



# **Electronic Federal Select Agent Program** (eFSAP) Information System - Updates

APHIS/CDC Form 4
Report of the Identification of a Select Agent or Toxin

















#### **APHIS/CDC Form 4A – Identification of BSAT**

Creat	te Form 4A - Section A&B Create	Form 4B Create F	form 4C
Form 4 Section ABs			
ld	Sele	ct Agent S	tatus Date Created
No Section A & B's have been cr	eated		
Form 4A- Section CD's			
ld		Select Agent	Status Date Created
No Section C & D's have been as	signed to this entity		
Form 4B			
ld	Select Agent	Status	Date Created
No 4B's have been created			
Form 4C			
ld	Law Enforcement Ager	cy	Status Date Created
No 4C's have been created			





#### **APHIS/CDC Form 4A – Section A**

SECTION A - REFERENCE LABORATORY INFORMATION		
1. Name of individual completing Sections A and B	2. E-mail address:	3. Telephone #:
First M Last		()ext

Complete section A questions 1-3.





#### **APHIS/CDC Form 4A – Section A**

For registered
entities, information
on this page is
automatically
pulled from your
Form 1.

Registered Entity	APHIS or CD	C Registration #:
○ Clinical or Diagnostic Laboratory	/ [non-registered entity (NRE)]	
5. Responsible Official or Laborator	y Supervisor name (if same as field 1 then skip t	to field 9):
Allen Atkins		
243 of 255 characters left		
3. E-mail address:	7. Telephone #:	8. Fax #:
aa@usa.edu	(333)458-5969ext.12343	(333)746-4486ext.17236
40 of 50 characters left		
9. Entity name:		
University of Select Agents		
228 of 255 characters left	ess):	
University of Select Agents 228 of 255 characters left  10. Address (NOT a post office address) 100 University Ave	ress):	
228 of 255 characters left  10. Address (NOT a post office address)  100 University Ave	ress):	
228 of 255 characters left  10. Address (NOT a post office add	ress): 12. State:	13. Zip Code:





#### **APHIS/CDC Form 4A – Section B**

Submitter completes section B questions 1-7.

SECTION B — SELECT AGENT OR TOXIN IDENTIFIED FROM CLINICAL/DIAG	SNOSTIC SPECIMEN(S)
1. Select Agent or Toxin Identified:	2. Date identified
	✓ mm/dd/yyyy
3. Case/patient/sample ID #(s):	4. # of samples received:
5. Sample type received:	6. Case/patient origin (zip code):
Select an option	
7. Type of test performed (e.g., PCR, mouse bioassay, ELISA):	





#### **APHIS/CDC Form 4A – Section B**

	8. Dispositions of select agent or toxin by entity listed in Block A9 (complete all that apply):		
Must answer at least one of the below  Transferred  Destroyed  Retained	☐ Transferred ☐ Destroyed	Select the correct disposition of the agent/toxin	

If retained, select the correct PI from the pre-populated choices based on the list of approved PIs at the entity.







#### **APHIS/CDC Form 4A – Section B**

9. Were any of the samples containing a select agent or toxin handled outside of primary containment which may have led to an unintentional release and/or exposure to the select agent or toxin? ○ Yes ○ No 10. Do you anticipate receiving additional samples/specimens for this case/patient that originate from the initial case (e.g., patient, environmental sample)? ○ Yes ○ No 11. Has the sender(s) (i.e., sample provider(s)) of the specimen(s) been notified of the identification of the select agent or toxin? ○ Yes ○ No ○ N/A Note Please request completed and signed Sections C & D from each facility that was in possession of the specimen(s). 12. Sample Provider Entity Name: 13. Sample Provider Point of Contact: 14. Sample Provider E-mail Address: 15. Sample Provider Contact Number: \_)\_\_-\_\_ext.\_\_\_ First M Last

Complete section B questions 9-15





#### **APHIS/CDC Form 4A – Section B**

16. Comments / Notes:		
	Signature of Responsible Official or Laboratory Supervisor:	Date Signed:
		11/07/2017
	responsible official	
	Please type name as above.	
	Choose the desired action	☐ Immediate Notification ☐ Save

- Immediate notification as required by the regulations (must submit name of select agent or toxin, date identified, and whether there was a theft, loss, or release).
- Save Draft only. This does not fulfill the requirements of the regulations. The Form 4A will not be reviewed by FSAP staff.
- Submit This option will activate once the Form is filled out in its entirety. Once submitted, the Form 4A will be reviewed by FSAP.





#### **APHIS/CDC Form 4A – Section C/D**

#### After submission by the identifying lab:

- FSAP staff will assign the Section C/D to the supplying laboratory identified in Section A/B for completion.
  - If the supplying laboratory is registered with FSAP then they will receive a notification on their eFSAP homepage.
  - If the supplying laboratory is unregistered, FSAP will contact the entity and they will use the forms on the FSAP website and continue to use current practices to submit.

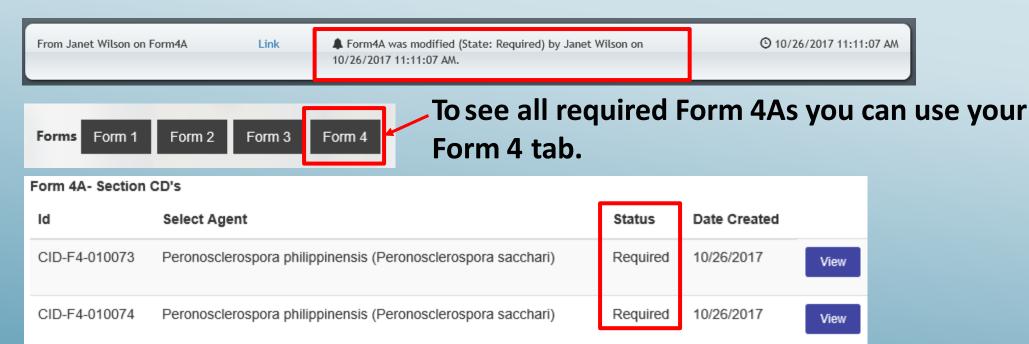




#### **APHIS/CDC Form 4A – Section C/D**

#### If your entity was the supplying lab:

 A notification will appear in your notification center informing you that a Form 4A is required.







#### **APHIS/CDC Form 4A – Section C/D**

To enter the information for this Form 4A, click the View button.

Form 4A- Section CD's				
ld	Select Agent	Status	Date Created	
CID-F4-010073	Peronosclerospora philippinensis (Peronosclerospora sacchari)	Required	10/26/2017	View
CID-F4-010074	Peronosclerospora philippinensis (Peronosclerospora sacchari)	Required	10/26/2017	View





#### **APHIS/CDC Form 4A – Section C**

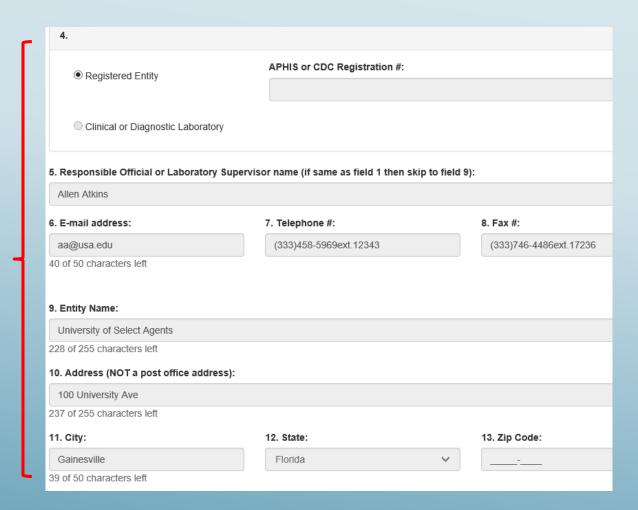
Complete section C questions 1-3.		
SECTION C - SAMPLE PROVIDER INFORMATION		
Name of individual completing Sections C and D:	2. E-mail Address:	3. Telephone #:
First M Last		()ext





#### **APHIS/CDC Form 4A – Section C**

For registered entities, this information is automatically pulled from your Form 1.







#### **APHIS/CDC Form 4A – Section D**

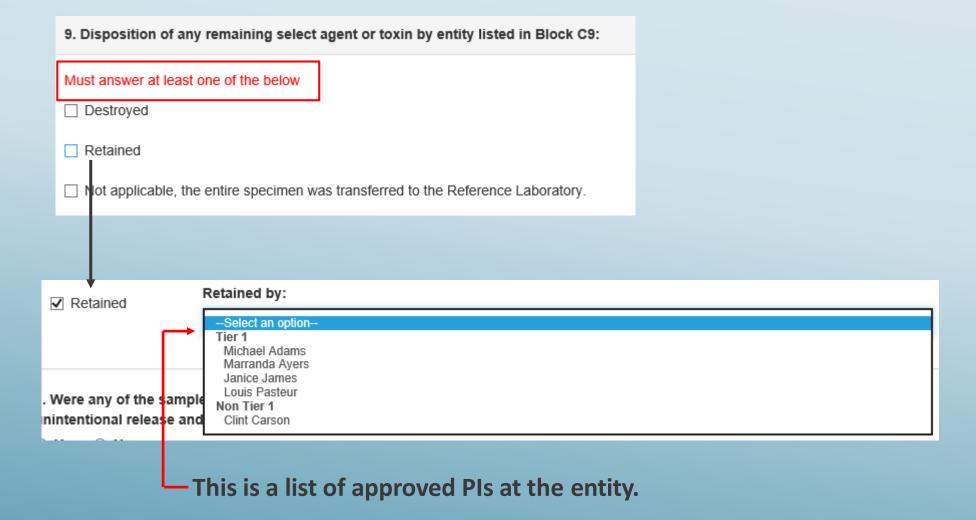
Question 1 is prepopulated with the
agent indicated by
the identifying
laboratory that filled
out section B.

SECTION D — SPECIMEN(S) CONTAINING SELECT AGENT OR TOXIN PROVI	DED TO REFERENCE LABORATORY
Select Agent or Toxin Identified:	2. Date notified of select agent or toxin identification:
Peronosclerospora philippinensis (Peronosclerospora sacc∨	mm/dd/yyyy
3. Case/patient/sample ID #(s):	4. # of samples shipped:
5. Sample type provided:	6. Case/patient/sample origin (zip code):
Select an option	
7. Date sample(s) shipped to Reference Laboratory:	8. Name of Reference Laboratory:
mm/dd/yyyy	
	→ Clear → Add Row





#### **APHIS/CDC Form 4A – Section D**







#### **APHIS/CDC Form 4A – Section D**

unintentional release and/or exposure to the	elect agent or toxin nandled outside of primary e select agent or toxin?	containment which may have led to an
○ Yes ○ No		
11. Was your entity the source of the sampl	e(s)?	
○ Yes ○ No		
12. Do you anticipate receiving additional sa environmental sample)?	amples/specimens for this case/patient that or	riginate from the initial case (e.g., patient,
○ Yes ○ No		
13. Has the sender(s) (i.e., sample provider(	s)) of the specimen(s) been notified of the ider	ntification of the select agent or toxin?
○ Yes ○ No		
, Note		
Please request completed and signed Section	ons C & D from each facility that was in possession	on of the specimen(s).
14. Sample Provider Entity Name:		
15. Sample Provider Point of Contact:	16. Sample Provider E-mail Address:	17. Sample Provider Contact Number:
First M Last		()ext

Complete questions 10-17.





#### **APHIS/CDC Form 4A – Section D**



- Save Draft only. The completed Form 4A will not be reviewed by FSAP staff.
- Submit This option will activate once the Form is filled out in its entirety.

  Once submitted, the Form 4A will be reviewed by the FSAP.