

Retention Matters: Test Substance & Sample Management

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Outline

- ▶ Test Substance & Containers
 - ▶ Crop Protection
 - ▶ Traits
- ▶ Field Samples

We're going to discuss...

- ❖ What Gets Retained?
- ❖ Where?
- ❖ For How Long?
- ❖ Documentation?

Crop Protection

-PESTICIDES APPLIED TO TEST SYSTEMS (CROP)

-SEED TREATMENTS

What gets retained? – Crop Protection

- ▶ Subpart F – Test, Control, and Reference Substance
 - ▶ §160.105 (d) test substance reserve sample retained
- ▶ Protocol
 - ▶ Return or Retain?
 - ▶ TS only, TS + Container, Container Only?
- ▶ Facility SOP
 - ▶ Facility practices based on absence of Sponsor requirements
 - ▶ May be above and beyond what is required in protocol (that's great!)

Where? – Crop Protection

- ▶ Protocol Requirements
 - ▶ If only retaining the container, what considerations for disposal of the TS?
 - ▶ GLP? Temperature Controlled?
- ▶ Facility SOP
 - ▶ Specify Where:
 - ▶ Location (s): container and test substance, disposal of TS regulations
 - ▶ Conditions of storage location

For How Long? – Crop Protection

- ▶ Protocol Requirements
 - ▶ Examples: x years or until approval by Study Director
- ▶ Facility SOP if no instructions in protocol
 - ▶ Arbitrary time – 5 years?
 - ▶ Arbitrary time IF no communication from SD/Sponsor
 - ▶ Effort should be made (in writing) before implementation.
 - ▶ Indefinitely?

Before we retain it, we must receive it!

§160.105

- Name, CAS or code number
- Batch Number
- Expiration Date
- Storage Conditions

§ 160.107

- Date(s) Received
- Amount(s) Received
- Condition at Receipt
- Storage Location
- (Formulation)

Documentation - Crop Protection



Documentation – Crop Protection

GLARS Chemical Storage Room Inventory Log § 160.107

Date Rec'd/Initials	Company/Trial #	Chemical/Test Substance	Formulation	Lot/Batch #	Amount Received	Date Returned or Transferred/Initial	Location Returned or Transferred to	Amount
12/11/25 LAW	25-0000	Pretty Pesticide	SL	abc123	1x100 ml 1 x 50 ml	1/30/26 LAW	GLARS Long Term Storage Area	1 x 25 ml 1 x 50 ml
12/15/25 LAW	25-0000	Pretty Pesticide	SL	abc123	1x100 ml	1/30/26 LAW	GLARS Long Term Storage Area	1 x 100 ml
12/20/25 LAW	25-0001	Funny Fungicide	EC	xyz456	1 x 150 ml	1/30/26 LAW	Container: GLARS Long Term Storage Area TS: Commercial Farm Inventory (non-GLP)	1 x 78 ml

Documentation – Crop Protection

GLARS Long Term Storage Inventory Log § 160.107

Company Trial #	Test Substance ID	Amount	Date In	Initials/Date	Date Notification to Dispose Received & Method	Initials/Date	Place Transferred to	Date Removed /Transfer	Initials/Date
25-0000	Pretty Pesticide	1 x 25 ml	1/30/26	LAW 1/30/26	1/30/29	LAW 2/15/29	Walworth County Clean Sweep	10/5/29	LAW 10/5/29
		1 x 50 ml			Via Email				
25-0000	Pretty Pesticide	1 x 100 ml	1/30/26	LAW 1/30/26	1/30/29 Via Email	LAW 2/15/29	Walworth County Clean Sweep	10/5/29	LAW 10/5/29
25-0001	Funny Fungicide	1 x 0 ml	1/30/26	LAW 1/30/26	5/30/29 3 years	LAW 6/1/29	Landfill (container only)	6/1/29	LAW 6/1/29

Traits

SEEDS WHICH ARE:

-APHIS REGULATED

-EPA REGULATED

-STEWARDED OR HANDLED
AS REGULATED

What gets retained? – Traits

- ▶ Subpart F – Test, Control, and Reference Substance
 - ▶ §160.105 (d) test substance reserve sample retained
- ▶ Protocol/Compliance Documentation
 - ▶ Destroy seed packets and leftover seed (if any)
 - ▶ This is a GLP Exception, more later
- ▶ Facility SOP
 - ▶ Facility practices based on absence (!) of Sponsor requirements

Where? – Traits

- ▶ Protocol/Compliance Requirements
 - ▶ Trial Site
 - ▶ Ship back
- ▶ Facility SOP
 - ▶ Facility practices based on absence (!) of Sponsor requirements
 - ▶ Trial Site

For How Long? – Traits

- ▶ Protocol/Compliance Requirements
 - ▶ Usually right away, if not before the end of the field phase
 - ▶ Could be before permit expires
- ▶ Facility SOP (suggestions)
 - ▶ GLARS does hold on to seed packets until it is determined the correct seed was planted in the correct plot.

*Before we
retain it, we
must receive it!*

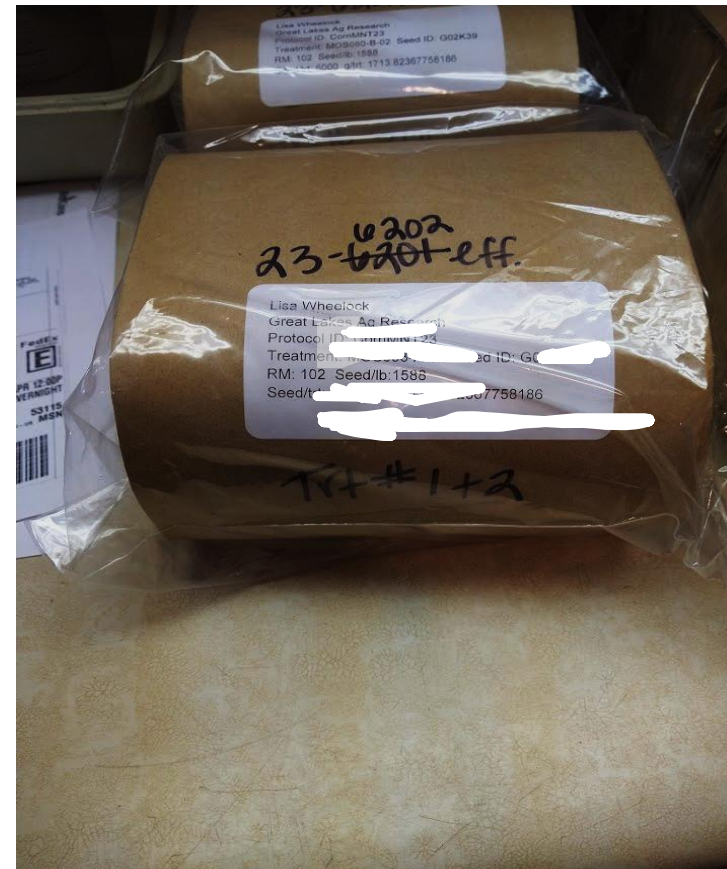
§ 160.105

- Name, CAS or code number
- Batch Number
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- Storage Conditions

§ 160.107

- Date(s) Received
- Amount(s) Received
- Condition at Receipt
- Storage Location
- (Formulation)

Documentation – Traits



Documentation – Traits

Seed Test Substance Inventory Log § 160.107

Date Rec'd & Initials	Company Rec'd From	Test Subs.	Lot/Batch #	Amount Received	GLARS Storage Location	Date Returned or Transferred /Initials	Amount	Location Returned or Transferred to
12/12/25 LAW	Biotech is Beautiful	Entry 1	1234567TPOX	24 packets x 42 seeds each	Seed Storage Cabinet	1/30/26 LAW	empty seed packets only	All trial seed planted 12/15/25. Empty seed packets burned at trial site 1/30/26.
12/22/25 LAW	Get 'em GMO	This x That	85200035623	1 x 4.4 kg	Seed Storage Cabinet	1/30/26 LAW	2.5 kg	After planting, seed returned to Seed Storage Cabinet. Leftover seed and packet burned at trial site 1/30/26.

Documentation – Traits

- ▶ Let's talk about destroying the seed packets...
 - ▶ GLP Exceptions/Compliance Statement
 - ▶ Suggestions for documenting information on seed packet(s)
 - ▶ Story time!

Field Samples

CROP MATRIXES – RESIDUE
OR BIOTECH

SOIL DISSIPATION

POLLINATOR

What gets retained? – Field Samples

- ▶ Subpart J – Records and Reports
 - ▶ §160.190 Storage and retrieval of records and data.
 - ▶ (a) *All raw data, documentation, records, protocols, **specimens**, and final reports generated as a result of a study shall be **retained**.*
- ▶ Protocol
 - ▶ Details of when, how much and labelling
- ▶ Facility SOP
 - ▶ Facility practices based on absence of Sponsor requirements
 - ▶ GLARS doesn't currently have this (!)

Where? – Field Samples

- ▶ §160.190 (b):
 - ▶ Archives (same as documents)
 - ▶ Conditions
 - ▶ Commercial Archives/Off-Site
- ▶ Protocol Requirements
 - ▶ Freezer or Dry Ice
 - ▶ Refrigerated
 - ▶ Ambient
- ▶ Facility SOP
 - ▶ Facility practices based on absence of Sponsor requirements

For How Long? – Field Samples

- ▶ §160.195 Retention of Records:
 - ▶ (b): Sponsor holds permit, 5 years or 2 if study discontinued
 - ▶ (c): Wet specimens for as long as the quality of preparation affords evaluation
- ▶ Protocol
 - ▶ Once samples are received (and possibly analyzed) at lab
 - ▶ Others?
- ▶ Facility SOP (suggestions)
 - ▶ In absence of sponsor requirements
 - ▶ Attempt to communicate with Sponsor before disposal
 - ▶ If not feasible for long-term storage onsite, request shipped to Sponsor

*Before we
retain it, we
must collect it!*

§160.130 (c)

-test system

-study

-nature

-date of collection

This information should be
on the sample container
(bag, vial, jar, etc.) or
accompanying
paperwork*

Documentation – Field Samples



Documentation – Field Samples

Freezer Usage Log ID: Freezer #8

GLARS Trial #	Sample Numbers	Sample Type (Nature)	Date & Time In	Initials	Date & Time Out	Place Removed To	Initials
25-2501	R2D2-5	Pollen	1/30/26 1:33 PM	LAW	2/17/26 2:03 PM	ACDS #123456	LAW
25-2501	R2D2-5R	Pollen	1/30/26 1:33 PM	LAW	3/1/26 9:53 PM	discarded at trial site	LAW

Summary – Key QA Points

- ▶ Test Substance - Crop Protection
 - ▶ Retention procedures (SOPs): what retained, where, how long, documentation
 - ▶ Look for SDS' and evidence of approval to dispose or length of time has passed
- ▶ Test Substance – Traits
 - ▶ Facility is following not only protocol but also APHIS requirements if applicable
 - ▶ Seed and containers destroyed, not retained
 - ▶ GLP Exception/Compliance Statement

Summary – Key QA Points (con't)

- ▶ Field Samples
 - ▶ Procedures similar to archives
 - ▶ Storage conditions appropriate and monitored
 - ▶ Notification of approval to discard

Any other key points you jotted down???

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Farming with Mom!

Thank you!