



# Welcome

**GLP Training – November 12, 2024**

# Agenda

- EPA Inspections – Juliet Thompson
- How to Write Deviations – Debbie Carpenter
- Lessons Learned – Nicole Soldan, Leona Horst, Chanz Robbins, Megan James Hickman
- Finding Educational Items for Growing Crops – Leona Horst, Kristen Searer-Jones



# EPA Inspection

Juliet Thompson

# Contents

- Who are the EPA inspectors
- Example of EPA Letter
- What to do after receiving the notice of inspection
- HQ and QA assistance
- Expectations during the EPA inspection
- What to expect after the inspection

# Poll Question

# EPA GLP Compliance Team

- Francisca (Frances) Liem – Head
- Elmer Griffin
- Daniel (Dan) Myers
- Mark Lehr
- Brittney Odom
- Christine Phebus
- Henry Armstead



# Poll Question



# EPA Inspection Letter

- Types of inspections
  - Neutral
  - For Cause

SCAN AND EMAIL  
CONFIRMATION OF RECEIPT REQUESTED

February 15, 2024

Dr. Matt Hengel  
IR-4 Western Region Laboratory  
Department of Environmental Toxicology  
One Shields Ave.  
University of California-Davis  
Davis, CA 95616  
(530) 752-2402  
mjhengel@ucdavis.edu

Dear Dr. Hengel,

This is to inform you that the Environmental Protection Agency (EPA) will conduct a Good Laboratory Practice (GLP) Inspection at your facility under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

The inspection will be conducted during the week of February 26, 2024. The inspection will be led by Daniel Myers. The inspection team will review your facility's compliance status with the EPA FIFRA GLP regulations, 40 Code of Federal Regulations (CFR) Part 160 and will audit those aspects of the studies listed in Attachment I performed by University of California, Davis IR-4 Western Region Laboratory.

In addition, the inspection team will choose one or more completed or ongoing studies from your Master Schedule for audit.

The purpose of study audits is to validate data in final reports which have been presented to the EPA in support of a registration or marketing petition under FIFRA.

The purpose of the compliance review is to determine that the GLP regulations of FIFRA are being observed in your testing facility's current procedures and practices for pertinent studies being conducted.



# Notice of EPA inspection – next steps

- Verify that your address and site information is correct
- Respond to the inspector's email acknowledging receipt
- Notify the National QA Manager, Regional QA Coordinator and Field/Lab Coordinator
- Gather related materials for the targeted trial (s)
- Identify a suitable space for the inspector (s) to review the data

# HQ and QA Assistance

- HQ QA will provide the appropriate materiel to include:
  - Characterization/Reference Data
  - Raw Data
  - SOPs
  - Organizational Chart, Job Description and related CVs for HQ staff
  - Correspondence and other documents
  - QA Statements and eQA Audit Workflow Pages
  - Final Report (s)
  - IR-4 Master Schedule

# During the Inspection

- Meet the Inspector
- Opening Meeting
  - Inspector shows credentials
  - Sign the Notice of Inspection (QA does not sign this letter)
- Inspection
  - Walk through of the facility
  - Audit of requested raw data
  - Audit of anything off the master schedule\facility files
- Inspector determines the length/days
- Closing Meeting

# After the Inspection

- If there are findings
- Be sure to complete the chain of custody/transfer form
- Return all contents sent from HQ back to HQ, using the box and return label provided

---



Thank You!



# How to Write Deviations

Christina Dineen and Debbie Carpenter



**A deviation is a departure from approved protocols or standard operating procedures (or GLPs).**

---

The Study Director, as the individual responsible for the overall conduct of the study, must assess and authorize any deviations, as these may impact study quality/integrity.

---

**Remember: Deviations are not necessarily a bad thing! You are documenting what happened.**

# What Makes a “Good” Deviation?



# Deviation Composition

- **Timing of Occurrence & Notification of Deviation**
  - Contact the SD as soon as possible after recognition
- **Description of Deviation**
  - What exactly occurred, provide as much detail as possible!
- **Why Deviation Occurred**
  - Was this unavoidable? Something we need to consider in the future?
  - How can we prevent this from occurring?
- **Impact of Deviation on Study**
  - SD must assess what impact this has on the study
  - Relying on you as the expert in your field for assistance

# Deviation Composition

- **Timing of Occurrence & Notification of Deviation**
  - Contact the SD as soon as possible after recognition
- **Description of Deviation**
  - What exactly occurred, provide as much detail as possible!
- **Why Deviation Occurred**
  - Was this unavoidable? Something we need to consider in the future?
  - How can we prevent this from occurring?
- **Impact of Deviation on Study**
  - SD must assess what impact this has on the study
  - Relying on you as the expert in your field for assistance

# Deviation Composition

- **Timing of Occurrence & Notification of Deviation**
  - Contact the SD as soon as possible after recognition
- **Description of Deviation**
  - What exactly occurred, provide as much detail as possible!
- **Why Deviation Occurred**
  - Was this unavoidable? Something we need to consider in the future?
  - How can we prevent this from occurring?
- **Impact of Deviation on Study**
  - SD must assess what impact this has on the study
  - Relying on you as the expert in your field for assistance

# Deviation Composition

- **Timing of Occurrence & Notification of Deviation**
  - Contact the SD as soon as possible after recognition
- **Description of Deviation**
  - What exactly occurred, provide as much detail as possible!
- **Why Deviation Occurred**
  - Was this unavoidable? Something we need to consider in the future?
  - How can we prevent this from occurring?
- **Impact of Deviation on Study**
  - SD must assess what impact this has on the study
  - Relying on you as the expert in your field for assistance

# Deviation Composition

- **Timing of Occurrence & Notification of Deviation**
  - Contact the SD as soon as possible after recognition
- **Description of Deviation**
  - What exactly occurred, provide as much detail as possible!
- **Why Deviation Occurred**
  - Was this unavoidable? Something we need to consider in the future?
  - How can we prevent this from occurring?
- **Impact of Deviation on Study**
  - SD must assess what impact this has on the study
  - Relying on you as the expert in your field for assistance

# Notification Process

- **Notify SD**
  - If the trial may be lost, please reach out by phone.
  - Otherwise, phone or email is fine.
- **Provide enough detail so an assessment can be made**
  - It is fine to send an email with details – the SD and FRD can put this in the study file.
- **If the SD is out of the office or unavailable for urgent notifications, other SDs or management may be contacted.**

IR4

Field ID: 7897899-CA999

Sweet Sucker Repellent / Sweetest Oranges

Example #1

DEVIATION FORM (*photocopy this part if necessary*)

THE DATE THAT THE DEVIATION OCCURRED

06/15/2023

THE DATE THAT THE DEVIATION WAS RECOGNIZED

09/21/2023

THE DATE THAT THE STUDY DIRECTOR WAS NOTIFIED

09/25/2023

METHOD OF NOTIFICATION (*e.g. telephone, email*)  
(*Include note of telephone or copy of email*)

email

THE DEVIATION IS FROM (*check appropriate*)

PROTOCOL X

SOP'S \_\_\_\_\_

SECTION OF THE PROTOCOL OR SOP'S THAT IS AFFECTED \_\_\_\_\_

BRIEF DESCRIPTION OF DEVIATION: Adjuvant Agral 90 application rate of 200 mL/1000 mL was approved by the SD (taken from Agral 90 label). An error was made by FRD in calculating volume and mixing amounts to be used for each application. A rate of 0.2% was used instead of 0.02%. 70 mL of adjuvant was added to each tank mix and each application instead of 7 mL each time.

EXPLAIN WHY THE DEVIATION OCCURRED: FRD oversight and miscalculation. Please note that nothing in the tank mix looked "off" during each mixing event and there was no phytotoxicity recorded in the FDB following each application.

ABOVE DATA ENTERED BY: \_\_\_\_\_

DATE: \_\_\_\_\_

**FIELD PERSONNEL: DO NOT WRITE BELOW THIS LINE**



IR4

Field ID: 8675309-NC01

Cinnamaldehyde / Pumpkin (Spice)

Example #2

DEVIATION FORM *(photocopy this part if necessary)*

THE DATE THAT THE DEVIATION OCCURRED

11/11/2011

THE DATE THAT THE DEVIATION WAS RECOGNIZED

11/11/2011

THE DATE THAT THE STUDY DIRECTOR WAS NOTIFIED

11/11/2011

METHOD OF NOTIFICATION *(e.g. telephone, email)*

Email

*(Include note of telephone or copy of email)*

THE DEVIATION IS FROM *(check appropriate)*

PROTOCOL X

SOP'S \_\_\_\_\_

SECTION OF THE PROTOCOL OR SOP'S THAT IS AFFECTED

BRIEF DESCRIPTION OF DEVIATION: Minimum sample size was not met.

EXPLAIN WHY THE DEVIATION OCCURRED: \_\_\_\_\_

Plants did not produce as much fruit as needed.





IR4

Field ID: 1800-AZ101

Fructose / Ageless Agave

Example #3

DEVIATION FORM *(photocopy this part if necessary)*

THE DATE THAT THE DEVIATION OCCURRED

06/07/2008

THE DATE THAT THE DEVIATION WAS RECOGNIZED

12/12/2008

THE DATE THAT THE STUDY DIRECTOR WAS NOTIFIED

12/13/2008

METHOD OF NOTIFICATION *(e.g. telephone, email)*

Email

*(Include note of telephone or copy of email)*

THE DEVIATION IS FROM *(check appropriate)*

PROTOCOL X

SOP'S \_\_\_\_\_

SECTION OF THE PROTOCOL OR SOP'S THAT IS AFFECTED \_\_\_\_\_

BRIEF DESCRIPTION OF DEVIATION: HOBO temp. recorder did not start  
at time of sampling.

EXPLAIN WHY THE DEVIATION OCCURRED: HOBO malfunction.

IR4

Field ID: 98765-KS100

Super Strength Supplement / Wild West Wheat

DEVIATION FORM *(photocopy this part if necessary)*

THE DATE THAT THE DEVIATION OCCURRED

02/14/2024

THE DATE THAT THE DEVIATION WAS RECOGNIZED

03/01/2024

THE DATE THAT THE STUDY DIRECTOR WAS NOTIFIED

03/01/2024

METHOD OF NOTIFICATION *(e.g. telephone, email)*

Email

*(Include note of telephone or copy of email)*

THE DEVIATION IS FROM *(check appropriate)*

PROTOCOL \_\_\_\_\_

SOP'S X

SECTION OF THE PROTOCOL OR SOP'S THAT IS AFFECTED \_\_\_\_\_

BRIEF DESCRIPTION OF DEVIATION: Dry down not collected.

EXPLAIN WHY THE DEVIATION OCCURRED: Oversight.

Example #4



## Reminder:

**Deviations are still handled by paper. There is no new process with regard to eFDB.**

- **When deviations are fully signed, they will be uploaded to the eFDB attachments (in addition to IR-4 Database)**
- **No requirement for FRD to upload a signed scan of deviation prior to shipment to HQ.**



# Lessons Learned

**From the North Central Region**

Nicole Soldan



# Problem

Crop loss



# Lesson Learned

- **For future trials, move harvest date up.**
- **Stay on top of maintenance sprays.**



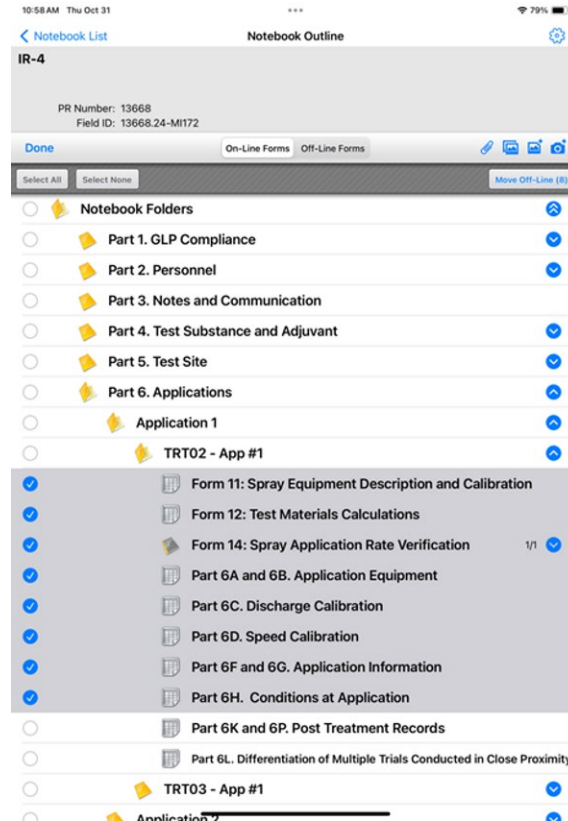
# Problem

**Checking out all application forms  
(applications 1 & 2) caused  
confusion in the field.**



# Lesson Learned

- Only check out the forms for the application needed.
- Take screenshots of forms after they are entered.





# Lessons Learned

Leona Horst



# Greenhouse Oops!

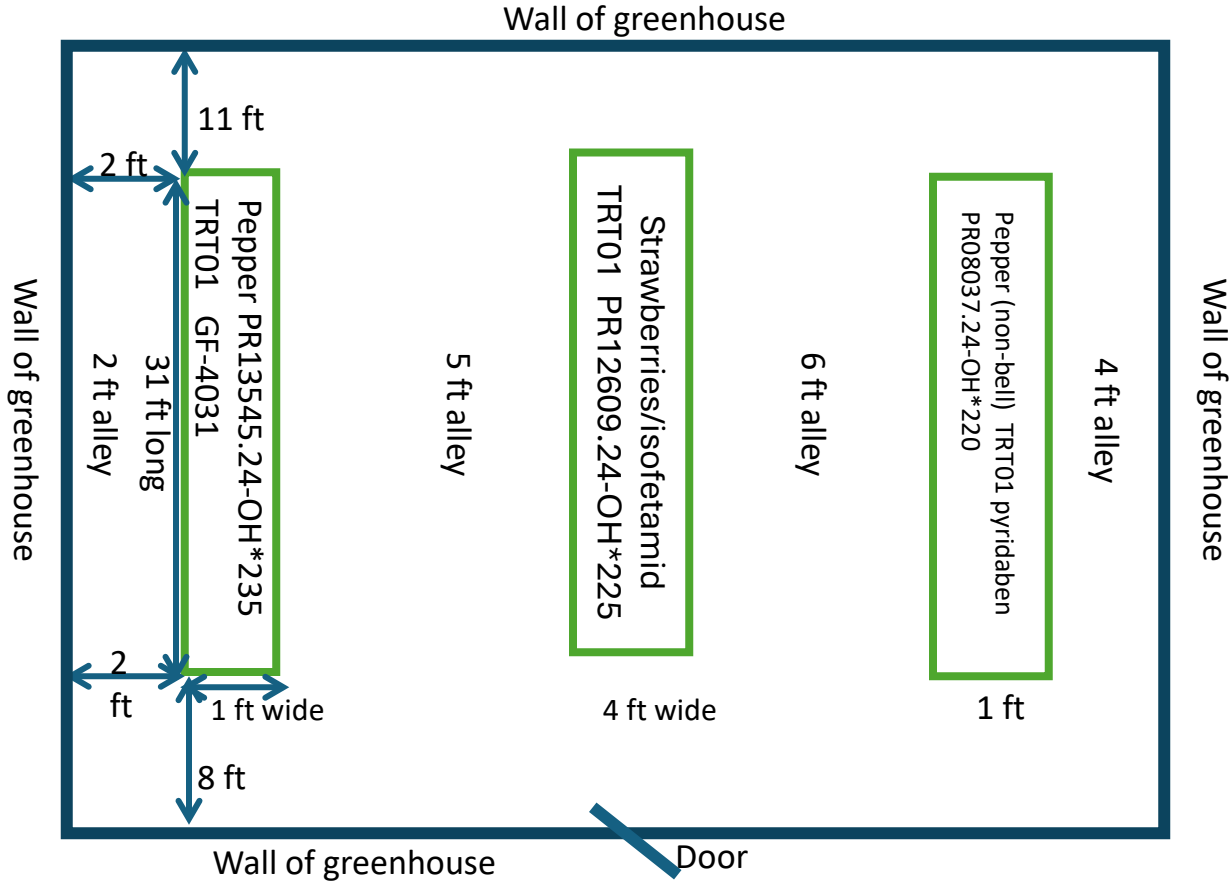
Maintenance  
Applications leading to  
protocol deviation

Lesson learned:



# Drawing maps on computer

Pepper PR08037.24-OH\*220  
Pepper PR13545.24-OH\*235  
GH108 Map



Lesson learned: double check before uploading to eFDB.

# New crop-Pennycress



- Contacted persons who had done this crop in the past for IR4
- Discussions with SD
- Discussions with farm crew
- Discussions with other FRDs



# New crop-Pennycress

Lessons learned: plant dates; plot size; harvest ideas

# Sample size vs protocol

## Melon

- Protocol required 12 fruit /4 lb
- Selected variety with smaller fruit for this year.





# Cabbage

- Heads are large
- Impossible to put 2 opposite quarters + wrapper leaves from 12 plants in 1 bag
- SD amended the protocol to allow 2 opposite eighths to be retained.
- Weight was to be <8 pounds.
- My samples ranged from 13.5 to 16 pounds using 2 eighths/head

Lesson learned: make sure protocol states eighths are allowed when draft protocols are available for review/comments.

# eFDB – lesson learned



- Location allowed me to use my iphone as a hotspot.
- What happens when that doesn't work?
- Additional issues:
  - ipad locked up due to error in password to unlock
  - Wind was to increase within an hour to 20-25 mph

Lesson learned: Have a downloaded paper version available to use





## Lessons learned with Sprayers

- Pressure gauge malfunction
- Always carry a spare boom/wand for the backpack sprayer
- Always have other spare parts for all sprayers
- Have backup harvest equipment

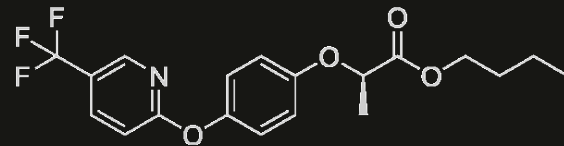
# Lessons Learned

Chanz Robbins



<sup>59</sup>Pr  
blems  
<sup>87</sup>Fr  
om

<sup>10</sup>Ne  
w  
Mexi  
<sup>27</sup>Co





# Problem

Oct. 2023 – asked experiment station about a potential project

Oct. 2023 – agreed to do a trial ~6hr drive away (2 sprays, 30 day phi)

Dec. 2023 – discussed trial requirements with farm

Jan. 2024 – confirmed plot locations and seed amount needed

Beg Apr. 2024 – told I had to pick up seed from CO

Mid Apr. 2024 – seed supplier asked farm to pick up seed

Mid Apr. 2024 – made FDB maps for planting / first spray

End Apr. 2024 – arrive at farm to plant and spray:

- » can no longer use the plot we agreed upon
- » not enough seed for even a single plot
- » planting supposed to be next day
- » 1<sup>st</sup> spray and QA inspection in 2 days

**Preserve and build relationships** – asked partner research if they had a local grower contact who could supply enough seed for the trial (~4000'² ...tomorrow). They did, and they could!

**Accept circumstances and adapt** – Despite planning, all of my plot maps and soil data were not accurate due to last minute changes in trial placement. Took the rest of the day to redo maps, measure plots, research soil data, and fill out FDB.

**Allow time for fixing problems** – My gut feeling before I left, was that things were not going to go as planned. I just scheduled the whole week so that I could arrive early and deal with any issues.



# Problem

Traveled ~6hrs. with equipment for harvesting

- Ice chests in the back of truck with thermometers inside
- Rained overnight, didn't look in ice chests
- On harvest day, opened ice chests and thermometers not working!

**Have back-up equipment and store properly**– Woulda, coulda, shoulda...but lesson learned!

**Communicate to SD and RFCs**– I was planning on purchasing dry ice for +6hr. transport anyway. Thermometers weren't working, but logically, if dry ice is present when putting samples in the freezer after 6hr drive, samples must be frozen.

**Be creative and proactive**– The facility had dryer ovens, so I thought if I could dry the thermometers out, the electronics would start working again. It took about 1hr., but did work.



# Problem

EPA inspector requiring federal certification for pesticide application of tribal lands. State certification is not valid per EPA.

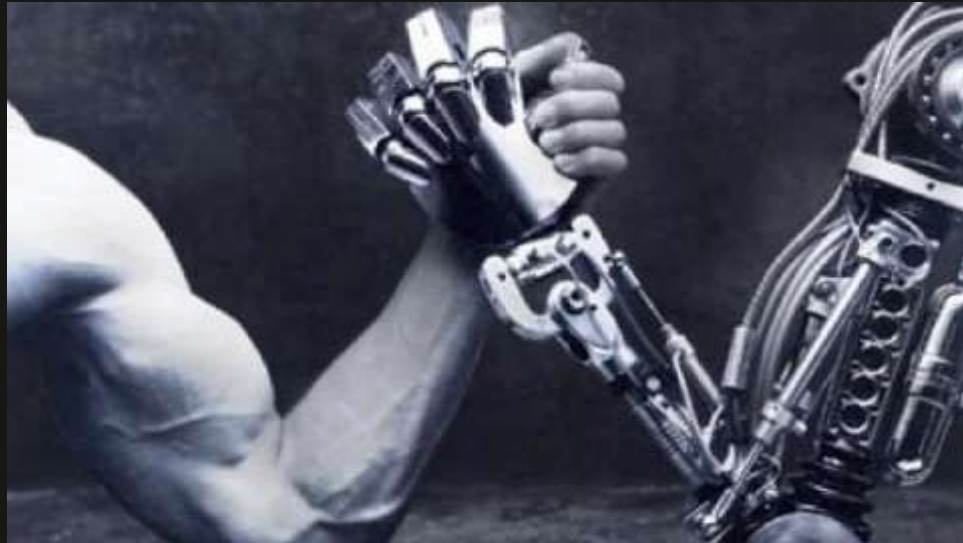
**Know when to stand your ground**– The federal certification is required for *commercial* and *private* applicators applying pesticides on tribal land. Since, generally we fall under '*public*' applicators, this allows a loop-hole where we are exempt from having to get federal certification. **Still, consult with local tribes** about their specific requirements when working on tribal lands.



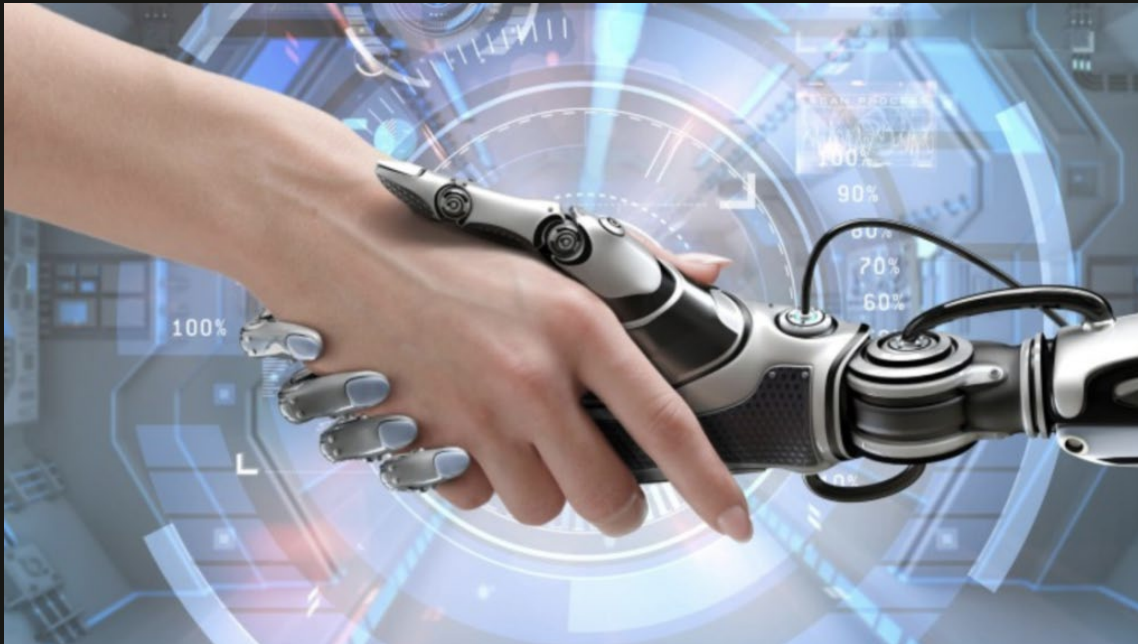


# Problem

Having hesitations with the eFDB. I like the theory, I'm horrible in practice. Human calculation error caused a +75% over-application in one trial. The trial was lost due to a completely avoidable mistake.

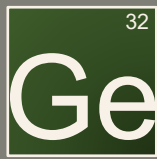


**Embrace technology** – Feeling more willing to use eFDB and confident in its ability to safeguard human error.





n



eneral...

**Supplementary funding**– try departments of ag, or commodity groups

**QA is a gift not a curse**– build relationships with QA inspectors and learn from them

**Have fun!**– be sure to enjoy what you're doing and make the most of it.



KEEP  
CALM  
AND  
CARRY  
ON





# Final Thoughts from the Northeast

Megan James Hickman

# Do not...

- Plant oversized plots that are too large to maintain.
- Plan harvest/sampling too early, especially if harvest date is based on a specific PHI.
- Underestimate how long sampling might take.
- Fail to look at the big picture.
- Be afraid to ask questions or promptly communicate with the SD and RFC.

# Do not...

- Take it personally when QA presents a finding.
- Hesitate to contact other FRDs with the same trial to discuss methods and techniques, varieties, cultural practices, application equipment, etc.
- Forget to review the protocol before each event.
- Forget to update your application and harvest schedule when a change occurs.
- Leave out details in descriptions.
- Forget to take pictures.

**Do not...**

*Second guess your  
instinct or*

**Be too hard on  
yourself.**



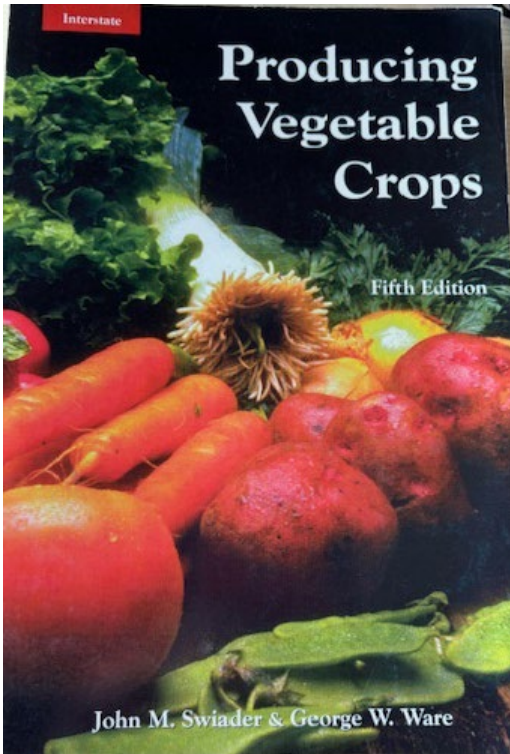


# Tools for crop production

Leona Horst



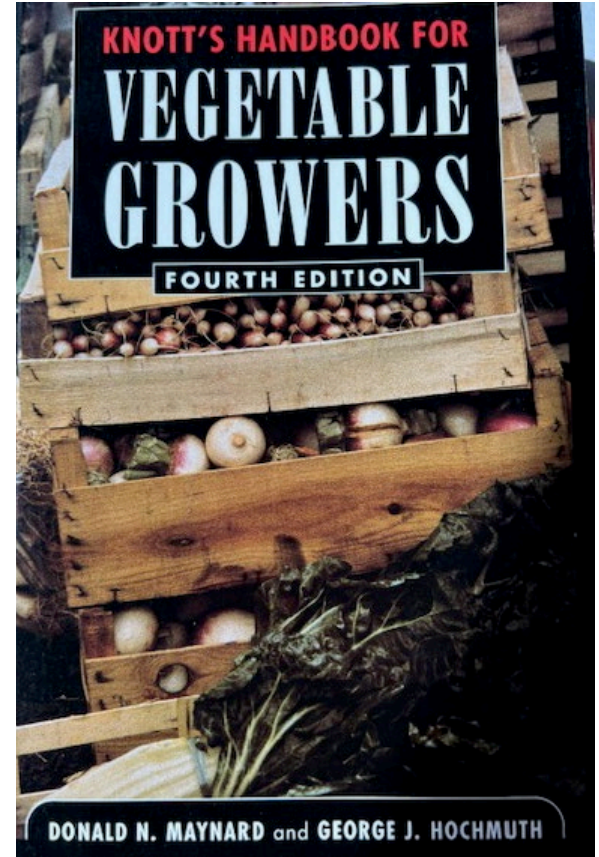
# General guide –used for new crop

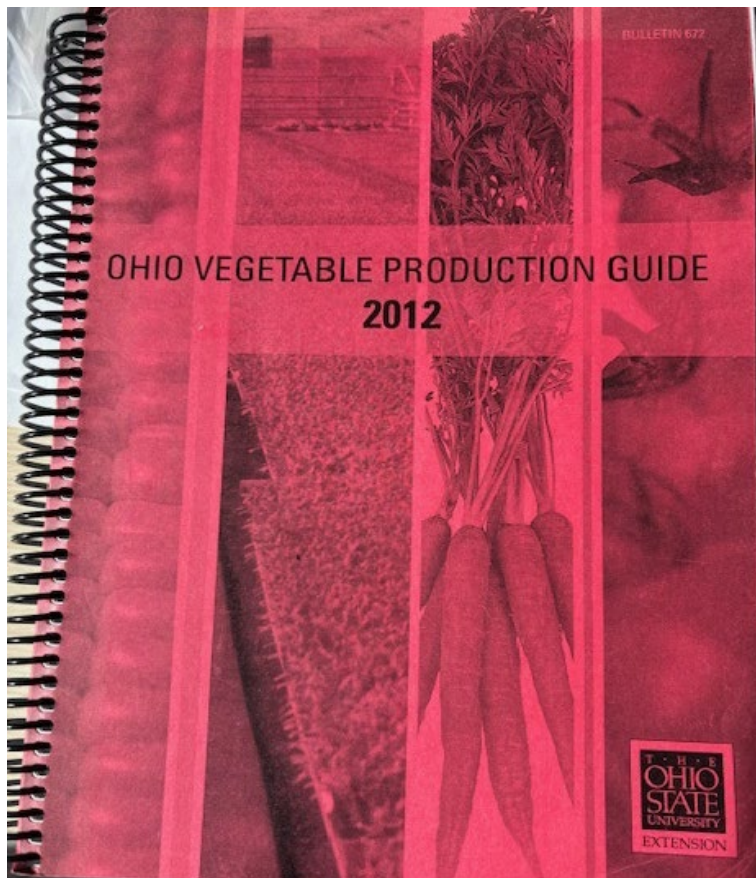


- Table with soil temperature conditions for seed germination: minimum, maximum and optimal temperature range
- Suggestions for hardening transplants before transplanting to field
- Soil pH ranges for representative crops
- Explanation of fertilizer applications and rates for various crops

# General Guide for Field Information

- Specific information on starting different transplants
- Direct seeding in field: Days from planting to emergence based on soil temperature
  - Seed spacing
  - Row spacing
- Commercial guidelines for product harvested





## Specific Crop info

- Written for growers
  - Contains germination guide
- Table for toxicity of pesticides
  - Insecticides and fungicides and phi
- Suggestions for IPM for pest control
- Suggestions for weed management

# Insecticides for use on vegetables in Ohio

	Biological action	Group	General characteristics	Toxicity class (to mammals) (I=most toxic)	Typical target pests	Impact on beneficial insects
<b>Carbamates</b>	central nervous system synaptic poison; acetylcholinesterase inhibitor					
Sevin (carbaryl)		1A	use can result in aphid outbreaks	II (S, WP), III (EC, F)	beetles, leafhoppers, caterpillars	disruptive

# Kale Production

- Information given
  - Varieties grown
  - Row spacing
  - Seeding rates
  - Weed control recommendations –pre and post
  - Insect control suggestions along with phi
  - Disease control suggestions with phi





# MW 20 VEG 24 GUIDE



This annually-revised guide is a summary of currently suggested fertility, horticultural, and pest management techniques and tools for commercial vegetable growers, and is a collaboration of land-grant universities from eight states.

It provides contact and vegetable production information that is valid for the current year in Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, and Ohio.



<https://mwvegguide.org/guide>

## Choose How to Begin



PICK MY CROP



PICK MY PEST



PICK MY  
CONTROL MEASURE

# Kale

## Restricted-Entry Interval (REI)

- 0-hour to 4-hour
- 5-hour to 12-hour
- 13-hour to 24-hour
- 24-hour to 48-hour

## Pre-Harvest Interval (PHI)

- 0-day to 3-day
- 4-day to 7-day
- 8-day to 14-day
- 15-day to 30-day
- 31-day to 50-day
- 51-day to 90-day

## Controls for Caterpillars

Pest Information

### Pesticide

Avaunt

indoxacarb

IRAC 22

Baythroid XL

beta-cyfluthrin

IRAC 03A

Brigade 2EC

bifenthrin

IRAC 03A

Bt (Bacillus thuringiensis)  
products for caterpillars

Bacillus thuringiensis aizawai strain GC-91

IRAC 11A

Bacillus thuringiensis kurstaki strain ABTS-351

IRAC 11A

Bacillus thuringiensis aizawai strain ABTS-1857

IRAC 11A



# My crop production spreadsheet

Crop	Year	Varety	GH or Field	DS/TP	Start TP	TP to field	Harvest date	Plant to harvest	General notes
basil	8,19,23	Emily	GH	DS	22Feb	-	22May	2-3 months	8-10 pounds fresh = 2 pounds dry or 4 times dry wt needed
basil	10,19,20, 21,23	Emily	field	TP	25April	6June	25July	70-80 days after TP	Start 5-6 weeks before TP to field; snip tips at 8 weeks to make bushier plants
basil	2018	Emily	GH hydroponic	DS	12March	-	22May	65-70 days	About 300 - 325 plants/trt for TP

# My crop production spreadsheet



# My crop production spreadsheet - field

---

- When break dormancy in OH
- When bloom
- When harvest
- Time for fruit to turn green to red

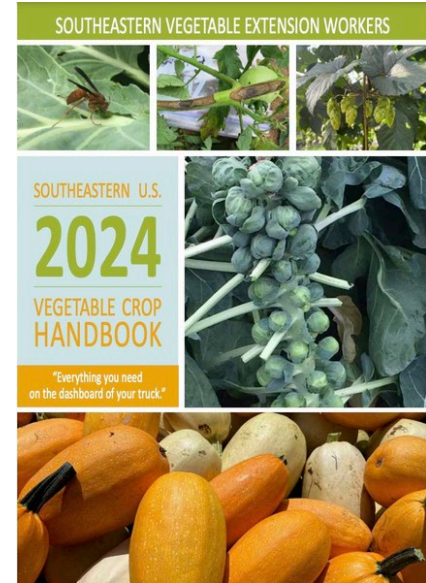


# Summary: Find what is helpful for you in your location



# Resources

- Network
- Southeast Vegetable Crop Handbook
- Midwest Vegetable Production Guide of Commercial Growers
- .edu Production Guides



# Resource Example

## Planting Considerations

Carinata will outcompete many winter weeds. However, including wild radish in the harvest may reduce carinata harvest value by decreasing oil quality. Therefore, one should identify fields with low weed pressure particularly from wild radish and wild mustard. These two weeds are likely to survive carinata registered herbicides, compete, and reduce yields.

Carinata is susceptible to residual herbicides, commonly used in peanut production such as Cadre (imazapic), Pursuit (imazethapyr), Classic (chlorimuron), and Strongarm (diclosulam). Hence, it is critical to consider the herbicide history of the field before planting. Herbicides used in cotton or peanut may reduce carinata establishment, growth, and yield. Most residual herbicides used in other summer rotational crops such as corn and soybeans should not represent a major risk for carinata establishment as long as they are applied early in the season and plant-back restrictions are met. Table 1 provides canola's crop rotation restrictions for some of the most restrictive residual herbicides due to their persistence in the soil. This table may be used as a preliminary guide for carinata rotation intervals.

## Planting Date

In the southeastern US, the crop is fall planted about 3-4 weeks before the first frost. In the Florida panhandle, southern Alabama, and southern Georgia, carinata should be planted between early to mid-November. Figure 4 highlights general planting windows for other regions in the Southeast. Planting outside the recommended window may incur a high incidence of freeze damage, reduced stand density, and reduced yield. Late plantings may result in increased pest damage and late harvest.

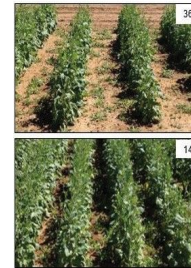
## Seeding Depth

Carinata should be planted not more than 0.5 inches deep because of its small seed size. Some seed visible on the soil surface is normal and an indication that the planting depth is not too deep. That said, greater planting depths should be considered for sandy soils. Fields may be prepared with a drag attached to a cultivator frame to establish a level seedbed. Seed drills should be calibrated to ensure consistent seeding depth and rate.

## Seeding Rate and Row Spacing

Carinata should be planted at 5 lb/ac (regardless of land preparation method) with a target end-of-season plant density of 6 to 10 plants per square foot. A lower seeding rate (4 lb/acre) is suggested if air or vacuum planters are used. Increased plant densities may reduce the number of days needed to reach maturity as well as reduce yield.

Row spacing, as shown in Figure 5, is a more important consideration than seeding rate (Mulvaney et al. 2018). From small plot research, row spacings of 7 to 14 inches will maximize yield, with a numerical yield advantage at 14 inches compared to 7 inches. Row spacing exceeding 14 inches lowers the crop's ability to compete with weeds and significantly reduces yield.



**“Carinata, the Sustainable Crop for a Bio-based Economy: Production Recommendations for the Southeastern United States” – [edis.ifas.ufl.edu](https://edis.ifas.ufl.edu)**





**Thank you!**

**Questions?**