

IR-4 Project Management Committee Fall Meeting

October 23 - 25, 2024 Agenda and Handouts



AGENDA Fall 2024 PMC Meeting (Hybrid)

https://ncsu.zoom.us/j/96986211519?pwd=yAe MoA3EoILHZ3vIbIXG3aORcsItuH.1 Meeting ID: 969 8621 1519 Passcode: 123456

Wednesday October, 23 11:45 am to 7:00 pm

11:45 am	Van leaves from Aloft Hotel to Witherspoon Student Center				
Noon to 12:45 pm	Lunch with RFCs and HQ staff				
12:45 to 2:30 pm	Attend joint meeting of RFC and HQ (optional)				
2:30 pm to 3:00 pm					
3:00 pm to 4:30 pm	Joint meeting of PMC, Regional Field Coordinators, Laboratory				
	Coordinators, QA Unit, and HQ staff				
	Zoom Link for this meeting: <u>HERE</u> Meeting ID 938 2671 7723				
	Passcode: 123456				
	Welcome (Hengel)				
	Program Successes (Baron)				
	Introduction of new Environmental Horticulture Manager				
	eField Databook (Moore)				
	<u>Technology Team</u> (Byrtus)				
	<u>New Protocol Template</u> (Dineen)				
	IS Listening Session (Axtell)				
	Research Symposium Update (Axtell)				
	<u>Communication Update</u> (Ross)				
	Preliminary Plans for the 2026 NEC (Dineen)				
	Reestablishment of National Directory on Website?				
	Closing remarks (Baron)				
4:45 pm	Van leaves from Witherspoon Student Center to Aloft Hotel.				
5:00 pm to 7:00 pm					

Thursday October, 24 7:20 am to 5:30 pm – Markle Conference Room in Venture IV

7:20 am	Van leaves from Aloft Hotel to the Venture IV Building			
7:30 am to 8:00 am	Continental Breakfast at IR-4 HQ			
8:00 am to 12:00 noon	Project Management Committee meeting items			
	<u>Approval of minutes of new agenda items</u> (Hengel)			
	Grants items			
	 Distribution of 2024 funds/end of existing grant cycle (Chojnacki) 			
	 CLC/Friends Update (Scholz and Beaudreau) 			
	OMB Meeting			

	 March 2025 Fly-in/Congressional Reception/Hill visits
	ARS strategies
	Farm Bill
	<u>Additional CLC items</u>
	 New Members
	Management Reports
	 Administrative Advisors (Buhler et al.)
	NRSP-4 Renewal
	 NIFA (C. Philips)
	NIFA Non-Competitive funding transition
	 ARS (Munyaneza)
	 Regions/ARS (<u>Zebelo</u>, Hausbeck, <u>Gu</u>, Hengel, Simmons)
	 Headquarters Report (Baron)
	Program Reports
	 Food Residue/Product Performance Research (Carpenter
	et.al)
	Existing research update
	(Field/Laboratory/QA/Submissions/Successes)
	Results of Food Workshop & NRPM
	 Integrated Solutions Platform
	 Biopesticide Regulatory Support Platform
	Existing project update
	Stakeholder feedback
	 Potential future directions
	 Decisions on pending proposals
	•
	Existing Activities (Baron & Byrtus) 2025 Driarity Setting Workshop
Noon to 12:45 pm	2025 Priority Setting Workshop
Noon to 12:45 pm	PMC Lunch
12:45 pm to 5:00 pm	Project Management Committee Meeting continued.
	 International/MUF (Drost & Gore)
	 <u>Sponsored Research Policy</u> (Baron)
	 <u>IS Program Changes</u>
	Resources
	Modifying timelines
	i) 2025 transition
	ii) 2026 beyond
	Resources
	i) Cost recovery from CDPR
	Cooperation with WGA's Platform 10
	 Allowing use of Priority Upgrade Proposals for IS research
	 <u>National SOPs</u> (Dineen)
	 <u>New employee orientation module(s)</u> (Welker)
	 <u>Network Expansion Project</u> (Patel)

	 Ways of working - Update
	o <u>eField Databook</u>
	Upgrades
	Electronic signature
	Other topics
	 Future Meetings
	 Spring PMC Meeting: March 4-6
	 Summer 2025 PMC Meeting: July 8-10 (Canada)
	 Food Use Workshop: Sept. 9-11
	 Environmental Horticulture Workshop: October 7-9
	 NRPM/Fall 2025 PMC Meeting: October 20-24
	 2026 National Education Conference: Feb. 3-5
5:10 pm	Van to Aloft Hotel

Friday October 25 8:00 am - 12:00 noon- Markle Conference Room in Venture IV

7:20 am	Van leaves from Aloft Hotel to the Venture IV Building		
7:30 am to 8:00 am	Continental Breakfast at IR-4 HQ		
8:00 am to 10:00 am	Project Management Committee meeting items continued		
	Executive Session I		
10:00 am to 11:00 am	 Environmental Horticulture Review (Upton & Martin) 		
11:00 am to 12:00 noon	Executive Session II		
12:15 pm	Van to Airport		

Technology Committee Update

Presenter: Jimmy Byrtus







Technology Team Update

October 2024

Where We Are Currently

- eQA updates are in progress and testing is being done in a "sandbox" environment
- Technology Team has been made available to test eQA updates
- Diligently working on identifying database options for further investigations presented in the following slides.





New Database Discussion

Initial Research into Available Options



Agmatix

DB Management and Artificial Intelligence

Positives

- **Data Standardization-** Across data inputs/outputs from all current platforms allowing for better automation and insights and decision making.
- Automation- Data input/outputs based on user permissions
- Integration Capabilities- Can integrate various third-party services. (Current eFDB)
- Security and Compliance- Data security and compliance based on user authentication, role-based access control, and encryption, login based security.
- Artificial Intelligence- Help with decision making insights and analysis generation.
- **Case Study-** Integrated data from 3,000 field trials across 100+ researchers, and 70+ countries
- Electronic Data Capture- Currently offer eFDB's for Non-GLP data collection





Caspio

Low-No Code DB Management

Positives

- **No/Low Code-** Public interfaces and custom workflows without having to code.
- **Turnkey Solution-** Includes everything you need to build, launch and manage database applications.
- **Fully Relational-** Define table relationships, whether one-to-many or many-to-many, using drag-and-drop tools.
- Enterprise Grade- Runs on SQL Server and AWS, earning the trust of IT departments with 99.9% guaranteed uptime.
- **Strict Compliance-** Protect data with built-in security and compliance standards specific to your use case or industry.
- **Scalability-** Provides automatic scaling, millions of records, unlimited app users and unlimited app creators.
- **Usable Anywhere-** Embed your apps on any website, CMS or portal. Caspio powers them behind the scenes.





Knack

Low-No Code DB Management

Positives

- Ease Of Use- Drag-and-drop interface and no-code capabilities make it exceptionally user-friendly.
- Customization- Customization, enables creating custom applications for custom online databases, workflows, automation, dashboards, and user interfaces to fit your needs
- **Real-Time Rapid Development-** Pre-built templates and components give the ability to import data, for app development.
- Integration Capabilities- Integrates various third-party services, databases, and APIs seamlessly.
- Security and Compliance- Knack strongly emphasizes data security and compliance. It offers user authentication, role-based access control, and encryption to protect your data.





Kintone

Low-No Code DB Management

Positives

- **Centralized data organization-** Database apps store a wide variety of data such as text, numbers, and file attachments.
- **Custom reporting capabilities-** Filter the data in your app to see it the way you want for quick reporting. Easily export data to a CSV file or PDF for easy sharing.
- Built-in collaboration features- Add comments and tag coworkers to individual data records in your app for easier team collaboration, task handoffs, feedback, and more.
- Create unique views for your data- Set filters on your entire database to quickly view your data from different angles based on permissions set by IR-4.







Low-No Code DB Management

Positives

- **Data organization-** Gives the ability to store data securely along with processing the data using a variety of sources
- Automation capabilities- Allows for logic based decisions to be used for automation of tasks, data entry, and workflows
- **Easy to Navigate Forms-** Easily moves from backend database development to public facing interfaces with forms, charts, dashboards, and reports
- Multi-user interfaces- Set permissions for access to data



New Protocol Template

Presenter: Christina Dineen







Residue Protocol Template

IR-4 All Hands Meeting October 2024 Christina Dineen

MOR Protocol Template Revision

- New Template is Complete! Highlights:
 - Restructure of sections; more tables
 - Address past sticking points
 - More SD notes
- Next Steps:
 - Background work to ease transition at HQ
 - Training scheduled November 21 (field)
 - Resolve any snags as they come!

Committee Members – <u>Thank you!</u> Cristina Marconi Mika Tolson Chanz Robbins Megan James Hickman Dan Heider Scott Muir Cole Smith Gail Mahnken

IR-4 Communications Update

Presenter: Hannah Ross







Communications Update Hannah Ross | Fall 2024





Branding Updates

Following logo & color palette refresh, updated resources continually available for the team

Brand refresh continues

Vertically-stacked regional logos increase usability





Looking sharp at events!

Exploring crop-specific handouts for regions with RFC input





The IR-4 Project is a federal organization that generates data to register pesticides for use on specialty crops and ornamental plants. Since its inception, IR-4 research has supported 63 registrations and re-registrations of pest control products in blueberry. Below are IR-4's current blueberry projects and their statuses, as of April 2024.

RESIDUE STUDY PIPELINE

Recent Registrations: Acequinocyl (Kanemite): Mites (May 2020)

US Tolerance Established

- Buprofezine (Centaur): Scale (March 2022)
- Sulfur Dioxide Postharvest Botrytis (Nov 2022)

Under EPA Review:

· None at this time

Data Complete, Ready for Submission;

- · Abameetin (Anri-Mek) Miter
- · Pyrifluguinazon (PQZ): Thrips

Final Report to MFG:

XDE-659: Botrytus, Anthracnose, Mummy Berry

Ongoing Studies:

- · Tiafenacil (Gamma): POST Broadleaf and Tolpyralate (Shieldex): POST - broadleaf
- Flutriafol (Rhyme): Anthracnose and stem blight

CURRENT PRODUCT PERFORMANCE STUDIES Florpyrauxifen-benzyL (Loyant): POST

- control of broadleaf weeds and grasses. · Fluroxypyr (Starane Ultra): POST control of broadleaf weeds.
- Novaluron (Rimon): Thrips

CURRENT INTEGRATED SOLUTIONS STUDIES · None at this time

- CONNECT WITH US

Cole Smith, North Carolina Field Research Director: scsmith7@ncsu.edu (828) 702-3726 (cell)

Alice Axtell, Biology Team Lead and Principal Entomologist: aaxtell@incsu.edu | (919) 515-3055

Roger Batts, Principal Biologist - Weed Scientist: rbbatts@ncsu.edu | (919) 515 3054

Jaimin Patel, Principal Biologist-Plant Pathologist jpatel38@ncsu.edu 1 (919)515-4287

ir-4_project@ncsu.edu

2024 IR-4 PROJECT SWEETPOTATO UPDATE

1. 1. 1.

plants. Below are IR-4's current sweetpotato projects, as of October 2024.

None at this time

The IR-4 Project is a federally-funded organization headquartered at NC State that

generates data to register pesticides for use on specialty food crops and ornamental

after use in previous crop.

CURRENT PRODUCT PERFORMANCE STUDIES

CURRENT INTEGRATED SOLUTIONS STUDIES

Metribuzin (Glory FDF): Reduce rotational interval

CONNECT WITH US

Kristen Searer-Jones, Southern Region Field Coordinator

k.seareriones@ufl.edu 1 (352) 294 3979

Dr. Alice Axtell, Biology Lead - Entomology

Roger Batts, Biology Lead - Weed Science

Dr. Jaimin Patel, Biology Lead - Plant Pathology

aaxtell@ncsu.edu | (919) 515 3055

rbbatts@ncsu.edu | (919) 515 3054

jpatel38@ncsu.edu | (919) 515 4287

IR-4 Headquarters

ir4project.org

ir-4_project@ncsu.edu

RESIDUE STUDY PIPELINE

Recent registrations:

- Thiabendazole (Mertect 340F): Post-harvest use . for black rot. (August 2021)
- Broflanilide (Nurizma): In-furrow for soil insects. . (April 2023)

US tolerance established but not labeled:

- Mandestrobin (Intuity SC): In-furrow spray use . for black rot. (March 2023)
- Paraguat (Gramoxone): Plantbed weed control. . (Existing potato tolerance)

Under EPA review:

· None at this time

Data complete; ready for submission:

- Diquat (Regione): Preplant burndown of weeds. Fenpropathrin (Danitol): Foliar spray for mites. .
- beetles and worms. Tebuconazole (Orius): Post-harvest use for soft

Final report to MFG to pursue European MRL:

Azoxystrobin + Fludioxonil + Difenconazole . (Stadium): Post-harvest use for soft and black

Petition prep:

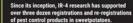
Linuron (Linex): EPOST broadcast weed control. . (May need to restart field trials)

Ongoing studies:

· Glufosinate (Rely): Preplant burndown of weeds. Tolpyralate (Shieldex): EPOST-broadleaf weeds.

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Scan to sign up for our newslette 6.44



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MARK YOUR CALENDAR

IR-4 Food Use Workshop Virtual option available

ir4project.org ir-4_project@ncsu.edu

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The strand to the

Quizalofop (Assure II):

Postemergence

Magnum): Preemergence³

*Sethoxydim (Poast):

*Trifluralin (Treflan, others);

Preplant incorporated

*s-Metolachlor (Dual

Postemernence

CURRENT PRODUCT PERFORMANCE STUDIES

post-directed to row middles. Study recently

· Glufosinate (Rely): Preplant burndown and

completed. Glufosinate safe to sesame.

· Pyroxasulfone (Zidua): Postemergence for

Treatments generally safe to crop in

CURRENT INTEGRATED SOLUTIONS STUDIES

Roger Batts. Principal Biologist - Weed Scientist:

rbbatts@ncsu.edu | (919) 515 3054

residual weed control. One final trial in 2024.

— CONNECT WITH US —

· Mesotrione (Callisto): Preplant and PRE.

Severe injury

previous trials

· None at this time

REGISTERED HERBICIDES *Ethalfluralin (Sonalan) Preplant incorporated Glynhosate (Roundum

others): Preplant burndown

*Prometryn (Caparol):

Postemergence-directed

2024 IR-4 PROJECT SESAME UPDATE

- Caprylic + Capric Acid (Suppress. others): Preplant burndown
- *Carfentrazone (Aim, Shark): Preplant burndown
- *Clethodim (Select Max, others):
- Postemergence Clomazone (Caravel)
 - Pyraflufen (ET, ETX): Prenlant humdown
- *IR-4 data petition or proposal used to gain registration. *Not registered in all states.

RESIDUE STUDY PIPELINE

None at this time.

None at this time.

- Data Complete, Ready for Submission:
- Diguat (Regione): Harvest aid

Detition Pren None at this time.

Ongoing Studies:

- Glufosinate (Rely): Post-directed to row middles.
- injury. Study will be cancelled.



- Mesotrione (Callisto): Preplant and PRE. Severe

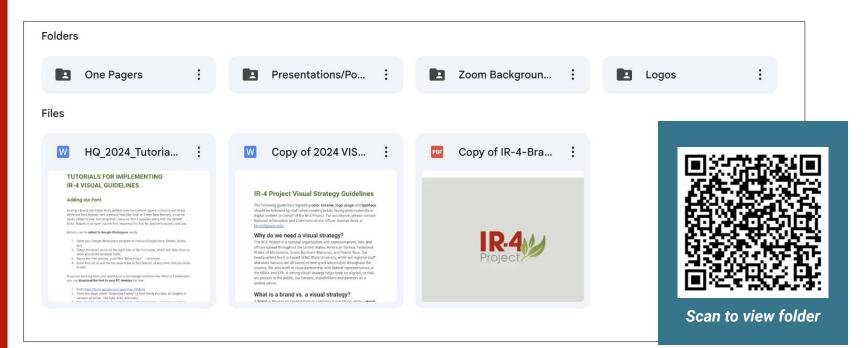


Preemergence¹

Recent US Tolerance Established and label pending:

Under EPA Review:

New, shareable Google Drive folder: Outreach Toolkit



Use this folder to share brand guidelines, promotional materials and templates with teammates and collaborators. This Google folder is an interim solution until intranet is live. Access is open to anyone with the link.



New Videos

- Now complete: 4 of 4 tutorials on our research cycle!
 - Latest addition: Priority Upgrade Proposals



NEW VIDEO

The IR-4 Priority Upgrade Proposal

Video links are now included on the Stakeholder Resources Page

Stakeholder Resources



The IR-4 Project works with stakeholders from the specialty crop industry, land-grant universities, commodity groups, registrants and other partners to provide safe and effective pest management tools for specialty crop growers. The following resources are here to help stakeholders get involved in our research cycle.

Video Tutorials Submitting a Project Clearance Request Nominating Projects for the Food Use Workshop The Food Use Workshop Process Priority Upgrade Proposals

Instructional Videos	Date Checked	# of Views
Submitting a Project Clearance Request	10/14/2024	174
Nominating Projects for the Food Use Workshop	10/14/2024	132
IR-4's Food Use Workshop Process	10/14/2024	156
Project Upgrade Proposal	10/14/2024	101
AI REV- Submitting a Project Clearance Request	10/14/2024	24
AI REV- Nominating Projects for the FUW	10/14/2024	11
General Videos	Date Checked	# of Views
The IR-4 Project: Sixty Years and Beyond	10/14/2024	384
60 Years of IR-4	10/14/2024	886

Video Project Findings

- Positive relationship built with Ruth Smith of **Rhombus Learning** in creation of 4 instructional videos; would utilize again in the future
- Partnering with **NCSU UComm** highly effective for promotional videos
- A challenge with instructional videos was narration: in-house approach was time-consuming and yielded inconsistent quality. Hiring a narrator is expensive. For final video, **AI narration** was a cost effective and satisfactory solution. We went back and updated PCR and Nomination videos with AI narration. Will use this from the get-go in the future.
- **Promotional videos** are highly valuable to our team as an outreach tool.
- Instructional videos have lower viewership but are effective tools, especially for new collaborators. The challenge is in presenting enough detail without making videos quickly obsolete; need to make content as evergreen as possible while still being granular enough to be helpful. For ex: video goes in depth on a particular form, then the form changes.



Digital Updates

Social Media, Newsletter, Website, Intranet



IR-4's 2024 EPA Specialty Crop Tour: A Celebratory Sign-Off For Van Starner

Enjoy highlights from this year's tour stops and learn about Van's contributions over 20+ years.



Hawaii's Cacao Industry Unites Around Goal to Become "Napa Valley of Chocolate"

Learn about IR-4's role in supporting Hawaiian cacao growers.



IR-4 Implements Electronic Field Data Book

Learn about IR-4's electronic Field Data Book rollout; by Raven E. Baez.

Read these stories at ir4project.org > About IR-4 > News



Spotlight on

Recent IR-4 Team Publications



Our communities and food systems are stronger and more vibrant thanks to our Latinx + Hispanic teammates, family, neighbors and friends!



Safe travels to the Food Use Workshop!





register at the early bird rate*!



Register & learn more: ir4project.org

*At midnight on 8/30, the rate will increase by \$100.

Today (8/29) is the last day to



-Megan James Hickman





Final prioritization lists posted!



News and Updates

Pest Management Solutions for Specialty Crops and Specialty Uses

Save the Date for IR-4's 2025 Industry Technology Session



- Maintaining a 30% average open rate (healthy rate =20-40%)
- Over 2,100 total contacts
- Net gain of 30 subscribers in past 3 months (steady growth)
- Newsletter is key comms channel for us - best way to encourage new folks to connect and stay in the loop is to have them subscribe.



INTRANET UPDATES

This resource library for internal team members is in the works
 Main goals: clean up ir4project.org by moving internal-only documents to a password-protected site; make resources easier to find; create a digital home for training materials and proprietary information

- WordPress development site established through NC State
- Unbranded theme = customized with IR-4 logo, colors
- Basic site architecture created (homepage, main menus, key content)
- Currently working with **HQ teammates** to plan + hone content
- Our contract **graphic designer** is lending WordPress expertise as needed
- Hannah has attended series of WordPress **content maintainer workshops** from NC State; site administrator class coming up this fall as well
- Western Region's IR-4 Works being used as helpful example
- Aim to have "rough draft" site ready for **review and testing** by more HQ and regional team members by **end of year/early 2025**

Sneak peek!



Food Program EH Program Lab

WISIT IR4PROJECT.ORG →



General

Welcome, IR-4 team!

Training

QA

The intranet is a library of resources designed to support your daily work.

UPDATES



Industry Technology Session

Save the date for our next event; February 20, 2025 \rightarrow



Looking for outreach materials?

Check out the new Outreach Toolkit for branded templates, logos and more.



Spring CLC/PMC Meeting Our annual joint meeting in D.C. will take place March 4-6, 2025.

INTRANET



AWARD UPDATES

Recent & Upcoming IR-4 Awards

2024 SOAR AWARDS

- 4 SOAR Award recipients selected for 2024
- Will be presented and awarded over the next few months
- One presented at FUW: JULIE COUGHLIN
- Another to be presented at NRPM/PMC reception

2024 SPECIAL RECOGNITION AWARDS (presented at FUW)

- Nancy Fitz, Minor Use Team Leader at U.S. EPA
- Dani Lightle, IR-4 FRD Oregon State University

MERITORIOUS & TECHNICAL SERVICE AWARDS

- To be presented at 2026 NEC
- We'll begin inviting regions to name their award recipients in 2025





NEC & Training

Presenter: Christina Dineen







2026 NEC & Training

IR-4 All Hands Meeting October 2024 Christina Dineen

2026 NEC in Charleston, SC

- Mark your calendars!
 - February 3-5, 2026
 - Embassy Suites by Hilton Charleston Airport Hotel & Convention Center

Committee Planning Activities

- Outside Speakers, Field Tour
- Ideas from IR-4
- Agenda









Training/Resources

Virtual Training Opportunities

RFC Quarterly Training Webinars (Field)

Summer Webinar (Aug 20) Hosted by Marylee/Nicole	*Upcoming* Fall Webinar (Nov 12) Hosted by Kristen
Completing eFDB eFDB: Compare processes, hardware, setup	EPA InspectionsWriting Deviations

- Sample collection & modifications, shipment
- Lessons learned this season
- Resources for growing (new) crops

Laboratory Trainings

First Lab Training!! (Sep 17)	*Upcoming* Second
Presented by Jeff Eichler	Lab Training (Nov 20)
Sample Arrival & Receipt	Sample Processing, TBD

Training/Resources

Environmental Horticulture

IR.4

About IR-4 ~

Food Crops v

Request for New (or Update to Existing)

Is there an issue/question/process that you feel could be addressed by the IR-4 Education & Training Committee as an Advisory or National SOP? Or do you think an existing

Advisory/National SOP could be updated? Share your thoughts/suggestions with us

IR-4 Advisory or National SOP

https://www.ir4project.org/fc/fcresearcher-resources/ir-4education-and-trainingcommittee/

Events & Training

Stakeholder Resources v

IR-4 Training Topic Suggestions/Ideas

Do you have ideas for training topics that would be valuable to you and your fellow IR-4

future NEC topics, etc. The possibilities are endless and we would like to hear from you!

researchers? This could be for new employees, field/laboratory topics, guarterly webinars,

Revamp E&TC Page

Submit a Request >

Forms for Suggestions

Looking Forward: Intranet

IR-4 Website

- NEC Page
- Recorded Trainings
- Other Training Options

Past Meeting Minutes for Approval







MINUTES Project Management Committee Summer 2024 Meeting July 9-11, 2024 Virtual Meeting

MOTIONS AND ACTION ITEMS

Motions/Consensus Items:

- 1. A motion to approve the Spring 2024 PMC & CLC Joint meeting minutes was made by Alvin Simmons, seconded by Todd Scholz; **unanimously approved.**
- 2. A motion to recess the meeting for the evening at 3:45pm was made by Jerry Baron, seconded by Liwei Gu; **unanimously approved.**
- 3. A motion was made to approve the parameters of the 2025 Field Research Food Program as outlined below:
 - 37 New "A" Priorities and 6 PUP/RUs "A" or "H+"
 - 9 Product Performance "H+" Priorities
 - 6 Integrated Solutions "A" Priorities and if funding remains move on to fund additional "B" Priorities
 - by Todd Scholz; seconded by Simon Zebelo; motion passed (1 absent: Alvin Simmons).
- 4. A motion was made to adjourn the meeting at 3:10 pm by Alvin Simons seconded by Liwei Gu; **unanimously approved.**

Votes Made Via Email In-Between Regular Meetings:

- The PMC voted via email for approval to provide biopesticide regulatory support to Soilcea in regards to CRISPR edited technologies to manage huanglongbing (HLB) in citrus. Approved by majority via written consent (1 decline: Liwei Gu; 2 abstentions: Jerry Baron and Mary Hausbeck).
- The PMC voted via email for approval to provide biopesticide regulatory support to USDA -ARS in regards to using SlaGemV1 mycovirus on sunflowers to reduce the virulence of disease causing Sclerotinia sclerotiorum. Approved by majority via written consent (1 decline: Matt Hengel; 3 abstentions: Jerry Baron, Mary Hausbeck, and Alvin Simmons).
- 3. The PMC voted via email to decline the provision of biopesticide regulatory support to Amalgamated Sugar Cooperative for the registration of Funibiol eucalyptus extract for disease management in sugar beets. **Declined by majority via written consent (2 abstentions: Jerry Baron and Alvin Simmons).**
- 4. The PMC voted via email for approval of Michelle Starke of CoverCress's membership to the Commodity Liaison Committee. **Unanimously approved by written consent.**

Action Items:

1. Action Item: J. Baron will reach out to biopesticide partners/stakeholders to request their review and input of the proposed biopesticide regulatory support review process and report back to the PMC.

- 2. **Action Item:** K. Chojnacki will reach out to financial contact at each regional subaward institution to request information on what will be needed for NCE moving forward.
- 3. Action Item: J. Baron will add an Integrated Solutions listening session to the 2024 Food Use Workshop Agenda and add a follow up agenda item for the fall PMC meeting.

Members:_

Jerry Baron; IR-4 Executive Director Doug Buhler; Administrative Advisor-NCR Rubella Goswami, USDA-NIFA Liwei Gu; Regional Director-SOR Mary Hausbeck; Regional Director - NCR Matt Hengel; PMC Chair; Regional Director-WR Marcel Holyoak; Administrative Adviser – WR

Presenters:_

Alice Axtell, IR-4 HQ David Beaudreau; DCLRS Michael Braverman; IR-4 HQ Debbie Carpenter; IR-4 HQ Krystal Chojnacki; IR-4 HQ Christina Dineen; IR-4 HQ Anna Gore; MUF Cristina Marconi; IR-4 HQ Johanna Mazlo; IR-4 HQ Steve Lommel; Administrative Adviser- HQ Todd Scholz; CLC Chair Alvin Simmons; USDA-ARS Simon Zebelo; Regional Director - NER

Philip Moore; IR-4 HQ Cristi Palmer; IR-4 HQ Jaimin Patel; IR-4 HQ Thomas Pike; IR-4 HQ Josh Peterson; IR-4 HQ Hannah Ross; IR-4 HQ Robert Welker; IR-4 HQ John Wise; Consultant

Tuesday July 9, 2024 11:00 am to 4:00 pm ET

Matt Hengel called the meeting to order at 11:01 am.-

- 1. Welcome and Introductions.
 - M. Hengel welcomed the group, reviewed virtual meeting etiquette, and initiated introductions around the room and on Zoom.
- 2. Approval of minutes & new agenda items. (Handout)
 - M. Hengel asked the PMC if there were any additional changes to be made to the minutes, several typos were corrected; none additional offered.
 - A motion to approve the Spring 2024 PMC & CLC Joint meeting minutes was made by Alvin Simmons, seconded by Todd Scholz; unanimously approved.
- 3. Administrative Advisors Updates
 - NCR: D. Buhler stated that he will be presenting on the NRSP renewal during a later agenda item.
 - NC State: S. Lommel reported that things have reached equilibrium at NC State in terms of personnel, operations and facilities and that he will defer the rest of his time for the NRSP renewal.
 - Jerry Baron added that Dr. Rich Bonanno is leaving NC State as the Extension Director and moving into the position of Executive Director of Southern Region Extension Directors Association.

- WR: M. Holyoak reported that they are recruiting a new Dean of their college and there are other changes in campus leadership as well; seismic renovations are still planned; and that operations are overall going well.
- ARS: A. Simmons shared comments on behalf of J. Munyaneza; and that ARS leadership expressed their appreciation of the work and partnership of the IR-4 Project.
- NRSP- 4 Renewal (Handout)
 - D. Buhler reported: that the notice to renew has been submitted; that there has been work on the approach to ensure that funding levels are maintained; and work to provide a response to the outcomes of the mid-term review.
 - J. Baron reported: that he visited with the four Regional Associations of Agricultural Experiment Station Directors and provided an overview of the current environment of pest management domestically and abroad including the implications of judicial rulings; and requested the group to reconsider the proposed cut to funding.
 - S. Lommel reported: that the sentiment to cut was grounded in eliminating perpetual NRSP funding to groups as well as the prospect of increased funding to IR-4 from NIFA; that the shift to organics and biologics positions IR-4 in an important way especially in the Chevron Doctrine ruling; and that climate change is bringing forth new pest issues that IR-4 is geared toward addressing.
 - A discussion was held regarding providing regional critical challenges and examples that link to IR-4 up front in the renewal request; regulatory authority is increasing, as is climate uncertainty and disease uncertainty; and that IR-4 has to be robust so it can pivot and be responsive to those uncertainties.
- ARS Umbrella Account Funds
 - A. Simmons reported: that there was a Congressional appropriation budget cut to ARS that resulted in a loss of umbrella account funding as well as others; the Commodity Liaison Committee (CLC)/ Friends of IR-4 wrote to ARS leadership to maintain these umbrella funds and ARS responded that they will make whole the funds for 2025 for the IR-4 Cooperative Agreement.
 - A discussion was held regarding a new "Dear Colleague" letter that was being drafted to maintain the funds that support IR-4-related work at ARS offices; that IR-4 was able to support the EHC work for a year, but that was not sustainable; and that there have been contingency plans developed in the amount of projects funded in the future if these funds are permanently removed.
- 4. NIFA Update
 - R. Goswami provided an update: thanking IR-4 for submitting the Congressional report; the NIFA budget has been reduced by 37 million and travel has been reduced as a result; the upcoming Farm Bill and calls for data and how NIFA can amplify our news stories; the FY 2024 grant has been submitted and NIFA hopes to return the continuation promptly; the next year grant would move to a non-competitive grant and that when it does, IR-4 should attach an NRSP mid-term review to the non-competitive application.
 - A discussion was held regarding NIFA representation on the NRSP committee.
- 5. CLC & Friends Update
 - T. Scholz provided an update on: membership currently 31- and working on adding several more members; appreciation for inclusion of CLC representation on the PMC; the status of subcommittees (government); activities to secure increased funding and working with DCLRS to make visits impactful.

- D. Beaudreau reported: the House Agriculture Appropriations Bill is being marked up tomorrow and thus far IR-4 has seen an increase; the current status of the Farm Bill and potential passage timeline; and reported that Friends of IR-4 currently has 26 members.
- A discussion was held regarding the mechanism by which IR-4 funds are allocated (Farm Bill vs Appropriations funding).
- 6. Unit Updates
 - NCR: M. Hausbeck provided a report on: decommissioning the South Dakota site this year and the need to have the QA audits in prior to that; an electronic field data notebook training in the spring; a State Liaison Representative (SLR) meeting held in spring; and the status of a problematic field trials.
 - A discussion was held regarding the reasoning for the decommissioning of the South Dakota site; and headquarters reaching out to the missing SLR states in the region.
 - NER (Handout): S. Zebelo provided a report on: the year 2 and 3 NIFA sub on subaward status and budget for no-cost extension; year 4 UMES subaward grant documents have been submitted; trials underway including QA and QC being conducted; eFDB GLP training that was held in the region; the US EPA crop tour was held in the NCR in June and NCR staff was able to attend; SLR meetings were held to discuss research needs; and research work in the Zebelo lab that is underway.
 - SOR (Handout): L. Gu provided a report: that Kristen has been doing a great job as the Interim Regional Field Coordinator; interviews will start next week for the RFC position; QC is going well; there was a loss of a FRD in the Homestead site and tropical trials are being relocated or delayed; there was a vacant chemist position and the position has been filled with the candidate starting later this year; the status of delayed ASRs; and QA is on schedule to finish their workload as planned.
 - WR: M. Hengel reported: that field trials are progressing as scheduled and books are being returned at a good pace; Dr. Arnold has been reaching out to stakeholders in the region to bring awareness around IR-4; held an SLR meeting in April in Hawaii; Sherita Normington retired from the QA unit and a new QA coordinator has been hired: Laurel Hsieh; the lab is in good shape and working on method development for several projects; several publications have been released out of the lab; the UC Davis the seismic retrofit will require the lab to move in the spring of 2025; and that UC Davis continues to struggle with their sponsored program getting their funding out their researchers.
 - A discussion was held regarding the journal that the publication was submitted and the increasing costs at some research sites.
 - ARS: A. Simmons reported: on the success of a controlled environment conference put on by ARS; on staffing levels and promotions at the various ARS laboratory facilities and research sites and that the leadership at the sites are committed to the IR-4 work; they are working to address backlog issues within the labs and updating SOPs; and funding challenges at some of the ARS sites due to budget cuts.
 - HQ (Handout): J. Baron reported: on the current headquarters organizational chart; that staff are quickly learning their new roles; and reviewed new hires.

Break at 1:03. The meeting reconvened at 1:20 pm.-

- 7. Program/Platform/Committee Updates
 - Food Program
 - Field Residue Studies (Handout)

- C. Marconi reported on the status of field data notebooks with the FRD, RFC, QA or Headquarters and on internal challenges such as analytical backlog and delayed field data books.
- Submissions (Handout)
 - T. Pike reported on regulatory challenges that impact submissions such as the Endangered Species Act (ESA), registration statuses of active ingredients in Europe, and holds on submissions by companies.
- Laboratory activities (Handout)
 - D. Carpenter reported on the status of each analytical laboratory, the plans for addressing challenges in labs moving forward, and addressing data quality in labs.
 - A discussion was held regarding the time needed to perform a stabilization study.
 - M. Hengel reported on the status of implementing a periodic training program for lab personnel, topics that will be covered, and the goal of giving all lab personnel a standard base of knowledge.
- Quality Assurance Unit (Handout)
 - J. Mazlo reported: EPA has a new inspector; QA completed an EPA inspection on an olive study; QA is working to decommission two sites; QA has been working closely with the eFDB rollout; and provided an update on new personnel and activities of the QA unit.
- Product Performance & Integrated Solutions (Handout)
 - A. Axtell reported: on the increase in product performance studies prioritized at the food use project; the number of trials and funding needed to complete 2023 and 2024 research including projects still on hold; the number of integrated solutions projects prioritized and trials underway for 2024; the number of trials and funding needed to complete trails from the 2023/2024 research plan; and reviewed the plans for the Industry Technology Session and the 2024 Food Use Workshop.
- Biopesticide Regulatory Support Update (Handout & Presentation)
 - M. Braverman provided an update and overview of the new biopesticide regulatory database; shared hurdles with building out the new database
 - M. Braverman reported: on the status of EPA submissions; new projects under development; future projects in the timeline; and announced his retirement.
 - Sentiments of appreciation for the work and contributions of Michael Braverman were shared.
- International/Minor Use Foundation (MUF)
 - A. Gore reported on the Global Minor Use Summit that took place earlier this year and reviewed the outcomes and key takeaways of the summit that the MUF is working on implementing; on the CODEX Committee on Pesticide Residue (CCPR) meeting; USDA has put out a call for proposal for the Assisting Specialty Crop Exports (ASCE) and the MUF is submitting a proposal; and Bill Barney will be participating in the 2024 Food Use Workshop to see where partnerships could take place.
 - J. Baron congratulated Anna Gore on her appointment as Executive Director of MUF.
- Environmental Horticulture (Handout)
 - C. Palmer reported on outcomes and impacts; 65,090 crop uses as of the end of June for the program's history; outstanding data reports; joint pilot project on thrips; and provided a wrap-up of the program over the past years.

- Sentiments of appreciation for the work and contributions of Cristi Palmer were shared.
- Communications (Handout)
 - H. Ross reported: on the 2024 visual strategy update; latest print materials including regional one pagers; new videos released and planned; digital updates including stories, social media, the newsletter and website; an update on the intranet project; and that the SOAR award nomination period is now open.
- Training Committee and other training activities (Handout)
 - C. Dineen reported: on the 2026 NEC planning underway; completed national SOPs and those in progress; magnitude of residue protocol template revision; updated IR-4 advisories; and national virtual training underway and planned.
 - A discussion was held regarding including the training committee chair in the lab training.
 - R. Welker provided a preliminary outline on the Field Research Director training and reported on work to create a slide deck and modules for the training.
- Technology Committee (Handout)
 - J. Peterson reported on results of a preliminary survey on technology needs including the IR-4 database and QA data management system updates.
- Network Expansion Project (Handout)
 - J. Patel reported: there are currently 9 members that meet monthly; publications submitted and underway; outreach and talks at conferences; and informational videos produced to bring about awareness about the priority setting process.
- 8. Proposed Parameters of 2025 field research program (Handout)
 - A. Axtell reported: on the proposed 2025 budget as compared to 2024; the number of residue and performance trials the funding will support along with other funding sources; reviewed scenarios of funding models for Integrated Solutions (IS) projects; and the total number of projects (by type) available for selection at the 2024 Food Use Workshop.
 - A discussion was held regarding: an alternate number of projects to be funded through the Integrated Solutions Platform; if the IS program has been refined in terms of measures of success; the flat budget for the EHC platform and if an increase could boost our recruitment efforts for a new EHC Program Manager; IR-4's commitment to the EHC platform; and revisiting the IR-4 cost of trial reimbursement for ornamental research.

A motion to recess the meeting for the evening at 3:45pm was made by Jerry Baron, seconded by Liwei Gu; unanimously approved.

Wednesday July 10, 2024 11:00 am to 4:00 pm ET

Matt Hengel reconvened the meeting at 11:01 am. --

- 9. Pesticide Program Dialogue Committee (PPDC)Update (Presentation)
 - J. Wise presented on the EPA's PPDC spring meeting, including refining maps that determine where endangered species are and impacted farms; a commitment from EPA to make mitigations more flexible; the herbicide strategy in place and forthcoming insecticide and fungicide strategies; label identifiers proposed related to the Endangered Species Act (ESA); and plans related to the ESA full roll-out.

- Proposed mitigation measures and the lack of data on whether the pesticide would actually harm the endangered species were discussed.
- 10. i-Advantage electronic Field Data Notebook update (Handout)
 - P. Moore reported on the statistics associated with the eFDB usage; training and support activities; new processes that resulted from the eFDB roll-out; challenges and changes that have resulted from the implementation; and the overall acceptance of the program from FRDs and other users.
- 11. Crop Protection technology trends/takeaways and challenges (Handout)
 - J. Baron shared takeaways from annual company meetings and industry trends, including new requests being down, EPA's stoplight analysis is "freezing" more requests, a low number of new pesticide chemistries from registrants, a low number of companies presenting at the Industry Technology Session, and research allocation observations.
 - J. Baron reported results and trends from investigating the future of biopesticides and emerging technologies, opportunities for growth in research in this area, and IR-4's biopesticide regulatory work to support registrations.
 - A discussion was held regarding: synergies of this work with the MUF; the possibility of IR-4 to conduct biopesticide studies; efficacy work and lab analysis needed for the registration of biologicals; whether or not this work is required by the EPA to be conducted under GLPs; drawing on the areas where biologicals have been a success to extend the uses of existing chemistries; and clarifying the purpose of Integrated Solutions.
 - A further discussion was held regarding reaching out to folks who had Integrated Solutions Projects in the past to learn what worked and what did not and the reduction in the number of researchers conducting residue work over the years.

Break at 1:00 pm. The meeting reconvened at 1:20 pm. -

- 12. Ways of Working in Food Program Addressing partners issues (Handout)
 - D. Carpenter reported on: operational challenges including funding, timing of partner input, test and reference substances, and modernization of systems; and potential solutions to those challenges including changes to IS priority setting at the Food Use Workshop.
 - A discussion was held regarding: the high cost of test substance; adopting the Canadian timeline; renaming IS to something more clear; holding a biennial IS workshop; if the eFDB is reducing the timelines; how adjusting the timelines impact industry/growers; and having a separate biological technology session.
- 13. Process improvements in the IS Platform (Handout)
 - A. Axtell reported: on the newly expanded research areas and products/devices/practices; updates to the website to provide clarity on the program; updates to the IS database and the search tools including a forthcoming updated request form; and requested help to get the word out about this program.
- 14. Biopesticide Regulatory Support Platform detailed discussion (Handout)
 - J. Baron reviewed an outline of a new process for new requests for biopesticide regulatory assistance including: a preliminary assessment; company/supporting group commitment to register; and secondary vetting by a qualified review team to determine if regulatory support will be provided.

- A discussion was held regarding vetting the process with CLC biopesticide representatives and EPA, current projects in the pipeline for approval, if information would be on our website to direct people to, and that the point system is a good idea and will help to give feedback to applicants.
- Action Item: J. Baron will contact biopesticide partners/stakeholders to request their review and input on the proposed biopesticide regulatory support review process and report back to the PMC.

15. Closing out the current grant (Handout)

- K. Chojnacki reported on the parameters of the current grant, the difference in the period of performance between year 1 and the new continuation, a no-cost extension issue, the period of performance moving forward, and managing end dates.
- A discussion was held regarding: distribution of researcher funds and completion of spending within two years; and issues with giving funding in arrears with the move award from regular residue work; and the possibility to write a proposal and make a request for two years' worth of funding in year 1&2.
- Action Item: K. Chojnacki will contact the financial contact at each regional sub-award institution to request information on what will be needed for NCE moving forward.

16. Future Meetings

- 2024 Food Use Workshop Milwaukee; September 10-12, 2024
- Fall PMC/NRPM-Raleigh; October 21-25, 2024
- Joint Spring PMC/CLC meeting Washington; March 4-6, 2025
- 2025 Food Use Workshop Denver/TBD September 9-11, 2025
- 2025 Environmental Horticulture Workshop Raleigh/TBD October 2025
- National Education Conference TBD; February 1-5, 2026

A discussion was held regarding hosting a summer virtual meeting every other year and an in-person every other year with a tour (with a virtual option) and the first meeting should be a joint meeting in Canada.

A motion to adjourn the regular session at 3:19 pm and to move to Executive Session was made by Alvin Simmons; seconded by Todd Scholz; unanimously approved.

The meeting recessed for the evening at 3:21 pm. --

Thursday July 11, 2024 - 11:00 am to 4:00 pm ET

Matt Hengel convened the Executive Session at 11:00 am. --

17. Executive Session

Break at 1:40 pm. The meeting reconvened at 2:00 pm. -

The members reconvened into regular session at 3:09 pm with the following motions or actions:

- A motion was made to approve the parameters of the 2025 Field Research Food Program as outlined below:
 - 37 New "A" Priorities and 6 PUP/RUs "A" or "H+"

- 9 Product Performance "H+" Priorities
- 6 Integrated Solutions "A" Priorities and if funding remains move on to fund additional "B" Priorities
- by Todd Scholz; seconded by Simon Zebelo; motion passed (1 absent: Alvin Simmons).
- Action Item: J. Baron will add an Integrated Solutions listening session to the 2024 Food Use Workshop Agenda and add a follow up agenda item for the fall PMC meeting.
- 18. Adjourn

A motion was made to adjourn the meeting at 3:10 pm by Alvin Simons seconded by Liwei Gu; unanimously approved.

Distribution of 2024 Funds & end of existing grant cycle

Presenter: Dr. Krystal Chojnacki







Distribution of 2024 Funds & end of existing grant cycle

Krystal Chojnacki



Existing/Current Grant

2024 Grant Fund Distribution



- Complete! All Regional subaward amendments have been completed.
- All SOR region researchers based at NC State have received their first 50% of funding allocation for 2024 trials.



Subaward end dates

FOR THE EXISTING GRANT/Subawards

- The Year 5 (NCE year) will end July 31, 2026. All funding must be expended by this time by NC State.
- Subawards will be processed with an end date of April 31, 2026
 - *Reason:* If a subaward returns funding, we need time to spend the amount returned prior to the grant closing date of July 31, 2026.
 - We do not want to return funds.



Researcher end date

- Researchers receive 2 years to expend funds.
- Majority of researchers at **NC State** have struggled to zero out their projects prior to the end date.
 - As a result: Move their end dates up 3 months in the Y5 NCE period to allow IR-4 to expend the funds.
 - End date will be <u>April 31, 2026</u>
- Again, we do not want to return funds.





New Grant

Period of Performance - New Grant

- We have been told the grant is again being processed as a continuation (1 year increments)
 - In that case, we only get 1 NCE and can only use it in the last year
 - Grant timing is mid field season issues with keeping research going.
- We will request for NIFA to put the full performance period (but this is not guaranteed in a continuation grant).
- Alternatively, we will need to know your host institution will need to allow you to keep spending. Such as:
 - The fact that it will be a 4 year grant is listed in the RFA. NC State can add the RFA as an attachment to the award.
 - A note in the award that this is a 4 year continuation grant.



LEARN MORE

ir4project.org ir-4_project@ncsu.edu

Commodity Liaison Committee (CLC) Update: New Member

Presenter: Todd Scholz







AMERICAN SPICE TRADE ASSOCIATION, INC.

1101 17th Street, N.W. • Suite 700 Washington, DC 20036 USA Tel: 202-331-2460 • Fax: 202-463-8998 E-mail: info@astaspice.org Web: www.astaspice.org

August 23, 2024

Mr. Todd Scholz Chair, Commodity Liaison Committee The IR-4 Project Venture IV, Suite 210 Raleigh, NC 27606

Dear. Mr. Scholz,

I am writing to formally request consideration and approval for membership on the Commodity Liaison Committee (CLC) of the The IR-4 Project.

If granted membership, I would serve as a representative of the American Spice Trade Association (ASTA), which is the trade association that represents the interests of the herb and spice industry in the U.S. I have served as Executive Director of ASTA since September, 2018. In this role, I represent more than 200 companies that grow, process, manufacture, import and trade spices. Our members include producers of spices and herbs, which are minor specialty crops, in the U.S. and overseas. I work on a variety of issues related to pesticides and crop protection and have submitted several pesticide petitions to EPA. Additionally, we advocate for harmonization with global pesticide regulations and have submitted project clearance proposals to The IR-4 Program.

Prior to this role, I served as the Vice President of Scientific and Regulatory Affairs for the National Confectioners Association. In this position, I also worked on pesticide issues for cocoa beans, which is a specialty crop, including several projects in conjunction with The IR-4 Program.

My entire career has focused on addressing technical and regulatory issues, including navigating pesticide regulations and petitions, for specialty commodities, which suits me well for the CLC.

I would welcome the opportunity to serve alongside you and the other CLC members. Please find my C.V. enclosed.

Warm regards,

Laura Shumow Executive Director American Spice Trade Association

LAURA SHUMOW 4119 7th St NW, Washington DC (630) 542-3482

lbshumow@gmail.com

SUMMARY

Food trade association executive with 14 years of experience in food regulatory and policy issues and trade association management. Demonstrated record of success in regulatory advocacy, issue management, and association leadership. In-depth knowledge of U.S., state, and global food regulatory, labeling and food safety issues, as well as established relationships with food regulatory leadership within FDA, USDA, and EPA. Ability to manage trade association operations.

EXPERIENCE

American Spice Trade Association (ASTA), Washington DC

2018-Present

Executive Director

Responsible for executing the association's strategic objectives and management of association operations and staff. Liaise with Board of Directors to develop and execute strategic objectives related to advocacy, food safety, and sector-wide collaboration. Collaborate with regulators, allied trade associations, and other stakeholders on global regulatory issues. Provide strategic direction on industry-wide regulatory, food safety, & quality challenges. Serve as a spokesperson and representative of the spice industry.

- Effectively advocated to halt unachievable action levels for heavy metals in spices in New York state, managed industry response to media pressure on heavy metals in spices and oversaw research on mitigation of heavy metal uptake of spice crops from the environment.
- Led strategy to reduce regulatory risk from non-compliant pesticide residues on spices through expansion of EPA pesticide tolerances for spices and spice farmer training programs in countries of origin.
- Collaborated with FDA and academic researchers to develop guidance on validation of spice process controls for groupings of spices, and oversaw research and education on validation of specific spice process controls (e.g. irradiation, fumigation, steam sterilization).

National Confectioners Association (NCA), Washington DC

2009-2018

Vice President, Science and Regulatory (2016-2018)

Led regulatory and scientific affairs function and Chocolate Council. Maintained relationships with key policymakers relevant to food industry (FDA, USDA, EPA, etc.). Developed consensus positions, drafted comments, advocated on regulatory issues and represented confectionery industry to federal agencies and congressional offices. Oversaw regulatory compliance and nutrition policy staff.

- Worked with outside counsel and member companies to obtain an industry-wide consent judgement under Prop 65 to establish concentration limits for lead and cadmium in chocolate products to prevent litigation.
- Obtained a new tolerance for the fungicide metalaxyl on cocoa to alleviate import compliance challenges.
- Fostered collaborative dialogue on research to mitigate milk allergen cross-contact between FDA and chocolate processors.

Senior Director, Science and Regulatory (2014-2016)

Executed association's regulatory advocacy and compliance education agenda on labeling and food safety issues. Served as staff liaison to the Chocolate Council by providing support on cocoa import challenges including traceability, contaminants, and child labor. Led global regulatory strategy and served as secretariat of the International Confectioners Association.

• Represented confectionery industry at Codex Committee on Contaminants in Foods and Codex Committee on Food Additive meetings.

- Advocated on labeling issues (BE, NFP, vending labeling, slack fill) on the hill and with USDA and FDA.
- Conducted research on pesticide use on cocoa in Indonesia and developed public-private intervention project with Ministry of Agriculture and farmer cooperatives.
- Oversaw labeling and food safety education, including organizing and teaching PCQI training courses, and drafting industry wide guidance documents on compliance with PCHF.

Director, Science and Regulatory (2011-2014)

Responsible for execution of nutrition policy strategy. Oversaw Science and Regulatory Committee, Health and Wellness Committee, and other relevant committees and task forces. Developed and implemented multiyear strategic nutrition research plan, including publication of research, scientific presentations and sessions at academic conferences. Fostered relationships with nutrition and regulatory thought leaders from academic institutions, federal agencies, health professional and non-governmental organizations.

- Developed messaging and drafted comments on role of treats in the Dietary Guidelines for Americans, and labeling initiatives, including Nutrition Labeling Reform, FOP, vending labeling, etc.
- Oversaw research program to investigate positive role of cocoa, chocolate and treats in the diet and organized sessions at academic and nutrition professional conferences (Experimental Biology, Academy of Nutrition and Dietetics).
- Led initiative to retain candy in the White House Easter Egg Roll following announcement of removing candy as part of the Let's Move Campaign.
- Promoted participation in confectionery Treat Right responsibility platform.

Manager, Technical and Regulatory (2009-2011)

Responsible for monitoring regulatory and policy developments relevant to the confectionery industry related to labeling, food safety, allergens, nutrition policy, food standards, California Prop 65, pesticides, and ingredient safety. Organized seminars, webinars, educational resources on labeling and food safety issues. Researched and provided responses to regulatory compliance questions from members.

- Drafted weekly newsletters for members on regulatory updates.
- Organized webinar series on *Salmonella* validation in nuts and cocoa.
- Developed in-person educational workshops on HACCP, GMPs, labeling, and confectionery formulation.

General Mills, Minneapolis, MN

Research & Development Intern

Responsible for granola bar reformulation projects.

- Identified potential formulations and ran trials on alternative sweetener systems to replace high fructose corn syrup and optimize costs of sweetener systems.
- Tested various brown rice syrups to identify the closest match to replace a discontinued ingredient from sole supplier.
- Performed sensory testing, label review, and shelf-life studies.

ADM Cocoa, Koog aan de Zaan, the Netherlands

Research Intern

Conducted research projects on applications of alkalized cocoa powder in baked products.

- Worked with customers to adjust chocolate wafer formulation for different types of cocoa powder. Conducted trials
 on moisture absorption in chocolate cookie applications using different degrees of alkalized cocoa.
- Drafted a technical brochure on applications of alkalized cocoa in various bakery products.

2008

2007

PROFESSIONAL BOARDS

- DC-Section IFT Board of Directors (Member-at-Large, Secretary, President)
- IFT Food Laws and Regulations Division Chair
- Food and Beverage Issue Alliance (Treasurer, Regulatory Committee Chair)

EDUCATION

2008-2009	Johns Hopkins Bloomberg School of Public HealthMasters in Health Science - Toxicology	Baltimore, MD
2003-2008	University of Wisconsin	Madison, WI
	 Bachelors of Food Science 	

Certificate in International Agriculture

Northeast Region Report

Presenters: Dr. Simon Zebelo





Northeast Region PMC Report

July 1 – September 30, 2024

M. Ross, M. J. Hickman, S. Zebelo and J. Forder

Program Summary

Trials At-A-Glance

Food Use MOR Trials - Summary	2022	2023	2024
Trials Placed	29	30	26
Canceled Trials	6	2	1
Completed Trials	23	28	19
FDBs/eFDBs Completed	23	28	0
Completed QC Reviews	23	28	0

Food Use Performance Trials - Summary	2022	2023	2024
# of Trials	10	20	17
Completed Trials	10	18	17
Reports Submitted	10	14	1

Env. Hort Efficacy - Summary	2022	2023	2024
# of Protocols	6	4	5
Projects Placed	6	4	5
Canceled Projects	0	0	0
Reports Submitted	5	2	0

Env. Hort Crop Safety - Summary	2022	2023	2024
# of Protocols	1	1	3
Trials Placed	21	21	19
Canceled Trials	0	0	0
Reports Submitted	21	12	0

Integrated Solutions- Summary	2022	2023	2024
# of Trials	10	8	7
Completed Trials	10	7	7
Reports Submitted	10	6	0

NORTHEAST REGION REPORT – FALL 2024

Update from the Director's Office

UMES continues processing a no-cost extension (NCE) for the 2023-2024 FY budget. The 2023-2024 FY (Year 3) sub-sub awards release is progressing well, see the table under for details, and for those serving as FRDs and SLRs, we are processing the subaward and SLR travel budget together. The 2024-2025 FY(aka, Year 4) budget was received, and we are establishing an account number and preparing to send the sub-sub awards.

Activities	2023-2024(Year 3)
Subawards completed	26
Number of Sub awards Signed	24
PR completed	19 (plus 5 for UMD)*
PO processed	8 (plus 5 for UMD)*
Invoices received	13
Checks issued	10
NCE Requested	10

UMES- School of Agricultural and Natural Sciences (SANS) completed renovating a hoop house with a cooling and heating system, and we are running EHC trials.

UMES' email system has moved from Google to Outlook, and UMD/UMES is moving to a new financial system. This change in the financial system might create some delays in processing the subawards.

I attended the 2024 Food Use Workshop from September 10 to 12 in Milwaukee, Wisconsin. I have also been attending some of the monthly IR-4 National Expanding Taskforce (NET) meetings.

The IR-4 NER team had several regular virtual meetings. Thanks to the hard-working colleagues Marylee, Megan, Jane, John, Josh (UMES research office), SLRs, and the researchers, things are progressing well in the NER.

Regards,

Simon Zebelo

Update from the Regional Coordinator's Office

Hello,

It seems like I start every note from the RFC's office saying that time flies and we've been very busy. Well, it is true every time.

In July, I visited our Field Research Directors (FRDs) in New Jersey spending one day at Rutgers Snyder Research Farm and one day at Rutgers Agriculture Research and Education Center in Bridgeton. It is no surprise that Jennifer Fisher and Wesley Bouchelle are doing a terrific job. We held our NE Region Priority Setting Meetings in preparation for the Food Use Workshop. We were hopeful for greater participation, but we were able to establish a proficient ranking and plan for the Northeast Region specialty crop challenges.

In August, we hosted a Twilight Tour at LESREC for regional researchers and stakeholders. It was a gorgeous evening and the participants filled 2 hay wagons for a tour around our farm. We saw a lot of interest when I spoke about our IR-4 program. Several of the other researchers presenting also spoke of IR-4's service to growers and the IR-4 trials they have completed.

We attended a Twilight meeting at University of Delaware Carvel Research and Education Center. There was a considerable amount of reference to IR-4 as the researchers explained the work they were doing.

I met with University of Maryland's new communications specialist, Haley Moore. I described our program and she is currently working on developing outreach within UMD about IR-4. Our intention is to introduce her to Hannah Ross to enhance the impact of our outreach. I also met with Jimmy Smith UMD's new Principal Specialist in International Programs in Agriculture and Natural Resources. He was fascinated to learn about our program and showed great interest in learning more.

We assisted with the summer National GLP Webinar. That went very well.

I made a trip to Lange Research in North Rose, NY to visit with Tessa Lessord who conducts performance trials for us and Keagan Handley who conducts Magnitude of Residue trials for us. Lange is a top-notch contract research facility.

There were many calls and meetings concerning the eFDB, National SOPs, planning for the FUW, etc. We held several RFC calls leading up to the Food Use Workshop in an effort to ensure efficiency as we worked through all of the nominations to identify the top priorities to best serve our stakeholders.

We were pleased with our NE region participation at the FUW and we achieved many of our goals.

I am impressed with the efforts and success shown by our FRDs as they adapt to the electronic Field Data Book. The eFDB is not without its glitches, but our FRDs are doing an excellent job!

As always; proud of IR-4 and dedicated to our growers,

marylee

Program Report

Food Use Program

Magnitude of Residue

In 2024, twenty-six magnitude of residue (MOR) trials are being conducted in the Northeast Region. MOR field trials were conducted in four locations, including:

- Lange Research, Inc., North Rose, NY (Contract Research Facility)

- Lower Eastern Shore Research and Education Center, Salisbury, MD (University of MD)

-Rutgers Snyder Research and Extension Farm, Pittstown, NJ (Rutgers University)

-Rutgers Marucci Center for Cranberry and Blueberry Research, Chatsworth, NJ (Rutgers University)

Nineteen sample sets have been shipped and no electronic Field Data Books (eFDBs) have been completed yet. All Quality Control (QC) reviews have been completed for 2023.

NORTHEAST REGION REPORT - FALL 2024

Performance

In 2024, seventeen performance trials are being conducted in the Northeast Region. The Efficacy and Crop Safety trials are being conducted at eight locations.

Efficacy and Crop Safety trials are being conducted at:

- Rutgers Center for Blueberry and Cranberry Research and Extension, Chatsworth, NJ (Rutgers University)
- Rutgers Agriculture Research and Education Center, Bridgeton, NJ (Rutgers University)
- Agricultural Experiment Station, Geneva, NY (Cornell University)
- Long Island Horticultural Research Lab, Riverhead, NY (Cornell University)
- University of Maryland Main Campus, College Park, MD (University of Maryland)
- University of Connecticut Main Campus, Storrs, CT (University of Connecticut)
- Carvel Center for Agricultural Research, Georgetown, DE (University of Delaware)
- Wye Research and Education Center, Wye Mills, MD (University of Maryland)
- WVU Plant Diagnostic Clinic, Morgantown, WV (West Virginia University)

To our knowledge at this time, all trials have been completed and one report has been submitted.

Environmental Horticulture Program

In 2024, there are five efficacy protocols and three crop safety protocols. Under these protocols, we placed five efficacy projects and nineteen crop safety trials.

The five efficacy projects are being conducted at:

-Long Island Horticultural Research Lab, Riverhead, NY (Cornell University)

- WVU Plant Diagnostic Clinic, Morgantown, WV (West Virginia University)

The nineteen crop safety trials are being conducted at:

-Long Island Horticultural Research Lab, Riverhead, NY (Cornell University -University of Maryland College Park, College Park, MD (University of Maryland)

To date, no reports have been submitted.

Integrated Solutions

In 2024, seven Integrated Solutions trials are being conducted.

The trials are being conducted at:

- -Agricultural Experiment Station, Geneva, NY (Cornell University)
- -Long Island Horticultural Research Lab, Riverhead, NY (Cornell University)
- -University of Delaware Carvel Research & Education Center, Georgetown, DE (University of Delaware)
- -Massachusetts Agricultural Experiment Station, Amherst, MA (University of Massachusetts)
- -Rutgers Marucci Blueberry and Cranberry Experiment Station, Chatsworth, NJ (Rutgers University)
- University of Maryland College Park, College Park, MD (University of Maryland)

To date, all trials have been completed and no reports submitted.

Quality Assurance

During the period of this report, I [Jane Forder] conducted 12 field in-life inspections, 7 in the Northeast Region and 5 in the North Central region. I conducted 1 field data book audit, 2 final report audits and I performed a second review on 1 final report, and I performed 1 closing report check. I performed 2 facility inspections in the North Central Region.

Southern Region Report

Presenter: Dr. Liwei Gu







Institute of Food and Agricultural Sciences Food Science and Human Nutrition Department Food and Environmental Toxicology Lab IR-4 Southern Region



1642 SW 23rd Drive PO Box 110270 Gainesville, FL 32611-0270 352-294-3983 352-392-9467 Fax

Southern Region Report for PMC

Liwei Gu, Kristen Searer-Jones, Gail Mahnken, and Kathleen Knight October 15, 2024

1. Field programs and QC

The search committee selected Kristen Searer-Jones to be our next Regional Field Coordinator. She started on September 13, 2024.

QC of FDBs:

2022 trials – 87 of the 90 2022 FDBs have been received as of early October. Outstanding FDBs are from trials conducted in 2023, including 2 ethaboxam/citrus trials in Florida with a CRO and 1 ethaboxam/grapefruit trial in TX.

2023 trials – As of early October, 67 of the 72 FDBs have been received, including three tomato and cucumber trials canceled by the manufacturer (BCS-CW64991). Two of these outstanding 2023 trials were conducted using electronic notebooks.

2024 trials - Four paper FDBs have been received as of early October. FRDs are working with Philip Moore to ensure trial information is correctly entered into the electronic notebooks. FRDs are working diligently to address any QC findings in electronic notebooks and learning from each experience.

SOP review: Between the 2024 and 2025 seasons, field sites will be working to update SOPs to reflect the new use of the electronic field data books. National SOPs are also forthcoming, and training has been requested regarding how to balance national and site SOPs.

2024 GLP assignments:

Seventy-three GLP trials were assigned to SOR for 2024. Three mesotrione/sesame trials have been canceled due to phytotoxicity. Four linuron/stevia trials (1 FL, 3 NC) have been terminated or delayed due to weather-related issues. Three replacement linuron/stevia trials were approved for NC and will be conducted in 2025. The search continues for a suitable FRD candidate for TREC in Homestead. Tropical trials are currently being placed in Puerto Rico, with additional trials being covered by the Western region if needed.

Food Crop Product Performance Trials: As of early October, 30 of 47 Food Crop Performance trials assigned to the Southern Region in 2023 have been received. Many trials are ongoing or

completed, with reports expected in 2024. Forty-eight Food Crop Performance trials have been assigned to SOR researchers in 2024, and four reports have been received.

Integrated Solutions (IS) trials: Reports have been received from fourteen of the twenty-one 2023 Integrated Solutions trials. Two projects were delayed: the root aphid rearing protocol for the IS hemp project took additional time to develop, and the timing for dormancy in FL for the weed control/stevia was not known and plants did not reach marketable height. These trials will be conducted in 2024. Twenty-two IS trials were assigned to SOR researchers in 2024, and one report has been received. Additionally, a second root aphid/hemp project was approved and started in 2024.

Environmental Horticulture Trials: Twenty-three reports out of the twenty-seven projects assigned in 2023 have been received. Several projects are ongoing and will be completed in early 2025. One pythium efficacy trial is being repeated this year. In 2024, thirty-seven projects were assigned across the region: seventeen weed science, nine plant pathology, and ten entomology projects. Four reports have been received for 2024 projects.

2024 SOR Priority Setting: A final priority-setting call was held in mid-August before the nomination period opened. It was well attended by participants from all disciplines. 23 southern region attendees participated in the 2024 Food Use Workshop, including state liaisons and commodity group representatives.

2025 Trial Assignments: Tentative trial assignments are being discussed with GLP researchers and entered into the database for discussion during NRPM. Conversations are taking place with performance and integrated solutions researchers about trial placements and funding for 2025.

Training: All SOR field research directors (FRDs) and technicians are being continuously trained in using the iAdvantage electronic field data book (eFDB). The southern region will be hosting the fall quarterly GLP training webinar. Topics will include EPA inspections, writing deviations, lessons learned from the season, and finding education and information on growing new crops.

Extension activities:

- Virtually attended Southeast Vegetable Extension Workshop July 16-17, 2024.
- Attended passionfruit field day in Citra, FL, August 1, 2024.
- Attended Food Use Workshop Milwaukee, Wisconsin, September 10-12, 2024.
- Virtually attended Vascular Streak Dieback meeting October 1-2, 2024.
- Planning to attend the Southeast Regional Fruit & Vegetable Conference January 9-11, 2025.

2. Analytical Lab

Personnel: Two vacant positions have been filled. Dr. Isil Gazioglu was hired as a senior chemist in August 2024. Elisha Mitchell was hired as a laboratory technician/sample receipt officer in October 2024.

ш	Submission	PR No	Pesticide	Commodity	Trial	
#	Date	PRINO	Pesticide		Year	Number
1	01/16/24	12673	Pydiflumetofen	Cucumber	2022	4
2	01/30/24	11881	Pydiflumetofen	Strawberry	2022	5
3	03/04/24	12975	Pyraziflumid	Lettuce	2022	5
4	03/20/24	13333	Pydiflumetofen	Cranberry	2022	5
5	03/20/24	08560	Zeta-cypermethrin	Lychee	2022	4
6	05/28/24	13242	Dimethomorph	Basil	2022	5
7	05/28/24	13242	Ametoctradin	Basil	2022	5
8	07/23/24	13259	Picoxystrobin	Coffee	2022	6

Projects and reports finished: The lab has targeted 17 projects for completion in 2024. To date, 8 analytical summary reports (ASR) have been submitted with projects 4, 6, and 7 listed as backlogged.

Ongoing Projects: The following projects are currently in progress in the laboratory.

#	Project Number	Chemical	Сгор	Last Sample Receipt Date	Status	Anticipated Date ASR to HQ
1	13540	Fluazifop-P-butyl	Squash (summer)	12/07/23	ASR in preparation	10/2024
2	13407	Isocycloseram	Strawberry (GH)	03/19/24	Method Development	12/2024
3	13405	Isocycloseram	Pepper (GH)	pending	Method Development	12/2024
4	13511	Inpyrfluxam	Tomato	11/04/23	Pending SS analysis	02/2025
5	13682	Tolpyralate	Blueberry	Pending	Field trial analysis	03/2025
6	13498	Tiafenacil	Cucumber	09/13/23	Pending SS analysis	05/2025
7	13500	Tiafenacil	Tomato	pending	Pending Field Trial and SS analysis	05/2025
8	13501	Tiafenacil	Pepper	pending	Pending Field Trial and SS analysis	06/2025
9	11568	Thiophanate-methyl	Radish	02/20/23	Pending SS	06/2025
10	13360	Thiophanate-methyl	Carrot	03/22/23	Pending SS	06/2025
11	13648	Zeta-cypermethrin	Beet greens	Pending	Method development	06/2025
12	13798	Fluazifop-P-butyl	Pepper (Bell & Nonbell)	pending	Field Trial analysis	09/2025
13	13541	Fluazifop-p-butyl	Pea (succulent shelled)	pending	Pending Field Trial and SS analysis	10/2025

14	07883	Pyridate	Sweet Corn	11/14/23	Field Trial analysis	10/2025
15	13449	Inpyrfluxam	Coffee	01/17/24	Method development	05/2026
16	13304	2,4-D choline	Strawberry	01/09/24	Method reevaluation	06/2026
17	13169	Fluazaindolazine	Radish	02/20/23	Field Trial analysis	04/2027
18	12752	Fluazaindolazine	Mint	10/07/22	Method reevaluation	09/2028

Pending Projects: Trials from the following projects have been received but work on the projects has not started.

	Project			Last Sample	Trial	
#	Number	Chemical	Сгор	Receipt Date	Year	Number
1	13078	Fludioxonil + Pydiflumetofen	Basil	01/11/24	2023	5
2	13293	Fludioxonil + Pydiflumetofen	Mint	9/11/24	2023	6
3	13489	Fludioxonil + Pydiflumetofen	Asparagus (fern)	06/24/24	2023	6
4	13496	Isocycloseram	Sunflower	12/07/23	2023	9
5	13504	Isocycloseram	Pomegranate	12/13/23	2023	4
6	13305	Zeta-cypermethrin	Dragon Fruit	Pending	2024	4
7	13289	GF-4031	Tomato (GH)	pending	2024	5
8	13545	GF-4031	Pepper (GH)	pending	2024	5
9	08037	Pyridaben	Pepper (Bell & Nonbell) (GH)	pending	2024	5
10	08266	Pyridaben	Lychee	pending	2024	4
11	13776	Fludioxonil + Pydiflumetofen	Guava	Pending	2024	4

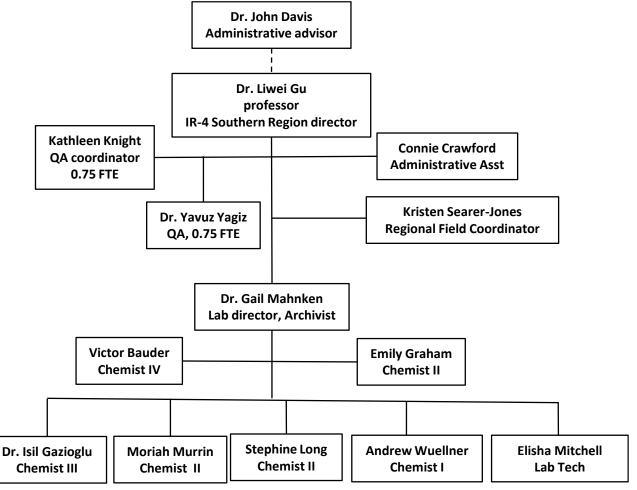
Projects with late ASR or backlogged:

#	Project Number	Chemical	Сгор	Last Sample Receipt Date	Status	Anticipated Date ASR to HQ
1	13498	Tiafenacil	Cucumber	03/08/23	ASR in QA review	05/2025
2	11568	Thiophanate- methyl	Radish	02/20/23	Pending SS interval in 04/2025	06/2025
3	13360	Thiophanate- methyl	Carrot	02/20/23	Pending SS interval in 04/2025	06/2025
4	13169	Fluazaindolazine	Radish	02/20/23	Field trial analysis	04/2027
5	12752	Fluazaindolazine	Mint	10/07/22	Method reevaluation	09/2028

3. Quality Assurance Unit

Function (man/days)	2024	2024	%	man/days
	completed	Assigned	Completion	
Draft Final 5	2	11	18%	5
Field Data Books 1.0	127	100	127%	95
Field Critical Point Insp 2.5	13	19	74%	20
Lab Facility Inspection 3	0	0	0	0
Lab Critical Point Insp 1.5	15	30	50%	15
Field Facility Inspection 2.5	1	2	50%	2.5
Contributing Scientist's Report Audit 3	0	0	0%	0
Analytical Sum Report 6	10	17	59%	54
Review Calculations 0.1	13			1.3
Training 1	6			5.2

Southern region organizational chart (effective October 14, 2024)



Program Update: Food Program Field Residue Studies & Submissions

Presenters: Dr. Debbie Carpenter, Thomas Pike and Cristina Marconi







Food Program October, 2024

Thomas Pike, Cristina Marconi

Outline

New Uses - 2024 Submissions – 2024 **Crop Group update Residue Research Program (10-year history) Outstanding Field Notebooks Timeline Summary Regulatory Challenges**



2024 New Uses

7 Actions (new uses through September 2024)

- Triclopyr (1)
- Cyclaniliprole (2)
- Cyflumetofen (28)
- Cyantraniliprole (696)
- Indoxacarb (139)
- Ethaboxam (7)
- Saflufenacil (57)

Total = 930 new uses, 46 tolerances



2024 Submissions - 6 (through September)

- Fenhexamid
- Tolfenpyrad
- Saflufenacil
- Fluazinam
- Clopyralid
- Flumioxazin
 - Provided to registrant
 - Potassium Phosphite/Peanut

Crop Group Update

- <u>Crop Grouping Initiative</u>
- All Commodity Classes have been approved by the Codex Alimentarus Commission.
- Remain to be published (IR-4 work is completed)
 - Phase VII: CG 17, Grass Forage, Fodder, and Hay Group; CG18, Nongrass Animal Feeds and CG9, Cucurbit Vegetables. Timing TBD.
 - CG1, Root and Tuber Vegetables and CG2, Leaves of Root and Tuber Vegetables expected early 2025
- EPA has requested that IR-4 provide feedback on the status of sweet sorghum/sugarcane as well as CG9 and CG18 with the goal of harmonizing with Codex



Field Research

2023 Residue Program

- 52 New Studies
- 354 New Field trials
- 30 Carryover trials

2024 Residue Program

- 54 New Studies
- 365 Residue Field trials
- 38 Carryover trials

2025 Residue Program

- 44 New Studies
- 29 Red A trials

Field Research Program

Region	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
NER	49	39	27/11*	34	39	36	33	26	28	34	26
NCR	68	59	67/4	66	61	39	50	51	49	81	63
SOR	76	92	78/19	85	78	90	100	95	90	73	74
WSR	171	185	162/16	167	149	164	140	151	128	129	138
ARS	54	62	52/15	67	55	49	62	49	46	56	52
Canada	41	36	32/3	31	19	29	31	10	6	11	12
TOTAL	451	472	418	450	401	407	416	382	347	384	365

*Indicates 2016 dropped trials, mostly due to study changes. Other dropped trials not included in numbers reported



Field Data Notebooks, 10/24

Year	Total	FRD	RFC	QA	HQ
2022	347	3	0	0	344
2023	384	42*	12	18	312

*Did not count 3 trials with harvest date after August/2024



Outstanding FDB, 10/24

Notebooks with FRD								
Year	ARS	WSR	NER	SOR	NCR	CAN		
2022	0	0	0	3	0	0		
2023	2*	27	0	7	6	0		

*Did not count 3 trials to be harvested in early 2024

Notebooks with RFC									
Year	ARS	WSR	NER	SOR	NCR	CAN			
2022	0	0	0	0	0	0			
2023	6	2	1	1	1	1			



Timeline Summary

- Completion of FDB is critical to meeting timelines.
 - There are 3 outstanding 2022 Field Data Books.
 - Approximate 80% of the 2023 Field Data Books havarrived at HQ.
 - 2024 Field Data Books are starting to come in.
 - *RFCs are doing a great job of moving Field Data Books along once received, but there are still 3 books from 2022 and 42 books from 2023 and with FRDst is crucial to move these along.*
- About sixty studies in final report processing (Writing/QA etc)
- More than 100 studies are TBD for submission. Most are signed and ready to submit.
 - Many cannot be submitted as a safety finding cannot be made or registrant is holding submissions.
 - 1 of the 2 registrants are now allowing us to move forward with some IR submissions and have shared submission plansfor 2024 and 2025.



Regulatory Challenges

Internal challenges

- Analytical backlog and quality
 - Delayssubmissions
 - Costs lab, study directors and QA resources to address

Delayed field data books

- More critical as analytical backlog is addressed.
- One outstanding book holds up the whole study.
- Concern that if we miss a submission, it could be years before it can go in.
- eFDBmay greatly help ease delayed field data books



Regulatory Challenges

<u>External issues</u>

Impacts from Endangered species act still a concern

- Concern about mitigation proposals and how they will impact stakeholders
- Once in compliance, will not want to be out ocompliance
- Working with EPA toaddress ESA for new uses

Registration status in Europe and impact on support from companies for stakeholder requests.

Slow down or hold on submissions by two companies

- Path forward is not clear due to ESA- resulting in some reluctance for submissions
- Lack of submission documents until previous labels have issued from EPA

Need for pollinator before registration of new uses may be an obstacle to submissions until current cycle of registration review is completed.



Thank You!



Program Update: Food Program Residue Research & Laboratory Backlog

Presenters: Dr. Debbie Carpenter, Thomas Pike and Cristina Marconi







Food Program October, 2024

Thomas Pike, Cristina Marconi

Outline

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Thank You!





Laboratory Update/Backlog October, 2024

Debbie Carpenter

Outline

Backlog (Data from Oct, 2024)

Current status at each lab

Plans to address backlog

Use of contract labs

Summary

Other



Backlog Details - TIR

TIR									
PR	Chemical	Matrix	Trials	ASR Due Date	Initial EPA Target Sub.	Revised EPA Target Sub.	Note	Late ASRs	Backlogged
13218	Ethaboxam	Almond		11/23					1
13353	Difenoconazole and azoxystrobin	Mint		10/23			Analysis for difenoconazole/met only		1
11331	Difenoconazole and azoxystrobin	Tomato (GH)		3/24			Analysis for azoxy and difenoconazole/met		2
13094	Difenoconazole and azoxystrobin	Spinach		2/23			Analysis for difenoconazole only	,	1
13219	Ethaboxam	Avocado		3/24					1
13256	Cymoxanil	Strawberry		8/24					1
13390	Fenpyroximate	Lychee		9/24					1
								Backlog	8



Plans for Moving Forward

Backlog – Tifton Eight studies are backlogged.

Concern about viability of samples which were delayed due to work on propiconazole method. Analyses in progress on these older studies but will remain in backlog until the time period elapses for determining stability in freezer storage.

Lack of personnel – position posted



Backlog Details - YAR

YAR									
PR	Chemical	Matrix	Trials	ASR Due Date	Initial EPA Target Sub.	Revised EPA Target Sub.	Note	Late ASRs	Backlogged
11997	Bicyclopyrone	Pineapple		04/23			All analysis done. Waiting for guidance regarding storage stability analysis.		1
12972	Fludioxonil +Pydiflumetofen	Peach	12	210/22			Pydiflumetofen submitted for QA review. Findings are problematic, so it will likely be pulled back for further work by the lab. Fludioxonil submission for QA review on hold until pydiflumetofen is reworked.		2
12817	s-metolachlor	Greens (Mustard)	10	12/22			Submitted for QA review. May be pulled back for further QC work by laboratory.		1
12818	s-metolachlor	Turnip Greens	6	612/22			Submitted for QA review. May be pulled back for further QC work by laboratory.		1
13046	Mefenoxam	Passion Fruit		08/24			Analysis on hold until ASR/Data issues are addressed by the laboratory.		1
13284	Ethaboxam	Lemon		3/24			Validated, field trial analysis in process. Storage stability study is in process, but a number of months from completion.		1
								Backlogged	7

Plans for Moving Forward

Backlog – YAR

Some progress during the past year although slower than anticipated.

Still seven ASRs that are backlogged. (Analyses complete for most but further analyses on hold until data quality issues are addressed).

Data quality still a major concern. On-going efforts with HQ staff and Davis staff to assist.

No 2024 studies were assigned to YAR. 2025 studies also may not be assigned, as data quality issues must be addressed, and previous studies at the lab must be analyzed. Will impact rest of program



Backlog Details - CAR

CAR									
PR	Chemical	Matrix	ASR Due Date		Initial EPA Target Sub.	Revised EPA Target Sub.	Note	Late ASRs	Backlogged
12634	sulfosulfuron	tomato	9/23	12/25			Awaiting long-term SS		*
13007	isofetamid	hemp	4/24				ASR Prep		1
13142	fluroxypyr	mint	9/24				Method Validation		1
13217	fluopicolide	almond	10/23	5/25			Awaiting long-term SS		1
13241	fluopicolide	avocado	5/24				ASR Prep		1
13311	flupyradifurone + spidoxamat	hops	10/23	6/24			ASR Prep		1
13487	tiafenacil	blueberry	9/24				Shipping to HQ		1
									6
							* = study is backlogged but		
							transferred from another lab		



Plans for Moving Forward

Backlog – CAR

Six backlogged studies, but one due to outside issues. All analytical work has been completed or is in progress.

CAR has analyzed many of the studies from Michigan. Storage stability delays-samples not spiked when received.

Hemp studies take much time, many crop fractions.

No action needed to reduce backlog, but cannot help other labs by taking additional studies.



Backlog Details - FLR

FLR										
PR	Chemical	Matrix	Trials	ASR Due Date	ASR Est.	Initial EPA Target Sub.	Revised EPA Target Sub.	Note	Late ASRs	Backlogged
12752	FLUAZAINDOLIZINE	MINT		11/23	09/2028			field trial analysis		1
13169	FLUAZAINDOLIZINE	RADISH		02/24	04/2027			method re-evaluation 12/2024		1
11568	THIOPHANATE METHYL	RADISH		02/24	06/2025			pending SS		1
13360	THIOPHANATE METHYL	CARROT		03/24	06/2025			pending SS		1
13498	TIAFENACIL	CUCUMBER		09/24	05/2025			pending SS		1
								_	backlog	5
								Pi	R-4	

Plans for Moving Forward

Backlog – FLR Five studies are backlogged. Three are waiting for storage stability.

Will not make submission timeline with Corteva newer chemistry, as method had to be redone due to data quality.

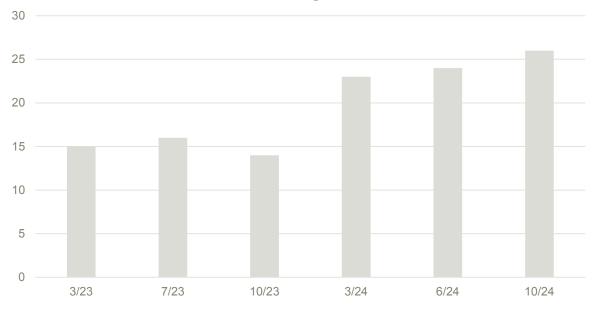


Studies at Contract Labs

CRO											
				ASR Due		Initial EPA	Revised EPA				
PR	Chemical	Matrix	Original Lab	Date	ASR Est.	Target Sub.	Target Sub.	Note			
12564	abamectin	Miracle Fruit	MIR(GPR)	9/22		10/22	4/26	Waiting for SS data			
12757	abamectin	sugar beet	MIR(GPR)	6/22		10/22	4/26	SS due in June 2025			
			Symbiotic								
11824	Asulam	Clover	(GPR)	6/21		10/21	6/23	Waiting on analytical data, study to be ca	ncelled		
10827	azosystrobin	pomegranate	MIR(GPR)	12/22		4/22	4/26	Draft ASR was sent to SD			
13179	benzovindiflupyr and difenoconazole	coffee	Adpen			10/25	4/26	Not started			
12220	diquat	grape	MIR(GPR)	10/20		10/21	4/26	Draft ASR was sent to SD			
12675	emamectin	limabean	MIR(GPR)	11/21		10/22	4/26	Sample analysis complete			
12714	ethofumesate	swiss chard	GPR			10/26		Method validation			
12903	Flutolanil	Radish	. ,	02/22		10/22	TBD	Waiting on ASR but low priority since on I			
12904	Flutolanil	Tomato	YAR(GPR)	10/21		10/21	TBD	Waiting on ASR but low priority since on hold			
11195	Flutolanil	Pepper, Bell and Nonbell	FLR(GPR)	12/21		10/22	TBD	Waiting on ASR but low priority since on hold			
9520	Flutolanil	Garden Beet	MIR(GPR)	5/22		10/22	TBD	Waiting on ASR but low priority since on hold			
12902	Flutolanil	Carrot	MIR(GPR)	6/22		10/22	TBD	Waiting on ASR but low priority since on hold			
9102	Flutolanil	Strawberry	GPR			10/25	10/25	SS due in December			
13295	GF-4031	Cherry	EUR			10/25	TBD	Method validation complete, analysis in the queue			
								Eurofins just completed sample analysis,	but we are past	SS data coverage, r	may need
13355	GF-4031	Strawberry	EUR			10/24	TBD	to run SS			
9493	Glufosinate	Coffee	MIR(Adpen)	10/22		10/21	8/23	ASR ready for signature at ADPEN			
11148	Glufosinate	Sesame	Adpen			10/24	4/25	ASR draft written, with SD for review			
13178	Glufosinate	Sunflower	FLR(Adpen)	(02/23)		10/23	8/23	ASR signed, waiting on raw data			
13330	Glufosinate	Dragon Fruit	Adpen			10/24	4/25	ASR signed, waiting on raw data			
13455	Glufosinate	Strawberry	Adpen			4/25	4/25	Method validation complete, analysis in the	ne queue		
13463	Glufosinate	Peanut	Adpen			4/25	4/25	Not started			
13408	halosulfuron	stevia	Adpen			10/24	10/24	SS due in December			
		Bean (Edible podded and succulen	t								
11772	Linuron	shelled)		9/22		10/22	12/23	Waiting for ASR			
12816	Linuron	Dry bulb	Adpen			10/25	10/25	Method validation complete			
13732	Linuron	Mint	Adpen			10/26		Not started			
13733	Linuron	Stevia	Adpen			10/26		Not started			
13734	Linuron	Green Onion	Adpen			10/26		Not started			
13092	Norflurazon	Clover	GPR			10/27		All samples received have been analyzed	l, more trials com	ning in 2025	

Backlog Graph Post MIR

Backlog Post MIR





Summary

Backlog (ASR not completed/signed one year after last field sample arrived at the lab.) Very little change since March/July in overall numbers – 26 backlogged studies in October. Many ASRs are in QA or awaiting storage stability. Backlog numbers do not include studies that have been sent to contract labs for completion.

Training - lab focused training for all analysts is in progress. The intent is to bring analysts to a baseline level and help with method development skills.

Other

MIR data

Storage stability samples not spiked in some cases – delays QA audits not addressed completely – time and resources as study directors, QA must identify and address as final report is written. This is still a huge item taking resources.

Data quality at YAR

Many resources required to address Includes not only Lab, but also Study Directors, QA personnel Potential Impacts on IR-4 Reputation



Thank You!



Results of Food Use Workshop

Presenter: Dr. Alice Axtell







2025 Research Plan: Product Performance

No of FUW Priorities approved by PMC for 2025

Residue & Product Performance:

- **37** new "A" priorities
- 9 new "H+" priorities
- 6 PUPs and/or Rus

Integrated Solutions:

• 6 new "A" priorities (vs. original 10)





FUW Outcomes



2025 New "A" Priorities (Residue & Performance)

		No. of Projects								
	Entomology	Plant Pathology	Weed Science	тот						
Residue Only*	1	1	11	= 13 (35%)						
Residue + Performance	9	9	6	= 24 (65%)						
тот	10	10	17	= 37 (100%)						

* The total No. of "RED A" trials as of 10/8/2024 is 16 and a total of 28 trials including back -up trials. Please note that there may be more "RED A" trials needed, as we complete the season.





2025 New "H+" Priorities (Product Performance)

	No. of Projects							
	Entomology	Plant Pathology	Weed Science	тот				
Potential	1	3	6	= 10 (91%)				
E/CS only	0	0	1	= 1 (9%)				
тот	= 1	= 3	= 7	= 11 (100%)				





2025 PUPs / RUs

Update

The total number of additional priorities to be used as a PUP or as a RU went from a total of **6** (approved in July by the PMC) to a total of **8** for the following reasons :

- 1. One A priority assigned during the Food Use Workshop was withdrawn by the requestor.
- 2. Lower than anticipated (budgeted) number of "Red A" trials identified.



	No. of Projects								
	Entomology	Plant Pathology	Weed Science	тот					
PUP*	0	4	1	= 5					
RU*	0	1	2	= 3					
ТОТ	= 0	= 5	= 3	= 8					

- 3 PUPs are an "A" priority and 2 are an "H+" priority, respectively
- 3 RUs are an "H+"priority





2025 IS Priorities

		No. of F	Projects	
Funding Agency	Entomology	Plant Pathology	Weed Science	тот
NIFA	4	2	2	= 8
CDFA	4	0	0	= 4
3 RD PARTY	0	0	1*	= 1
ТОТ	= 8	= 2	= 3	= 13*

*TBD, pendingPMC approval.



Integrated Solutions Platform

Presenter: Dr. Alice Axtell







Integrated Solutions: 2023-2025 Brief Review

Alice Axtell Ph.D.

2023 in Review

- **19** new "A" priorities (2 CDFA-funded)
- **17** carryover projects (trials that failed or trials needed to complete the project)
- **73** total trials (~2 trials / project)
- **Cost:** \$499,500
- 57 (out of 73) reports received to date



2024 in Review

- **19** new "A" priorities (6 CDFA-funded)
- 14 carryover projects (trials that failed or trials needed to complete the project)
- 62 total trials (~2 trials / project)
- **Cost:** \$518,889
- 4 (out of 62) reports received to date



2025 in Review

- **12 + 1 (?)** new "A" priorities (4 CDFA-funded, + 1 funded by stevia group)
- ~20 carryover projects (trials that failed or trials needed to complete the project)
- Budget needs (TBD)
- Budget available **\$600K**



Some Successes (across 55 projects)...

New PCRs under Residue & Product Performance:

- IS00437 resulted in 3 new PCRs under Residue & Product Performance
- IS00386 resulted in 1 new "A" priority under Residue & Product Performance
- IS00445 (dragonfruit /stem & fruit canker) resulted in a new PUP

Publications:

- IS00382 (mites / hemp) results were published on *Environmental Entomology*
- IS00386 (root aphids / hemp) results will be published on Arthropod Management Tests
- IS00436 (sugar beet / cercospora) in progress
- IS00110 (squash / phytophtora root rot) in progress

Label expansions:

• IS00026 results supported the registration of the novel technology *Combi Protec* in certain states



Key Challenges to Address for Grower Success

- Determining the number of carryover trials (and relative budgeting) in July is a guessing game since reports are received between November and March.
- Finding researchers (for 70+ unique trials) is difficult and usually completes by April, which has delayed studies to the year after.
- Protocols must be completed to meet the field season and current capacity leads to protocols being rushed.



...KeyChallenges to Address for Grower Success

- CDFA-funded projects expand the list of priorities without a corresponding increase in resources. AND support for carryover trials is not always guaranteed, which caused NIFA funds to be used for local priorities or projects to be left uncompleted.
- IS and the Biopesticide Regulatory Support Program operate in 2 distant, separate silos.
- The program is being reviewed and there is a need to establish clear guidelines to improve the oversight of deliverables.



Program Update: Biopesticide Regulatory Support

Presenters: Bill Barney & Dr. Jerry Baron





The IR-4 Project, Biopesticide Regulatory Support, Existing Project Update

Pest management solutions for specialty crops and specialty uses



Biopesticide Regulatory, Submitted/Pending EPA Review

- 1071B, American chestnut, submitted follow-up documentation [Chestnut blight]
- 1072B, Nudivirus, sterile moths, submitted follow-up documentation. Note: Section 18: Sterile moths released on 1750 acres of sweet corn in 2024 [Helicoverpa virescens]
- 1077B, Alum, Biochemical classification, in science review [Fireblight]
- 1081B, Cucumber green mottle mosaic virus vaccine, need to submit additional documentation and remove references to human studies, or PRIA fees/study for M002 [CGMMV]
- 1084B, Citrus tristeza virus, spinach defensin, submitted [Citrus greening]



Biopesticide Regulatory, Submission packages in development:

- 1070B, Bacteriophages, pre-submission meetings held [Varroa mite of honeybees]
- 1075B, Pseudomonas soli, pre-submission meetings held [Fireblight, Citrus canker, Citrus greening]
- 1082B, Walnut rootstock [Crown gall]
- 1086B, *Pseudomonas fluorescens* M18, presubmission meeting held [fungal and viral diseases]
- 1087B, Citrus CRISPR HLB resistant rootstock, presubmission meetings held [Citrus greening]



Biopesticide Regulatory Requests – Not evaluated

- Pseudomonas fluorescens strain 14og [insects]
- Phytogenesis novel technology from U of KY, fruits and vegetables [Zoom meeting]
- Plasma activated water [on-farm fungicide]
- Streptomyces nourseii var. xichangensis [PCR request received, tomato yellow leaf curl virus]
- T-DNA transformation of citrus with AtNPR1 gene [PCR request received, U FL, citrus greening]
- Terra Vera Varroa mite product [Zoom meeting]



Biopesticide Regulatory Support Platform

Biopesticide Regulatory Support

- Reached out to Keith Pitts/Amy Plato-Roberts/Keith Jones/Terry Stone regarding the proposal presented at the July PMC Meeting
- Comments received were favorable (N=1)
 - IR-4 serves a useful role in registering biopesticide technology from the public sector
 - Was not aware of the numerous referrals from EPA-BPPD for assisting small businesses that could not afford to retain a private consultant
 - Provided additional feedback on the assessment survey to support products that are useful in an integrated approach
- RECOMMENDATION-Maintain a Biopesticide Regulatory Support Platform
- Side note; Michael Braverman is returning to IR-4 on a <50% time to work on already approved projects.

The IR-4 Project Executive Director will assign a staff member who will be responsible for processing new requests for Biopesticide Regulatory Assistance Platform utilizing the following steps:

1. PRELIMINARY ASSESSMENT

- a. Assess if the Request for Assistance (PCR) differs from any existing request.
 - IF YES, establish a new PCR entry in the IR-4 Biopesticide Regulatory Assistance Database (BRAD).
 - If the Request for Assistance is substantially similar to an existing request, add a comment to the BRAD about the submission of a substantially similar request, including additional submitter(s) and additional requesting state(s).
- b. Assess if the PCR is relevant in the IR-4 Biopesticide Regulatory Support platform, which includes
 - Is the Request for Assistance from someone in the public sector or associated with that crop (i.e. commodity association) and

• Will the technology be regulated by EPA's Biopesticide and Pollution Prevention Division? If YES to both, proceed to Step 2. If NO, seek guidance from the IR-4 Executive Director

- 2. COMPANY/SUPPORTING GROUP COMMITMENT TO REGISTER
 - a. Solicit input from the company that manages the technology to assess if they are willing to cooperate/partner with IR-4 in facilitating the registration, including (but not limited to): providing necessary data required by EPA and their willingness to register the product/use once approved. If the company is willing to cooperate/partner with IR-4, make a note in the BRAD and proceed to Step 3.
 - b. If the company that manages the technology has the proposed use(s) as a registration objective or is not willing to cooperate with IR-4, make an appropriate note in IR-4 BRAD and stop further assessment of PCR.

3. SECONDARY VETTING

- a. The Executive Director will establish an ad hoc review team for Secondary Vetting of new requests for biopesticide regulatory support.
- b. The review team members will be asked to complete one or more sections of the "IR-4 Project Biopesticide Regulatory Support Secondary Vetting Survey. This Survey will assist the reviewers in assessing each new PCR on a 0-100 scale. If there are multiple reviews for a section, their scores for that section will be averaged
- c. The review team will provide the Executive Director with a comprehensive score and additional comments.
- d. IR-4 will only provide regulatory assistance it the TOTAL score exceeds 66. The higher the score, the higher the project is in IR-4 Biopesticide Regulatory Assistance Que. If a PCR is below 66, the stakeholder submitting the PCR can request a reassessment every 12 months.

IR-4 Project Biopesticide Regulatory Support Secondary Vetting Survey

Section 1- Biology

Part A -Does the product effectively control or suppress the target pest? Include documentation or reference to support the conclusion (assign a maximum of 10 points).

Guidelines:

- If deemed "Control" assign between 8-10 points
- If deemed "Suppress" assign between 3-7 points
- If deemed "Not Effective" or no hard data is available, assign between 0-2 points

Part B - What is the importance of the pest (assign a maximum of 10 points). Guidelines:

- If deemed "Always Damaging," assign between 8-10 points
- If deemed "Under Certain Conditions can be Damaging," assign between 3-7 points
- If deemed "Damage is Limited" or no data is available, assign 0-2 points

Part C – Intangible "Bonus Points"

- Potential for the product to be used in managing pest resistance to products assign 1 bonus point
- Potential for product to be used in residue mitigation assign 1 bonus point

Section 2 – Product Support (assign a maximum of 10 points)

Guidelines:

- Product was discovered/developed by a United States public sector entity that is working with a company that is an experienced registrant in the United States (10 points)
- Product was discovered/developed by a private sector entity that is working closely with a public sector scientist and an experienced registrant in the United States (5-7 points)
- Product was discovered/developed by a United States public sector entity that is working with a company that is not an experienced registrant in the United States (3-6 points)
- Product was discovered/developed by a private sector entity that is working closely with a public sector scientist that is working with a company that is not an experienced registrant in the United States (1-4 points)

Section 3-EPA'Experience with Technology (assign a maximum of 10 points)

Guidelines:

- Known technology/Known data requirements(7-10 points)
- Novel technology/with known data requirements (3-6 points)
- Novel technology/with unknown data requirements (0-2 points)

Section 4-Estimate of Financial Support for Product (assign a maximum of 10 points) Guidelines:

- Company/group has significant resources to develop data needed for registration (7-10 points)
- Company/group has some resources to develop data needed for registration (3-6 points)
- Company/group has no resources available to develop data needed for registration (0-2 points)

Section 5-Path Forward to Registration/Likelihood of Waivers (assign a maximum of 50 points) Guidelines:

- All required studies are acceptable (50 points)
- Most (>75%) of the required studies are acceptable; other required studies in progress (40 45 points)
- Some (<74%) of required studies are acceptable, other required studies in progress (30 -40 points)
- Testing for all studies in progress (25 points)
- Testing for most (>75%) required studies in progress (20 points)
- Testing for some <74%) in progress (5-15 points
- None of the required studies are available or in progress (0 points)

Sponsored Research Policy

Presenter: Dr. Jerry Baron





Title	Sponsored Research ¹ Policy and Process October 2024 (Version 2)
Purpose	To provide a mechanism for commodity groups and industries representing a commodity to work with IR-4 and assist by sponsoring the cost of research data development for high-priority IR-4 research projects.

Background: Since 1992, IR-4 has been following the recommendation of the Commodity Liaison Committee that "*IR-4 formalize a program allowing individuals or commodity organizations representing the agricultural industry to sponsor registration or reregistration projects that are important to them*". This process was justified with the following: "Both IR-4 and the sponsoring individual or organizations would benefit from such a plan. The sponsor would have available the expert consulting services of the IR-4 Project, including interaction with *EPA and product registrants*". It was further noted, "IR-4, on the other hand, would be committing little or none of its regional laboratory fiscal resources to the support of the sponsored project and thus would be able to direct a proportionately greater research effort toward reducing the minor use registration and reregistration backlog of priority projects".

IR-4 has effectively used the existing policy to obtain sponsorship resources from commodity groups and industry to take on priority projects that were deemed high priority but did not make the funding cut associated with being identified as "A" or "H+" priorities during IR-4's priority-setting process. However, some of the terminology in the original policy is outdated or no longer relevant. Furthermore, the original policy does not address IR-4 Integrated Solutions Platform or Environmental Horticulture research access. This update is intended to correct these deficiencies.

Scope: This policy and procedures covers all IR-4 research program/platform areas:

- Food Program
 - Magnitude of the residue studies
 - Product performance projects
 - Integrated Solutions Platform projects
 - Biopesticide Regulatory Support
 - Environmental Horticulture Program
 - Product performance projects
 - If appropriate, Integrated Solution Platform projects
- Miscellaneous—EPA may require additional data to establish a tolerance and/or registration that is beyond the scope of the IR-4 Project. In certain circumstances, IR-4 may be able to provide staff assistance for research beyond its traditional scope.

¹ Sponsored Research is used in the context of an organization providing IR-4 funds to perform research. It is not to be confused with the term "Sponsor" in the EPA Good Laboratory Practice regulations (Chapter 40, <u>Code of Federal Regulations</u>, Part 160)

Eligibility — It is important to note that **IR-4 is not a contract research organization**. Unless extenuating circumstances exist, potential sponsored research activities must be limited to projects assessed via the established IR-4 Food or Environment Horticulture Program priority-setting process and considered a high priority. Specifically;

Food Crops Program:

- Projects discussed and classified as Researchable at the conclusion of the IR-4 Food Use Workshop are considered high priority and eligible for sponsored research.
- Projects submitted through IR-4's Priority Regional Upgrade Proposal process and deemed Researchable are considered high priority and eligible for sponsored research.

Environmental Horticulture Program:

• Potential projects must be submitted and vetted at the Environmental Horticulture Biannual Priority setting Workshop to be eligible for sponsored research.

As noted above, the assessment through the established IR-4 Food or Environment Horticulture Program priority-setting process is the "almost always" mechanism for establishing eligibility with the Sponsored Research program. However, certain circumstances warrant a different approach. In these cases, the potentially sponsoring organization must develop a detailed proposal that will be submitted to the IR-4 Project Executive Director to respond to the unique circumstances. The proposal should address factors that the EPA considers during "Weight of Evidence" assessment if a fee waiver is warranted, see (Factors for IR-4 Public Interest Finding LUS EPA).

The IR-4 Executive Director will be the point of contact for Sponsored Research proposals and implementation. For contact points, see the IR-4 website: <u>https://www.ir4project.org/hq-staff/</u>.

Process

When a commodity group or a company directly involved in the production/marketing of a crop wants to utilize IR-4 Sponsored Research opportunities, it must submit a letter of intent to the IR-4 Executive Director. Requests for inclusion in IR-4 sponsored research activities can be submitted anytime during the calendar year. *Depending on the time of year, seasonality of the crop, the timing of the response to questions, and other factors, the time from submission of the letter of intent to start the research may take six months to a year.* Below are some of the key steps.

Step 1. A letter of intent from a sponsoring organization to participate in IR-4-sponsored research opportunities is received by the IR-4 Executive Director. IR-4 Headquarters staff will confirm that the request is eligible for IR-4's sponsored research. If not, the request is returned, and further instructions are provided to document circumstances that warrant special treatment.

Step 2. If the proposed project is eligible, IR-4 will develop a cost estimate for sponsored research. Assuming no additional EPA and registrant guidance is needed, IR-4 will return a cost estimate approximately 21 days after receiving the request.

Step 3. If the sponsoring organization agrees with the research plan and the cost of the research, it will provide a written letter to the Executive Director documenting its concurrence with the plan. The sponsoring organization will also transfer at least 75% of the total cost estimate to the IR-4 Project Headquarters.

Step 4. IR-4 will start preparing the research protocol and establishing cooperating research sites. Please note, that depending on the time of year and the biology of the crop, this step may be delayed or deferred to the next growing season.

Step 5. IR-4 establishes field trials, assigns residue laboratory, and schedules all appropriate Quality Assurance inspections.

Step 6. Data received at IR-4 Headquarters. Appropriate reports are drafted.

Step 7. Headquarters provides the final report/submission package to the sponsoring organization. Following the Project Strategy, submit documents to the registrants or the EPA. After which the sponsoring organization will transfer the remaining 25% of funds to IR-4 Headquarters.

Research Capacity IR-4 does not have unlimited research capacity. Depending on workload, staffing, and other circumstances, IR-4 may not take on all potential sponsored research projects. This means IR-4 may have to delay or decline sponsorship opportunities.

Below is the order of priority for utilizing IR-4's research capacity.

- 1. Government (publically) funded research
- 2. Sponsored research proposed/supported by commodity groups/associations
- 3. Sponsored research proposed/supported by not-for-profit foundations and organizations
- 4. Sponsored research proposed/supported by companies involved in crop production

Prepared by:

Approved by:

Integrated Solutions Program Reboot

Presenter: Dr. Jerry Baron





Integrated Solutions - Original Goals

From IR-4's website:

Integrated Solutions explores the synergistic use of various products, practices, and technologies to better equip growers' pest management toolboxes. Aligned with the principles of <u>Integrated Pest Management</u>, the IS platform is designed to generate innovative answers to problems that may not have a single, simple solution.

Integrated Solutions - Success

Definition of success:

- <u>Simple success</u>: When effective strategies are identified by IS research, IR-4 facilitates the registration of new products, uses, or applications.
- <u>Complex success</u>: When IS data supports an expert recommending or modifying a practice. For example, a crop advisor recommends using a resistant variety in combination with a registered biopesticide to manage a pest. These types of "successes" would be hard to measure and track.

<u>Question 1:</u> Do we stick only to IS projects with the potential for "Simple success"? This would truncate research and not allow testing of resistant varieties, mechanical pest management, etc., with chemical and bio-based pesticides.

Integrated Solutions - Timing

- Regional Field Coordinators are strongly against decoupling IS Priority Setting from Food Use Workshop...HQ Agrees
- Proposal: Classify each priority project as Fast track or Normal track (will need to add a tracking field into the IS database to track this classification)
 - <u>Fast Track Projects</u>: These are projects with good knowledge of the treatments in the protocol, and it is feasible that IR-4 can place these trials in a short time frame. Start the next research season.
 - <u>Normal Track Projects</u>: Projects with complex objectives and uncertainty about test products or treatments. Protocol development will take some time.
- The ratio between Fast Track and Normal Track may vary by year based on the evaluation of the specifics involved in the proposed project.

Staging "Fast Track" Integrated Solutions Projects

- 1. Priority established at Food Use Workshop
- 2. Over the next 6-12 months, IR-4 (Biologists, RFC, and other stakeholders) will work with researchers, companies, and EPA to develop a research plan and establish adequate research sites.
- 3. Research*
- 4. Reporting results

*Ideally, IR-4 will perform the necessary research in multiple locations in a single year. However, in some cases, the research will be carried over to a second or even third year.

Staging "Normal Track" Integrated Solutions Projects

- 1. Priority established at Food Use Workshop
- 2. Over the next 6-12 months, IR-4 (Biologists, RFC, and other stakeholders) will work with researchers, companies, and EPA to develop a research plan and establish adequate research sites.
- 3. Research*
- 4. Reporting results

*Ideally, IR-4 will perform the necessary research in multiple locations in a single year. However, in some cases, the research will be carried over to a second or even third year. <u>Question 2</u> – To keep things simple, do we place all projects on Normal track?

Integrated Solutions - Guardrails

CDFA and other sponsored research projects are important; however, projects need to be done correctly. HQ staff brings significant expertise to the potential projects, such as regulatory knowledge and technical interactions with appropriate company contacts. Input from HQ staff includes:

- Feedback from Biologists, Registration Team members, companies, and regulatory authorities (EPA and DPR)
- Direct sponsoring organizations to spend resources on potential "winners ." That means only working on products that will pass EPA and DPR regulatory scrutiny.
- Input on projects will take time.

<u>Question 3</u>: Should CDFA and other sponsored projects be eligible for Fast Track status?

Integrated Solutions Platform – Cost Recovery

Residue Mitigation projects require residue analysis. When using a contract laboratory, the analysis cost must be included in the IS project budget.

<u>Question 4</u> - If using an internal IR-4 laboratory to analyze samples makes sense, should the analysis cost be transferred out of the IS funding allocation and shared with the IR-4 laboratory?

IR-4 has a role in ensuring the success of CDFA and other sponsored funded projects. However, IR-4 Headquarters has limited resources to take on unlimited sponsored projects.

<u>Question 5</u> – Should the sponsoring organization provide nominal funding for IR-4 Headquarters contributions to the sponsored funded projects?

Funding Challenges

- Significant interest in IS Platform; FUW considered 112 requests
- Twelve IS Priorities established at 2024 FUW
 - 8 potentially funded with NIFA resources, 2 more than the target
- PMC allocated \$600,000 for 2025
 - Need approx. \$250,000 for legacy 2023/2024 projects
 - Allocation may be more as we get a clear picture of successful trials and the potential to enhance some of the projects with integrated products
 - \$350,000 for new NIFA-funded projects

IR-4 does not have adequate resources to fund all eight priority projects in 2025.

Funding Challenge \rightarrow Path Forward

- IS research is expensive, with multiple treatments/multiple products.
- We cannot get a reasonable estimate of the research costs without a draft protocol.
- Proposed plan....Start 2-3 Fast Track priorities from the "NIFA" pool. Funds not used in 2025 will be rolled over into 2026 ISP research.
- HQ will provide a cost estimate of the IS research for the remaining 2024 priorities by July 2025.
 - The remaining 5-6 **Normal Track** priorities from the 2024 workshop will be funded in 2026.
 - The PMC will decide how many new IS priorities to allow during the 2025 FUW based on the cost estimate and any remaining (carryover) funds.

Potential Cooperation

- Western Growers has joined Platform 10.
 - Platform10 is *"an international, multi-year collaboration that will accelerate promising biopesticide companies, rigorously assess products, enhance grower confidence, and facilitate market development and adoption"*.
 - They are not looking for funds.
 - Potential to cooperate on the same/similar protocols. Be part of a more extensive data development network.
- Canadian Pest Management Centre (PMC)
 - They have started their version of ISP. There may be opportunities to work closely with them on joint protocols.

Question 7 – Should IR-4 consider cooperation with the organizations

One More Thing

- Some have suggested that Integrated Solutions is a "Mission Creep."
 - While IS has been part of IR-4 since 2018, it is different. There are many pest management challenges on specialty crops, and this platform is designed to find solutions to some of the most difficult problems.
- Please note that the funds for IS were from legacy Biopesticide efficacy testing research.
 - It was thought that useful pest management systems could be developed by integrating biopesticides with conventional chemical pesticides.
 - There have been some successes, but we have yet to burn the barn down.
 - The COVID shutdown and HQ move significantly impacted IS. Also, turnover in IS management
- A reboot will require a cultural change.

<u>Question 8</u> – Should IR-4 consider suspending IS research and reestablishing Biopesticide efficacy testing?

Questions

- 1. Do we stick only to IS projects with the potential for "Simple success"?
- 2. Do we place all projects on the Normal track to keep things simple?
- 3. Should CDFA-funded projects be placed on the Normal Track?
- 4. If an internal IR-4 laboratory volunteers to analyze samples in a Residue Mitigation project, should the analysis cost be transferred from the IS funding allocation and shared with the IR-4 laboratory?
- 5. Should CDFA and other sponsors be expected to provide nominal funding to offset the cost of IR-4 HQ contributions to the sponsored projects?
- 6. Is the proposed plan for funding acceptable?
- 7. Should IR-4 consider cooperation with Platform 10 and/or PMC?
- 8. Should IR-4 consider suspending IS research and reestablishing Biopesticide efficacy testing?

National SOPs

Presenter: Christina Dineen







National SOP Update

IR-4 PMC Meeting October 2024 Christina Dineen

National SOPs

- SOPs in Progress
 - eFDB (N-02.1) **Revision 1** in review
 - EPA Inspection Procedures (N-01.2) in review
 - QA Inspections (N-01.3) to be reviewed
 - Training & Documentation (N-01.4) to be written

Looking Ahead

- Plans for additional webinar(s)/support
- Additional SOPs?



Committee Members: Leona Horst Martin Beran Mika Tolson Alex McFall

IR-4 Advisories

- Working Through Updates
 - 2005-01 Test Substance Container Disposal
 - 2004-02 Application Type Definitions

Committee Members: Mika Tolson Nicole Soldan Robert Welker Johanna Mazlo

Potential to Move Advisories to National SOPs

- Similar review process between both
- Difficulties knowing where to find advisories
- Training in eQA



IR-4 Advisories to National SOPs?

	National	
Title	SOP?	Notes
05-01 Test Substance Container Disposal Website Approval Procedure		Updates mostly complete
IR-4 Application Type Definitions	Yes	Working on updates
Responding to FDB QA Findings	Yes?	Retire? Update for eFDB, include in QA Insp. or eFDB SOP?
Storing & Maintaining Adjuvants (Spray Additives) for Use in IR-4 Field Residue Studies	Yes	
Maintaining Freezer Storage Systems at IR-4 Field and Lab Research Sites	Yes	
Shipping via Commercial Carrier with Dry Ice and Training/Certification Guidance	Yes	Expand to cover all practices for shipping commercially
Inventory and Transfer of GLP Raw Data and Other Records to IR-4 HQ	Yes	
Weighing Field Trial and Processing Trial Residue Samples	Yes	
Test/Reference Substance Container Labels - Required Information	Yes	
Test substance characterization results vs nominal formulation concentration	No	Retire, covered in protocol
Field Research Director Disposal of Field Data Book Copies	No	Retire, potential for additional eFDB SOP?
Foliar Broadcast Spray Swath vs Plot Width	No	Retire, roll necessary info to Application Type Definitions
Conflicting Chemistries in IR-4 Studies	No	Retire, covered in protocol
Test Substance Container Disposal	No	Retire, see 2005-01
	Test Substance Container Disposal Website Approval ProcedureIR-4 Application Type DefinitionsResponding to FDB QA FindingsStoring & Maintaining Adjuvants (Spray Additives) for Use in IR-4 Field Residue StudiesMaintaining Freezer Storage Systems at IR-4 Field and Lab Research SitesShipping via Commercial Carrier with Dry Ice and Training/Certification GuidanceInventory and Transfer of GLP Raw Data and Other Records to IR-4 HQWeighing Field Trial and Processing Trial Residue SamplesTest/Reference Substance Container Labels - Required InformationTest substance characterization results vs nominal formulation concentrationField Research Director Disposal of Field Data Book CopiesFoliar Broadcast Spray Swath vs Plot WidthConflicting Chemistries in IR-4 Studies	TitleSOP?Test Substance Container Disposal Website Approval ProcedureYesIR-4 Application Type DefinitionsYesResponding to FDB QA FindingsYes?Storing & Maintaining Adjuvants (Spray Additives) for Use in IR-4 Field Residue StudiesYesMaintaining Freezer Storage Systems at IR-4 Field and Lab Research SitesYesShipping via Commercial Carrier with Dry Ice and Training/Certification GuidanceYesInventory and Transfer of GLP Raw Data and Other Records to IR-4 HQYesWeighing Field Trial and Processing Trial Residue SamplesYesTest/Reference Substance Container Labels - Required InformationYesTest substance characterization results vs nominal formulation concentrationNoField Research Director Disposal of Field Data Book CopiesNoFoliar Broadcast Spray Swath vs Plot WidthNoConflicting Chemistries in IR-4 StudiesNo

Discussion: Can we move identified advisories to National SOPs?



National SOP Discussion

- Does committee need to come to PMC each time new National SOP is recommended?
- Does PMC want to review every new National SOP (and Advisory, if applicable)?



New Employee Orientation Module

Presenter: Rob Welker







New Employee Orientation Training

IR-4 PMC Meeting October 2024 Rob Welker

Training

• Outline of topics "complete"

- Input from management, QA and Study Directors
- Continues to evolve new items added as items arise
- Topics range from GLP training, to study overview, to how IR-4 operates

Building the presentation has begun

• Plan to have a rough draft together for review by Mid-Feb. 2025



Training

- Working with training committee
 - Input will be requested from the committee on the final draft

Final product

- Broken into modules for easy use
- Flexibility to use as in-person training or as pre-recorded online versions
- Exploring options for putting on the new IR-4 intranet and possibility for training certificates when online modules are completed.
- A resource for new employees as well as refresher for seasoned employees



Committee Update: Network Expansion Project

Presenter: Dr. Jaimin Patel





NET (Network Expansion Taskforce) Updates from Jaimin (July 2024 onward):

- **Monthly Meetings:** Regular discussions are held with NET taskforce members, including Jerry Baron, Rich Bonanno (recently transitioned from NCSU to the Extension Foundation as Executive Director), Michelle Samuel-Foo, Michelle Infante-Casella, Gregory Goins, Moses Kairo, Simon Zebelo, Alice Axtell, and Jaimin Patel.
- **Publication Submission:** Alice and Simon have submitted an article for publication in *Entomology Today*. The article highlights the background of IR-4 and its initiatives to foster collaboration with minority-serving institutions. We expect this publication by the end of December 2024.
- **Resource Provision:** IR-4 posted valuable resources for stakeholders for active participation in the Food Use Workshop, including:
 - 1. Video: The Food Use Workshop Process
 - 2. Video: How to Submit a Project Clearance Request
 - 3. Video: Nominating Projects for the Food Use Workshop
 - 4. IR-4 Terminology Handout
 - 5. IR-4 Research Cycle Handout
- Small Farmers Conference: Simon Zebelo is organizing a Small Farmers Conference on November 1-2 at UMES, featuring an IPM session where Marylee Ross is expected to deliver a 10-15 minute presentation on IR-4.
- **Board Membership:** Jerry has joined the Board of Directors with the Minor Use Foundation.

Event Participation and Presentations by IR4 Biologists:

- 1. Jaimin presented an IR-4 poster at the Annual Phytopathological Society meeting in Memphis, TN, from July 28-30, 2024, where he connected with a potential new FRD from the 1890 institution. EPA expected to release Fungicide Strategy draft sometime in early next year to reduce impact of fungicides on endangered & threatened species.
- 2. Roger presented at the Sesame Field Day and showcased an IR-4 poster at the Clinton Research Station in NC in July 2024.
- 3. Roger explored local specialty crop fields in Wisconsin with Dan Heider, identifying key pest management needs.
- 4. Jaimin gave a brief introduction about IR-4 to the Association of Research Directors of 1890 Institutions during the ARD Fall Business Meeting on September 23, 2024, in Raleigh, NC. Dr. Moses Kairo (UMES) and Dr. Gregory Goins (NCA&T) joined me in emphasizing the importance of partnering with IR-4. Our communications officer (Hannah Ross) informed me that a couple of folks registered for IR4 newsletter on that day due to my presentation.
- 5. Jaimin attended a virtual workshop on the emerging Vascular Streak Dieback disease, hosted by Dr. Fulya Baysal-Gurel at Tennessee State University, noting its threat to redbud nurseries and other ornamental crops.
- 6. On October 4, Alice introduced IR-4 to undergraduate students at the University of Wisconsin, at the invitation of Dr. Clint Beiermann, who teaches a pest management class.
- 7. Roger distributed handouts at the NC Sweetpotato Field Day on October 10, updating stakeholders on the status of ongoing and completed projects.

Ways of Working in the Food Program

Presenters: Dr. Jerry Baron & Dr. Debbie Carpenter





Updated Operational Challenges & Potential Solutions

Challenges articulated by companies

- Projects with new products added after the Workshop
- Incomplete Directions for Use when reviewing PCRs
- Patchwork of Test Substance requests
- Disconnect between performance and residue protocols

<u>Reminder</u>

Food Workshop in September \rightarrow NRPM in October \rightarrow Spring Research

- Residue field trials assigned at NRPM
- Product Performance, IS and Ornamental trial assignment occurs after NRPM

<u>Workload Issue - Study Directors, RFC, and Biologists have significant</u> <u>work to do in concentrated time</u>

Projects added after the Food Use Workshop

- Syngenta is now limiting IR-4 research with its products
 - Deferred approval of any PCR received after July 1, 2024
 - Would not support the use of their products in PUP/RU as well as new Integrated Solutions Platform projects
- Integrated Solutions is the primary driver of the concern.
 - IR-4 has a solid research plan for residue and performance shortly after NRPM.
 - IS Protocol development can be complex and take time. We will not know what will be included until closer to the field season. Addressed by:
 - Delaying the start of most of the new IS Platform research by 18 months gives all parties adequate time to develop appropriate and realistic protocols....more later

Incomplete Directions for Use (DFUs)

- Some PCRs that are submitted close to the PCR submission deadline come in with limited information
- Address by:
 - Establishing an earlier deadline for submissions of new requests. In 2024, the deadline was modified to July 31. For 2025, it will be July 1.
 - Training PCR submitters on the need for complete and logical DFUs as well as the IR-4 Biologists screening new requests and having follow-up inquires if incomplete or questionable info is provided.

Test and Reference Substances

- Test/Reference substance ordering is getting more complex
 - Company systems and larger demands for IS Projects
 - Sometimes, IR-4 competes with company priorities for available product
 - Significant cost; limit requests to what is needed
- Addressed by:
 - HQ piloting the use of the Smartsheets system in 2025 ordering with Syngenta, Corteva, and Bayer
 - Single point of contact for all orders
 - Earlier notification of IR-4 needs
 - Easy for all to see what is being requested

Disconnect between performance and residue protocols

- For projects where performance and residue data are needed (about 75% of the studies in 2024), HQ establishes a process to connect protocol development. Addressed by:
 - Both protocols will be sent to the company simultaneously to facilitate ease of review.
 - Once the protocol is ready for authorization, the biologist will sign the performance protocol, and the SD will sign the residue protocol.
- For performance protocols without a corresponding residue study, the biologist drafts the protocol and sends it to the registrant for comment.

iAdvantage electronic Field Data Notebook Update

Presenter: Philip Moore







eFDB Update

October 2024 PMC Meeting

Overview: eFDBUsage by the Numbers*

- **347** eFDBtrial notebooks for 2024 have been created
- 848 application forms provided for 2024 trials
- **573** applications conducted / entered in eFDB for 2024 trials
- 33 FRDs have entered application data, out of 44 total for 2024
- **41** eFDBhave reached the QC review phase (<1 week turnaround)
- First few eFDBshave completed QA field data audits
- At 1st eFDBcompletion, FRDs receive a Thank You letter and Gift.
 Three FRDs have received it
- 1 instance of data loss. 2 sample forms describing: sample modification, weights, time collected and placed in freezer, and transportation method. Due to Windows mobile edition error.



Overview: Current Status and Future Plans

• Progress Since July PMC meeting:

- Finalized eFDB forms for 2025 (eFDBv. 2.0), changes based on user feedback
- Revised paper (backup) Field Data Book matchingeFDBforms
- Surveyed users for desired training they would like before the 2025 field season
- In-progress: <u>eFDBGuidance Document</u> and <u>National SOP</u> for version 2.0 changes

• Changes for eFDBVersion 2.0:

- <u>Facility Files eFDB</u> will be optional for IR-4 FRDs. Includes common site log forms. Other facility docs are uploaded there rather than each trial eFDB
- <u>New forms:</u> communication log, document upload log, shipping CoC, and FRD information
- <u>Modified forms</u> to remove required date format and other limitations to user entries
- Combined application calibration forms, to limit need to switch between forms
- eFDBs in the system will now be identified by Field ID/ Chemical/ Crop. Rather than only FID#

2025 eFDBwill be Fully Electronic

- 2024 IR-4 allowed users to enter data in paper forms at any time. Including old style forms. As long as it was transcribed and uploaded to the eFDB.
 - Allowed users to be more comfortable with the transition to eFDBs, by utilizing old data collection methods. They see how that translates into the electronic version upon transcription.
- Use (or over-use) of paper forms in 2024 have impacted reviewers, who must compare transcriptions. And often requires FRD changes to match entries.
- 2025 IR-4 protocols will only allow paper forms in specific instances. If used outside that allowance, a deviation is required.
 - Users will be expected to use the eFDBas the first data collection method, except for facility files and other forms not available in the eFDB, like the application diagram and plot maps.
- Paper forms are still provided and should be available for when devices fail.
 - FRDs should communicate with the Study Director if they cannot use the eFDBas intended.



Can we remove the old FDB from website?

- Historically, FRDs received a paper FDB and had access to print current and past forms.
- Currently, each trial eFDB contains paper forms for use in that trial.
- For 2025, <u>plan to remove this</u> webpage and only allow the eFDB forms in the system.
- FRDs will need to ask Debbie Carpenter to use old style forms (and protocol change).
 - A good reason is required, such as an announced retirement.

bout IR-4 🖌 🛛 Food Crops 🖌 Envi	ironmental Horticulture Events & Tr	raining 🛛 Stakeholder Resources 🗸	Submit a Request >
Food Crops 🔗	Field Data B	ook	
Food Crop Program	Every year, IR-4 Project field research directors (FRDs) use a physical field data book to trac information as part of IR-4 residue studies. Sections of the three most recent field data books are linked below. FRDs are encouraged to print additional pages/sections as needed for their records.		
Food Use Workshop			
Biopesticide Regulatory Support Program			
Crop Grouping +			
Database Search Options	Test Substance Chain of Custody Form		
Integrated Solutions			
International Programs			
Researcher Resources -	2024 Protocol and Crop	2023 Protocol and Crop	2022 Protocol and Cro
EPA Regulatory Documents	Library	Library	Library
- Food Crops Field Data Book	Protocols	Protocols	Protocols
Monthly Activity Reports			
Residue and Product Performance	Crop Library	Crop Library	2022 Field Data Book
Submit a Request	2024 Field Data Book 2023 Field Data Book	Revisions for 2022	
Successes & Stories			
Quality Assurance +	2024 Cover Page	2023 Cover Page	Instructions and Changes

Reached the Limit of User Licenses

- IR-4 annual contract license is for up to 100 users: \$ 249,917.99
 - ~\$2500 per user / ~\$720 per FDB
 - After that 100 user threshold, iAdvantage will charge for an "unlimited" license, which is 2X fee
- Must avoid going above 100 total users or pay 2X
 - Currently have 103 users, with two 2025 retirements and one user nolonger doing GLP trials.
- We are ok for now, but no new user space is available!
- Users will be disabled as needed to make room for new FRDs, etc.
- Usernames are provided to all who enter or should have access to field data:
 - Temp-technician or students
 - Faculty advisor as a backup
 - Regional admin office staff
 - Note: 25 users are Canadian





We've come a very long way from 1 year ago. IR-4 nation-wide commitment to eFDBs has taken hold. I think, all see the value and want to improve the system. Issues and questions come up and are being handled quickly.