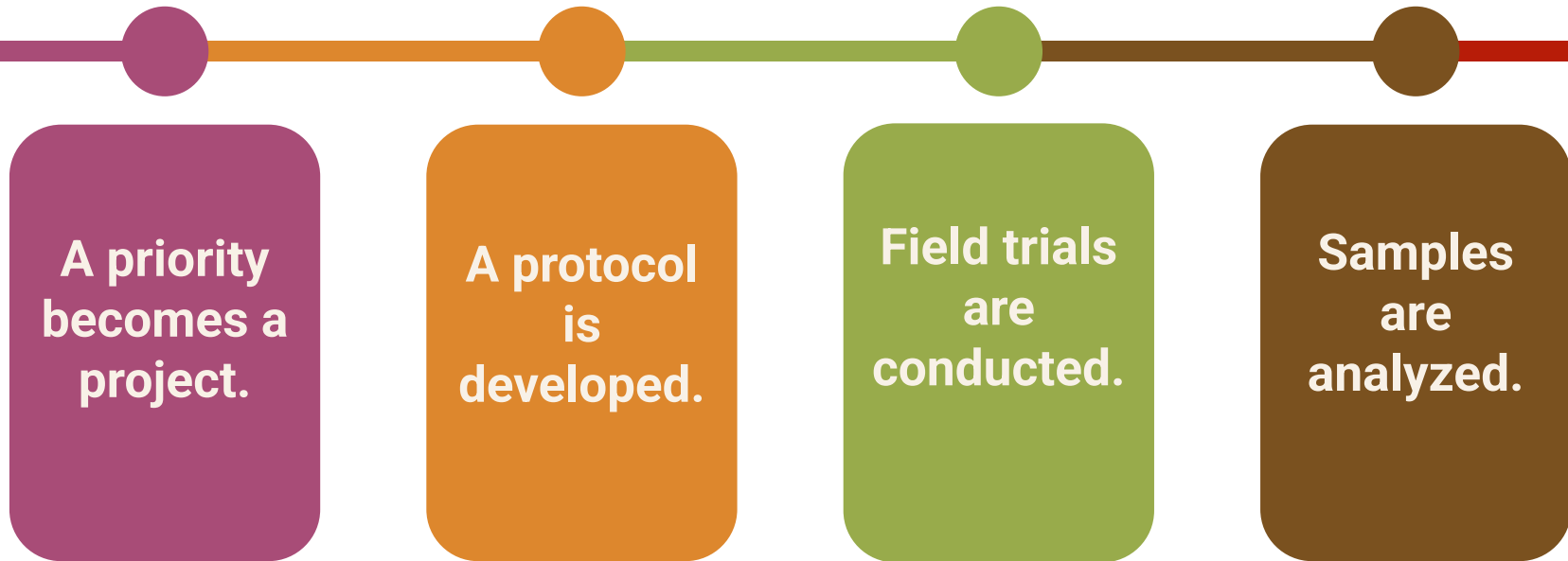




**NATIONAL EDUCATION
CONFERENCE** February 3-5, 2026

Life of a Project - Part 2

Jimmy Byrtus, Scott Muir, Tom Pike & Cristina Marconi



Quick Review...



**Final Report is
written.**

SD Perspective



Jimmy Byrtus

Final Report Writing

1. **What you do matters!**
 - a. Executive Summaries
 - b. Tables
 - c. Field Data Summaries

Final Report Writing

1. **Information for Executive Summary**
 - a. Number of Applications (TRT02 & TRT03)
 - b. Retreatment Interval
 - c. Application Rates, and Total Rate for the trial
 - d. Sampling PHI, Decline Trial Sampling Days

Final Report Writing

1. Information for Tables

- a. Proper Trial ID
- b. Trial Location (not necessarily FRD site)
- c. Trial Start Year
- d. Soil Characteristics: Type, %OM, pH, CEC
- e. Meteorological: Rainfall, Temperatures (normal?, above or below average?)
- f. End Use Product (test substance trade name)

Final Report Writing

1. Information for Tables (continued)

- g. Application Method
- h. Crop and Variety
 - i. Timing of Application (vegetative, flowering, fruiting)
 - j. Rate per Application (lb. ai/A)
 - k. Spray Volume (gal/A)
 - l. Retreatment Interval
- m. Adjuvant Used
- n. PHI (Pre-Harvest Interval)

FIELD DATA SUMMARY

Pesticide/Commodity/Field ID No.: Bifenthrin/Coffee/11527.18-HI152

Field Research Director (FRD): James Kam

University of Hawaii (Manoa), College of Tropical Agriculture & Human Resources,
Affiliation of FRD: 3190 Maile Way, St John 307, Honolulu, HI 96822

Other Field Personnel: Julie Coughlin

TEST SUBSTANCE RECORDS					
Test Substance (Trade Name):		Brigade WSB			
Batch/Lot No.:	M1709-017	Date Received:	5/9/2018		
		Expiration Date:	4/3/2020		
Storage Location:	University of Hawaii-CTAHR, Plant and Environmental Protection Service, 3190 Maile Way, St John Room 006, Honolulu, HI 96822				
Storage Temperature Range (from receipt of test substance to last application):		23.665-26.28 °C			
Spray Additives (Adjuvants) Used:		Liberate, Nonionic surfactant (Non-Silicone)			
TRIAL SITE INFORMATION					
Test Site:	Waimanalo Experiment Station, 41-698 Ahiki St, Waimanalo, HI 96795				
Soil Type/Texture:	Waialua (WnB), Clay Variant				
% Sand:	8.7	% Silt:	45.2	% Clay:	46.1
% Organic Matter:	3.366	Soil pH:	6.1	CEC:	33.34
Crop Variety:	Guatemalan (Kona Typica)	Age of Trees:	9 years		
Row Width (ft):	12	Plant Spacing:	N/A ¹		
No. Trees/Control Plot:	N/A	No. Trees/Treated Plot:	N/A		
Control Plot Dimensions:	12' X 5 rows X 100'=6000 ft ²	Trt 02 Plot Dimensions:	12' X 3 rows X 100'=3600 ft ²		
Maintenance Fertilizers and Pesticides (does not include adjuvants)					
Glyphosate; 1/21/18, 2/21/18		Beauveria bassiana; 6/28/18			
Spinetoram; 5/10/18					

¹N/A=Not Applicable

Final Report Writing

Field Data Summary Information

Field Data Summary		Application No.: 1 of 3 (Treatment 02)	
Pesticide/Commodity/Field ID No.:		Bifenthrin/Coffee/11527.18-HI152	
APPLICATION RECORDS			
Application Date:	9/14/2018	Days From Last Application:	N/A ¹
Application Equipment:	Mistblower – Solo Port 423 – Serial No. 503678		
Type of Application:	Foliar Directed		
Length of Row (ft):	100	Number of Trees:	N/A
Number of Nozzles:	1	Row Width (ft)	12
Screen Mesh:	N/A	Nozzle Spacing (in):	N/A
Nozzle Brand/Size/Type:	Standard nozzle that comes with sprayer. Setting = 4		
Equipment Calibration Date:	9/14/2018	Treated Area (ft ²):	3600
Boom Discharge Rate (mL/sec):	35.78	Total Pass Time (sec):	749.04
Calculated Delivery of Spray Solution (GPA):	86		
Tank Mix Amounts for Treatment:			
Carrier (Water) (mL):	30000		
Volume of Carrier (Water) Removed (mL):	35		
Formulated Product (g):	42.29		
Adjuvant (mL):	37.5		
Total Mix Volume (mL):	30002.5		
Actual Application Rate:			
Treatment No.	Protocol Rate (lb ai/A)	Actual Rate (lb ai/A)	% Deviation From Protocol Rate
01	N/A	N/A	N/A
02	0.1	0.101	1
Air Temperature (° F):		90	
Wind Speed (mph):		0-4	
Crop Height:		8-10 feet	
Commodity Growth Stage:		Fruiting	
Date of First Rain after Application:		9/27/2018	
Time after Application of First Rain:		13 Days	
Amount of First Rain after Application (in):		1.5	
Date of First Irrigation after Application:		N/A	
Time after Application of First Irrigation:		N/A	
Amount of First Irrigation after Application (in):		N/A	

¹N/A=Not Applicable

Final Report Writing

Field Data Summary Information

FIELD DATA SUMMARY		HARVEST AND SAMPLING		
Pesticide/Commodity/Field ID No.:		Bifenthrin/Coffee/11527.18-HI152		
SAMPLE COLLECTION AND STORAGE				
Harvest Date:	10/11/2018	Sample Date:	10/12/2018	PHI (days): 14
Crop Fraction Sampled:		Ripe to overripe (red to brown) coffee cherry		
Harvesting Equipment:		Picked cherry by clean, gloved hands into plastic bags		
Harvesting Procedures:		Started by collecting with TRT#1 sample "A" by removing about 16 lbs. of coffee cherry from both sides of the untreated rows. They were sampled from high, middle, and low areas, from exposed and sheltered with consideration for fruit load. Changed gloves between samples. Collected sample B in the same manner with a separate pass. After completion of sampling for treatment #1, placed samples into a cooler with gel ice packs and securely closed. Sampled treatment #2 samples C and D in a similar manner. Less than 50% of the harvestable crop was sampled.		
Trimming, Cleaning, Cutting, Drying, Composting, etc:		On 10/11/2018 the flesh was removed from beans by running through a mechanical pulper and demucilager and then placed into an oven for drying. Samples were dried in the ovens for 18-19 hours. Parchment coffee was polished to obtain the green bean fraction. Placed green bean sample directly into residue bags, and placed bags into freezer for shipment to residue lab.		
Sample Handling between Field and Freezer (or Field and Shipment):		Sample bags containing coffee cherry placed in coolers with gel ice packs and transported by truck to University of Hawaii field lab for pulping and drying on 10/11/2018. 10/12/2018 samples of green bean were placed into residue bags for all samples.		
Maximum Length of Time from Treated Sample Collection to Frozen Storage:		15 minutes		
Samples were kept frozen from sampling to shipment:			Yes	X
No				
<i>"Kept frozen" indicates storage at temperatures generally <0 °F (-18 °C).</i>				
If "No" is indicated, explain:				
Shipped: Frozen, in 30 kg of dry ice, in sealed Styrofoam boxes				
Shipped Via:	FedEx; Priority Overnight	Shipment Date:	12/10/2018	
METEOROLOGICAL INFORMATION				
Were the test plots irrigated?	Yes, but not from first application through sample collection			
Type of Irrigation:	Drip			
Was the weather during this field trial normal for this test site?	Yes			
Unusual weather occurrences:	Yes, Tropical storm Olivia came through the islands on 9/12/2018 bringing heavy rains and flooding. (two days before the first application)			
PHYTOTOXICITY, EFFICACY & YIELD				
Were any phytotoxic effects seen?	No			
Severity & symptoms of any phytotoxic effects:	N/A ¹			
If efficacy/yield data were recorded, describe any differences between treatment(s) and controls:	N/A			

¹N/A=Not Applicable

Final Report Writing

Field Data Summary Information



**Final
Report is
written.**

**Quality Assurance
audits are complete.**

QA Perspective



Scott Muir

Field Critical Phase

(Examples: Application, Harvest/Sampling, Sample Handling, Test Substance Handling)

- Is the protocol being followed?
- Are SOPs being followed?
- Is equipment properly calibrated/maintained?
- Is the Test Substance properly stored and labeled?
- Is personnel properly trained?
- Are samples labeled/handled/stored properly?
- We generally target 30% of your trials. Please help us schedule our visits.



Laboratory Critical Phase

(Examples: Sample receipt/storage, extraction/clean-up, reference substance handling, preparation and storage/stability of standards)

- Is sample chain of custody properly tracked?
- Is the Analytical Method being followed?
- Are modifications to the reference method documented?
- Are SOPs being followed?
- Is equipment properly calibrated/maintained?
- Are reference materials and reagents properly stored and labeled?
- Is personnel properly trained?



Image generated by Google Gemini

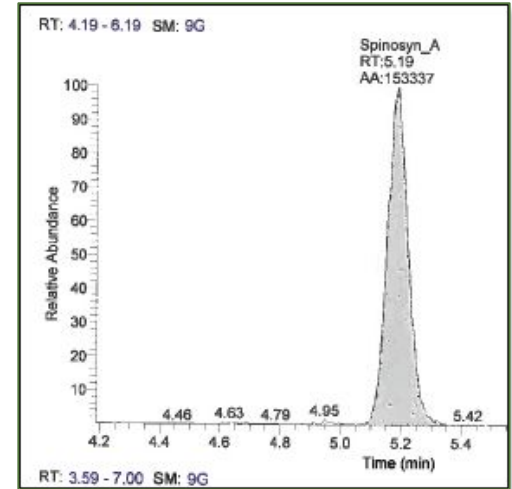
Field Raw Data

- The Field Data Book is checked for accuracy and Protocol/GLP compliance.
- Anything that can be verified is
 - Is training documented?
 - Compare time points on sampling sheets to freezer content logs.
 - Independently calculate boom discharge, application rate, spray volume, etc.
 - Are any changes GLP compliant?
 - Are eFDB *Notes* adequate?

PR Number: 06529	
Field ID/ Chemical/ Crop: 06529.25-CA17/ Pyridate/ Tomato	
	Completed By
Part 1. GLP Compliance	
Part 2. Personnel	
Part 3. Notes and Communication	
Part 4. Test Substance and Adjuvant	
Part 5. Test Site	
Part 6. Applications	
Part 7. Sampling and Storage	
Part 8. Sample Shipment	
Part 9. Weather and Irrigation	

Laboratory Raw Data

- The entire data package is checked for accuracy and Protocol/GLP compliance.
- Anything that can be verified is
 - Is training is documented?
 - Compare COA purity to reference standard concentration.
 - Compare chromatogram peak area to residue calculations/recoveries.
 - Are the instrument parameters comparable to the reference method?
 - Are all modifications to the reference method included in the working method/ASR?
- Is there a valid reason for rejecting data? Is the rejected data retained?



Analytical Summary Report

- Is this report an accurate presentation of the data and results?
- Are all participants included?
- Is the Compliance Statement accurate?
- Is any rejected data explained?
- Is the recovery chromatogram included?
- Are the residue/recovery example calculations included?
- QA provides a Quality Assurance Statement with the types/dates of inspections and the date(s) findings were reported to TFM and SD.

ANALYTICAL SUMMARY REPORT	
Project No. 13103 Spinosad: Magnitude of the Residue on Pea (succulent shelled) (seed treatment)	
<i>Authors</i> Victor S. Bauder Gail E. Mahnken, Ph. D.	
<i>Laboratory Research Director</i> Gail E. Mahnken, Ph. D.	
<i>Performing Laboratory</i> Food and Environmental Toxicology Laboratory University of Florida P.O. Box 110720 Gainesville, FL 32611-0720	
<i>Study Director</i> Thomas Pike	
<i>Sponsor</i> Interregional Research Project No. 4 (IR-4) Headquarters NC State University 1730 Varsity Drive Venture IV Suite 210 Raleigh, NC 27606	
<i>Laboratory Study ID No.</i> 13103.21-FLR10	
<i>Field Study ID No.</i> 13103.21-CA77 13103.21-OR275 13103.21-MH195 13103.21-WA347 13103.21-NI233 13103.21-WI363 13103.21-OH253	
<i>Study Timetable</i> Study Initiation Date: March 16, 2021 Experimental Termination Date: April 27, 2022	
<i>Report Date</i> August 01, 2023	

Contributing Scientist Report

These activities, data and reports are audited in the same manner as the field and lab.

Examples:

- Processing or Seed Treatment Trials
- Samples initially shipped to one lab and then shipped to another lab for analysis.
 - Impending government shutdown
 - Lab closure
- QA provides a Quality Assurance Statement with the types/dates of inspections and the date(s) findings were reported to TFM and SD.

The image shows the cover page of a report from SGS. At the top left is the SGS logo. In the center, a box contains the title: "SPINOSAD: Magnitude of the Residue on PEA (succulent shelled) (seed treatment) Seed Dose Verification Phase Report". Below this, the report details are listed in a two-column format:

DATA REQUIREMENT(S):	EPA Series 860 Guidelines
AUTHOR(S):	Zhilong Zhang, Ph.D. Erica Varenhorst M.S.
COMPLETION DATE:	March 14, 2023
PERFORMING LABORATORIES:	SGS North America, Inc. 1405 32 nd Ave. Brookings, SD 57006 USA
LABORATORY PROJECT ID:	Study Number: 13103 JR-4 PR No. 13103.VD-SGS01 SGS Internal Project Number: A2139BK
SPONSOR:	JR-4 Project Headquarters NC State University 1730 Varsity Drive Venture IV, Suite 210 Raleigh, NC 27606

Final Report

- Is the report an accurate presentation of the protocol, data, analysis and results?
- Is the Compliance Statement accurate?
“This study as indicated by responsible individuals, meets current Good Laboratory Practice Requirements of 40 CFR Part 160, except as noted below. These deviations do not affect the conclusions presented in this report.”
- QA Provides a Quality Assurance Statement
“The project described in this report was subject to inspection by Quality Assurance personnel for the following aspects of the project and at the intervals listed below.”

TITLE PAGE			
SPINOSAD: MAGNITUDE OF THE RESIDUE ON PEA (SUCCULENT SHELLED) (SEED TRT)			
<u>Data Requirement</u>			
U.S. EPA OPPTS 860 Series Guidelines			
<u>Author</u>			
Christina Dineen IR-4 Project North Carolina State University 1730 Varsity Drive, Suite 210, Venture IV Raleigh, NC 27606			
<u>Study Completed on</u>			
See page 7 for Study Director's signature			
IR-4 PR. No. 13103			
<u>Performing Laboratories</u>			
See pages 5-6 for list of performing laboratories			
<u>Analytical Laboratory Identification Number</u>			
13103.21-FLR10			
<u>Seed Treatment Identification Number</u>			
13103.ST-CAT01			
<u>Seed Treatment Verification Identification Number</u>			
13103.VD-SGS01			
<u>Field Identification Numbers</u>			
13103.21-CA77	13103.21-MI195	13103.21-NU233	13103.21-OH253
13103.21-OR275	13103.21-WA347	13103.21-WI363	



**Final
Report is
written.**

**Quality
Assurance
Audits are
complete.**

**Final submission and
tolerance established.**
Regulatory Perspective



Tom Pike

What is a Tolerance Petition?

A tolerance petition is a formal request to EPA to establish pesticide tolerances on the target crops

The tolerance petition contains (or references) all of the material that EPA needs to evaluate in order to establish the requested tolerances

Initial Preparation

- Determine what studies will be included in the submission
 - Studies are submitted on a “per Active Ingredient” basis
 - More efficient to bundle multiple reports into a single submission
 - Can only submit a given AI once per 12 month period
- Check on status of final reports to be included in the submission
 - Signed or close to signature
- Ensure that registrant is satisfied with E/CS data generated by IR-4

Drafting the Petition



Information included in Tolerance Petition

- Use instructions to be added to label(s)
- Any relevant ChemSAC decisions that may impact the submission
- Final Reports
- Proposed tolerances
 - New uses and updated tolerances

New/Revised Tolerances

- In addition to new tolerances being proposed, IR-4 also updates older tolerances for the active ingredient
 - Converting existing tolerances on older crop groups/subgroups to the updated ones, aka Crop Group Conversion
 - Expanding individual tolerances to crop group/subgroup tolerances, aka Crop Group Expansion
- Remove erroneous tolerances that may result from these new additions

Reasons for Need

- Critical portion of the submission, need to justify why it is in the public interest
- Will often reach out to the stakeholder to request their input
- Adding this information in the original PCR is SUPER helpful when it comes time to make the submission

International Coordination

- IR-4 coordinates submissions with PMC in Canada
 - Joint Review – IR-4 and PMC submit to their respective agencies simultaneously, done in cases where IR-4 and PMC both conducted trials for a study
 - Workshare – One party provides their data to the other for submission some time after that initial submission was made
- IR-4 aligns new tolerance requests with existing Codex tolerances where appropriate
 - Registrant may not want to harmonize with Codex if aligning with Canada is more important, for instance

Reaching out to the Registrant



Once the Petition is Ready...

- IR-4 provides materials to the registrant needed to prepare the rest of the submission package
 - Tolerance petition, final reports (if not already provided), document checklist
- IR-4 then waits to receive the submission documents from the registrant

Once Documents are Received...

- IR-4 reviews the submission documents for accuracy
 - Is the proposed use pattern supported by the residue data?
 - Were all necessary label changes made to support any updated tolerances?
- Most critically – ensure that there are no changes to the labels not associated with items included in the IR-4 submission
 - Essential to receive the waiver from PRIA fees
- Once everything is accurate, the submission is made through the Central Data Exchange (CDX) Portal



Tangent: What are PRIA Fees?

PRIA Fee Category Table - Registration Division (RD) - New Uses

Table 2.

EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	FY'25 - FY'26 Fees (\$)
R130	14	First food use; indoor; food/food handling. (2) (3) (5)	23	288,108
R140	15	Additional food use; Indoor; food/food handling. (3) (4) (5)	17	67,230
R150	16	First food use. (2) (3) (5)	23	477,215
R155	17	First food use, Experimental Use Permit application; active ingredient registered for non-food outdoor use. (3) (4) (5)	21	397,680
R160	18	First food use; reduced risk. (2) (3) (5)	18	397,680
R170	19	Additional food use. (3) (4) (5)	17	119,415
R175	20	Additional food uses covered within a crop group resulting from the conversion of existing approved crop group(s) to one or more revised crop groups. (3) (4) (5)	14	99,513
R180	21	Additional food use; reduced risk. (3) (4) (5)	12	99,513

PRIA Fee Overview

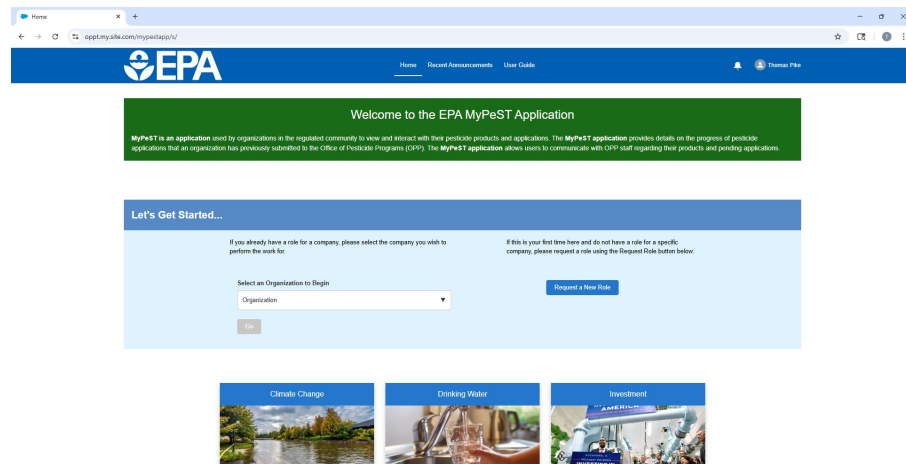
- Fees associated with specific action categories, tied to review periods
- IR-4 is exempt from PRIA fees provided we meet the Public Interest Finding, but PRIA categories still dictate review time
 - Generally 15 months for most IR-4 submissions (at least on paper...)

Post-Submission



Tracking Projects

- After submission, IR-4 tracks status of the submission through the MyPest App
 - Provides updated Expected Completion Date for submissions
- If requested, IR-4 provides updated submission documents to EPA
 - Typically revised tolerances in response to HED review



Tolerances Established/Use Registered

- When review completed by EPA, tolerances proposed in the petition are published in the Federal Register
- Following this, registrant will work with the states to implement labels

Growers MUST have a label with the use in order to use the pesticide on the crop(s) in question, a tolerance alone isn't sufficient!

- Supplemental labels can get the use to the grower faster



**Final
Report is
written.**

**Quality
Assurance
Audits are
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**Final
submission
and
tolerance
established.**

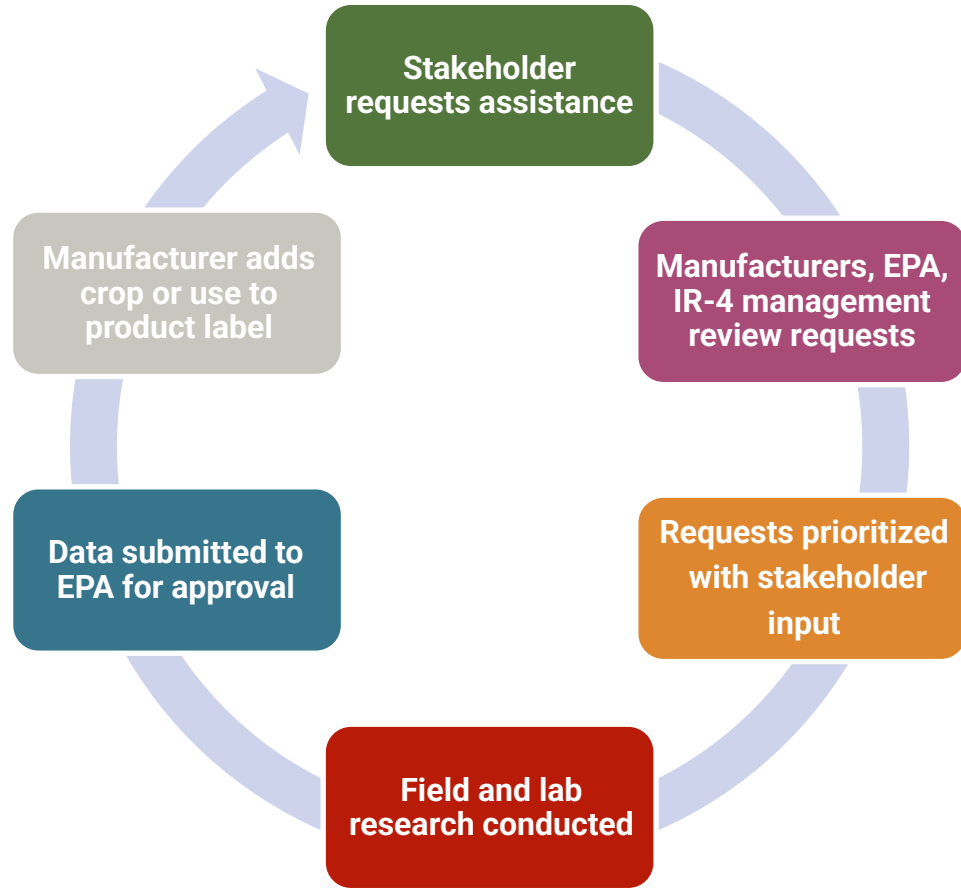
**The Finish Line:
Another tool for the
growers.**

Management Perspective



Cristina Marconi

FOOD CROP RESEARCH CYCLE



Once the new use is on the label...

MISSION ACCOMPLISHED!

Another tool for our US growers





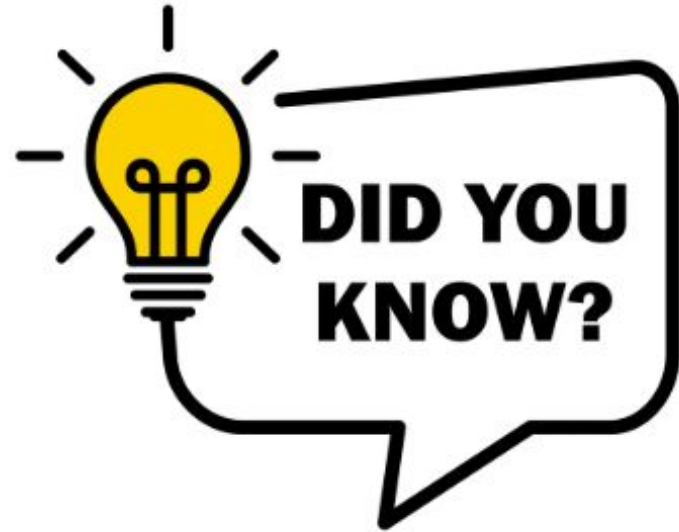
IR-4's Mission

Facilitate regulatory approval of sustainable pest management technology for specialty crops and specialty uses to promote public well-being.

In other words...

- Ensure that specialty crops and minor uses have legal access to **safe, effective crop protection** tools
 - Work with **growers and other stakeholders** to identify pest management needs and solutions
 - Conduct necessary crop safety, efficacy, and residue **research**
 - **Submit data** to the U.S. Environmental Protection Agency (EPA) and other entities for approval of new uses

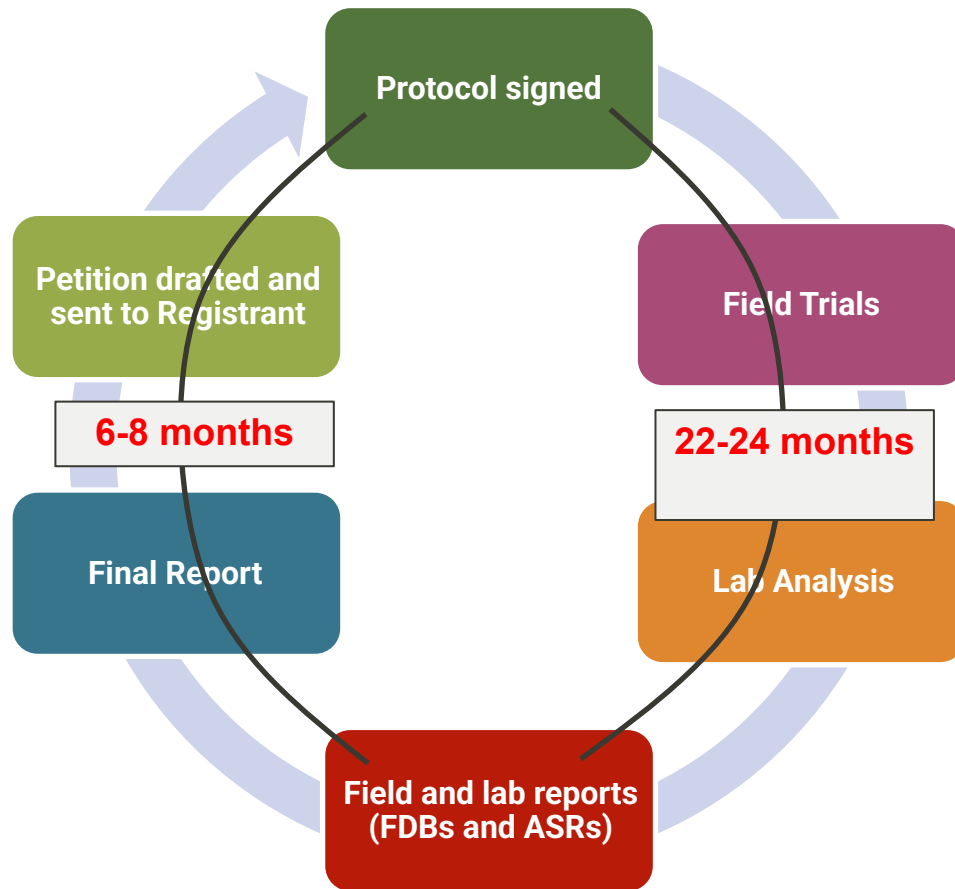
IR-4 is the only publicly-funded program that conducts research and submits petitions to the U.S. EPA for the approval of new tolerances and registration of additional uses of pest management tools.



Why Our Work Matters

- **Pest pressure** on specialty crops is significant
- **Resistance** to existing pest products is increasing
- **Limited tools** are accessible for managing pests on specialty crops
- **Changing climate** = increasing pest problems
- **Reduced-risk** products and emerging technologies are needed by growers
- **International harmonization** helps growers access export markets
- **Specialty crops** are vital to public health, the environment & the economy

30-MONTH TIMELINE



PROJECT TITLE: _____
PR No.: _____

SPONSOR/TESTING FACILITY:

IR-4 Project Headquarters, North Carolina State University, 1730 Varsity Drive, Venture IV, Suite 210, Raleigh, NC 27606, Telephone# (919) 515-1552

STUDY DIRECTOR¹:

_____ IR-4 Project Headquarters, North Carolina State University, 1730 Varsity Drive, Venture IV, Suite 210, Raleigh, NC 27606, (919) 515-6596, cdineen2@ncsu.edu

STUDY AUTHORIZATION:

_____	_____
Sponsor Representative / Date	_____ Study Director / Date

STUDY DIRECTOR INITIALS: _____

1 GENERAL INFORMATION

1.1 JUSTIFICATION AND OBJECTIVES:

IR-4 has received a request for the minor use of flazasulfuron on peach for pre- and post-emergence control of annual broadleaf weeds, sedges such as yellow nutsedge, and annual grasses.

To establish this tolerance, this study will collect and analyze residue samples to determine the magnitude of the residue in or on the commodity per EPA Series 860 Guidelines. The purpose of this study is to collect and analyze treated and untreated residue samples from appropriate field sites according to the application parameters requested to provide the sponsor with residue chemistry data to support a pesticide tolerance.

PROPOSED DATES:
Experimental Start: _____ 01/2026
Experimental Termination: _____ 11/2027
Study Completion: _____ 10/2028

- Protocol signed
- Field and lab work completed
- Final report signed and ready for submission



Things that impact the timeline

Prioritizing projects

- Stoplight analysis
- New chemistry

Ongoing projects

- Completing field work on the year assigned
- Prompt completion of field (eFDBs) and lab reports
- Reference substance receipt or recertification
- Preparing SS samples and running the 0-day samples (GLP studies)
- Addressing QA findings and SD questions in a timely fashion (GLP studies)
- Writing Final Reports based on submission timelines

Submissions (GLP studies)

- **Registrant schedule for submissions**
- Delays on receiving submission documents from registrants
- EPA hold for chemical submission

IR-4 Culture

“It takes a village”

Working together and being aligned towards the common goal - serve the specialty crop and minor use community - is our main goal.

We are a service provider

Can you picture in your head the responsibility each of us carry in our day-to-day work?

IR-4 in the past 10 years

The food use program

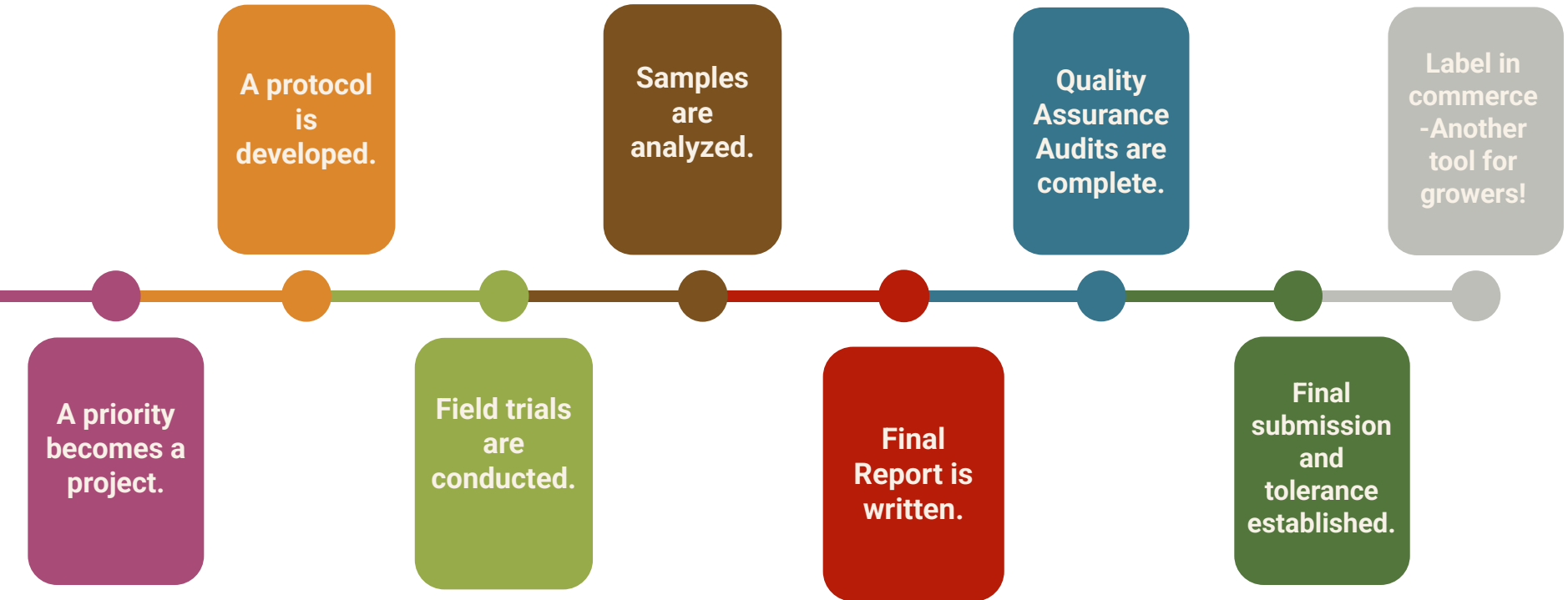
**1834 new tolerances established
which translated into 8708 new uses**

How can IR-4 stick to its mission?

By working together to produce high quality and reliable data that will support the proposed tolerances in our submissions. And this will allow our growers to have the much needed tools to produce safe and high-quality food and plants for all of us.



The Life of a Project



Thank you!

Jimmy Byrtus (jpbbyrtus@ncsu.edu)

Scott Muir (rsmuir@ncsu.edu)

Thomas Pike (tjpike@ncsu.edu)

Cristina Marconi (cmarche@ncsu.edu)