



Executive Summary

TO: Project Management Committee/Administrative Advisors/ Meeting Attendees

FROM: Sherrilynn Novack & Van Starner

DATE: April 8, 2009

SUBJECT: Spring 2009 Project Management Committee (PMC) Meeting Minutes

Please find attached the February 2009 PMC meeting Executive Summary and minutes from discussions February 24-26 at the Drury Hotel, San Antonio, TX.

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.

February 2009 PMC Meeting - Executive Summary

The IR-4 Project Management Committee (PMC) held its Spring 2009 meeting on February 24-26 at the Drury Hotel in San Antonio, TX. The meeting was held in conjunction with the IR-4 National Education Conference and Commodity Liaison Committee meeting. The following items were discussed:

General Items

- Monte Johnson reported: \$700,000 funding increase; RFA to be published 3/25/09; deadline 4/27/09; money to arrive in 7/09
- EPA reviewed a record number of 41 chemistries in 2008, resulting in 999 new uses registered thru IR-4! KUDOS to EPA!

ARS/Regions/HQ Updates

- ARS has critical funding and laboratory productivity issues; the accountability report is unchanged from last year
- Northeast Region –finishing up studies; no productivity issues; when the lab closes, QA workload will be decreased, thus QA work in the NE should be redistributed
- Southern Region – received grant for citrus greening to support 10-15% of a person in the lab and 85% as a senior chemist; Michele Samuel-Foo is on board as the new RFC
- Western Region - saddened by the death of Debbie Efron; hired Paul Kuzmicky in lab who brings analytical and IT expertise; Kudos to Jim McFarland for EPA inspection in Colorado
- HQ – Annual Report and Year in Review completed and posted to website; travel is being restricted to conserve funds

Other items

- The 2009 Biopesticide proposals selected by the review committees were approved by PMC to be funded
- The Ornamental Horticulture Program will receive an additional \$50K to get back to the 2007 funding level
- The PMC met with Regional Lab Coordinators: they proposed formation of an Analytical Chemistry Advisory Committee, which the PMC approved; and they raised the laboratory workload issue
- The PMC met with the Quality Assurance group; they discussed routing issues, and were challenged brainstorm a revised routing procedure; QA was to come back to PMC after their meeting in FL with potential audit routing scenarios, and with proposals related to contract QA \$s spent vs hiring in-house
- New media page is up and running on the IR-4 website
- A motion was approved that all IR-4 standing committees appointed by PMC should institute a term limit policy for membership, that will be approved by the PMC
- Regional directors will bring base budget figures for sustaining their research center to the July PMC meeting

- CLC input to Strategic Plan (SP) includes adhering to the core IR-4 mission and supporting International Harmonization and efficacy needs; the SP should also communicate how budget cuts affect infrastructure
- PMC input to the SP includes having the plan span 5 years to be in line with NRSP-4 peer review; Public Health initiative should be called Regulatory Support for Vector borne disease; biotechnology should be decoupled from Biopesticides and Organic Support
- FUW/NRPM proposed improvements were accepted
- NRSP-4 Review May 19, 2009 - Jerry will send out agenda for comment



February 2009 PMC Meeting Minutes

The IR-4 Project Management Committee (PMC) held its Spring 2009 meeting on Feb 24-26, at the Drury Hotel in San Antonio, TX.

Attendees:

- Jerry Baron - IR-4 Executive Director
- Tammy W. Barkalow - IR-4 Assistant Director, Quality Assurance
- Michael Braverman (via phone) – Biopesticide and Organic Support Program Manager
- Doug Buhler - North Central Region Administrative Advisor
- Mary Duryea – Southern Region Administrative Advisor
- Bob Hollingworth - North Central Region Director
- Monte Johnson (via phone) - CSREES National Program Leader
- Dan Kunkel - IR-4 Associate Director, Registrations
- Rocky Lundy - Commodity Liaison Committee Chair
- Marty Marshall - Southern Region Director and PMC Chair
- Marion Miller - Western Region Director
- Sherrilynn Novack – IR-4 Public Relations & Communications Manager
- Cristi Palmer (part-time) – IR-4 Ornamental Horticulture Program Manager
- Michael Parrella – Western Region Administrative Advisor
- Nancy Ragsdale – Retired ARS Administrative Advisor
- Mark Robson– Northeast Region Administrative Advisor
- Paul Schwartz - ARS Regional Director
- Dave Soderlund - Northeast Region Director
- Van Starner - IR-4 Assistant Director, Research Planning

PMC met with Regional Laboratory Coordinators in the morning of Tues., Feb. 24, and with the Quality Assurance Unit the morning of Thur., Feb. 26

Regional Laboratory Coordinators:

Wlodzimierz (Wlodek) Borejsza-Wysocki	Emy Pfeil
Thomas Hendricks	Todd Wixson
Matt Hengel	Jau Yoh
Wayne Jiang	

Quality Assurance Unit:

Barbara Anderson	Jane Forder
Tammy L. Barkalow	Kathleen Knight
Martin Beran	Jim McFarland
Zhongxiao (Michael) Chen	
Jane Forder	

Tuesday, February 24 th

Regional Laboratory Coordinators (RLC)/PMC meeting:

1) M. Hengel, acting as spokesperson for the coordinators, requested that the PMC consider the formation of a Laboratory Chemist Peer Review Committee (LCPRC). The purpose of the committee is to help resolve contentious issues, like a study-specific analytical question; if resolution is not reached, even with the two HQ “gatekeepers”, this committee would review the situation and provide professional guidance. An outcome of such an issue could be communicated in the form of an IR-4 Advisory. The idea is to bring in this committee sooner than later, before an issue gets out of hand. The idea was posed to bring in registrant chemists as needed, but this would likely add too much time to resolve an issue that needs a quick response. D. Kunkel suggested that the idea of this committee can be considered an extension of the Lab Guidance Document committee, but with someone else as chair, and him as an ad hoc member.

There was discussion about the make-up of the committee - it should include either D. Carpenter or J. Corley to represent the study directors, as well as the RLCs. Someone from QA should also be on the committee. M. Miller wanted to make sure the committee was pro-active and not just formed when there is a dispute, and that the committee facilitate dialogue, not be judgmental. B. Hollingworth suggested the committee could help bring about standardization, for example answering the question of when it is appropriate to do a manual integration.

It was suggested the committee be called the Analytical Chemistry Advisory Committee (ACAC)

From the Study Director perspective, D. Carpenter reminded the group that there is a place for the committee but it has to be understood that by law, the study director is the single point of control of the study and is the one who signs the final report. Studies must be conducted under regulatory controls on the basis of good science. There is no problem writing a deviation if the analysis is conducted using good science. She felt the committee was a good idea for fostering communication.

During PMC continuation of this discussion the next day, the following was decided:

The LRCs do meet regularly now, but this will formalize the group with an ongoing charge of three goals:

- 1) review lab policies and procedures as a continuation of the Laboratory Guidance Document
- 2) adjudicate issues when there are disagreements
- 3) facilitate dialogue between study directors and LRCs

There was a good deal of discussion regarding the make-up of the committee, as well as its role in being advisory. The committee should meet 3 times a year.

MOTION: IR-4 should form an Analytical Chemistry Advisory Committee (ACAC) comprised of all Regional and ARS Laboratory Coordinators, HQ Study Director, QA, and PMC ex-officio and IR-4 Associate Director of Registrations; motion approved 5-0.

ACTION ITEM: Task #1 for the ACAC committee - review and recommend immediate equipment needs and options

2) A second concern of the RLCs was the workload, and they asked how PMC might assist in alleviating the pinch they are all feeling. With the closing of the NE lab, the remaining labs will need more money to support people and equipment (and that is the plan). The labs are already falling behind before the NE lab shut-down kicks in, due to crumbling infrastructure (machines are becoming obsolete and freezers are full); difficult-to-analyze compounds like the triazoles; a larger than expected number of samples from some studies, due to decline trials, processing fractions, more than one treated plot (two formulations, or 1X/2X rates, or 3 application techniques, etc); much larger than average studies, like potatoes/tomatoes, etc.

J. Baron asked the coordinators how they would spend money (people or equipment) if IR-4 put a “set aside” for the laboratories. M. Marshall suggested that if money was rotated, the lab receiving the additional funding that year would pick up extra trials. D. Kunkel charged the ACAC with the task of looking into the cost of equipment, leasing, contracting, and personnel, and asked them to make a recommendation on best possible solution.

Approval of Minutes/new agenda items: Minutes of the Fall 2008 PMC meeting held December 9-10, 2008, in Crystal City, VA, were approved. An Executive session was added to the agenda.

Biopesticide and Organic Support Program - Michael Braverman (via conference call slides included in meeting materials) reported: EPA funding of Demonstration grants was not eliminated this year after all. He discussed the overview of the 2009 program, and the projects that the program would like to fund.

B. Hollingworth noted the NC region only received 4 grants and wondered how the NC region can improve on this. Michael responded it was just how it turned out this year. That rejection or acceptance has nothing to do with regions. The committee reviews the projects and together they decide the best proposals based on good science. In fact last year they left \$36K on the table because the committee did not find enough acceptable proposals.

C. Meister approached J. Baron requesting that he use Southern region funds to support some proposals that were turned down by the committee. P. Schwartz thinks this will set up the wrong precedent. It would be better if the granter review the comments from the committee, rewrite the proposal and resubmit it for the Biopesticide program to consider or to the Southern Region for their funding.

MOTION: To approve the 2009 Biopesticide and Organic Support Program grants - approved: 6-0

Brief updates:

Administrative Advisors – No report

ARS – P. Schwartz reported Tifton has to install lab alarm/back-up system for freezers; the ARS labs only completed 26 trials in '08; critical funding issues are going on; if there is no increase in budget, will need to look at ARS program efficiency. Salinas, is in good shape and is well funded, as are Wooster, Wapato and Charleston; future of AZ site is not certain

Accountability report is in the PMC materials - there are no differences from last year; it was suggested that P. Schwartz get his numbers from D. Kunkel, as they should be the same as what he gets from RFC and RLC.

CSREES – M. Johnson reported IR-4 got an increase of \$700,000, which still needs final Congressional approval; he just received a draft of the RFA and will have it opened for 30 days. Monte will relay that no indirect costs can be associated with the grant; also to make sure to include fee for service. The grant electronic submission program will be switched to ADOBE and M. Johnson will make them aware of some issues as reported by D. Soderlund associated with the program. J. Baron asked if the RFAs could be filled out taking the \$700,000 increase into account – Monte's response was Yes.

North Central Region – B. Hollingworth reported field trials are going well. Was concerned that this year they have fewer than normal trials, which is making some centers question their commitment to IR-4 research. QA is reasonably smooth and the lab has had a stressful year which resulted in reduced productivity. There are still unanswered questions regarding the lab being moved but they have submitted a request for the lab to remain on campus. They do have money to hire a new analyst, possibly two. If they hire 2, they will need to purchase new equipment.

Northeast Region – D. Soderlund stated the lab was doing surprisingly well under the circumstances. Dave has had many reports about what a pleasure it is to work for the new lab coordinator, Wlodek. They are finishing up the studies and have had no issues with productivity. His plan is to lay off staff 2/1/2010 with the exception of Wlodek, whom he will keep on until the lab is officially closed and paperwork completed to decertify the lab. Dave is still concerned with the issue of severance and how it can be funded. He will consult

his financial folks at Cornell along with Monte. He will need ~ \$200,000-\$250,000 for severance. Some of the analysts are available to move if the other regions are interested in them and Dave encouraged the regional directors to consider this when looking to increase laboratory staff. When the laboratory closes, the QA person's workload will decrease, freeing her to pick up other IR-4 QA work. The field program has been significantly reduced this year with only 57 trials planned for the NE in 2009. This might be a good thing this year because it helps with the "learning curve" of new personnel in the field centers. But, Dave agreed with Bob about the need to provide a funding structure for years when some centers have fewer than normal trials and need a steady amount of money to keep them open and running.

Southern Region – M. Marshall announced Michelle Samuel-Foo is on-board as the new Southern Region Field Coordinator. The Southern Region received a special projects grant for citrus greening. This grant will support a person 10-15% and a chemist 85%. The Southern Region will have 140 field trials this year. They are hiring a new QA person for the analytical laboratory.

Western Region – M. Miller reported the Western Region will have 218 field trials this year, which is a good number for them. They have added Paul Kuzmicky to the lab. In addition to analytical expertise, Paul also brings his computer skills to the job, which is a real plus. All were saddened by the death of Debbie Effron, who was the IR-4 administrative assistant for the West. It will be a challenge to find another administrative assistant at this time due to decreased funding; this position was shared by another program that no longer has the funding to support the shared role. Kudos were given to Jim McFarland for the Colorado EPA inspection that went well. As an FYI, M. Miller met with DPR regarding a UC/Mexico grant. DPR is enthusiastic about doing work in Mexico. This is a good program and could be a good opportunity. NRSP-7 also met with M. Miller via conference call.

HQ – Jerry Baron reported that the Annual Report and Year In Review are completed; HQ travel is being restricted based on conservative budget estimates. In May, the EPA will hold a Public Health Summit, but the timing conflicts with the IR-4 Peer Review; therefore, IR-4 will not be represented. This person, and 10% of J. Baron's and Keith Dorshner salary will be covered on the money received from USDA-ARS to fund this initiative. D. Soderlund commented HQ should make it very clear that this initiative has its own funding to avoid the perception that HQ is spending core money on new initiatives.

Ornamental Program (slides included in meeting materials) – The program will get an additional \$50K to move the budget back to the 2007 level of \$400K. Outstanding question was how much of the \$700K IR-4 increase will go toward the Ornamental Horticulture program.

Communication Update- The newsletter committee response to advice on how to handle the calendar errors brought about a flurry of activity. The new media page is now running on the website. It will include approved PMC minutes, and all agreed that would be appropriate. Committee participation was discussed and the need for all committees to have term limits for its members. It was recommended committees stagger their term limits. Having limits will help those who feel overwhelmed by their involvement, as well as provide fresh perspectives and input from newly elected members. This was also indicated to be pertinent to the IR-4 Training Committee.

MOTION: Any standing committee appointed by the PMC should institute a term limit policy for membership that will be approved by the PMC. Approved 5-0

Wednesday, February 25, 2009

National Field Program – the idea of "base" funding for field research centers:

Especially the Southern, Northeast and North Central regions need flexibility in funding to provide financial support to keep field research centers stable in years of low trial numbers due to changes in crop focus of priority residue studies. It is critical to maintain the centers year-after-year – IR-4 can't afford to lose a researcher in years when his/her trial load is below the minimum number needed to maintain a fully operational site based on the IR-4 payment per trial (\$4750 in 2009). At the Feb. PMC meeting each year

Regions will know which centers will need extra \$\$ due to a smaller-than-needed # of trials, and they can then request PMC to allocate additional funds. Requested funds must be justified and approved by the PMC.

ACTION ITEM: For the July PMC meeting, each region is requested to assign a base budget needed for each research center, solicited by M. Marshall in an email to Regional Directors. These base needs will then be the basis for Regions requesting additional “bridging” funds.

PMC/Commodity Liaison Committee joint meeting, with these CLC members attending:

Rocky Lundy, chair

Kirk Baumann

Mike Bledsoe

Todd Scholtz

Lori Berger and Lin Schmale, via conference call

- 1) **Discussed budget increase of \$700,000;** thanks to the CLC for all their efforts on The Hill!
- 2) **Strategic Plan (SP) discussion** – all agreed with posting/distributing (through listserv, email, website) the draft plan, after revisions from this PMC/CLC review, for broader stakeholder review/input; this 2009-2013 plan will be part of the documentation needed for the May NRSP-4 review, and will be done in April to be given to the review panel in May.

R. Lundy reiterated the CLC concern regarding the Strategic Planning Conference, particularly that there was limited participation by USDA-ARS, EPA and CLC; therefore, the SP may not be totally representative of the views of these stakeholders. J. Baron responded in agreement, and explained the plan for SP finalization described above. Although the SP will be sent to the NRSP-4 reviewers in lieu of a project statement, a project statement will be needed by the fall.

M. Miller requested the SP must make it clear that new initiatives are to be funded from sources other than the core funding from CSREES. D. Soderlund commented that the new initiatives don't affect regions directly; however, this has the potential to dilute the core IR-4 mission due to personnel and oversight of the initiative, thus diluting expertise at HQ. This needs to be clearly described and understood.

R. Lundy suggested that PMC needs to come up with a policy on the Public Health initiative. There are liability concerns/risks associated with IR-4 involvement, and even though the funds for this type of initiative may be able to support specific staff to do the work, HQ oversight still has a cost vs the core mission of IR-4; a risk/benefit analysis may be recommended. J. Baron indicated that there could be benefits from this initiative that go beyond the funding question - ARS has been pro-pesticide in animal and public health research, and these materials potentially have applicability to crops (i.e. making pesticides specific to pests via RNAi technology, etc.).

International Harmonization - the CLC (except tropical fruit growers) supports this work and feels IR-4 has a role, but is seeking a clearer understanding of this role.

Biotechnology - D. Buhler commented that there are a lot of crops that are a good fit for this (mint is one) but are being “left on the shelf”. There is a huge biotech proposal for funding that is patterned after the IR-4 program that Ag. Exp. Stations will be reviewing/discussing at their meeting this year. The group had a conversation with J. Baron, and D. Buhler sent him the proposal to see if there could be a link to IR-4; if so, this should be included in the SP, but separate from the Biopesticides and Organic Support Program.

Efficacy needs - due to University and other budget cuts and loss of state people who do this kind of work, CLC suggested that IR-4 expand on this initiative; possibly make this “A priorities without solutions” as they do in Canada. Efficacy is very important to the Ornamental Program, and the SP needs to reflect this stakeholder need.

2009 FUW/NRPM – revisions in the plans for these project prioritization processes compared with 2008 were described by V. Starner, and were accepted by the PMC; the most significant changes include the following: FUW workshop participants will assign 55 “A” priority projects for 2010 research (compared with 36-39 in recent years), with a minimum of 10 “A” priorities for each discipline, and the additional 25 distributed between disciplines based on the number of projects available for nomination in August; a pre-NRPM conference call is planned for HQ discipline managers and RFC to agree on “A” projects from Regional upgrades and Priority Upgrade Proposals, and in the weeks prior to the NRPM, the majority of lab/field sites will be assigned to 2010 projects (previously ALL completed at the NRPM), so that NRPM attendees can spend more time resolving site under-/over- bookings, etc.

Thursday, February 26, 2009

QAU Discussion with PMC

- T. Barkalow reviewed her QA report (handout), and their annual spring planning meeting in 2 weeks
- routing of QA inspection reports is taking too long, and revised routing procedure options were discussed (move to electronic system per EPA requests, etc.)
- J. Baron challenged QA to look at routing procedures as if we were just organizing a new system – what can we do (without considering the current system), given the unique aspects of IR-4’s organization
- All agreed the system is not broken, but just needs better mechanisms
- D. Soderlund asked QA to reallocate QA in the Northeast when the lab is no longer functional
- M. Marshall will follow up with assessment of how much IR-4 is spending on contract QA to determine if it would be more effective/efficient to hire someone to work in-house

ACTION ITEM: QA to come back to PMC after their FL meeting with potential scenarios on the routing question and with proposal related to contract money spent vs. hiring “in-house”

EPA Registrations, Work Plans, FDB/ASR Completion Status, 30-month Timeline Status, EPA Update

- **D. Kunkel** (slides included in meeting materials)

- 41 chemistries were approved by EPA in 2008 - this is an incredible number!!
- 2009 field program - 112 residue trials (88 new, 16 carry over, 8 EPA DCI) 11 additional performance studies; total of 69 chemicals.
- there was significant discussion about why there is such a serious backlog in the labs, and how to resolve this in the midst of transitioning to 3 labs; D. Soderlund proposed that NY could have some capacity to take on a study or two as their shut-down proceeds
- D. Kunkel will reduce his database to just the '06 and '07 studies where there are late ASRs and provide these to RLCs and request the exact status of each study; for ARS, of four studies from '06, two are in report prep, one with samples analyzed, and one in analysis phase

ACTION ITEM: D. Kunkel will follow up on this, and additional dates from labs will be incorporated into the new IR-4 database

Industry Issues - While IR-4 welcomes the opportunity to work with companies early in the development phase, there have been a couple times where this strategy has not paid off. IR-4 submitted a petition for a particular chemical in early 2008 and found out later in the year that the company was not interested in investing in cooperating to provide submission documents required of them until 2010. With a bit of intervention from the EPA, the company did follow through and a timeline is established, but in the future IR-4 may need to pull AI’s if companies will not honor their commitments. This was brought up to make PMC aware that such difficulties occur at times.

There seem to be a lot of new chemistries in various company pipelines.

2009 Budget – the RFA publish date is to be 3/25/09, with submission deadline of 4/27/09, and money should arrive in 7/09. The Budget looks similar to last year and the maximum figure should be used in RFA.

MOTION: to accept the budget allocations as proposed by Jerry in his email which all around the table received; this was approved.

D. Soderlund requested that each region include a letter in their grant proposal to the RFA as an attachment about the closing of the NE laboratory

R. Lundy would like a document that describes how the expected ~\$700,000 budget increase will be used for infrastructure support. IR-4 needs to continually upgrade equipment in order to maintain its high level of productivity, and the typical 6-year shelf life of analytical equipment should be documented. J. Baron will formulate a document detailing what IR-4 is doing with the additional \$632,000 it will receive in the final budget.

PMC comments on the Strategic Plan

- B. Hollingworth suggested the SP cover until 2013, not 2011, to line up with the 5-year NRSP-4 review cycle.
- the Public Health initiative should be renamed “Regulatory Support for Vector-borne Diseases”; the fact that this initiative is paying 5% of Dan & Keith’s time/salary, 10% of Jerry’s, and supports a full-time employee (to be funded at \$260,000/yr), made this acceptable to PMC; it was recommended that this initiative be presented in the SP as an “exploratory” program - with the Dept. of Defense coming to IR-4 for assistance, this is a major plus from a public relations standpoint; the SP must show that this program is self-sufficient and will not negatively impact the core mission of IR-4 for specialty crop growers; IR-4 must demonstrate that the savings from salaries being paid by this program are going back into core IR-4 programs; it was recommended that IR-4 move forward in this area as a pilot, as it is budget neutral, and see where it goes; also, it should be called a “Cooperative Project” rather than an initiative
- the Biotechnology initiative needs to be presented as an exploratory program, not related to the IR-4 Biopesticides program in the SP; IR-4 can provide regulatory support; but the PIP program is actually complimentary to what IR-4 does; the SP needs to show more money directed toward organic support than PIP initiatives; PMC agreed to remove this from the SP and get involved in such work only if it makes sense and as opportunities arise; the SP should remove “Biotech” from the title wording, but make certain the text shows that this topic is also covered for regulatory aspects through EPA’s BPPD

NRSP-4 Peer Review (chair is Larry Chandler [ARS Associate Director]; other members include: Cheng-i Wei, Dean and Director of the MD Agr. Exp. Station; Janice McFarland, Regulatory Affairs, Syngenta Crop Protection, Inc.; Dan Rosenblatt [EPA], Jerry Lee [Morovia Nurseries], Wally Ewart [former CLC member]) – May 19-20, 2009; the 2003 peer review documents should be located/distributed/consulted for guidance in formulating this review’s documents; J. Baron to contact L. Chandler to confirm the format for the review

ACTION ITEM: J. Baron should draft an agenda and send out for comment

Upcoming IR-4 Events:

- March 17-18, 2009
Western Region SLR/CLC Meeting
Bozeman and Pray, MT
- May 19-20, 2009
IR-4 Peer Review
Princeton, NJ

- July 7-9, 2009
PMC/AAFC Meeting
Halifax, Nova Scotia

- August 10-11, 2009
NCR SLR Meeting
Kansas City, MO

- August 25-26, 2009
SLR Meeting
Myrtle Beach, SC

- September 15-16, 2009
2009 Food Use Workshop
Cleveland, OH

- October 6-8, 2009
2009 Ornamental Horticulture Workshop
Cleveland, OH

- October 14-15, 2009
2009 ARS LR Meeting
Cleveland, OH

- October 27-28, 2009
National Research Planning Meeting
Princeton, NJ

- October 28-30, 2009
Fall PMC Meeting
IR-4 Headquarters
Princeton, NJ

- Week of March 1, 2010
Spring PMC Meeting
Washington, DC area