

**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**



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



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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.