Executive Summary

TO: Project Management Committee/Administrative Advisors/ Meeting Attendees
FROM: Sherrilynn Novack & Van Starner
DATE: September 9, 2010
SUBJECT: Summer 2010 Project Management Committee (PMC) Meeting Minutes

Please find attached the Summer 2010 PMC meeting Executive Summary and minutes from discussions July 20-21 at Wingate Hotel in Bozeman, MT.

If you have any questions about this report, please feel free to contact the appropriate PMC or Headquarters Staff member listed by the agenda item, or us, for clarification.
July 2010 PMC Meeting - Executive Summary

The IR-4 Project Management Committee (PMC) held its summer 2010 meeting on July 20-21, 2010, at the Wingate Hotel in Bozeman, MT. A tour of Montana State University was held in the afternoon of July 21.

General Items

- Monte Johnson reported the proposed dates for the 2011 RFA to be published are 11/1/10 with a proposal deadline of 12/15/10. It is highly likely that 2011 funding will remain at current level.

- An Ad-hoc Timeline Evaluation Committee will be established to look at some pressing issues such as shortened timelines
  - **ACTION:** J. Baron/M. Marshall to notify chemists and study directors and IR-4 community as a whole about the closure of the Beltsville lab and to hold 2010 samples in the field and to address IR-4 timelines.

- The ACAC committee will lose its chair due to the closure of the Beltsville lab and her relocation. With the closing of the Beltsville and New York laboratories, the labs will need to continue developing a national focus.
  - **MOTION:** In the interim of the Chair of the Analytical Chemistry Advisory Committee (ACAC) stepping down Debbie Carpenter will convene the ACAC so that they can continue their work and the committee can act to elect a new chair. Approved
  - **MOTION:** Reiterate the original ACAC Charter (3/25/10) with specific expectation to point #3 to meet monthly for collaboration and coordination of achieving timely ASR completions. Approved

2011 Field Program -

- **MOTION:** to plan for 400 NIFA trials, and target 50 “A” priorities at the FUW, (plus an additional 20 studies via upgrades). Approved
- **MOTION:** Also approved to support an expanded efficacy/crop safety research program with $250,000.

ARS/Regions/HQ Updates

  - **ACTION:** S. Schneider will see if it is possible to extend this date (closure of Beltsville lab).
  - **ACTION:** Follow-up PMC conf. call is needed to determine all the implications.

- Northeast Region – lab personnel are doing a tremendous job finishing trials under the lab closure circumstances. Edith Lurvey, Barbara Andersen, and Jane DeCann moved into the Barton Laboratory in April - phone, email, address will stay the same.

- North Central Region – hired new Lab Coordinator, Sue Erhardt and a new QA auditor, Brian Bowman.

- Southern Region – Jau Yoh has retired and will be hired as a temp through HQ for a few months. There are 7 candidates for Jau’s position, which is hoped to be filled by NRPM.

- Western Region – Mika Tolson has joined the WSR as an Assistant Research Field Coordinator. She will work on more of the Ornamental and Biopesticide trials and tracking data. Also, Jackie Hale became the full-time Administrative Assistant.

- HQ – J. Baron reported on new hires, office space negotiations, a Biopesticide registration success (plum pox resistant honey sweet plum), and encouraging visits with NIFA and EPA. Also reported on the improvements made in Tifton to the freezer system.
J. Baron presented a white paper titled: “Maintaining IR-4’s Relevance in Food Crop Registrations: A Seven-Step Approach” which will help IR-4 address critical timelines issues.

Other items

• A new logo design has been selected and is being distributed. It is available for download on the website.

• When the NER lab closes, D. Soderlund will be the PMC rep on the AACAC. Until then Dave and Marion will overlap their participation.
July 2010 PMC Meeting Minutes

The IR-4 Project Management Committee (PMC) held its Summer 2010 meeting on July 20-21, at The Wingate Hotel, Bozeman, MT.

**PMC Attendees:**
- Jerry Baron - Executive Director
- Tammy W. Barkalow - Assistant Director, Quality Assurance
- Michael Braverman – Biopesticide and Organic Support Program Manager
- Doug Buhler - North Central Region Administrative Advisor
- Debbie Carpenter - Assistant Director, Registrations
- Mary Duryea – Southern Region Administrative Advisor
- Bob Hollingworth - North Central Region Director
- Monte Johnson - NIFA National Program Leader
- Dan Kunkel - Associate Director, Food & International Programs
- Rocky Lundy - Commodity Liaison Committee Chair (via teleconference)
- Marty Marshall - Southern Region Director and PMC Chair
- Karl Malamud-Roam - Public Health Pesticides Program Manager (via teleconference)
- Marion Miller - Western Region Director
- Sherrilynn Novack – Public Relations & Communications Manager
- Cristi Palmer – Ornamental Horticulture Program Manager
- Sally Schneider – ARS Administrative Advisor (via teleconference)
- Paul Schwartz - ARS Regional Director- (via teleconference)
- Dave Soderlund - Northeast Region Director
- Van Starner - Assistant Director, Research Planning & Outreach
Tuesday, July 20, 2010 & Wednesday, July 21, 2010

Approval of Minutes/new agenda items: Minutes of Spring PMC meeting held March 3-4, 2010 at The Quincy Hotel in Washington, DC, was approved.

Brief updates:

Administrative Advisors – D. Buhler commented IR-4 needs to have some serious conversations on the possibility of host institutions requiring subsidy or indirect costs.

NIFA – M. Johnson stated the RFA is proposed to be released Nov. 1, proposals due Dec 15. The President’s proposed budget keeps IR-4 funding at $12.18 million. RFAs will go through if there is a continuing resolution. The new NIFA director, Roger Beachy, is making the rounds within NIFA to meet with the subunits. See attached report. Tawana Deshazo from The NIFA’s Awards Management Branch came to Rutgers to complete an audit.

ARS - P. Schwartz report is in PMC materials. ARS is providing $88K for repeat field trials for which samples were lost in the Tifton freezer failure. $100K is being provided to HQ for contract analyses of diflubenzuron samples which can’t be completed at the Beltsville lab.

ARS - S. Schneider commented on the ARS peer review of the Minor Use Pesticide Program, held March 17-18, 2010. The review team was chaired by Larry Chandler who had previously chaired the NIFA review team for IR-4 (other reviewers were Paul Francis (industry), Dan Kunkel (IR-4), Ray Ratto (Ratto Bros, CA), Dan Rosenblatt (EPA), Cheng-I Wei (Univ. of MD), another??)

Recommendations of the review team:
1) Paul Schwartz should have input on performance of all ARS employees doing IR-4 research
2) There needs to be a succession plan for Paul
3) At least one of 3 labs will be closed. (Note-ARS Management will close the IR-4 laboratory unit at Beltsville on Oct. 1, 2010. This lab was chosen because the costs to conduct research in Beltsville are the highest, and there are other ARS jobs that affected employees could easily move into. There are 600 sample sets that will need to be analyzed at other labs; ARS committed to providing funds to support the analysis of these samples. ACTION: Sally Schneider will see if it is possible to extend this date. Her concern is that the personnel who will all be offered other jobs within Beltsville will lose the opportunities if the closing is delayed; ACTION: Follow-up conf. call with PMC is needed to decipher the implications.
4) Need to update old equipment (maybe through leasing); suggestion for upgrading some personnel ($s from Beltsville closure to pay for these upgrades)
5) Close out Maricopa, AZ filed site via 1-year transition by Oct. 1, 2011 (there is a commitment to B. Miller whether or not trials are completed)
ACTION: Each Maricopa, AZ field trial should be reviewed to see if it is actually needed in order to proceed; D. Carpenter suggested a tiered approach to using data from this site.
6) Continue expansion of Ornamental program in invasives, efficacy and biopesticides

Dr. Sally Schneider will provide the final report when it is appropriate.

HQ – J. Baron reported on two new temporary employees at HQ: Kathleen Hester will work with Cristi, and Jau Yoh has been hired as a temporary employee to assist the Florida lab.

University funding scenarios are looking worse, and it will be smart to take a proactive approach and do more within host Universities.
Negotiations for increased HQ office space is ongoing (Rutgers has approved) to extend lease to 2019 and add an additional 2,000 square feet.

NJ recently approved the use of medical marijuana and the Governor was counting on Rutgers to grow it and allow a number of teaching hospitals to sell it. There was some discussion as to how this would impact IR-4, and possibly Cream Ridge. - (Update: on Friday, July 23, 2010, Rutgers declined to grow and research medical marijuana because the university does not want to risk more than $500 million in federal funding because of marijuana’s illegal status at the Federal level.) IR-4 has started receiving some request from other states, however, since IR-4 is federally funded, it is unlikely IR-4 will accept project requests.

The Biopesticide and Organic Support Program has had its first biotech registration of honey sweet plum, a transgenic stone fruit resistant to the plum pox virus. IR-4 provided regulatory advice, prepared the regulatory package and made the submission to EPA’s Biopesticide Division (BPPD). It was also mentioned that the call for proposals for the 2011 Biopesticide and Organic Support Program would be released soon. The program focuses on development of efficacy data so a specific question about a situation in Florida was discussed in regard to the scope of the program. An independent lab validation will be needed for a Papaya Ringspot Virus Resistant Papaya. Although this project does not involve efficacy, if the project would help in completing the registration package then the PMC would approve this type of project.

K. Malamud-Roam will be working two weeks a month in California (UC Davis) and two weeks in New Jersey at HQ for one year. July 2011, his base will be New Jersey (outside regular work travel).

Steve Bradbury is new EPA OPP director. D. Kunkel and J. Baron met with him in June. Barbara Madden has been charged to put together the Public Interest definition for IR-4, which is very good for IR-4.

M. Johnson and J. Baron visited with Ralph Otto and briefed him on IR-4 new initiatives.

FAS has new leadership which is very much in line with trade issues that IR-4 is working on - will plan meeting with new leadership.

APHIS gave the Ornamental Program a grant on studying gladiolus rust. IR-4 and APHIS are planning to discuss the possibility of M. Braverman to work with APHIS as a mini-sabbatical to learn more about APHIS biotechnology permits and deregulation packages and reviews.

D. Carpenter, T. Barkalow, J. Baron visited the Tifton ARS lab and field site and were encouraged with the improvements they have made since the freezer breakdown. Also encouraging was the positive energy of the laboratory staff and support of local management, B. Scully. The freezer is doing well - routine testing and monitoring is vital in maintaining these systems.

Regarding 2010 registrant visits by the HQ team, a lot of new AIs are coming to market (especially fungicides and insecticides). In order for companies to work with IR-4, they are strongly encouraging IR-4 to work within their timelines, as well as streamline these timelines to remain relevant for specialty crop growers.

**North Central Region** – B. Hollingworth reported the new lab director, Sue Erhardt, has hit the ground running and is doing very well. North Central Region field trials are going well. They’ve had a nice growing season in MI due to dry conditions. Ohio and Indiana however were late due to a wet spring. They have an interesting aerial trial on wild rice this year on the Canadian border. They have hired a second experienced QA, Brian Bowman. They held a lab GLP training session and hosted USDA-sponsored Malaysian trainees who visited their lab. The only unknown currently is the housing situation for the regional lab and offices - the good news is they are still in the same lab and facilities and have not heard of needing to move elsewhere as of yet.
Northeast Region – D. Soderlund reported the northeast field program is smaller this year but sustainable. They have had a pretty nice growing season this year. They are looking at reding some of the lost Tifton trials - they have the capacity. They also have 4 remaining lab studies and 3 analysts are hired back until the end of September (two have moved on). QA is up to date and B. Anderson is doing a lot of field audits. NY announced an early retirement plan which may impact J. McCann; if she takes an early retirement package, they may bring her back on contract to finish the global tomato study. Edie, Barbara, and Sarah have moved their offices into Barton Lab. Dave has been appointed the interim Associate Chair of the Department of Entomology – Geneva and Ithaca departments have merged.

Southern Region – M. Marshall reported Jau Yoh has retired and rehired temporarily through HQ until a replacement can come on board hopefully by NRPM. The SOR has had fewer field studies this year. There seem to be more fruit trials than crop trials. Some SOR field books have been coming back with a lot of findings. Additional training is needed, and will be provided to assist personnel in filling out the field data books with all needed information. Currently, the administrative staff are performing QA and QC duties part-time. The person doing part time analytical QA recently left. Marty is monitoring the situation to determine whether additional QA resources are needed. SOR is looking to fill another chemist position, but not until a new LRD is hired. Several good candidates have applied for the LRD position – they expect to interview the top four applicants before Sept. The SOR has purchased its 3rd LC/MS/MS and it is interchangeable with Thermogenesis. The purchase deal came with an agreement for service for the older LC/MS/MS which should give it an extra 3-4 years.

Western Region – The field program is in good shape with 211 trials, including a repeat of the etofenprox aerial trial which was successful. Mika is taking on more responsibility for ornamental and biopesticide programs in the region. Jackie Hale is now full-time IR-4, but Lisa Stevenson moved on to another dept. at Davis. The Western Region completed a successful training event in Parlier. CA and SLR meeting in Yuma, AZ (with several CLC members attending). Gowan visited campus, requested a meeting with IR-4, and Marion briefed them about the program. Lab backlog is in better shape, and the HI lab is re-invigorated. QA is hiring someone additional soon.

Dr. Barry Jacobson gave an overview of the work on Biopesticides from the grass roots perspective. One area where IR-4 is very helpful is in providing guidance and counsel before the first meeting a researcher has with EPA.

CLC - No report

Lab Update - D. Carpenter
Overall, there continues to be a backlog. Some priority projects are not clearly understood as being priority. While many of the regional labs have decreased their backlogs, there are still quite a few in a backlogged ranking. The PMC expects the Lab directors to communicate on a monthly basis to update the spreadsheet of priority projects. There needs to be a focus on keeping the ACAC going while the chair is being relocated out of the IR-4 Project (E. Pfeil from the Beltsville lab).

There needs to be a process or formal declaration when a project is over or “dead in the water”. The discussion surrounded oxyfluorfen. This chemical will not proceed to registration (at this time) yet the lab director was continuing to work on this when other priorities could have been addressed. While HQ had been given a “heads up” that there were registration concerns, a study is not formally cancelled if there is any chance that it might be used for registration in the future. This exposes a problem as to who makes the decision to drop one analysis in favor of another. It was decided that the Regional Directors and P. Schwartz need to be notified on a regular basis as to the priorities of their labs and the possible need to “bump” one study in favor of a more urgent one.
D. Soderlund commented on how surprised he was at the level of non-awareness the committee members were of the national issues of IR-4 and that this culture must change. Having PMC members on the ACAC emphasizes it is a national program and the regional directors need to make it clear to their lab directors that this is a national program, not a regional one. Progress is being made, and must continue, with PMC oversight and intervention.

**MOTION:** In the interim of the chair of the ACAC stepping down, Debbie Carpenter will act to convene the ACAC so that they can continue their work and the committee can act to elect a new chair: Approved.

**ACTION:** J. Baron and M. Marshall should notify chemists and study directors and the IR-4 community as a whole about the closure of the Beltsville lab and to hold 2010 samples in the field until decisions can be made regarding which labs will be taking on analyses.

**MOTION:** Reiterate the original ACAC charter (3/25/10) with specific expectation to point #3 to meet monthly for collaboration and coordination of achieving timely ASR completions: Approved

Hard to analyze chemicals - last year IR-4 spent >$180K designated for sending analyses of “difficult to analyze chemicals” to contract labs. Every year, there are projects which are difficult to analyze. In the mean time, two studies (diflubenzuron in alfalfa and peanuts) have recent additions to this list. Good news is that Canada is opening up a lab (could provide some help), and the EPA lab at Fort Meade, MD, has offered to do analysis. This could be a real plus, but IR-4 needs to consider GLP implications as this lab is not currently GLP, has freezer storage limits, etc.

The PMC agreed to contract out difenoconazole on apple/pear PH and diflubenzuron in alfalfa and peanuts.

**EPA Registrations, Work Plans, FDB/ASR Completion Status, Timeline Status, EPA Update – in meeting materials (D. Kunkel)**
- 11 chemistries were reviewed to-date, resulting in 506 new uses

**International Activities**
International Program - Dan submitted an article in the *Summer 2010 IR-4 Newsletter* that gives an update on the International activities. Plans are being made to hopefully have the next GMUS in 2011, but still trying to identify a venue.

Several IR-4 people attended the IUPAC Pesticide Congress in Australia in early July. The quality and quantity of papers at this year’s meeting were very high caliber. The IUPAC accepted the OECD MRL calculator.. IUPAC will come to San Francisco in 4 years.

Hops in the EU (according to EFSA) is considered a major crop and is now requiring 8 trials whereas CODEX requirement is only 4. This will need to be resolved.

**QAU- T. Barkalow** presented an Audit update and an overview of QA Goals, which included 4 key points for 2010: 1) connecting with more people; 2) operating as a “whole” to meet timelines; 3) looking into GANT charting; and 4) working cooperatively with RFCs by taking them to test sites

**Biopesticide and Organic Support – M. Braverman** talked about the Impact of Research and Registrations within the Biopesticide and Organic Support Program. Also, a presentation on The Process of Project acceptance into the IR-4 Biopesticide Regulatory Assistance Program was given. The only difference from current procedures is getting PMC acceptance of registration target projects.
Ornamental Horticulture Program – C. Palmer discussed new hires (Kathleen Hester’s role in the Orn Hort Program and complimenting the WSR on Mika Pringle Tolson), current research program, future research including the 2010/2011 Grower & Extension Survey and the PGR meeting at the OFA Short Course in July, the Website & Facebook communication tools, and an update on the SOAR award.

Communication Update - S. Novack discussed the new logo and its distribution. She also talked about the very well attended IR-4/USDA/EPA tour of the DelMarVa peninsula.

FUW, E/CS & NRPM Review/2011 Research Plan – D. Kunkel and V. Starner presented plans for 2010 Food Use Workshop (FUW) nomination plans/deadlines, FUW Agenda, proposed efficacy and crop safety research plan and draft NRPM itinerary. It was agreed to fund the value program at a minimum of $250,000 for 2011 and other funds may become available depending on budgets in the regional offices.

Public Health – K. Malamud-Roam gave an update on the Public Health Pesticide Program that included the timeline and budget, program goals, primary objectives and activities, the product portfolio, the regulatory process, and outreach and product identification.

IR-4 Timelines Reduction discussion: J. Baron presented the PMC with a White Paper which presents a Seven-step approach for addressing critical IR-4 timeline issues.

The steps include (briefly stated below; see paper for complete recommendations):

1. **Reduce the annual commitments for IR-4 in data development/new studies** – Currently, IR-4 conducts approximately 100 studies annually, supported by approximately 650 field trials funded with resources from NIFA, ARS and the Pest Management Centre in Canada. Without a major infusion of additional resources, it is recommended that IR-4 reduce the new annual study/field trial commitments.

2. **Internal Priority Setting** – IR-4’s stakeholders do an excellent job identifying the most important research priorities (Priority A projects). It is recommended that IR-4 develop a system/process to identify which of the research projects are the highest priorities, which are second tier and so on. This information would be clearly communicated to all IR-4 personnel involved in the study. Everyone within IR-4 would focus on getting the highest priority packages done first, then the next set, etcetera.

3. **Take advantage of opportunities to start field trials in the fall season** –
   a. IR-4 HQ will anticipate potential “A” priorities and have draft study protocols for early crops prior to the Food Use Workshop. Additionally we will give the cooperating companies early warning on the need for test substance needed for these early crop trials.
   b. IR-4 consider moving up the Food Use Workshop to early September
   c. From the “A” priorities selected at the Workshop, the Regional Field Coordinators would work with the Registration Manager/SDs to identify and expedite start of these trials with early crops as soon as practicable and possible.

4. **Better management of sample shipment** – It is recommended that the Regional Field Coordinators and/or Study Directors take a more active role in scheduling shipment of residue samples from field site to analytical laboratory.

5. ** Expedite residue sample analysis/reporting at the laboratories** – It is recommended that all laboratories target the completion of sample analysis/reporting within 6 to 8 months of receipt of the last sample set.

6. **Quality Assurance Review** – Look into technologies to eliminate multiple redundant reviews while maintaining excellent GLP compliance.

7. **Report Writing** – Study Directors would be expected to be working on final reports prior to the receipt of all of the data.
Some concerns were voiced regarding a reduction in field trials that would accompany a reduction in timelines. With increases in NIFA funding the past 3 years, such a scenario would not send a good message to stakeholders (unless we receive a budget cut, which doesn’t seem likely). One thought was “could we limit the number of AIs we work on each year.” Another thought was reducing the number of “A” priorities at the workshop, to allow more flexibility to add projects afterward. If host institutions start requiring indirect costs from IR-4, this will affect the IR-4 budget, and the result may be that fewer trials can be done. Following discussion, the idea was approved of convening a small group from throughout IR-4, tapping all areas of the program, with the mandate for identification on various “pinch-points” in our processes where timeline reductions could be made. Then these pinch points would be addressed and IR-4 would develop new process that would create more efficiencies and reduce timelines. **Action:** J. Baron to formulate a plan, seek PMC review/approval, and put the plan into action, with a goal of having some recommendations ready for PMC to examine at the Oct. 2010 meeting in FL.

### 2011 Food Use Field Program
Potential strategies/scenarios were discussed for the 2011 field research plan (see [2011 Food Use Field Program](#)). **Motion:** To maintain the $2.3M commitment to residue studies, but to make a small reduction in the NIFA trials supported (400 trials compared with the ~460 trials in 2010), and 50 “A” priority studies chosen by stakeholders at the NV Food Use Workshop, and ~20 additional studies chosen via regional upgrades and upgrade proposals. **APPROVED** (see below).

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<tr>
<th>Number of priorities</th>
<th>Projects</th>
<th>Trials</th>
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<tbody>
<tr>
<td>FUW “A”</td>
<td>50</td>
<td>350*</td>
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<tr>
<td>Upgrades (regional/proposals)</td>
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<td>150*</td>
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<tr>
<td>Carry over trials (“Red A’s”)</td>
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<td>50</td>
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<tr>
<td><strong>Total</strong></td>
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*based on an average 7 trials per study

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<td><strong>Total</strong></td>
<td><strong>550</strong></td>
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*Total $2,300,000

Discussion of funding for an expanded efficacy/crop safety (E/CS) research plan resulted in consensus and approval that $250,000 be used to support this program in 2011 (an increase of $125,000 from 2010). Expectations are that this amount of funding will likely not completely cover all the E/CS trials needed to support all the projects which have residue work done or ongoing, and which require E/CS data before registration (“committed-to projects”). Although at the FUW there will be discussion time within each discipline dedicated to prioritizing E/CS research, it is likely the 2011 research plan will not include work on any of the “H” (high need E/CS projects) priorities.
**Upcoming Meetings**

North Central Region SLR Meeting  
Aug 30–31, 2010  
Brookings, SD

2010 Food Use Workshop  
September 14–15, 2010  
Summerlin, NV

ARS/ IR-4 Liaison Meeting  
**October 13-14, 2010**  
Charleston, SC

PMC Meeting  
October 19-20, 2010  
Ft. Meyers, FL

NRPM  
October 26-27, 2010  
Princeton, NJ