeholders and participants who provided input on future directions for the IR-4 Project. In addition to the Strategic Planning Conference, input on this Plan was obtained through a broad solicitation of comments from stakeholders.

¹ Renamed Biopesticide and Organic Support Program in July 2008

The IR-4 Project Mission Statement

The mission of the IR-4 Project is to facilitate registration of sustainable pest management technology for specialty crops and minor uses.

Vision and Beneficiaries

The IR-4 Project focuses its efforts on providing value and exceptional service to the primary beneficiary of the Project, the growers and processors 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 human health 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.

Benefiting from activities of IR-4 is 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.

Objectives and Performance Standards

The first three strategic objectives, presented below, describe the plan to sustain and enhance the Food, Ornamental Horticulture and Biopesticide and Organic Support Programs during 2009–2014. A set of performance measures is identified to track progress in attaining the stated objective. Achieving these goals is contingent upon the IR-4 Project receiving sufficient funding.

Also included within the core programs are potential new initiatives that will fit under the existing core programs. New initiatives are:

- **Facilitate Identification of Pest Management Solutions to Answer Priority Grower Needs (Food Program)**
- **Harmonization of Maximum Residue Levels to Remove Pesticides as a Trade Barrier (Food Program)**
- **Invasive Species Management (Food and Ornamental Horticulture Programs)**
- **Registration Assistance for Products for Organic Markets (Biopesticide and Organic Support Program)**

The cooperative project, “**Registration Support for Pesticides Managing Medically Important Arthropods**”, between IR-4 Headquarters and USDA-Agriculture Research Service (ARS)/Department of Defense is also noteworthy. IR-4 Headquarters will provide basic regulatory support for their public health pesticide discovery/development efforts.

Core Objective 1: Food Program

Purpose: 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.

Detailed Discussion: This objective is broken down into three steps: (1) identification of pest management solutions to answer priority grower needs; (2) development of required data to facilitate federal and state approval/registration; and (3) harmonization of Maximum Residue Levels to remove pesticides as a trade barrier. Step (2) involves the traditional scope of the IR-4 Food Program, that is, the development of Magnitude of the Residue data to support pesticide tolerance establishment by EPA. Steps (1) and (3) are enhancements of the Food Program. These are further explained below:

Step (1): Facilitate identification of pest management solutions to answer priority grower needs.

Numerous specialty crop stakeholders have expressed the need for the IR-4 Project to assist in finding an effective pesticide or other solution to manage a new or difficult to control pests. IR-4 is uniquely qualified to successfully administer and supervise multi-region/multi-product product performance studies because of expertise of personnel and access to the newest pest management technology. The process will work as follows:

On an annual basis, IR-4 stakeholders, at the priority setting workshop, will identify several critical pest management voids on food crops that have limited weed, insect or plant disease management options available. The pest management void selected can include but not limited to pests that are classified as invasive pests. Companies will be solicited for inclusion of their products, innovative application methodology including seed treatment and cold fogging as well as new technology such as plant incorporated protectants (PIP's), into testing protocols. IR-4 will cooperate with scientists from public and private research institutions to test multiple tools to determine the most appropriate solution(s), i.e. more than one product/solution may be pursued in order to facilitate resistance management. Once a sustainable pest management "Solution" is identified, IR-4 will develop data for establishing domestic registrations.

This process has been successfully tested when IR-4 "piloted" a product performance testing of various products for control of onion thrips. Here, two of the highest performing products identified in the product performance testing have since been registered by EPA. The process is similar to the Canadian "A Priorities Without Solutions" process.

IR-4 is requesting \$900,000 from CSREES/NIFA funding sources to support comparative product performance testing aimed at quickly identifying promising pest management products for at least nine high priority pest management voids, including invasive pests on specialty crops and minor uses on major crops. Supporting dollars for manufacturers and or grower groups will be sought to augment this program.

Step (2) - Development of required data to facilitate federal and state approval/registration

In this step, IR-4 will conduct research to provide pesticide and PIP's registrations for the most important pest management needs affecting growers of specialty crops and minor uses on major crops. The process works as follows:

Using the established priority setting tools, stakeholders will identify the most important research needs. The majority of the work will be Magnitude of the Residue studies. Here, IR-4 will authorize and supervise field trials at IR-4 research centers or other sites when needed to test the pesticide product on the targeted crop. Residue samples will be shipped to a participating analytical laboratory for analysis. Results are collated and submitted to EPA requesting an establishment of a pesticide tolerance. All data will be conducted under EPA's Good Laboratory Practices standards. When appropriate, IR-4 can conduct product performance (efficacy and crop safety) to support expansions of registrations.

Data development will be done in the most efficient manner, utilizing standardized EPA data requirements for field and laboratory research. IR-4 will promote the use of crop groups and other available data extrapolations whenever possible. The crop grouping approach allows data developed on a few crops to suffice for many, increasing the efficiency of IR-4's activities. The IR-4 Project will continue to propose expansion and enhancement of the crop groupings to EPA. In most cases each updated and enhanced crop group doubles the number of member crops in that group. It is also useful to note that the

modifications to the domestic crop groups will likely be used as a base to establish a harmonized global crop grouping.

USDA currently invests \$12.7 million dollars to support the field, laboratory, quality assurance and study management efforts associated with IR-4's Magnitude of the Residue Studies and efficacy/crop safety work on food crops. IR-4 is requesting an increase of \$1.5 million for this phase to allow the IR-4 Project to undertake at least six more high-priority magnitude of the residue research projects annually. This increase will also allow IR-4 to invest in much needed improvements to study related equipment for laboratory and field research to maintain existing levels of productivity. One million dollars (\$1,000,000) of this new funding is being requested from USDA-Cooperative State Research Education and Extension Service/National Institute of Food and Agriculture (CSREES/NIFA) sources and the other \$500,000 coming from USDA Agriculture Research Service (ARS).

Step (3) – Harmonization of Maximum Residue Levels to Remove Pesticides as a Trade Barrier.

This step involves efforts to reduce or remove pesticide residues as a potential trade barrier for the export of US-produced specialty commodities as well as to promote the use of new, safer pest control products. IR-4 will work with the crop protection industry and foreign governments to assist in removing these barriers by taking a leading role to harmonize US established pesticide tolerances and international Maximum Residue Limits (MRLs), crop group classifications, and other data critical to ensure free trade of US based commodities. IR-4 will gather and reformat the data packages, supplement them with additional data and information and submit them to foreign regulatory bodies so they may establish MRLs which are harmonized internationally. Additionally, working with minor use programs throughout the world, IR-4 will conduct cooperative studies and generate the data required to obtain international registrations for new specialty crop uses and minor uses on major crops. Finally, IR-4 will provide leadership and foster a spirit of cooperation with global entities by organizing international reviews, participating on CODEX and OECD committees, conducting joint field trials and engage in other activities that may arise.

USDA currently invests \$250,000 in IR-4 global activities via a Technical Assistance for Specialty Crops (TASC) grant from Foreign Agriculture Service (FAS). The IR-4 Project requests an additional \$1.25 million of new resources from FAS via TASC and/or Emerging Market Program grants for assisting in reducing trade barriers with US trading partners caused by pesticide residues in specialty crops. These resources would allow IR-4 to have the ability to reformat existing data and submit the data to international bodies for harmonization of US pesticide tolerances with international MRL's. These resources would also allow the IR-4 Project to continue in its leadership role in global harmonization of pesticide issues with specialty crops including activities within Codex Committee on Pesticide Residues, Expert Group on Minor Uses of OECD and through the organization of the Second Global Minor Use Summit.

Core Objective 2: Ornamental Horticulture Program

Purpose: 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 (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.

Detailed Discussion: This objective will develop necessary data to facilitate federal and state approval and registration. Using established priority setting tools, IR-4 will identify the most critical pest management voids, including management of newly emerged invasive pests that pose a threat to the production and sales of ornamental horticulture crops. Effective tools for these voids will be assessed for resistance management strategies and impact on previously identified beneficial organisms. Companies will be solicited for inclusion of their products and new technology, including plant incorporated protectants into testing protocols. IR-4 will cooperate with scientists at public and private facilities to develop the relevant product performance data in support of new and/or expanded registrations. Once sustainable pest management options are identified and data developed, IR-4 will transfer the data to the companies to allow them to establish domestic registrations.

The IR-4 Project requests an increase of \$1.2 million annually above the Fiscal Year 2008 funding of \$1.0 million for the Ornamental Horticulture objective. This increase includes an additional \$700,000 for field research and regulatory support (\$450,000 from CSREES/NIFA and \$ 250,000 from ARS sources, respectively). This will allow IR-4 to have a greater impact on providing more data to support adding new pests and/or new plant species to the labels of lower-risk chemical products and to characterize the resistance management potential and the impact of beneficial organisms. The total increase also includes \$500,000 to support a research effort with the intent to rapidly test pest management technology leading to the identification of products that could be used in the eradication and/or management of invasive pests that harm ornamental specialty crops. These funding increases will allow IR-4 to better support the needs of this rapidly expanding segment of specialty crop agriculture and provide a more rapid response to critical grower needs.

Core Objective 3: Biopesticide and Organic Support Program

Purpose: 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.

Detailed Discussion: This objective is broken down into three areas: (1) competitive funding of research proposals to assist in the development and use of biopesticides; (2) regulatory support for the registration and/or approval of publically developed biopesticide as well as regulatory support for the registration and/or approval of biopesticide for specialty crops developed by small businesses; and (3) provide organic growers access to approved and relevant pest management solutions by adding new products to the National Organic Program's National List of substances approved for organic production.

IR-4 will fund grants to scientists at agricultural experiments stations, USDA and other public and private institutions to develop data on biopesticides to manage pests. This funding is accomplished via a competitive grant process. On an annual basis, IR-4 will release a Request for Applications for Biopesticide grants in three categories (Early Stage, Advance Stage, and Demonstration Stage). IR-4 will receive these applications, convene a review panel of experts and decide on which proposals are the most relevant and worthy of funding. Only about 40% of requested funds are awarded.

Additionally, IR-4 provides regulatory assistance to small businesses and public institutions for biopesticide registrations within the EPA regulatory process. Here, IR-4 will work with stakeholders and the EPA to determine the particulars of what is needed for registration and how to best achieve registration.

The new initiative in the Biopesticide area is to provide support to growers of certified organic crops by facilitating the listing of biopesticides and other pest management technology as an approved product for use by the National Organic Program's National List of Substances Approved for Organic Production. Here, the anticipated need is additional efficacy data to support getting registered biopesticide products approved for use for pest management in certified organic farms. Additionally, IR-4 expertise can help pesticide manufacturers evaluate existing products or advise on the reformulation of existing products to meet the criteria established by the NOP organic rule. Here IR-4 will act as a prescriber/advisor to companies before they submit their materials to an accredited certifier for review and inclusion on their approved materials lists.

Approximately \$650,000 of USDA CSREES/NIFA funds are currently invested in the IR-4 Biopesticide and Organic Support Program. Additionally, EPA provides an additional \$100,000 for Biopesticide Demonstration research through its Biopesticide and Pollution Prevention Division's Pesticide Environmental Stewardship Program. The IR-4 Project requests that funding for the Biopesticide and Organic Support Program funding will be increased by \$350,000 over FY 2008 levels to \$1.0 million. It is anticipated that \$250,000 would be directed into new projects to directly assist growers of organic crops and \$100,000 to expand IR-4's role in biopesticide registrations for specialty crops and minor uses on major crops. This would allow IR-4 to fund at least five additional proposals and have adequate personnel to provide regulatory support for the publically developed biopesticides.

Cooperative Project

Registration Support for Pesticides Managing Medically Important Arthropods

Purpose: To facilitate the registration of pest management products that control arthropod pests responsible for transmitting vector borne diseases and threatening human health.

To facilitate the registration of pest management products that control arthropod pests that transmit vector borne diseases that threaten human health.

Background and Description: In 2008, IR-4 Project Headquarters entered into a cooperative agreement with USDA-ARS and the US Department of Defense to provide regulatory support for new pesticides and other technologies in the control of arthropod pests that transmit diseases to humans, concentrating on pests relevant to US military troops deployed in environments where vector borne diseases threaten human health. The scope of this initiative was limited, concentrating on pests and pest management technology that was relevant to USDA and Department of Defense priorities. In this cooperative agreement, IR-4 Project Headquarters provides basic regulatory support.

USDA-ARS/ Department of Defense currently fund this cooperative program at \$260,000 annually. The need for additional resources to complete the cooperative agreement is not necessary at this time. If additional resources were needed it would be the responsibility of the stakeholders of this cooperative agreement to obtain the funding from sources such as US Department of Health and Human Services and the Bill and Melinda Gates Foundation.

Though this cooperative project is somewhat out of the scope of IR-4 traditional mission, the management of arthropod of medical importance is a priority objective of US government as well as numerous non-

government organizations. The need of an organization, like IR-4, to provide regulatory support for the minor uses of pesticides for public health uses was articulated in Minor Use Title of the 1996 Food Quality Protection Act.

The IR-4 Project's expertise in data development in support of pesticide registrations on minor uses was requested to provide those involved in public health pest management with the newest generation of lower/reduced risk pesticides that are less hostile to humans and the environment while being effectively controlling pests that transmit human health diseases. This offers significant benefits to humans and the environment. IR-4 can assist in this effort by working with registrants of pesticides, biopesticides and other pest management technologies and engaging them in opportunities to cooperatively develop their products for the public health arena. IR-4 would also assist in efforts to integrate the concept of harmonization, joint reviews and data sharing into the public health pesticide registration. Finally, if and when appropriate, IR-4 would directly assist in the development of data for registration. For example, in certain cases Magnitude of the Residue Data is needed to support the registration of pesticides that control mosquitoes near food crop growing sites and allow for its use.

IR-4 will also benefit from this cooperative project by gaining access to new chemical and biological control technology that is being developed by USDA-ARS for public health uses. This new technology could have applicability in specialty crop pest management. For example, USDA-ARS has patented sprayable RNA interference technology for public health uses that could be modified for agriculture uses.

Current Funding (FY 2008)

Proposed Funding for FY 2009 to 2014

| | <u>CSREES</u> | <u>ARS</u> | <u>OTHER¹</u> | <u>Total</u> | | <u>CSREES</u> | <u>ARS</u> | <u>OTHER</u> | <u>Total</u> |
|---|---------------------|--------------------|--------------------------|---------------------|--|---------------------|--------------------|--------------------|---------------------|
| Food | | | | | | | | | |
| Comparative Product Performance (Step 1) | | | | | | \$900,000 | | | \$900,000 |
| Research/Regulatory Support (Step 2) | \$9,400,000 | \$3,300,000 | | \$12,700,000 | | \$10,400,000 | \$3,800,000 | | \$14,200,000 |
| Remove Pesticides as a Trade Barrier (Step 3) | | | \$250,000 | \$250,000 | | | | \$1,500,000 | \$1,500,000 |
| SUBTOTAL | \$9,400,000 | \$3,330,000 | \$250,000 | \$12,950,000 | | \$11,300,000 | \$3,800,000 | \$1,500,000 | \$16,600,000 |
| Ornamental | | | | | | | | | |
| Research/Regulatory Support | \$500,000 | \$500,000 | | \$1,000,000 | | \$950,000 | \$750,000 | | \$1,700,000 |
| Invasive Species | | | | | | \$500,000 | | | \$500,000 |
| SUBTOTAL | \$500,000 | \$500,000 | | \$1,000,000 | | \$1,450,000 | \$750,000 | | \$2,200,000 |
| Biopesticide | | | | | | | | | |
| Biopesticide Grants/Regulatory Support | \$650,000 | | \$100,000 | \$750,000 | | \$750,000 | | \$100,000 | \$850,000 |
| Organic Support | | | | | | \$250,000 | | | \$250,000 |
| SUBTOTAL | \$650,000 | | | \$750,000 | | \$1,000,000 | | | \$1,100,000 |
| Cooperative Program - Public Health | | | | | | | | | |
| Regulatory Support | | | \$260,000 | \$260,000 | | | | \$260,000 | \$260,000 |
| NET FUNDING | \$10,550,000 | \$3,800,000 | \$610,000 | \$14,960,000 | | \$13,750,000 | \$4,550,000 | \$1,860,000 | \$20,060,000 |
| USDA Holdback | \$750,000 | | | \$750,000 | | \$900,000 | | | \$900,000 |
| Total | \$11,300,000 | \$3,800,000 | \$610,000 | \$15,710,000 | | \$14,650,000 | \$4,550,000 | \$1,860,000 | \$21,060,000 |

¹ Funds provided from USDA-Foreign Agriculture Service for "Remove Pesticides as a Trade Barrier", \$100,000 for Biopesticide Grants from EPA Biopesticide and Pollution Prevention Division and \$260,000 from USDA-Agriculture Research Service for Regulatory Support in the Cooperative Program-Public Health.

Accomplishments of the 2006–2008 Strategic Plan

The IR-4 Project continues to provide outstanding service and deliverables to US stakeholders. From 2006 to 2008, IR has met or exceeded the objectives of its core programs and new initiatives as specified in the 2006–2008 Strategic Plan as well as proactively recognizing and supporting additional programs that meet certain situational needs of growers and other stakeholders.

During the 2006–2008 Strategic Plan, the IR-4 Project directed the majority of its resources toward the three core programs that comprise the heart of its mission—the Food Program, Biopesticide Program, and Ornamental Horticulture Program. As detailed below, the IR-4 Project exceeded its stated performance goals in all three of these core programs.

In addition to the core programs, the IR-4 Project added two new initiatives to its objectives for the 2006–2008 time period—the Global Specialty Crop and Aquatic Herbicide Registration initiatives. The results of the Global Specialty Crop Initiative significantly exceeded expectations, with the IR-4 Project leading and driving numerous collaborative activities with international partners aimed at minimizing trade and export barriers for US food crop producers. The Aquatic Herbicide Registration Initiative was hampered by lack of funding from government sources and participation on the part of IR-4’s research partners. This initiative only achieved modest results.

The IR-4 Project also provided expertise and support for time-critical efforts to control outbreaks of invasive pests that posed serious threats to the nation’s food supply, economy and environment.

Specific accomplishments for the five stated objectives of the 2006–2008 Strategic Plan are described below.

Core Programs

Objective 1—Food Program

Purpose: To obtain and maintain regulatory clearances of effective crop protection agents for high-value specialty food crops and for minor uses on major food crops, with special emphasis on lower-risk chemicals and uses that are compatible with Integrated Pest Management (IPM) programs.

Performance Measure: To obtain at least 500 potential registrations each year, with at least 75% of the registrations focusing on lower-risk technologies and uses suited for IPM systems.

Results: During the 2006–2008 Strategic Plan, the IR-4 Project developed data and provided oversight that supported the potential registration of 2425 new uses of crop protection products for food crops, exceeding the objective of 1,500 registrations by 60%. Many of these new registrations are potential replacements for older technology or can be used to manage pesticide resistance. This allows sustainability of pest management options for specialty crop growers.

Providing 2425 new registrations is a significant accomplishment. Equally impressive are the findings of a study conducted by the Center of Economic Analysis at Michigan State University in 2007, which concluded “the efforts and success of the IR-4 Food Program objective contributes \$7.7 billion annually to the US gross domestic product”.

Under the umbrella of the Food Program, IR-4 is leading an effort to validate and if appropriate, expand and enhance the groupings of crops for pesticide tolerance and registration purposes. In December 2007,

US EPA published the first installment of the updated crop groups as a Final Rule in the Federal Register. The updated groupings expanded the Berries and Small Fruit group from 8 to 45 commodities and the Bulb Vegetable group from 7 to 26 commodities. In addition, EPA's Final Rule established a new Edible Fungi group containing 20 commodities. IR-4's involvement in these activities resulted in a significant number of additional registrations for crops that belong to the expanded or new groups. It is anticipated that these modifications to the domestic crop groups will eventually be used as a base to establish a harmonized global crop grouping.

Also under the umbrella of the IR-4 Project's Food Program objective, IR-4 began a Seed Technology Initiative that is assisting in the registration of products as seed treatments. Seed technology has recently emerged as an excellent mechanism to deliver crop protection chemicals where they can be most effective and provide the greatest benefit while reducing the chemical load on the environment. This sustainable practice is viewed as a preferred way to use pesticides. Working cooperatively with industry, this initiative achieved success. Based on IR-4 data, registrations of several insecticides, such as spinosad, imidacloprid, and thiomethoxam were expanded to include seed treatment uses patterns.

Objective 2 —Ornamental Horticulture Program

Purpose: To support research on crop protection products that will expand their uses on ornamental crops (nursery, floral, turf, and other non-food crop systems) to allow management of new and important pest species.

Performance Measure: To obtain at least 450 new clearances for expanded use of crop protection products on ornamental crops.

Results: Since 2006, efficacy and crop safety data developed by the IR-4 Ornamental Horticulture Program data have contributed to 35 registrations. Recognizing that registrations should not be the only measurement of success, IR-4 has attempted to better capture this objective's outcomes and outputs by assessing the number of ornamental crops impacted by the IR-4 Ornamental Horticulture Program data. IR-4 supported registrations impacted 1775, 3057, and 3095 ornamental crops in 2006, 2007 and 2008, respectively. This important distinction between registrations and crops impacted is significant because adding a new pest to a registration can be much more important than adding a new species to a registration. However, both are considered registrations.

In order to better capture the value of IR-4 efforts to the ornamental horticulture industry, IR-4 commissioned Michigan State University's Center for Economic Analysis to conduct an economic assessment of IR-4 on ornamental agriculture. Their study concluded "the IR-4 Ornamental Horticulture Program and its annual research investment of \$1.2 million contribute \$1.176 billion annually to the US gross domestic product", a return on investment of over 900 times.

Objective 3—Biopesticide Program

Purpose: To support research to enhance the development and registration of biopesticides for use in food and non-food pest management programs.

Performance Measure: To fund at least 40 research projects annually to evaluate and demonstrate the use of biopesticides in IPM programs and to facilitate registration of at least 60 new uses.

Results: During the 2006–2008 timeframe, the IR-4 Project funded a total 119 grants on biopesticide research projects, compared to the program objective of 120 projects. In addition, IR-4 study data were critical in obtaining EPA registration of two new biopesticide products for use by growers. One product

was approved for management of aflatoxin on cotton, corn, and pistachio. The other product provided transgenic resistance to plum pox virus in Honeysweet plum. In total, IR-4 facilitated 322 new biopesticide uses compared to an objective of 60 clearances.

In another important initiative that is still continuing, IR-4 provided regulatory assistance in the development of a biological product to combat Israeli acute paralysis virus in honeybees. This virus has been linked to honeybee colony collapse disorder, a serious threat to crops that rely on bees for pollination.

Finally, in an effort to assist growers of organic specialty crops, IR-4 started efforts to add new products to the National Organic Program's National List of substances approved for organic production. Through data developed by IR-4, Dow AgroSciences was able to register and gain organic listing of the ENTRUST formulation of Spinosad. This new listing gives organic growers a very effective insect management tool that is also a cornerstone of conventional specialty crop production. In addition, IR-4 developed an on-line searchable database that provides organic and conventional growers a list of registered biopesticides options for their crops.

Additional Initiatives

The IR-4 Project's 2006–2008 Strategic Plan contained two additional objectives; the Global Specialty Crop Initiative and the Aquatic Herbicide Initiative.

Objective 4—Global Specialty Crop Initiative

Purpose: To support international competitiveness of US specialty crop producers by using IR-4 data and resources to harmonize US pesticide tolerances and international Maximum Residue Levels (MRLs) to eliminate pesticides as regulatory barriers to international trade.

Performance Measure: To submit to international regulatory bodies at least 60 data packages to establish harmonized MRLs.

Results: The IR-4 Project took the lead in reaching out to international partners and working through the challenging issues associated with this initiative. IR-4 employed a dual approach to harmonization of US pesticide tolerances with international MRLs. Using existing US data, IR-4 Headquarters staff gathered and reformatted existing data packages, supplemented them with additional data and other information, and submitted them to CODEX, the European Union, Japan and other international regulatory entities to support establishment of harmonized MRL's. At the same time, IR-4 led initiatives to cooperate with other countries or entities on registering new uses. IR-4 conducted over 100 joint field trials with the Minor Use Centre of Agriculture and Agri-Food Canada. Joint projects were also coordinated and conducted with grower associations in the United Kingdom and Australia. IR-4 also provided leadership by planning and conducting the Global Minor Use Summit in December 2007 at the UN Food and Agriculture Organization headquarters in Rome, Italy. At this Summit, 325 participants from developing and developed countries discussed mechanisms to work together to collectively address the minor use issue on a global basis. Action item priorities were established.

An important enabling activity within the Global Specialty Crop initiative was that of globally harmonizing food crop groupings. Again, IR-4 leveraged the work already done with the EPA as a springboard for promulgating globally harmonized crop groupings. As with EPA-approved crop groupings, globally harmonized crop groupings enable the establishment of residue tolerances for a group of crops based on residue data from representative crops from that group or subgroup, reducing or eliminating the need to

establish tolerances for each crop individually. This allows for more regulatory clearances and therefore more tools for growers (and more export opportunities) in a shorter amount of time.

Objective 5—Aquatic Herbicide Registration Initiative

Purpose: To facilitate and develop the appropriate data to establish registrations by the EPA for new herbicides for use in aquatic environments.

Performance Measure: To facilitate and develop data to establish registrations by the EPA for at least six herbicides for use in aquatic environments.

Results: Public sector funding required to start this initiative was not available; thus activities have been limited. IR-4 did work with one corporate partner to develop supporting Magnitude of the Residue data to remove a restriction on an existing aquatic herbicide and allow the herbicide to be used in irrigation water.

Invasive Pest Initiative

On several occasions, IR-4 played a key role in a coordinated effort among growers, regulators, and the scientific community in the US to control and minimize damage from outbreaks of invasive pest species. Invasive pests, some of which already are or can easily become resistant to conventional pesticides; pose a serious threat to the production of food and non-food crops and the environment. In the 2006–2008 timeframe, IR-4 provided funding and research in support of time-critical projects to control outbreaks of two such invasive pests, chili thrips and the B- and Q-biotypes of whitefly, which posed major threats to numerous food, fiber, and ornamental crops.

It should be noted that this Invasive Pest Initiative was not a part of the 2006 to 2008 Strategic Plan, it was added because of the critical need to help the growers of specialty crops find safe and effective pest management tools. IR-4 is committed to accomplishing core objectives and will remain flexible to respond quickly to unforeseen stakeholder needs.

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