2025 Updated Protocol Template – Overview (Field)

11/21/2024

General Information

Christina Dineen

Overview of Protocol Changes

Why are we making a change?

- **Interest in revising the template for some time**
- **Management request to E&TC**
- **Subcommittee formed**
  - Does the layout make sense?
  - Which sections cause confusion/deviations?
  - Can we trim down excess language?
  - Where can we make things easier to read/find?

IR-4 Project

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Thank you *Committee Members –*
Cristina Marconi
Mika Tolson
Chanz Robbins
Megan James Hickman
Dan Heider
Scott Muir
Cole Smith
Gail Mahnken

Thank you *to everyone who reviewed the draft throughout the review process, and thank you in advance for handling these changes gracefully!*

IR-4 Project

New Protocol Structure

Main Study Information
General Information

Field Phase
Laboratory Phase

PROJECT TITLE: Oxathiapiprolin: Magnitude of the Residue on Apple
PR No.: 13683

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 DIRECTOR[1]:

Cristina Marconi, IR-4 Project Headquarters, North Carolina State University, 1730 Varsity Drive, Venture IV, Suite 210, Raleigh, NC 27606, (919) 515-8723, cmarche@ncsu.edu

STUDY AUTHORIZATION:

Sponsor Representative / Date	Cristina Marconi / Study Director / Date

STUDY DIRECTOR INITIALS: _____

Top of Protocol: Main Study Information

Section 1: General Information

1.1 Justification & Objectives

1.2 GLP Compliance

1.3 Quality Assurance

1.4 Protocol Amendments & Deviations

1 GENERAL INFORMATION

1.1 JUSTIFICATION AND OBJECTIVES:

IR-4 has received a request for the minor use of Oxathiapiprolin on Apple for control of Soft Rot.

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

PROPOSED DATES:

Experimental Start:	m/y signed
Experimental Termination:	MM/YYYY
Study Completion:	MM/YYYY

1.2 GOOD LABORATORY PRACTICE COMPLIANCE:

Christina Dineen (cdineen2@ncsu.edu) is signed

This protocol will be conducted using appropriate Standard Operating Procedures (SOPs) and will follow provisio
accordance with EPA's current Good Laboratory Practice (GLP) Standards (40 CFR Part 160). The appropriate
cooperative testing facility (field and laboratory) will be responsible for certifying that its portion of the study will be
conducted in accordance with GLP Standards. A statement of GLP compliance will be signed and submitted by
appropriate Research Directors in their report or data package.

Section 1: General Information

1.1 Justification & Objectives

1.2 GLP Compliance

1.3 Quality Assurance

1.4 Protocol Amendments & Deviations

1.4 PROTOCOL AMENDMENTS AND DEVIATIONS

Discuss any desired changes in the protocol with the Study Director prior to occurrence. If appropriate, an amendment will be issued.

Any deviations from the protocol will require the appropriate Research Director to complete a written report to the Study Director promptly (i.e. within 14 days of occurrence or recognition) for review and approval. All deviations must be signed by the Study Director as soon as possible.

All deviations from the approved SOPs also require documentation and approval by the Study Director.

Previously, field & lab had separate sections for amendments/deviations.

Section 2: Field Phase

> **2 FIELD PHASE**
>
> The term Field Data Book (FDB) in this protocol can refer to either the paper or electronic record (eFDB).

2.1 Test Substance

2.2 Application

- Treatment Summary
- Application Description
- Phytoxicity
- Application Verification
- Application Practices
- Equipment Calibration

For planning purposes, we moved these two sections to the forefront of the Field Phase section.

Section 2: Field Phase

2.3 Test System
- **Test Site & Crop**
- **Design & Statistical Method**

2.4 Sample Collection
- **Sample Inventory**
- **Collection Instructions**

2.5 Sample Handling & Shipping

2.6 Samples for Processing
- **Handling & Shipping**
- **Processing Instructions**
- **Sample Inventory**
- **Documentation & Record Keeping**

2.7 Field Documentation

2.8 Archiving

2.9 Personnel Information

Section 3: Laboratory Phase

3.1 Lab Personnel
3.2 Lab Sample Inventory
3.3 Lab Sample Identification
3.4 Lab Sample Storage/Prep
3.5 Lab Reference Substance
3.6 Analytical Methodology
3.7 Disposition of Samples
3.8 Lab Documentation & Record Keeping
3.9 Lab Research Report
3.10 Archives

3 LABORATORY PHASE

Test Substance

Chanz Robbins

Test Substance changes overview

- TS info now in a table
- Beginning temp monitoring timeframe increased
- More TS concerns listed for contacting SD
- TS container disposal SOP ~ WIP
- Removed registrant info for TS container shipping

Test Substance ~ section 2.1

old protocol

new protocol

13. TEST/CONTROL SUBSTANCE:

2.1 TEST SUBSTANCE:

- **TS information is first part of section 2 ‘field phase’**

TS information

- **TS info in tabular form**
- **Registrant contact info present, but procurement process still through SD**

Formulation/End Use Product (Code Name)	Orondis Gold 200
EPA Reg. No.	100-1571
Active Ingredient (A.I.)/Common Name	Oxathiapiprolin
A.I. CAS Number	1003318-67-9
Nominal A.I. Content of End Use Product	1.67 lb ai/gal
Registrant/Contact	Luis Payan, Syngenta Crop Protection Inc., 336-509-1737, luis.payan@syngenta.com

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TS temp monitoring

old protocol

- **Within 2 days of receipt**

new protocol

- **Within 3 days of delivery**

- **If traveling, put min/max device where TS will be ‘delivered’**

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TS concerns for contacting SD

old protocol

new protocol

- **Contact SD with concerns:**
  - GLP status
  - Labeled information
  - Expiration date

- **Contact SD with concerns:**
  - GLP status
  - **Container condition**
  - Expiration date
  - TS name
  - **Container / CoA discrepancies**

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TS container National SOP

- **Expect draft SOP in coming weeks**
- **Approval before TS containers need to be disposed**
- **SD / SOP will inform on TS disposal, not protocol**

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TS disposal / disposition

old protocol

new protocol

- **FRD to contact registrant**

Alternatively, some registrants will archive the test substance containers. If test substance containers are shipped to another location, the shipment must be conducted in accordance with local, state, and Federal regulations. See shipping documents for directions for return of the test substance; if none are given contact the registrant representative: Karol Krey, ISK Biosciences Corp.; Phone: (216) 372-2569, e-mail: kreyk@iskbc.com.

- **SD to confirm with registrant**

Before the completion of this study, the Study Director shall receive confirmation from the registrant of the location of a retention sample of the test substance.

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Test Substance section improvements

- Table format makes information easier to find
- New temp monitoring is more specific / gives FRDs more flexibility
- Concerns list encompasses broader range of issues with TS receipt
- National SOP shortens protocol replaces advisories of TS containers
- Streamlined TS disposition by study rather than by trial

IR-4 Project

Application

Megan James Hickman

Application

- Adding additional units in target rate of formulated product
  - Note that IR-4 Application Type Definitions is slated to become National SOP
- Directed applications moved to where description of application will go
- Removed phytotoxicity instructions specifically for CA – now see instructions in eFDB
- 2.2.3 Application Practices – agitation changed from 30 minutes to just prior to

2.2 TEST SUBSTANCE APPLICATION:

2.2.1 Treatment Summary:

A. These treatments shall be applied in all trials except 13683.24-FL91:

Trt #	Treatment	Target Rate of active ingredient	Target Rate of formulated product [1]	Application Type [2]	Spray Volume Range [3]
01	Untreated	Not Applicable	Not Applicable	Not Applicable	Not Applicable
02	Oxathiapiprolin	0.13 lb ai/acre (140.4 grams ai/hectare)	284 mL/acre + adjuvant [4] (0.075 gal/acre) (702 mL/hectare + adjuvant [4] (0.702 L/hectare)	Soil directed	10 GPA (94 L/Ha)

[1] Calculated from the nominal concentration of the formulated test substance (see Section 2.1).

[2] Refer to IR-4 Advisory #2004-02, IR-4 Application Type Definitions.

[3] GPA=gallons per acre and L/Ha=liters per hectare

[4] Include an adjuvant at the labeled rate and add a copy of the label to the Field Data Book.

Adding additional units in target rate of formulated product & Future Advisory Change

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Application Description:

All trials except Decline Trial 13683.24-FL92, 13683.24-HI129: Make 2 applications at intervals of 30 days with the last application on the day of harvest (0-day PHI).

Decline Trials 13683.24-FL92, 13683.24-HI129: Make 2 applications at intervals of 30 days with the last application on the first day of multiple harvests (0-day PHI).

For directed applications, calculate the rate using the entire plot area. Do not proportionally reduce the amount of active ingredient applied per acre. Direct the entire per-acre rate onto the target area. If row widths in the research plots are greater than local commercial practices, then the application rate should be calculated using a local commercial row width. Treated area for directed applications is calculated as row spacing X number of rows X row length.

Directed applications moved to where description of application will go

IR-4 Project

Phytotoxicity:

Document any phytotoxicity and communicate to the Study Director as soon as possible upon observation.

California field trials require additional phytotoxicity rating documentation (follow instructions in the Field Data Book).

Removed phytotoxicity instructions specifically for CA – now see instructions in eFDB

2.2.3 Application Practices

Simulate local commercial application practices using appropriate equipment to provide thorough, uniform coverage of the treated area. **Note to SD** (remove if N/A): for foliar applications "result in adequate canopy penetration and coverage".

Agitate the application mixture just prior to or during the application to ensure it is well mixed and document in the Field Data Book. Test substance mixtures must be applied within 2 hours of mixing.

Each field trial requires a unique application mixture. Do not use the application mixture from one field trial on another field trial.

All study participants must follow all laws and regulations applicable to the safe use of pesticides utilized in this study.

Agitation changed from 30 minutes to just prior to

IR-4 Project

Calibration

Christina Dineen

Calibration

Previously:

- **Definition of calibration/recheck**
- **Discharge & speed separate with lists:**
  - Yes/No List if first application in the trial
  - List of when a full calibration is required
  - List of when a recheck is required
  - Exceptions where recheck is not required
- **Target outputs**

Is this the first application of test substance in this trial?

YES: A full speed calibration is required.
Exceptions: 1) When a handgun is used to spra
predetermined time, a speed calibration is not
trials on the same site, same day, using the sa
only required for the first application made that

NO: A single run recheck may be conducted to cont
calibration or ±5% of a target speed) just prior

Full speed calibration is required when:

1. A major equipment change has been ma
2. A complete output calibration is performe

Speed recheck is required when:

1. Speed calibration data from another trial is used,
the same farm, using the same equipment and sa
2. Whenever an output recheck is performed, excep
the same day on the same farm.

Speed recheck is not required when the same Field Research
day for multiple trials in this study, or multiple treatments in the s
change or the treated plots are located on separate farms.

Calibration

<u>Updates:</u>

- **NOTE: the overall substance is mostly the same**
  - Removed requirement for full calibration if change in delivery pressure by >5%

- **Three parts:**
  - Definitions
  - When full calibration is needed (table)
  - When recheck can be used in place of full calibration (table)

Calibration

2.2.4 Equipment Calibration

To ensure accurate delivery, full calibrations for equipment output and speed (equipment or walking) must be performed. Rechecks may be used under certain conditions (see 2.2.4.2).

A full calibration is a minimum of three, consecutive measurements that are within ±5% of the mean output* or speed.	A recheck is a single run to confirm the measurement is within ±5% of the mean output* or speed of the most recent full calibration.
A target value is a theoretical value imputed for either speed or output to be achieved within ± 5% during application. Target values must be verified with a full calibration.	

*For mean output, the discharge rate of each run must be within ±5% of the mean of all runs. Additionally, the discharge rate of each individual nozzle (except airblast sprayers) must be within ±5% of the mean of the same run.

Full equipment calibration for each application is preferred. If using previous calibration data, a true copy (or a clone calibration, in the eFDB) must be included in the Field Data Book for each application. This data must also be included if a recheck is used. Post-application verification calculations must use the most recent full calibration data, not recheck data.

Definitions

Full Calibration

2.2.4.1 Full Calibration

A full calibration (on the day of or the day before application) is required when:

Condition	Output	Speed
This is the first application of test substance in this trial.	✓	✓
A recheck or full calibration does not meet the specifications listed in the table above.	✓	✓
Application parameters or equipment components have changed (i.e. nozzles, boom parts, screens, etc.).	✓	
A major equipment change has been made (i.e. tractor-pulled sprayer to backpack sprayer).	✓	✓
A full output calibration is performed.		✓

Situation

Output and/or speed calibration needed

Recheck

2.2.4.2 Recheck

A recheck must fall within ±5% of the most recent full calibration. A recheck (just prior to application) can be used in place of a full calibration when**:

Condition	Output	Speed
The most recent full calibration is greater than one day before the application.	✓	✓
The most recent full calibration or recheck was done at a different location (outside of the same farm or research station) or equipment has been transported in a manner that may affect output/speed.	✓	✓
Equipment has been cleaned, nozzles have been removed, or pressure tank has been changed.	✓	
An output recheck is performed.**		✓

**Output and speed rechecks are not required when the same Field Research Director (FRD) is making applications on the same day for multiple trials in the same study or multiple treatments in the same trial, unless application parameters have been changed as described above.

Situation

Output and/or speed recheck may be used

Design & Statistical Method

Mika Tolson

Design & Statistical Method

- **Plot design – 50%**

Plot Design: Trials will consist of one untreated and one or more treated plots.

Design plots such that no more than approximately 50% of the plot area will be needed for sampling across all sampling events. See Part 2.4 for requirements for residue sampling.

Processing Trial 13683.24-FL91: Ensure plots are large enough to provide adequate samples for processing.

Decline Trials 13683.24-FL92, 13683.24-HI129: Ensure treated plot(s) are large enough to provide adequate samples for each sampling date.

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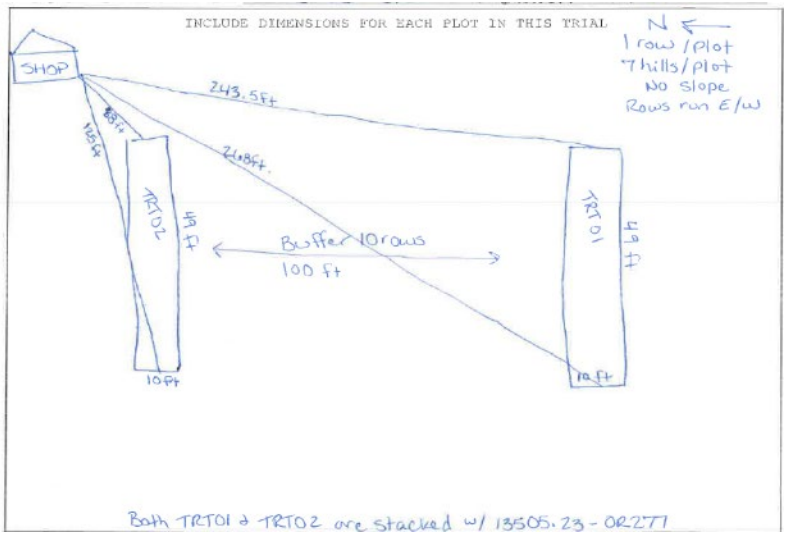
Design & Statistical Method

- **Buffers – language has changed regarding buffer zones between plots to now between treatments**

Buffers are defined as the distance between treatments within a trial or the distance between treatments of multiple trials utilizing the same active ingredient. Employ the adequate buffers as listed below to prevent contamination.



Design & Statistical Method

- **Buffers – GH trials, added removal of UTC**

Greenhouse Buffers/Barriers: Utilize separate greenhouses or barriers between treatments. If barrier is temporary, do not remove until spray has dried. Alternatively untreated plants may be moved to a separate location for application(s) and returned to the greenhouse after the spray solution has dried, or treated plants may sprayed in a different greenhouse or other enclosed area other than the one housing the untreated plants) and returned to the greenhouse after the spray solution has dried while ensuring that end plot plants (for treated plants) remain end plants after application and moving. Drench applications may be made in the same greenhouse without barriers, but care must be taken to prevent test substance percolation through potting media from contaminating other treatments.

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Design & Statistical Method

- **Trial differentiation – check if there are nearby FRDs**

Trial Differentiation: Multiple trials in the same study conducted by the same FRD or by different FRDs with trials in the same area must be differentiated by one of the following options:

Option	Description
A	Trial sites must be separated by at least 30 km (18.6 miles) [measured as straight line distance]
B	Planting date (for annual crops) or first application date in each trial is separated by at least 30 days

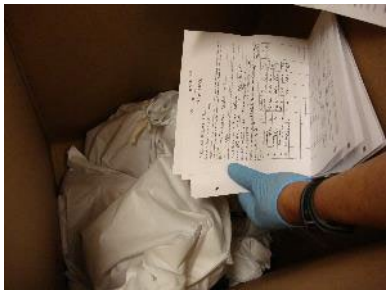
If these differentiation criteria cannot be met, contact the Study Director.

Sample Handling & Shipping

Mika Tolson

Sample Handling & Shipping






Sample Handling & Shipping

- **Shipping information regarding sample integrity + lab contact moved to table form**

Shipment Type	Additional Measures to Ensure Sample Integrity	Laboratory Contact Timing
Personnel Transport - Fresh (never frozen) Samples	If sampling-to-freezer interval is >1 hour, an appropriate method of cooling and temperature monitoring must be used. Document in the FDB.	Before shipment
Personnel Transport - Frozen Samples	Appropriate methods must be used to keep the samples frozen during transport. Document in the FDB.	Before shipment
Express Shipments (overnight carriers such as Federal Express or Airborne)	Requires the addition of sufficient quantities of dry ice (see IR-4 Advisory 2007-01 for more information)	Before shipment: Confirm shipment type is acceptable for delivery
Freezer Truck	None	Before shipment or up to one day after the samples have been shipped

Sample Handling & Shipping

- **Section 2.6 will now be for processing**

2.6 RESIDUE SAMPLES FOR PROCESSING

This protocol does not include samples for processing. No processed commodities will be generated for this study.

2.6 RESIDUE SAMPLES FOR PROCESSING

2.6.1 SAMPLE HANDLING AND SHIPMENT:

Contact the processing lab as soon as you know the date you expect to ship the large, fresh samples for processing, so that the lab will be ready to receive them and begin the processing part of the study as needed. If samples for processing are not shipped to the processing facility on the day of harvest, they should be stored in a refrigerator at approximately 4□C until they are shipped. At the time of shipping large samples, contact the processing lab (document this communication in the field data book).

Send samples for processing to: @@@

2.6.2 PROCESSING:

Immediately prior to processing apples, remove representative "grab" samples of untreated and treated fruit from the larger samples (approximately 4-6 lb. for each sample). Process the "grab" samples as indicated in section 2.4.2 of this

Field Documentation, Archiving, Personnel Information

Cristina Marconi

2.7 Field Documentation

eFDB Language

- Raw data, study operations, and observations must be recorded directly and promptly.
- eFDB must be used in this study.
- It is expected that electronic forms be used for the majority of the study.
- Any raw data or other information associated with each field trial must be uploaded to the eFDB prior to study completion

2.7 Field Documentation

eFDB Language

SO WHAT CHANGED???

Only the eFDB paper raw data pages can be used.

<u>Expectation</u>: everyone will use the eFDB to enter raw data associated to a trial with the exception of the paper forms mentioned below:

If it is not on this list, it will require a deviation

- Facility files (see SOP [illegible] umentation)
- Maps related to test si[illegible]
- Equipment diagram(s)
- Paperwork associated with test substance receipt
- Adjuvant label and calculation of the adjuvant for application (if applicable)
- Shipping documentation
- Soil testing report (if applicable)
- Pre-application calculations

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2.7 Field Documentation

eFDB Language – Scenario Time!

1. You used your own form to record min/max temperature for your freezer. Deviation or not? (answer: NO, part of facility files)
2. Used 2024 FDB paper form (Part 4A) to record TS receipt and storage before protocol was signed. Deviation or not? (answer: YES) – Not a deviation if using eFDB paper raw data.
3. What if I used the eFDB paper raw data pages for my pre-application calculation? (answer: NO) What is you use your custom form? Then it's a deviation.
4. I was out in the field ready for the first application and my laptop decided it was the best time for an update. So while it was doing its thing, I recorded the output and speed calibration on the appropriate eFDB paper raw data pages, transcribed it to the eFDB and continued recording the rest of the application on the eFDB. Deviation or not? (answer: YES, protocol states "Actual application data must be entered directly into the eFDB.")

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2.7 Field Documentation

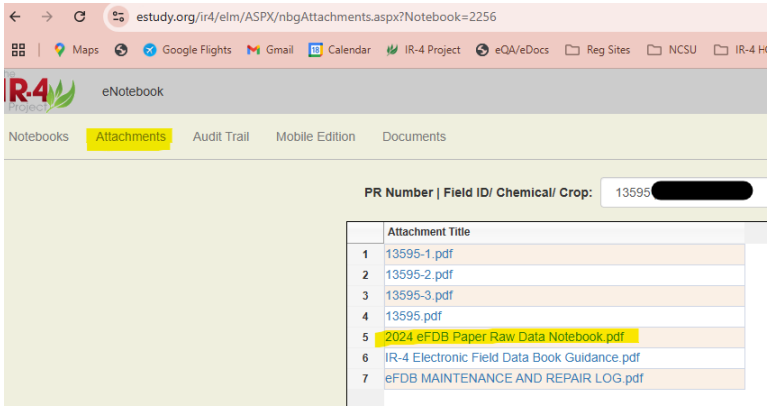
eFDB Language

Why a deviation???

- It will help HQ/QA identify areas of concern with eFDB system and possible training needs.

Why only eFDB paper raw data pages? And where can I find them?

- Standardized forms/pages facilitates the review of the data by QA, SD and outside reviewers (EPA).
- Found as an attachment in each eFDB.



2.7 Field Documentation

eFDB Language

There’s no form in the eFDB or eFDB paper raw data to record the data.

WHAT SHOULD I DO????

REMAIN CALM!

And record the data/info electronically using Word, Excel (or anything that can converted to PDF), uploaded directly into the eFDB.

This is NOT a deviation.

(As long as you DON’T print it)

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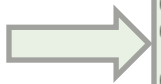
2.7 Field Documentation

REMEMBER: Documentation should be sufficiently detailed to completely reconstruct the field trial.

- **Items on the list of minimum requirements moved around to follow eFDB sections.**



At a minimum, collect and maintain the following raw data:

01- GLP compliance information

02- Names of all personnel conducting specific research functions

03- Relevant communication

04- Test substance (receipt, use, disposition, expiration date, temperature and storage records)

05- Trial site (directions, plot maps, planting, soil and/or soilless substrate characteristics, trial site history, maintenance applications, cultural practices, crop destruct or lack thereof)

06- Test substance application data (calibration and/or recheck, equipment diagrams and maintenance logs, and post application rate verification, phytotoxicity)

07- Sample collection (harvest/sample date, handling, weights, times of sampling and frozen storage, sample IDs contamination prevention measures, sample modifications (if applicable), drying procedures (if applicable), storage/transport conditions, and freezer contents, temperature, and maintenance logs)

08- Residue sample shipping information and chain of custody

09- Daily Meteorological/Irrigation records for field trials and/or temperature/humidity/irrigation records for greenhouse trials; Follow instructions in the Field Data Book for records requirements regarding annual/perennial crops and transplants, if applicable.

10- Other applicable data requested in the IR-4 Field Data Book necessary for confirmation that the study was conducted in accordance with the protocol

The following records do not need to be determined under GLP standards:

- Soil information
- Trial site history
- Cultural practices
- Maintenance chemicals
- pH measuring devices
- Daily meteorological/irrigation records (temperature/humidity for GH trials)
- Equipment used for measuring the weight of samples collected from field/processing trials does not need to be maintained in strict adherence to GLP.

IR-4 Project

2.7 Field Documentation

REMEMBER: Documentation should be sufficiently detailed to completely reconstruct the field trial.

- **Items on the list of minimum requirements moved around to follow eFDB sections.**

- **Non-GLP items are listed below for clarity.**

At a minimum, collect and maintain the following raw data:

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10- Other applicable data requested in the IR-4 Field Data Book necessary for confirmation that the study was conducted in accordance with the protocol

The following records do not need to be determined under GLP standards:

- Soil information
- Trial site history
- Cultural practices
- Maintenance chemicals
- pH measuring devices
- Daily meteorological/irrigation records (temperature/humidity for GH trials)
- Equipment used for measuring the weight of samples collected from field/processing trials does not need to be maintained in strict adherence to GLP.

IR-4 Project

2.7 Field Documentation

REMEMBER: Documentation should be sufficiently detailed to completely reconstruct the field trial.

PLEASE NOTE: some items refer to eFDB for instructions

At a minimum, collect and maintain the following raw data:

01- GLP compliance information

02- Names of all personnel conducting specific research functions

03- Relevant communication

04- Test substance (receipt, use, disposition, expiration date, temperature and storage records)

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The following records do not need to be determined under GLP standards:

- Soil information
- Trial site history
- Cultural practices
- Maintenance chemicals
- pH measuring devices
- Daily meteorological/irrigation records (temperature/humidity for GH trials)
- Equipment used for measuring the weight of samples collected from field/processing trials does not need to be maintained in strict adherence to GLP.

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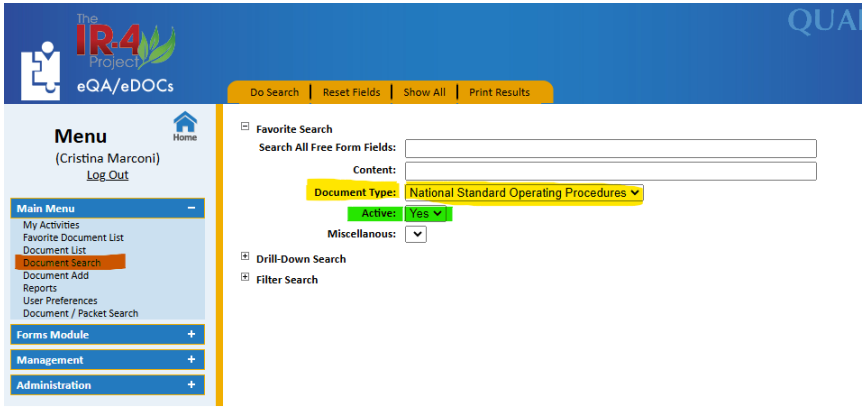
2.8 Archiving

- **Complete eFDB and other raw data – archive asap after shipment of samples.**

- **Follow IR-4 National SOP N-02.1 section Raw Data Submission for archiving procedure.**

Where to find IR-4 National SOPs???

eQA/eDocs>Document Search – select Document type (National Standard Operating Procedures); verify the prompt “Active” is marked as “Yes”



2.9 Personnel Information

Draft review - Confirm contact info, EPA Region, TS amount and need by date.

Field Research Director (FRD)	Field ID No.	EPA Region	RFC	Test Crop	Formulation	Amount of TS	Date Needed
Signed Protocol	Signed Protocol	Draft protocol only	Signed Protocol	Signed Protocol	Draft protocol only	Draft protocol only	Draft protocol only

Field Research Director (FRD)	Field ID No.	EPA Region	RFC	Test Crop	Formulation	Amount of TS	Date Needed
Paul Wade, USDA-ARS, Vegetable Laboratory, 2700 Savannah Highway, Charleston, SC 29414; (843) 402-5376; e-mail: Paul.Wade@usda.gov;	13683.24 -SC*291	2	ARS	Apple	Orondis Gold 200	100 mL	03/15/25