APHIS/CDC Forms 3 and 4 Overview and Updates

29 June 2023

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

CDC CENTERS FOR DISEASE CONTROL AND PREVENTION

USDA

APHIS/CDC Form 3

APHIS/CDC Form 3 Overview

- The APHIS/CDC Form 3 is the mechanism used by entities to report whenever there is a theft, loss, or release of a select agent or toxin
- The APHIS/CDC Form 3 is also used to report if an occupational exposure occurred due to the release
- The eFSAP Information System is the preferred method for registered entities to report a theft, loss, or release

*42 CFR §73.19, 7 CFR §331.19, 9 CFR §121.19

Select Agent Regulations: Section 19(a) (Theft or Loss)

- Upon discovery of the theft or loss of a select agent or toxin, an individual or entity must immediately notify CDC or APHIS and appropriate Federal, State, or local law enforcement agencies. Thefts and losses must be reported even if the select agent or toxin is subsequently recovered or the responsible parties are identified
- A completed APHIS/CDC Form 3 must be submitted within 7 calendar days

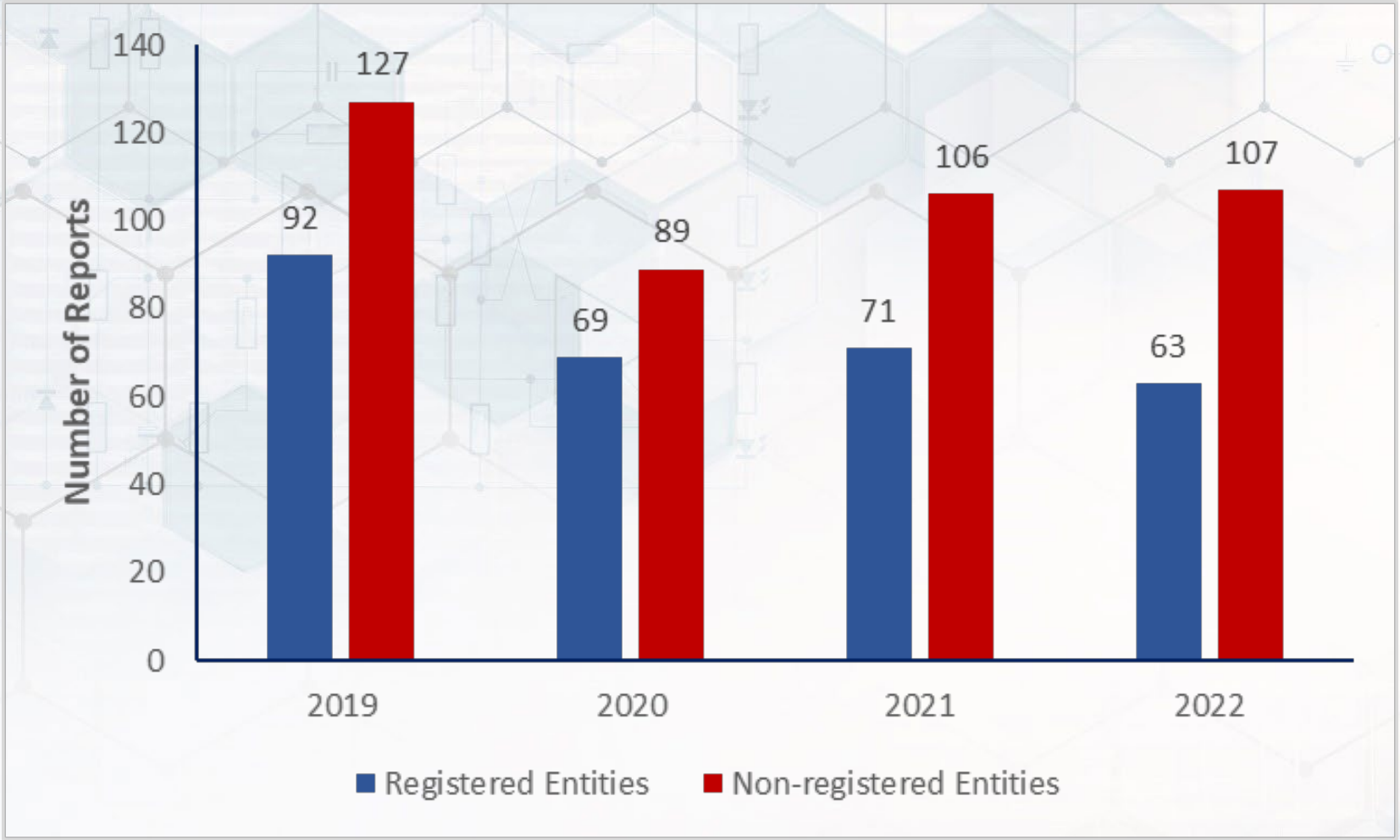
*42 CFR Part 73, 7 CFR Part 331, 9 CFR Part 121

Select Agent Regulations: Section 19(b) (Release)

- Upon discovery of the release of an agent or toxin causing occupational exposure or release of the select agent or toxin outside of the primary barriers of the biocontainment area, an individual or entity must immediately notify CDC or APHIS
- A completed APHIS/CDC Form 3 must be submitted within 7 calendar days

*42 CFR Part 73, 7 CFR Part 331, 9 CFR Part 121

APHIS/CDC Form 3 Statistical Information (2019-2022 Releases)



Text version of information can be found in the **Theft, Loss, and Release** section of BSAT Annual Reports for the corresponding years:

2019 Annual Report - https://www.selectagents.gov/resources/publications/docs/FSAP_Annual_Report_2019_508.pdf

2020 Annual Report - https://www.selectagents.gov/resources/publications/docs/FSAP_Annual_Report_2020_508.pdf

2021 Annual Report - https://www.selectagents.gov/resources/publications/docs/FSAP_Annual_Report_2021_508.pdf

2022 Annual Report - https://www.selectagents.gov/resources/publications/docs/FSAP_Annual_Report_2022_508.pdf

APHIS/CDC Form 3 Statistical Information (2019-2022 Losses)

Text version of information can be found in the **Theft, Loss, and Release** section of BSAT Annual Reports for the corresponding years:

2019 Annual Report - https://www.selectagents.gov/resources/publications/docs/FSAP_Annual_Report_2019_508.pdf

2020 Annual Report - https://www.selectagents.gov/resources/publications/docs/FSAP_Annual_Report_2020_508.pdf

2021 Annual Report - https://www.selectagents.gov/resources/publications/docs/FSAP_Annual_Report_2021_508.pdf

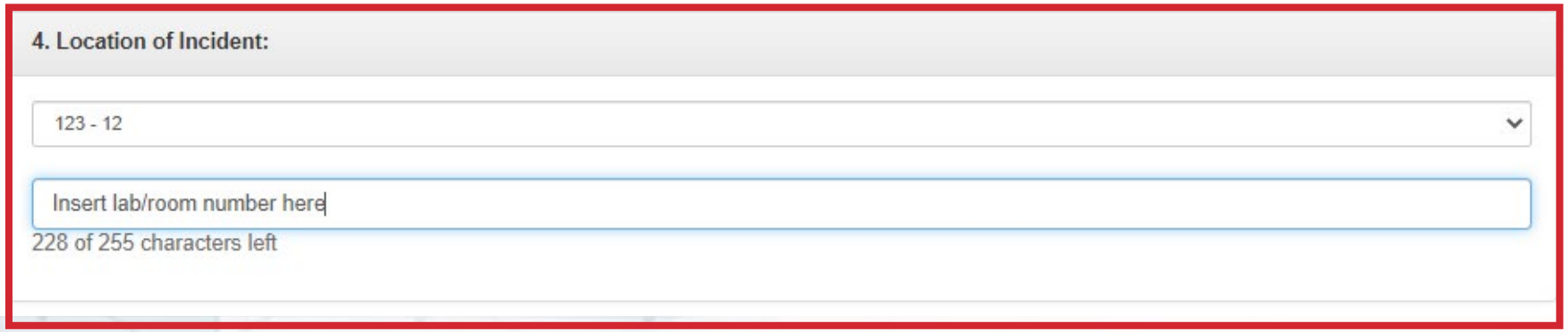
2022 Annual Report - https://www.selectagents.gov/resources/publications/docs/FSAP_Annual_Report_2022_508.pdf

APHIS/CDC Form 3 – Making an Immediate Notification

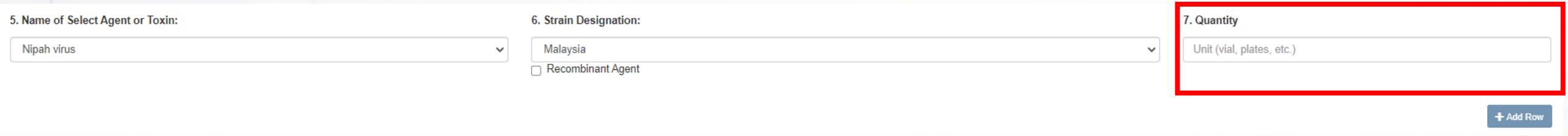
- **<u>eFSAP Immediate Notification (Preferred Method)</u>**
  - When selecting the agent/toxin and if unclear what select agent/toxin manipulated, select the agent/toxin last worked with at time of incident
  - Complete the required questions on the form and click the “Immediate Notification” button
- **<u>eFSAP General Discussion</u>**
  - Include the minimal submission requirements in the General Discussion as described in the Select Agent Regulations (Section 19a and/or 19b)
- **<u>Email or Phone Call</u>**
  - Check homepage for FSAP's acknowledgment

APHIS/CDC Form 3 Helpful Information (1/3)

- Block B4. Location of Incident



- Block B7. [BSAT] Quantity



APHIS/CDC Form 3 Helpful Information (2/3)

- Block C6. Medical surveillance and/or treatment

6. What medical surveillance and/or treatment was provided to individuals, if any?

- [ ] None
- [x] Physical evaluation
- [ ] Fever/symptom watch
- [ ] Serology screening
- [ ] Antibiotics or other prophylaxis
- [x] Other

114 character limit (with spaces)

- Block C7b. Corrective actions

7b. What corrective actions have been initiated to lessen the likelihood of recurrence of incident involving the select agents and toxins at this entity? (choose all that apply)

- [ ] Retraining on existing policy
- [ ] New PPE provided
- [ ] Audit/remove faulty PPE
- [ ] New/modified policy
- [ ] New equipment provided
- [ ] Audit/remove faulty equipment
- [ ] New training developed
- [ ] Equipment repair
- [ ] None
- [ ] New/updated SOP
- [ ] Review/revise risk assessment
- [x] Other:

<100 characters

APHIS/CDC Form 3 Helpful Information (3/3)

Appendix 1 - EVENTS TIMELINE

Provide a detailed summary of events, including a timeline of what occurred.

- Who was involved?
- What happened?
- When did it happen?
- Where did it happen?
- Why and how (root cause) did it happen?

APHIS/CDC Form 3 – Responding to Request For Information (RFI) and Returning to Agency

- If additional information is needed, an RFI letter is uploaded into eFSAP Information System by the Form 3 team and the status of the report is changed to “Request For More Information”
- In this status, the report can be edited to change/correct information on the APHIS/CDC Form 3
- After making changes and uploading the responses to the RFI in the entity documents section of the report, select the “Return to Agency” button

APHIS/CDC Form 3 Scenarios

APHIS/CDC Form 3 Scenario A

- During a severe weather event, an ABSL-3 facility experienced a power outage and an airflow reversal into a clean area. The entity's IT system communication required manual restart after power outages. However, initial investigation showed that backup generators and the IT system communication with the building automation system (BAS) operated as expected and a root cause was not identified.
- What may have been identified as the most likely final root cause(s) for this airflow reversal incident?
    A. Power outage
    B. Severe weather
    C. Loss of communication between IT system and BAS
    D. Power outage response steps not taken

APHIS/CDC Form 3 Scenario A Response

- What may have been identified as the most likely final root cause(s) for this airflow reversal incident?

  D. Power outage response steps not taken

APHIS/CDC Form 3 Scenario B

- Today, your entity notified FSAP and submitted a complete APHIS/CDC Form 3 into eFSAP Information System for a select agent release discovered 4 days ago.
- Is your entity compliant with the requirements of Section 19 of the select agent regulations?
    A. Yes, because the Form 3 was submitted within 7 days
    B. No, because the Form 3 was not submitted within 3 days
    C. No, because FSAP was not immediately notified of the release
    D. I do not know

APHIS/CDC Form 3 Scenario B Response

- Is your entity compliant with the requirements of Section 19 of the select agent regulations?

C. No, because FSAP was not immediately notified of the release

APHIS/CDC Form 3 Scenario C

- During an Ebola virus study with 20 non-human primates (NHPs), all NHPs had multiple blood samples drawn. The entity was short staffed, so only two technicians performed the procedures of sedating and drawing blood from the NHPs. During the blood draw of last larger NHP, the technician drawing the blood experienced a needle stick. Sudden movement by the NHP during the blood draw was stated as the root cause after initial investigation.
- What may have been identified as the most likely final root cause(s) for this needle stick incident?

A. The NHP sudden movement
B. Insufficient sedation of the NHP
C. Lack of adequate animal care staffing for the procedure
D. Animal care technicians were overly tired
E. All of the above

APHIS/CDC Form 3 Scenario C Response

- What may have been identified as the most likely final root cause(s) for this needle stick incident?

  E. All of the above

APHIS/CDC Form 3 Scenario D

- A laboratorian noticed a small hole in the right index finger of their Positive Pressure Protective Suit (PPPS) glove while handling mice in the biosafety cabinet (BSC) for an Ebola virus study in an ABSL-4 laboratory.
- Is this reportable using an APHIS/CDC Form 3?
    A. Yes, because any breach in an ABSL-4 containment must be reported
    B. No, because it is not a breach in containment while working in the BSC
    C. Maybe, it depends if the mice were infected with Ebola virus at the time of the incident
    D. Not sure

APHIS/CDC Form 3 Scenario D Response

- Is this reportable using an APHIS/CDC Form 3?
    C. Maybe, it depends if the mice were infected with Ebola virus at the time of the incident

APHIS/CDC Form 4

Identify What Is Not True: APHIS/CDC Form 4 Questions

Man with magnifying glass

APHIS/CDC Form 4 Question 1

- What should occur after identification of a select agent or toxin?

A. The Responsible Official (RO) is the only person who can complete and submit the APHIS/CDC Form 4 in eFSAP Information System
B. If destroying the select agent or toxin, destruction must be on-site
C. If a tier 1 select agent or toxin, immediate notification can be completed by telephone, email, fax, or eFSAP Information System

Select the statement that is not true

APHIS/CDC Form 4 Question 1: The Untrue Statement Is ….

A. The Responsible Official (RO) is the only person who can complete and submit the APHIS/CDC Form 4 in eFSAP Information System

APHIS/CDC Form 4 Question 2

- When should the identification of a select agent or toxin be submitted in eFSAP Information System?

A. The select agent is identified to the genus and species levels
B. The select agent is identified to the genus level
C. The select agent is identified within the last 7 days

Select the statement that is not true

Image of thumbtack on calendar day 7

APHIS/CDC Form 4 Question 2: The Untrue Statement Is ….

B. The select agent is identified to the genus level

APHIS/CDC Form 4 Question 3

- When should the APHIS/CDC Form 4B be submitted in eFSAP Information System?

A. After the identification of a select agent or toxin excluded strain
B. Within 90 calendar days of receipt of the select agent or toxin
C. Within 90 calendar days of identification of the select agent or toxin

Select the statement that is not true

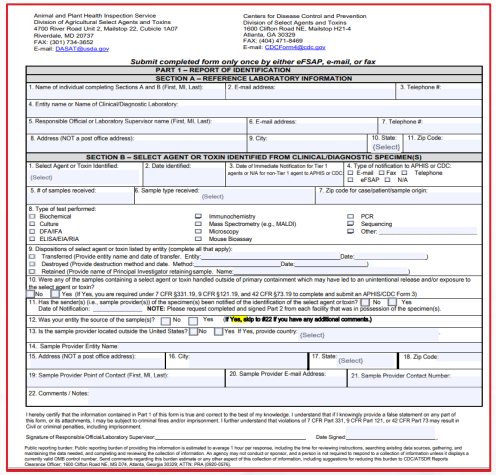
APHIS/CDC Form 4 Question 3: The Untrue Statement Is ….

C. Within 90 calendar days of identification of the select agent or toxin

APHIS/CDC Form 4 Purpose and Overview

APHIS/CDC Form 4 Purpose

- The APHIS/CDC Form 4, Reporting the Identification of a Select Agent or Toxin, is used by clinical or diagnostic laboratories and other entities to notify FSAP of the identification of a select agent or toxin as the result of diagnosis, verification, or proficiency testing and of the final disposition of that identified agent or toxin.



Animal and Plant Health Inspection Service
Division of Agricultural Select Agents and Toxins
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
FAX: (301) 734-3652
E-mail: DASAT@usda.gov

Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road NE, Mailstop H21-4
Atlanta, GA 30329
FAX: (404) 471-8499
E-mail: CDCForm4@cdc.gov

Submit completed form only once by either eFSAP, e-mail, or fax

PART 1 – REPORT OF IDENTIFICATION

SECTION A – REFERENCE LABORATORY INFORMATION

1. Name of individual completing Sections A and B (First, MI, Last): | 2. E-mail address: | 3. Telephone #

4. Entity name or Name of Clinical/Diagnostic Laboratory:

5. Responsible Official or Laboratory Supervisor name (First, MI, Last): | 6. E-mail address: | 7. Telephone #

8. Address (NOT a post office address): | 9. City: | 10. State: {Select} | 11. Zip Code:

SECTION B – SELECT AGENT OR TOXIN IDENTIFIED FROM CLINICAL/DIAGNOSTIC SPECIMEN(S)

1. Select Agent or Toxin Identified: {Select} | 2. Date Identified: | 3. Date of Immediate Notification for Tier 1 agents or N/A for non-Tier 1 agent to APHIS or CDC: | 4. Type of notification to APHIS or CDC: ☐ E-mail ☐ Fax ☐ Telephone ☐ eFSAP ☐ N/A

5. # of samples received: | 6. Sample type received: {Select} | 7. Zip code for case/patient/sample origin:

8. Type of test performed:
☐ Biochemical ☐ Immunochemistry ☐ PCR
☐ Culture ☐ Mass Spectrometry (e.g., MALDI) ☐ Sequencing
☐ DFA/IFA ☐ Microscopy ☐ Other:
☐ ELISA/EIA/RIA ☐ Mouse Bioassay

9. Dispositions of select agent or toxin listed by entity (complete all that apply):
☐ Transferred (Provide entity name and date of transfer. Entity: Date:)
☐ Destroyed (Provide destruction method and date. Method: Date:)
☐ Retained (Provide name of Principal Investigator retaining sample. Name:)

10. 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?
☐ No ☐ Yes (If Yes, you are required under 7 CFR §331.19, 9 CFR §121.19, and 42 CFR §73.19 to complete and submit an APHIS/CDC Form 3)

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? ☐ No ☐ Yes
Date of Notification: NOTE: Please request completed and signed Part 2 from each facility that was in possession of the specimen(s).

12. Was your entity the source of the sample(s)? ☐ No ☐ Yes **(If Yes, skip to #22 if you have any additional comments.)**

13. Is the sample provider located outside the United States? ☐ No ☐ Yes If Yes, provide country: {Select}

14. Sample Provider Entity Name:

15. Address (NOT a post office address): | 16. City: | 17. State: {Select} | 18. Zip Code:

19. Sample Provider Point of Contact (First, MI, Last): | 20. Sample Provider E-mail Address: | 21. Sample Provider Contact Number:

22. Comments / Notes:

I hereby certify that the information contained in Part 1 of this form is true and correct to the best of my knowledge. I understand that if I knowingly provide a false statement on any part of this form, or its attachments, I may be subject to criminal fines and/or imprisonment. I further understand that violations of 7 CFR Part 331, 9 CFR Part 121, or 42 CFR Part 73 may result in Civil or criminal penalties, including imprisonment.

Signature of Responsible Official/Laboratory Supervisor: Date Signed:

Public reporting burden: Public reporting burden of providing this information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering, and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road NE, MS D74, Atlanta, Georgia 30329. ATTN: PRA (0920-0576).

Image of APHIS/CDC Form 4A

APHIS/CDC Form 4 Overview (1/2)

- The RO must report the identification and final disposition of any select agent or toxin contained in a specimen presented for diagnosis or verification
  - Tier 1* select agents and toxins must be immediately reported by telephone, fax or email
  - A completed and signed APHIS/CDC Form 4A must be submitted within **seven calendar days** after identification

Image of thumbtack on calendar day 7

42 CFR §73.9(c), *7 CFR §331.9(c), *9 CFR §121.9(c)

APHIS/CDC Form 4 Overview (2/2)

- The RO is required to report the identification and final disposition of any select agent or toxin contained in a specimen presented for proficiency testing
  - A completed and signed APHIS/CDC Form 4B must be submitted within **90 calendar days of receipt of the agent or toxin**

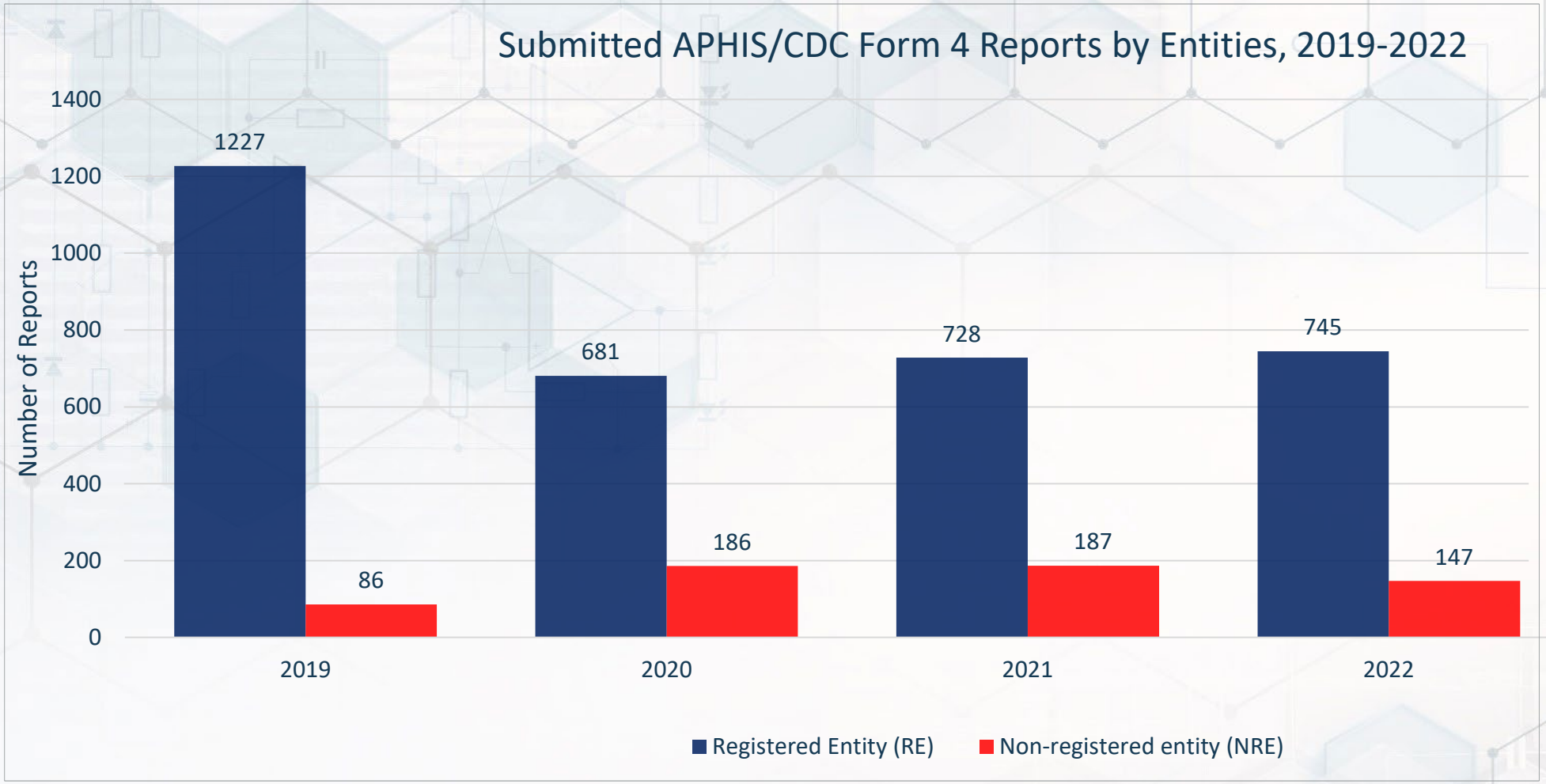
42 CFR §73.9(d), 9 CFR §121.9(d)

Tier 1 Select Agents and Toxins Requiring Immediate Reporting

- *Bacillus anthracis*
- *Bacillus cereus* Biovar *anthracis*
- Botulinum neurotoxins
- Botulinum neurotoxin producing species of *Clostridium*
- *Burkholderia mallei*
- *Burkholderia pseudomallei*
- Ebola viruses
- Foot-and-mouth disease virus
- *Francisella tularensis*
- Marburg virus
- Rinderpest virus
- Variola major virus (Smallpox virus)
- Variola minor (Alastrim)
- *Yersinia pestis*

Note: List is not all inclusive

APHIS/CDC Form 4 Statistical Information



Text version of information can be found in the **Report of the Identification of BSAT** section of BSAT Annual Reports for the corresponding years:

2019 Annual Report - https://www.selectagents.gov/resources/publications/docs/FSAP_Annual_Report_2019_508.pdf

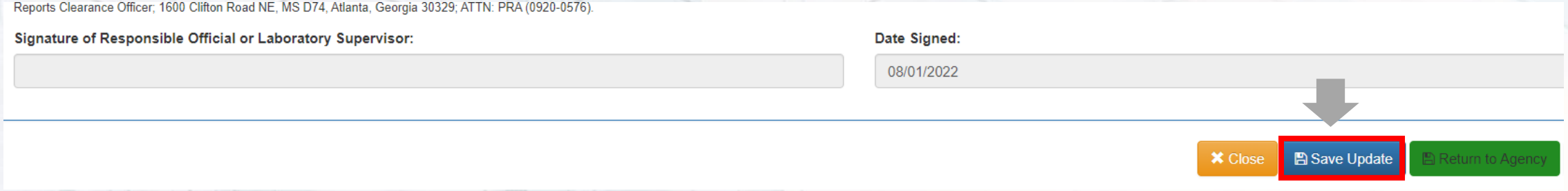
2020 Annual Report - https://www.selectagents.gov/resources/publications/docs/FSAP_Annual_Report_2020_508.pdf

2021 Annual Report - https://www.selectagents.gov/resources/publications/docs/FSAP_Annual_Report_2021_508.pdf

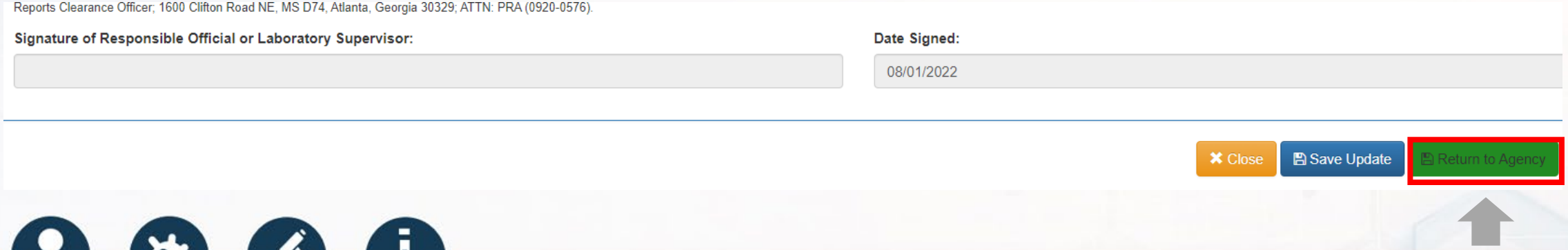
2022 Annual Report - https://www.selectagents.gov/resources/publications/docs/FSAP_Annual_Report_2022_508.pdf

APHIS/CDC Form 4 Helpful Information

- After updating the form, select the “Save Update” button



- Select the green “Return to Agency” button to notify FSAP that the form has been updated and is ready for review



APHIS/CDC Form 4 Retaining Select Agents and Toxins

- Selecting Retained for Disposition?
  - Question B9 or D8
  - Question B4 – APHIS/CDC Form 4B
  - Update your APHIS/CDC Form 1 Section 3
    - For any select agents and toxins that were not previously possessed
  - Update your APHIS/CDC Form 1 Section 7B
    - If the select agent and toxin strain/type is known

www.selectagents.gov

CDC Contact Information
Division of Select Agents and Toxins
LRSAT@cdc.gov
404-718-2000

APHIS Contact Information
Division of Agricultural
Select Agents and Toxins
DASAT@usda.gov
301-851-2070