



IR-4 PMC & CLC MEETINGS MINUTES

Fall Meeting, 2020

Zoom Virtual Meeting

MOTIONS AND ACTION ITEMS

Motions/Consent Items:

1. Motion for approval of the Summer Meeting minutes. **Approved.**
2. The PMC provided consent of the proposal to add Wilfredo Robles as the Southern Region FDR representative on the Education and Training Committee. **Consent Provided.**

Action Items:

1. Southern Region: Dr. Gu to share benchmarking system with other Regional Directors.
2. 2021 Funding Update: Tom Bewick to meet with CLC and share NIFA presentation.
3. Modified Search/Selection Process for Associate Director Position: Jerry Baron to send an email to the PMC requesting names of potential candidates for the Associate Director- Regulatory Sciences open position. Matt Hengel, Mike Bledsoe, John Wise volunteered to participate on the Associate Director – Regulatory Sciences Selection Committee.
4. Efficacy/Crop Safety data requirements: Jerry Baron will communicate to the HQ team and Biology Leads of the data a review requirements prior to the FUW.
5. iAdvantage Pilot: This item was tabled and requested to be brought back at the March meeting with more cost analysis detail.
6. Electronic Protocol Distribution: Debbie Carpenter will email regional coordinators and get their input on how best to move forward.
7. Analytical Laboratories including laboratory backlog & ACAC discussions: Jerry will issue an initial letter to lab director to establish a meeting regarding laboratory backlog.

PARTICIPANTS

Jerry Baron; IR-4 Executive Director
Tom Bewick; USDA/NIFA
Michael Bledsoe; CLC/Chair
Doug Buhler; Administrative Advisor-NCR
John Davis; Administrative Advisor-SOR
Liwei Gu; Regional Director-SOR
Matt Hengel; Regional Director-Western Region
Marcel Holyoak; Administrative Adviser - WR
Moses Kairo; Administrative Adviser – NER
Dan Kunkel; Senior Associate Director
Steve Lommel; Administrative Adviser- HQ
Joseph Muyaneza; Administrative Adviser ARS
Alvin Simmons; USDA-ARS
John Wise; Regional Director-NCR/Chair PMC
Simon Zebelo; Regional Director - NER

GUESTS

Michael Braverman
Debbie Carpenter
Krystal Chojnacki
Amer Fayad
Robert Hedberg
Michael Horak
Cristina Marchesan Marconi
Johanna Mazlo
Philip Moore
Cristi Palmer
Venkat Pedibhotla
Dan Rossi
Van Starner

Thursday October, 29 10:30 am to 4:00 pm with 30 minute break at 12:30 pm

John Wise called the meeting to order at 10:36 am.

1) Approval of minutes, new agenda items (Wise)

- **A motion for approval of the minutes was made by Jerry Baron and seconded by Mike Bledsoe; unanimously approved.**
- Item #10 on Friday, specifically the efficacy crop safety requirements, there was a discussion on the need to request Michael Horak to attend the zoom call; Michael's participation was confirmed (Hengel).
- Addition of Training committee report as item #11 on Friday (Baron).

3) Updates from AAs, NIFA, ARS, CLC, NE, SO, WR, NC, HQ

AAs

- Marcel Holyoak: No Updates.
- Moses Kairo: Stated that he was pleased to join the meeting as and Administrative Adviser and is looking forward to working with the team moving forward.
- Steve Lommel: Reported that some NSRP's have not been approved, and may get shut down, which shows the importance of IR-4 and how it is viewed on the national level. Provided an update on secured office space and hiring underway for HQ despite a hiring freeze. Noted that the state of the College and University are mixed; they are planning to open in the spring for classes in a modified way and that labs are open but density is limited, and that there will be expanded testing in the spring that will be extended to faculty and staff.

NIFA – Tom Bewick

- Tom Bewick: stated he was the lead NPO for the IR-4 Project. Robert Hedberg is on a time limited appointment and is assisting with the SARE program. Amer Fayad is a new NPO, is working on the Tactical Sciences program, and it is anticipated that he will eventually assume the responsibilities for the IR-4 Project.

USDA-ARS - Alvin Simmons

- The ARS field laboratory sites are still in the maximum telework posture but priority has been given to IR-4 work through the pandemic. The federal government is on a Continuing Resolution until December 11, however it is not impacting the IR-4 activities right now.
- The President's budget showed a decrease for ARS, the house was status quo, and the overall expectation is that there will be no cut and the agency is still supportive of ARS's effort in support of IR-4. The new 5-year Cooperative agreement has been established with NC State and closing the agreement with Rutgers.
- An offer was made for a support scientist to assist Alvin, he is optimistic that the offer will be accepted. This candidate's skillset is aligned with specialty crops and this will be someone who can help Alvin to copy field data notebooks before sending them on.

Commodity Liaison Committee (CLC) Chair - Michael Bledsoe

- Reported that the Governmental Affairs Sub Committee that is meeting quarterly and is growing more active. Currently they are trying to bring in an outside consultant team to assist the CLC with their efforts to support IR-4 on the Hill. A discussion was held regarding potential leadership committee changes resulting from the election and how they may affect IR-4.
- An invitation was extended to external IR-4 members who may be interested in joining the IR-4 CLC. PMC members held a discussion and made suggestions of new potential members.

Northeast Region – Simon Zebelo (Handout)

- Transition has been smooth thanks to Marylee Ross, Megan James, Jane Forder, and others from the team. A new Program Coordinator has been hired to support the expeditious transferring of funds as Rutgers staff are transitioning out and working to close grants out.
- Has established a subaward to University of Maryland College Park and is currently working on getting funding to researchers in the region.
- Upcoming UMES program will have an IR-4 session for producers in the Northeast region.
- Reported on concerns over limitations from COVID-19 and budget funds left; will look at a NCE from Rutgers. Trials are moving along successfully.

Southern Region - Liwei Gu (Handout)

- Field program is going well. The number of field trials in the Southern region are larger than in past years and is creating a larger workload for Janine and a new assistant position to support her work has been drafted for hire in January.
- Analytical lab is expected to complete 10 NSR and shared instrument updates that are underway in the lab that will enhance capacity. Reported that there are six on-going projects in the lab, the rest will be completed in January or February, and that there are five projects in the backlog but there is a strategy in place to prevent this from happening again in the future. QA is doing well, finished 75% of assigned activity and considering travel restrictions imposed by COVID, this is great.
- John Wise requested that the benchmarking system be shared with the other Regional Directors.

Western Region - Matt Hengel

- Field program: things are progressing nicely, some changes in New Mexico (NM) and there are plans to restart the NM site (hiring).
- Submitted a grant with CA State Bureau of Cannabis Control Commission to dovetail hemp projects with IR-4 projects. Existing Hemp grant rolling for 2021 and 2023 CDFA funding can help with the food program and integrated solutions.
- QA is working well, and inspections are being covered. A contract QA was used for an inspection in Hawaii which worked out well.
- Lab: All is going well, one product is late. Instrument relocation has taken place and lab is under one roof. Thanked the folks in Michigan for transferring items cleanly and accurately.

North Central Region - John Wise

- Field: Pleased with what they have been able to accomplish and how little the COVID restrictions impacted field trails.
- QA: Facing struggles with travel restrictions, was able to use contractors to keep the work moving and are finding ways for travel to continue.
- Lab: Not able to be productive for 2+ months due to COVID restrictions; working to accommodate individual employee comfort levels with returning to work. Up to almost full

productivity but there remains a large backlog; looking for ways to overcome the loss of productivity. Looking to bring on existing chemistry capabilities but that has budgetary impacts. They recognize the issues the backlog is having on the National and Registrant level and are working to remedy them.

Headquarters – Jerry Baron

- Rutgers & NC State:
 - Worked to increase the frequency of communications and meetings; Overall, the entire Project made it through 2020 with minimal shut downs or losses.
 - HQ operations at Rutgers and NC State continues with remote/ limited in-person working options and submissions to EPA continue.
 - Operations update: Loss of four retirees in critical positions. Struggling to fill the Associate Director of Regulatory Sciences position (Kunkel position) and re-thinking how we will be recruiting for this position. Expect that 2021 will bring additional retirements and it is anticipated that the Rutgers team will stop their work in July and start closing down operations through the end of September.
 - Cristi Palmer, Michael Braverman and Susan Bierbrunner are moving to the Plant Biology Department and reporting to the Department chair. An MOU has been circulated to make the continuity of operations clear. Debbie Carpenter will assume the duties as Acting National Director at Rutgers and she will be supported by Dan Rossi.
 - New Hires at NC State: Johanna Mazlo, Jimmy Byrtus, and Jennifer Heiss.
 - HQ at NC State is moving forward with hires and trying a new process of obtaining a blanket approval to post all the positions.
 - Secured permanent space on Centennial Campus (~6,500sq.ft.). Take possession on November 1st and will share the building with crop protection groups. Annual rent is under budget of the Rutgers lease in New Jersey. The new location will no longer have long term archive space; this will be hosted offsite.

4) NRSP-4 Reauthorization (Doug Buhler)

Next Steps:

- The NRSP-4 Reauthorization was renewed as presented. Discussion around the reauthorization included that IR-4 has been funded for too long, and how the impact of the work of IR-4 is apparent; the final vote for approval was near unanimous as presented.
- A few things that came up for the next authorization:
 1. As part of the re-education process for association representative turnover, explain how the NRSP is a small but vital percentage of the overall funding model for IR-4 (graphics).
 2. Establish a more clear identity for NRSP funding in overall program (the important of the partnerships in overall funding structure).
 3. Make a larger and clearer connection of how IR-4 links to the land grants.
- Reported that there has been a substantial change in NSRP guidelines that added a second track of long term funding for base / core programs that IR-4 will need to focus on for the next proposals justification.

-- 12:05 pm -- Break – The meeting reconvened at 12:20pm.

5) 2021 Funding Update (Baron/Bledsoe/Bewick/Hedberg)

Tom Bewick (PowerPoint):

- Operations: The state of NIFA was reviewed including staffing levels. They are currently hiring aggressively and are up to 180 employees from 80 a year ago; 90% of new hires are still in probationary period. The grant management office (OGFM) has been re-staffed. Started Project café- a stakeholder input process on how to remake NIFA, including posting a calendar of RFA release dates. The IR-4 RFA is targeted for mid-December.
- Reviewed the Authorization for the IR-4 Project in the past as a special grant and the transition to a research activity under (7 U.S.C. 450i(e)) that can now be funded longer than 3 years and also allows limited Indirect Costs. The idea is to make a single four year grant to HQ and HQ make sub awards out to the regions. This would streamline the application and reduce the reporting requirement and administrative burden.

Jerry Baron/John Wise:

- Led a discussion regarding what the potential indirect cost rate would be, progress report expectations with new structure (5-10 pages) and the budgeting process for a 4-5 year grant.
- Opportunities for an increase: A discussion was held regarding the uncertainty of the budget following an election year; the potential for the addition of indirect costs with no funding increase and the implications on budgets; with a single grant the potential issues of subawards on subawards; the potential for the CLC to work through the stimulus process as a way of augmenting USDA budget.
- Mike Bledsoe requested that Tim Bewick meet with CLC and make the same presentation.
- *Item added to executive session for further discussion and feedback on award set-up (Wise).*

6) HQ Transitions Update – Jerry Baron

Hiring/Grants/Office Space/IT Systems

- Provided an update on hiring thus far at IR-4 Project Headquarters at NC State including hurdles such as the pandemic, and the development of a new Environmental Horticulture Program Assistant Manager position.
- Reviewed the timeline of transitions, including the IT transition, reporting that NC State is purchasing licenses and web server space to establish a development server, and update to the latest software, as well as managing security provisions to prevent hacking.

Modified Search/Selection Process for Associate Director Position

- Reported that there has been difficulty in getting a large pool of candidates for this position and a few professional headhunters have been contact to provide assistance, but there is a substantial fee associated with this. The position announcement was posted last week in Agro newsletter (American Chemical Society), and a request to the PMC to provide names of potential candidates was made.
- The PMC asked Jerry Baron to send an email to the PMC requesting names of potential candidates.
- Discussed search committee members, for this position, he would like the PMC members to participate in the selection committee (Matt Hengel, Mike Bledsoe, John Wise volunteered).

7) Northeast Region Transition Update

- Simon Zebelo: Noted that he provided an update on the transition in his earlier report on the region and added that they preparing new content on their website and seeks to link it to the IR-4 national website.

8) Workshop Debrief (PowerPoint)

- Van Starner: Shared reflections on the first virtual Food Use Workshop. One benefit was how many people were able to join us (326 people registered). Worked with a consultant: Fountainworks to assist us with running the workshop.
- The New Technology Session was also held virtually in advance of the workshop, pre-recorded, and it was well received. There were several new active ingredients announced and it resulted in new requests received and nominated as “A” projects.
- 14th year of on-line project nomination period. Starner reviewed the targets of 40 “A” priorities, 8 “H+” projects and drops/”moth-balled.”
- Reviewed the survey results from participants, and workshop results: 43 residue projects. NRPM allowed for some “B” list bumps up to “A.”
- The PMC and staff held a discussion regarding: the benefits of hosting the New Technology session early; the positive feedback from the virtual meeting; the possibility of holding the workshop in the future in conjunction with Canada; pre-ranking projects (IS and residue) in the regions prior to coming into the meeting to streamline the process; the necessity (or not) for a virtual conference consultant in the future; and the virtual nature democratizing the process by opening it up to more people.
- Jerry Baron: In 2021 there will be a combined week of workshops. Due to the uncertainty of travel by September 2021, a decision will be made in March/April on whether or not we will hold the meeting virtually again in 2021. Have a contract for 2022 (in-person) that was in exchange for getting out of the contract for 2020 due to the COVID-19 pandemic.

9) Executive Session 1

-- 2:05pm – Break. The meeting reconvened at 2:20pm into Executive Session. The meeting adjourned at 3:29pm with no reportable action items out of Executive Session.

Friday October, 30 10:30 am to 4:30 pm with 30 minute break at 12:30

10) Change Protocols

Efficacy/Crop Safety data requirements

- Michael Horak: Following the FUW there were four projects that were selected to move forward that there was no efficacy data provided to IR-4; asked for consideration if there needed to be guidance on whether or not to consider project that does not have any data on crop safety or efficacy.
- A discussion was held by the PMC Members and staff regarding: whether historically there was a formal rule requiring data or not (there was an expectation that there is data); if we want to look at novel/ brand new chemistry, then very rarely we will have data in the beginning; greenhouse difficulties getting data and the need to ask for it; specifying that data is different than a summary slide from the new technology session.
- Jerry Baron: There is a need for more of efficacy and crop safety data (driven by state regulatory authorities, for example) by companies because of liability concerns and with our new biologists we will have greater capacity in this area.
- *John Wise added this item for further discussion in Executive Session.*

iAdvantage Pilot (Report in Handout and PowerPoint)

- Philip Moore: Reviewed the benefits of iAdvantage eNotebooks including costs of archiving and paper, improved monitoring of studies and time savings for Study Directors. Provided specs: web-based platform, auto archiving; and downsides (will not completely eliminate paper,

eliminate risk of data loss). Proposed a pilot study inclusive of 5 trials at an estimated cost of \$145,000 inclusive of purchasing the minimum number of licenses, convert FDB to eNotebook, training, and evaluations.

- Discussion and Questions: A discussion was held by the PMC and staff regarding connectivity issues, EPA have restrictions on cloud based data with GLP's, academic institution fee structures, EPA auditing printing requirements, where data is stored, in the cloud or on the device, whether there would be a pilot project in each region, and the system used for data back-ups.
- *John Wise added this item for further discussion in Executive Session.*

Electronic Protocol Distribution

- Debbie Carpenter: Brought before the PMC for consideration the idea to distribute protocols and amendments through eQA during COVID due to the restrictions with coming into the office and copying/mailing items. Debbie notes the normal process is that they are sent via email but the process is to follow-up with a hard copy to the participants. We have the ability to do this electronically through eQA and send through to participants for them to print at their own locations.
- Discussion: The PMC and staff held a discussion regarding the need to develop SOP's if we move to this system, that it may make it easier for HQ staff but not field staff, getting feedback from regional coordinators, FR's and lab coordinators will be critical, and the potential to use Kinko's to print and deliver it.
- *John Wise added this item for further discussion in Executive Session.*

-- 11:59pm -- Break – The meeting reconvened at 12:15pm.

11) Program update/discussions

Education & Training Committee

- Cristina Marconi: Brought forth requests from the training committee would like to propose that Wilfredo Robles from Puerto Rico to backfill her vacancy in the Southern Region as the FRD on the training committee.
- The PMC provided consent of the proposal to add Wilfredo Robles as the Southern Region FDR representative on the Education and Training Committee.

Food Program

Residue Research (PowerPoint)

- Debbie Carpenter: Provided an update on 2020 new uses (18), submissions (19), crop group updates, research underway, 10 year history of field research program, and a status update of Field Data Notebooks (2019 lagging).
- Discussion: A discussion was held regarding if HQ suspended their process of handling backlog, and if we need to formally acknowledge the backlog to move toward remedy.

(1) Field

- Debbie Carpenter: and backlog of studies. Ensure Regional Field coordinators can check status of notebooks.

(2) Analytical Laboratories including laboratory backlog & ACAC discussions

- Process in eliminating backlog, maintaining progress in COVID-19 environment, and implications of not meeting timelines: Matt Hengel (Handout)
 - Reported on the late and backlogged projects within each IR-4 lab including staffing issues and COVID related items that contributed to the delays. Reported the backlog of late ASRs and Backlogged projects is 27 and pure backlogged projects is 21.
 - Discussion and Questions: The PMC and staff held a discussion regarding what drove the spike in backlog during the pre-COVID times including that many trials come in at the end of the year/season, and some projects are more difficult to analyze than others are. Further discussion was held regarding having better recognition of if there is struggle, that we cannot let that just go, and of implementing a better system to identify what is the likelihood of being successful is with projects (from the registrant side).
 - *John Wise added this item for further discussion in Executive Session.*

(3) Quality Assurance

- Johanna Mazlo (PowerPoint):
 - EPA GLP Compliance Monitoring Program: No EPA Inspections during COVID-19 and changes as a result including virtual compliance monitoring, electronic desktop audit.
 - eQA/eDocs: Training is underway on eQA, and HQ is working on electronic SOP training.
 - In-life inspection: Hawaii has lifted their 14 day quarantine and the NCR is using a contractor for an in-life.
 - Working on scheduling a larger QA meeting in November.

Product Performance

- Venkat Pedibhotla: Noted that Van Starner covered this portion yesterday.

Integrated Solutions (PowerPoint)

- Venkat Pedibhotla: Shared 2020 priorities with about 38 trials, reviewed entomology, plant pathology and weed science projects, and reported that the 2021 research includes 10 new "A" projects plus three projects funded by California grants.

International (PowerPoint & Handout)

- Michael Braverman:
 - Global Minor Use Priority Setting Workshop: Reported the event was held on September 21-22; reviewed the dates, activities and process leading up to the workshop; 45 top global crop pest priorities; a merit analysis was performed on the top 45 projects; and shared unofficial results.
 - Externally funded residue mitigation projects: Reviewed projects performed in conjunction with the Standards and Trade Development Facility including work in Asia, Africa and Latin America; and working to build relationships with Japan, Korea and Taiwan.

Environmental Horticulture/Current Communications (PowerPoint)

- Cristi Palmer:
 - Provided a report on program data summaries, program registrations, crops impacted by registrations (~600-700), environmental horticulture website usage, COVID-19 impacts and delays, and data collection issues and remediation plans. Shared plans for future improvements including portal refinements, conversions from ColdFusion into ASP.NET.
 - Pollinator protection research update: Reported that they are in the final year of this program, not many delays in field research due to COVID-19, however there were delays due to the California wild fires.
 - Provided a report on invasive species.

Biopesticides Regulatory Support (PowerPoint)

- Michael Braverman: Provided a report of regulatory assistance provided and registered products including a registration and tolerance for grasses that also aid in preventing wildfires, among others.

Communications (PowerPoint)

- Cristi Palmer: Provided a report the transition from ColdFusion into ASP.NET underway, reported on success stories that have come out, reviewed website stats, and reviewed a transition plan for the new communications staff.
- Krystal Chojnacki: Reported on the new IR-4 generic email at NC State, the IR-4 HQ listserv established, provided a hiring update on the National Information and Communications Officer, and reported on a newly implemented weekly communications meeting.

12) Executive Session

-- 3:08pm -- Break – The meeting reconvened at 3:20pm. The meeting reconvened at 2:57pm into Executive Session.

Executive Session Action Items:

- Efficacy/Crop Safety data requirements: Jerry Baron will communicate to the HQ team and Biology Leads the responsibility to assess efficacy and crop safety data needs of new requests prior to the FUW.
- iAdvantage Pilot: This item was tabled and requested to be brought back at the March meeting with more cost analysis detail.
- Electronic Protocol Distribution: Debbie Carpenter will email regional coordinators and get their input on how best to move forward.
- Analytical Laboratories including laboratory backlog & ACAC discussions: Jerry will issue an initial letter to lab director to establish a meeting regarding laboratory backlog.

--The meeting adjourned at 4:58pm.