

APHIS/CDC Form 3 – Report of a Release/Loss/Theft of a Select Agent or Toxin

Multi-Agency Informational Meeting (webinars) to Discuss Select Agent and Toxin Reporting Requirements
October 6 and November 3, 2021

Centers for Disease Control and Prevention
Division of Select Agents and Toxins
Program Services Branch
APHIS/CDC Form 3 Team



APHIS/CDC Form 3 Section B Updates

- Incident Information:

- Question B6: Recombinant agent selection box
- Question B8: Order change
- Question B9: 'None' selection removed
- Question B10: Containment levels removed
 - Recombinant (NIH)
 - Large animal (N)
 - Large scale (LS)
 - Plant pathogen (PPQ)

SECTION B – INCIDENT INFORMATION			
1. Date and Time of Incident: _____	2. Date of Immediate Notification: _____	3. Type of notification: <input type="checkbox"/> E-mail <input type="checkbox"/> Fax <input type="checkbox"/> Telephone <input type="checkbox"/> eFSAP	4. Location of Incident (bldg., room, equipment, etc.): _____
5. Name of Select Agent or Toxin: {Select} _____	6. Strain designation of Select Agent or Toxin: <input type="checkbox"/> Recombinant Agent <input type="checkbox"/> PPQ Agent		7. Quantity (Unit (vial, plates, etc.)): _____
{Select} _____	<input type="checkbox"/> Recombinant Agent <input type="checkbox"/> PPQ Agent		
{Select} _____	<input type="checkbox"/> Recombinant Agent <input type="checkbox"/> PPQ Agent		
8. Type of Incident: <input type="checkbox"/> Release/ Potential Exposure (After completing Section B. Go to Section C) <input type="checkbox"/> Loss (After completing Section B. Go to Section D) <input type="checkbox"/> Theft (After completing Section B. Go to Section E)		9. Severity of the incident: <input type="checkbox"/> Negligible <input type="checkbox"/> Low <input type="checkbox"/> Moderate <input type="checkbox"/> High	10. What Biosafety Level did the incident occur? <input type="checkbox"/> BSL2 <input type="checkbox"/> ABSL2 <input type="checkbox"/> BSL3 <input type="checkbox"/> ABSL3 <input type="checkbox"/> BSL4 <input type="checkbox"/> ABSL4 <input type="checkbox"/> ACL 2 <input type="checkbox"/> BSL3 Ag <input type="checkbox"/> ACL 3 <input type="checkbox"/> Storage area <input type="checkbox"/> ACL 4 <input type="checkbox"/> Other _____
Note: Please complete Appendix 1, event timeline, to provide details on the theft/loss/release incident.			
11. Is this incident associated with an APHIS/CDC Form 2 (Transfer): <input type="checkbox"/> Yes, APHIS/CDC Form 2 transfer #: _____ <input type="checkbox"/> No		12. Is this incident associated with an APHIS/CDC Form 4 (Identification): <input type="checkbox"/> Yes, APHIS/CDC Form 4 clinical ID#: _____ <input type="checkbox"/> No	



APHIS/CDC Form 3 Section C Updates

- Report of a Release:
 - Question C2: 'Yes' or 'No' response option
 - Question C4b: Sub-question for the number of laboratory staff
 - Question C6: Types of medical surveillance and treatment options
 - Question C6: Sub-question for the number of individuals
 - Question C7b: Selection for the types corrective action(s)

SECTION C - REPORT OF RELEASE													
<p>1. Type of Potential Exposure/Release (choose all that apply):</p> <table border="0"> <tr> <td><input type="checkbox"/> Animal bite/scratch</td> <td><input type="checkbox"/> Equipment/mechanical failure</td> </tr> <tr> <td><input type="checkbox"/> PPE failure</td> <td><input type="checkbox"/> Package damaged in transit/ complete B-11</td> </tr> <tr> <td><input type="checkbox"/> Spill</td> <td><input type="checkbox"/> Decontamination failure</td> </tr> <tr> <td><input type="checkbox"/> Needle stick/Sharps</td> <td><input type="checkbox"/> Unintended Animal/Plant Pathogen</td> </tr> <tr> <td><input type="checkbox"/> Release</td> <td><input type="checkbox"/> Work performed on an open bench</td> </tr> <tr> <td><input type="checkbox"/> Inactivation failure</td> <td><input type="checkbox"/> Other: _____</td> </tr> </table>	<input type="checkbox"/> Animal bite/scratch	<input type="checkbox"/> Equipment/mechanical failure	<input type="checkbox"/> PPE failure	<input type="checkbox"/> Package damaged in transit/ complete B-11	<input type="checkbox"/> Spill	<input type="checkbox"/> Decontamination failure	<input type="checkbox"/> Needle stick/Sharps	<input type="checkbox"/> Unintended Animal/Plant Pathogen	<input type="checkbox"/> Release	<input type="checkbox"/> Work performed on an open bench	<input type="checkbox"/> Inactivation failure	<input type="checkbox"/> Other: _____	<p>2. Was there a release outside containment barriers?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, (choose all that apply)</p> <p><input type="checkbox"/> Release outside primary containment (e.g., biosafety cabinet)</p> <p><input type="checkbox"/> Release beyond secondary containment (e.g., laboratory)</p> <p><input type="checkbox"/> Release outside all containment barriers of the facility (e.g., resulting in possible agricultural/environmental/public health threat)</p>
<input type="checkbox"/> Animal bite/scratch	<input type="checkbox"/> Equipment/mechanical failure												
<input type="checkbox"/> PPE failure	<input type="checkbox"/> Package damaged in transit/ complete B-11												
<input type="checkbox"/> Spill	<input type="checkbox"/> Decontamination failure												
<input type="checkbox"/> Needle stick/Sharps	<input type="checkbox"/> Unintended Animal/Plant Pathogen												
<input type="checkbox"/> Release	<input type="checkbox"/> Work performed on an open bench												
<input type="checkbox"/> Inactivation failure	<input type="checkbox"/> Other: _____												
<p>3. What PPE was worn at the time of the incident (choose all that apply)?</p> <table border="0"> <tr> <td><input type="checkbox"/> Hand Protection (gloves)</td> <td><input type="checkbox"/> Foot Protection (e.g., booties, shoe covers)</td> </tr> <tr> <td><input type="checkbox"/> Head Protectors/Covers</td> <td><input type="checkbox"/> Respiratory Protection: Type _____</td> </tr> <tr> <td><input type="checkbox"/> Body Protection (e.g., lab coat)</td> <td><input type="checkbox"/> Other: _____</td> </tr> </table>	<input type="checkbox"/> Hand Protection (gloves)	<input type="checkbox"/> Foot Protection (e.g., booties, shoe covers)	<input type="checkbox"/> Head Protectors/Covers	<input type="checkbox"/> Respiratory Protection: Type _____	<input type="checkbox"/> Body Protection (e.g., lab coat)	<input type="checkbox"/> Other: _____	<p>4. Did the release result in potential exposure(s)?</p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p>4a. If yes, how many individuals/animals/plants were exposed? _____</p> <p>4b. Of the number in 4a, how many individuals were laboratory staff: _____</p>						
<input type="checkbox"/> Hand Protection (gloves)	<input type="checkbox"/> Foot Protection (e.g., booties, shoe covers)												
<input type="checkbox"/> Head Protectors/Covers	<input type="checkbox"/> Respiratory Protection: Type _____												
<input type="checkbox"/> Body Protection (e.g., lab coat)	<input type="checkbox"/> Other: _____												
<p>5. Did the release result in a laboratory acquired infection or an infection/outbreak in agriculture or in the environment?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not currently known</p>	<p>6. What medical surveillance and/or treatment was provided to individuals, if any? (choose all that apply)</p> <p><input type="checkbox"/> No treatment</p> <p><input type="checkbox"/> Physical evaluation</p> <p><input type="checkbox"/> Fever/symptom watch</p> <p><input type="checkbox"/> Serology screening</p> <p><input type="checkbox"/> Antibiotics or other prophylaxis</p> <p><input type="checkbox"/> Other: _____</p> <p>6a. Total number of individuals medical surveillance and/or treatment provided to: _____</p>												
<p>7a. Has an internal investigation been initiated to lessen the likelihood of recurrences of incident involving the select agents and toxins at this entity?</p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes (If yes, please provide additional details below)</p> <p>Describe the internal investigation initiated following the incident (if any), and any root cause(s) identified.</p> <p>_____</p>													
<p>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)</p> <table border="0"> <tr> <td><input type="checkbox"/> Retraining on existing policy</td> <td><input type="checkbox"/> New/modified policy</td> <td><input type="checkbox"/> New training developed</td> <td><input type="checkbox"/> New/updated SOP</td> </tr> <tr> <td><input type="checkbox"/> New PPE provided</td> <td><input type="checkbox"/> New equipment provided</td> <td><input type="checkbox"/> Equipment repair</td> <td><input type="checkbox"/> Remodel lab/facility</td> </tr> <tr> <td><input type="checkbox"/> Audit/remove faulty PPE</td> <td><input type="checkbox"/> Audit/remove faulty equipment</td> <td><input type="checkbox"/> None</td> <td><input type="checkbox"/> Other: _____</td> </tr> </table>		<input type="checkbox"/> Retraining on existing policy	<input type="checkbox"/> New/modified policy	<input type="checkbox"/> New training developed	<input type="checkbox"/> New/updated SOP	<input type="checkbox"/> New PPE provided	<input type="checkbox"/> New equipment provided	<input type="checkbox"/> Equipment repair	<input type="checkbox"/> Remodel lab/facility	<input type="checkbox"/> Audit/remove faulty PPE	<input type="checkbox"/> Audit/remove faulty equipment	<input type="checkbox"/> None	<input type="checkbox"/> Other: _____
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<input type="checkbox"/> Audit/remove faulty PPE	<input type="checkbox"/> Audit/remove faulty equipment	<input type="checkbox"/> None	<input type="checkbox"/> Other: _____										



APHIS/CDC Form 3 Sections D and E Updates

- Report of a Loss and Theft:
 - Question D10: Switches order of questions
 - Question E9: Adds 'Date of recovery' for a 'Yes' response
 - Question E10: Removes the 'unsure' box as a response selection

SECTION D - REPORT OF LOSS			
1. Type of Loss: (choose all that apply) <input type="checkbox"/> Inventory/Recordkeeping error <input type="checkbox"/> Sample lost/discarded at entity <input type="checkbox"/> Sample lost in transit/ complete B-11 <input type="checkbox"/> Other: _____		2. Has Local Law Enforcement been Notified: (If yes, complete D3-D5) <input type="checkbox"/> Yes <input type="checkbox"/> No	3. Local Law Enforcement Agency: _____
4. Local Law Enforcement Agent Name (First MI Last Name): _____		5. Local Law Enforcement Contact Information (phone/email): _____	
6. Was the FBI Notified: (If yes, complete D7-D8) <input type="checkbox"/> Yes <input type="checkbox"/> No	7. FBI Agent Name (First MI Last Name): _____	8. FBI Agent Contact Information (phone/email): _____	
9. Was the lost select agent or toxin material found? <input type="checkbox"/> Yes <input type="checkbox"/> No	10. How long was the select agent or toxin material missing? Date recovered: _____ Duration of loss (hours/days): _____	11. Give the date of the last inventory/audit performed: _____	12. Was there a potential exposure: <input type="checkbox"/> Yes/Unknown at this time (go to Section C) <input type="checkbox"/> No
SECTION E - REPORT OF THEFT			
1. Type of Theft: (choose all that apply) <input type="checkbox"/> Forced Entry <input type="checkbox"/> Insider/Insider assisted access <input type="checkbox"/> Unauthorized access		2. Has Local Law Enforcement been Notified: (If yes, complete sections E3-E5) <input type="checkbox"/> Yes <input type="checkbox"/> No	3. Local Law Enforcement Agency: _____
4. Local Law Enforcement Agent Name (First MI and Last name): _____		5. Local Law Enforcement Contact Information (phone/email): _____	
6. Has the FBI been Notified: (If yes, complete E7-E8): <input type="checkbox"/> Yes <input type="checkbox"/> No	7. FBI Agent Name: (First M. Last Name): _____	8. FBI Agent Contact Information (phone/email): _____	
9. Was the stolen select agent or toxin material recovered: <input type="checkbox"/> Yes; Date of Recovery: _____ <input type="checkbox"/> No		10. Was there a potential exposure: <input type="checkbox"/> Yes/Unknown at this time (go to Section C) <input type="checkbox"/> No	



APHIS/CDC Form 3 Helpful Information

- Clarification for requested information on Section B
 - Question B1: Indicate the date and time of earliest exposure
 - Question B2: Immediate notification date is when FSAP was notified
 - Question B3: How was FSAP notified
 - Question B4: Specify the location where the exposure/release occurred

SECTION B – INCIDENT INFORMATION			
1. Date and Time of Incident: _____	2. Date of Immediate Notification: _____	3. Type of notification: <input type="checkbox"/> E-mail <input type="checkbox"/> Fax <input type="checkbox"/> Telephone <input type="checkbox"/> eFSAP	4. Location of Incident (bldg., room, equipment, etc.): _____
5. Name of Select Agent or Toxin: {Select} _____	6. Strain designation of Select Agent or Toxin: <input type="checkbox"/> Recombinant Agent <input type="checkbox"/> PPQ Agent		7. Quantity (Unit (vial, plates, etc.)): _____
{Select} _____	<input type="checkbox"/> Recombinant Agent <input type="checkbox"/> PPQ Agent		
{Select} _____	<input type="checkbox"/> Recombinant Agent <input type="checkbox"/> PPQ Agent		
8. Type of Incident: <input type="checkbox"/> Release/ Potential Exposure (After completing Section B. Go to Section C) <input type="checkbox"/> Loss (After completing Section B. Go to Section D) <input type="checkbox"/> Theft (After completing Section B. Go to Section E) Note: Please complete Appendix 1, event timeline, to provide details on the theft/loss/release incident.	9. Severity of the incident: <input type="checkbox"/> Negligible <input type="checkbox"/> Low <input type="checkbox"/> Moderate <input type="checkbox"/> High	10. What Biosafety Level did the incident occur? <input type="checkbox"/> BSL2 <input type="checkbox"/> ABSL2 <input type="checkbox"/> BSL3 <input type="checkbox"/> ABSL3 <input type="checkbox"/> BSL4 <input type="checkbox"/> ABSL4 <input type="checkbox"/> ACL 2 <input type="checkbox"/> BSL3 Ag <input type="checkbox"/> ACL 3 <input type="checkbox"/> Storage area <input type="checkbox"/> ACL 4 <input type="checkbox"/> Other _____	
11. Is this incident associated with an APHIS/CDC Form 2 (Transfer): <input type="checkbox"/> Yes, APHIS/CDC Form 2 transfer #: _____ <input type="checkbox"/> No	12. Is this incident associated with an APHIS/CDC Form 4 (Identification): <input type="checkbox"/> Yes, APHIS/CDC Form 4 clinical ID#: _____ <input type="checkbox"/> No		



APHIS/CDC Form 3 Helpful Information

- Clarification for the Narrative
 - List all manipulations of biological select agents and toxins (BSAT) outside primary containment
 - Provide additional dates and times, as needed
 - Explain the number of individuals manipulating the BSAT material
 - Describe others in the area when BSAT manipulated
 - Include dates of medical surveillance or treatment

APPENDIX 1 EVENTS TIMELINE

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

- Day 1 – Monday, January 4, 2021
 - Aerobic blood culture bottle - positive at 7pm. Culture media (plates) were set up in BSC and incubated
 - Gram stain was also set up, slide was inoculated in the BSC then heat fixed and stained outside of primary containment. No organisms were identified on gram stain.
- Day 4 – Thursday, January 7, 2021
 - Plates observed for growth at approx. 8am by Tech A, all plates had no growth and were re-incubated. Plate observations done in BSC.
- Day 5 – Friday, January 8, 2021
 - Plates observed for growth at approx. 10am by Tech B, growth was noted on CHOC media plate. Lab staff suspected Neisseria or Haemophilus spp. A gram stain slide was inoculated and allowed to dry in BSC, and NH panel setup for identification. The slide was then heat fixed and stained outside of containment on open bench.
 - Gram-stain showed what appeared to be tiny Gram-negative. Staff had concerns with the staining so a second gram stain was set up in the same manner as the first.
 - The NH panel was set up, incubated, and read on the open bench with 2 other Techs present in the laboratory. Sample identified as >99.9% Agg. Actinomycetemcomitans.
 - CHOC plate sent to reference laboratory for confirmation at 2pm.
 - BSC is cleaned routinely using 70% ETOH.
- Day 9 – Tuesday, January 12, 2021
 - Lab received a call from the reference laboratory around 1pm with a suspected identification of Francisella tularensis. Notified Infection Control of possible exposures.
 - At approximately 6pm, we received a presumptive identification of Francisella tularensis from the reference laboratory and advised to monitor anyone who had potential exposure.
- Day 10 – Wednesday, January 13, 2021
 - 3 Techs instructed to watch for fever and other symptoms and report to Occupational Health
- Day 12 – Friday January 15, 2021
 - Notified by reference laboratory with final report as positive for Francisella tularensis.



APHIS/CDC Form 3 Helpful Information

- Form location
 - <https://www.selectagents.gov/forms/form3.htm>
 - Preferred form type for submission
 - More user-friendly
 - Faster processing
 - Easier to read
 - Does not require faxing



APHIS/CDC Form 3: Report of a Release/Loss/Theft

The APHIS/CDC Form 3, Report of a Release/Loss/Theft, is used by entities to report a theft, loss, or release of a select agent or toxin. The discovery of a theft, loss, or a release (occupational exposure or release of an agent or toxin outside of the primary barriers of the biocontainment area) of a select agent or toxin is required to be immediately reported. Registered entities report a theft, loss, or release through [eFSAP](#).

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
Email: DASAT@usda.gov

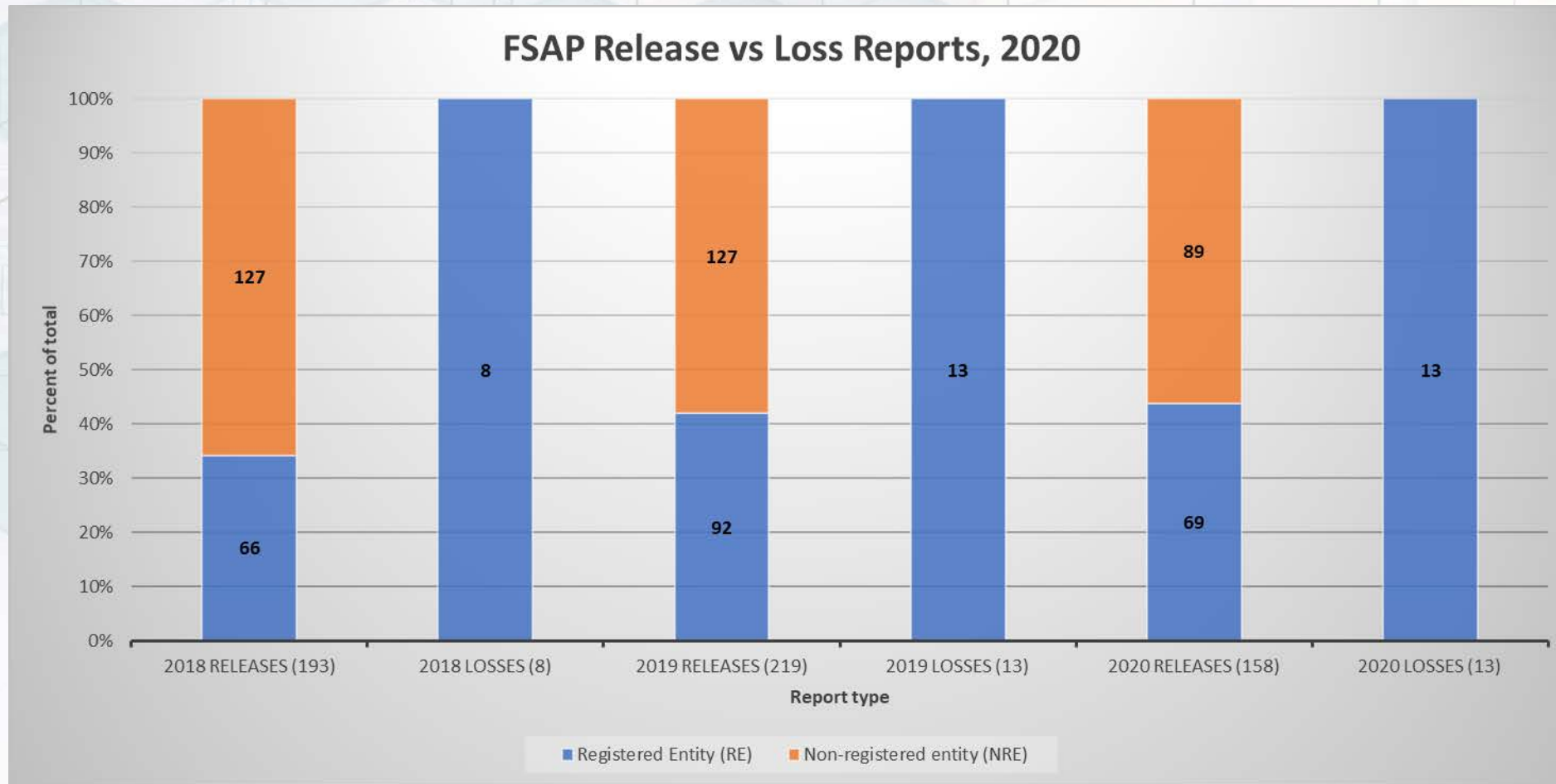
Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road, NE, Mailstop H21-7
Atlanta, GA 30329
Fax: 404-471-8375
Email: form3@cdc.gov

[Guidance Document for the Completion of APHIS/CDC Form 3](#)  [PDF – 505 KB]

- Fillable PDF: [APHIS/CDC Form 3](#)  [PDF – 291 KB]
- Print Only PDF: [APHIS/CDC Form 3](#)  [PDF – 297 KB]



APHIS/CDC Form 3 Statistical Information



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

