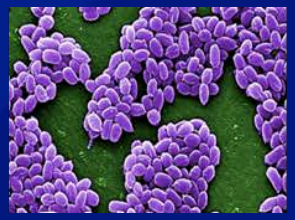


APHIS/CDC Forms 2,3,4

Updates and Common Questions

2020 Federal Select Agent Program
Responsible Official Webinar Series

APHIS/CDC Forms 2, 3, and 4 Agenda and Presenters

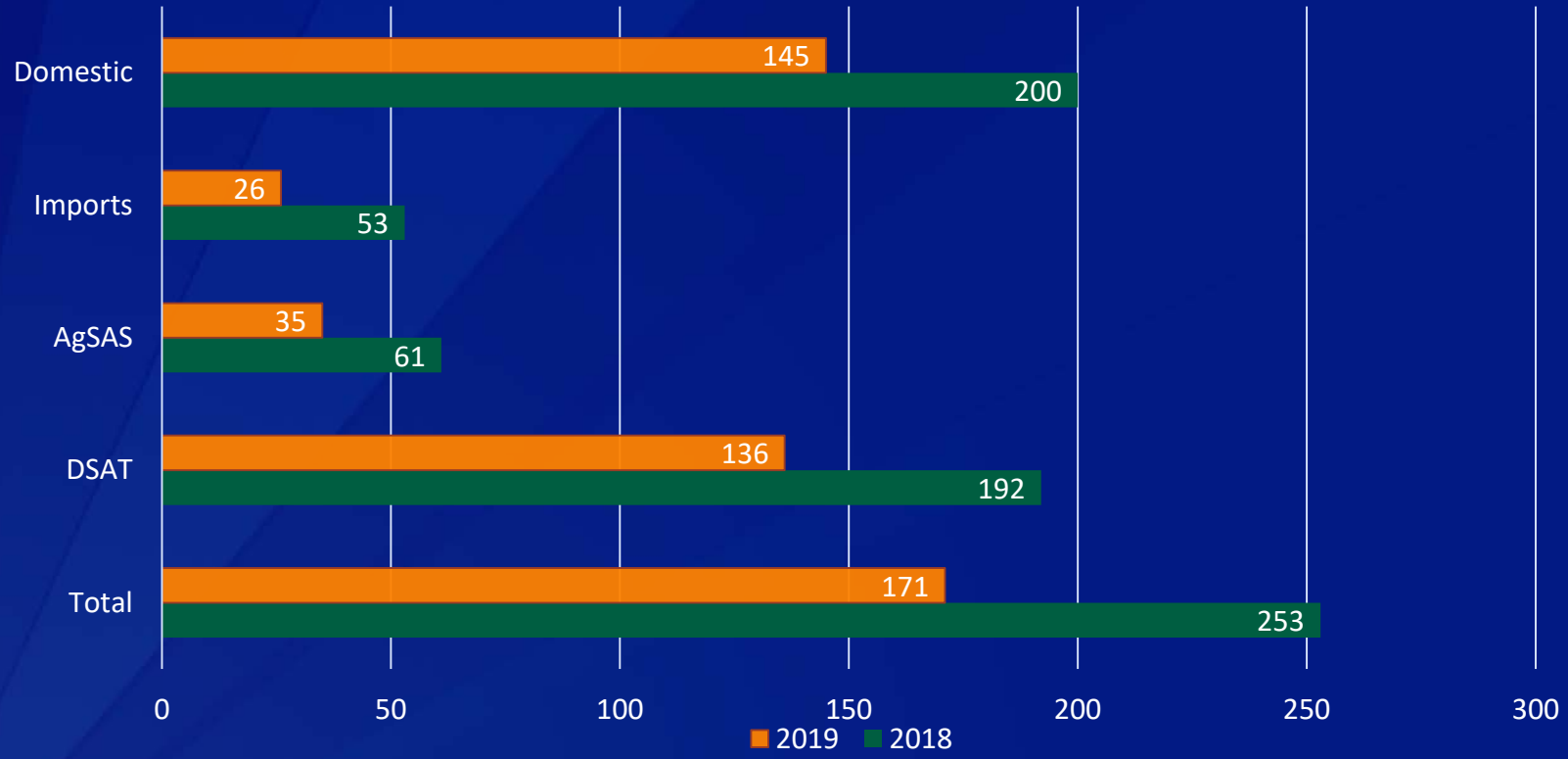
- **Statistical Overview**
  - Technical Unit Director, Agriculture Select Agent Services (AgSAS)
  - Forms 2-4 Team Lead, Division of Select Agents and Toxins (DSAT)
- **APHIS/CDC Form 2**
  - Form 2 Coordinator, DSAT
- **APHIS/CDC Form 3**
  - Form 3 Coordinator, DSAT
  - Security Program Manager, AgSAS
  - Compliance Officer, AgSAS *
- **APHIS/CDC Form 4**
  - Security Specialist/Form 4 Coordinator, DSAT

Statistical Overview

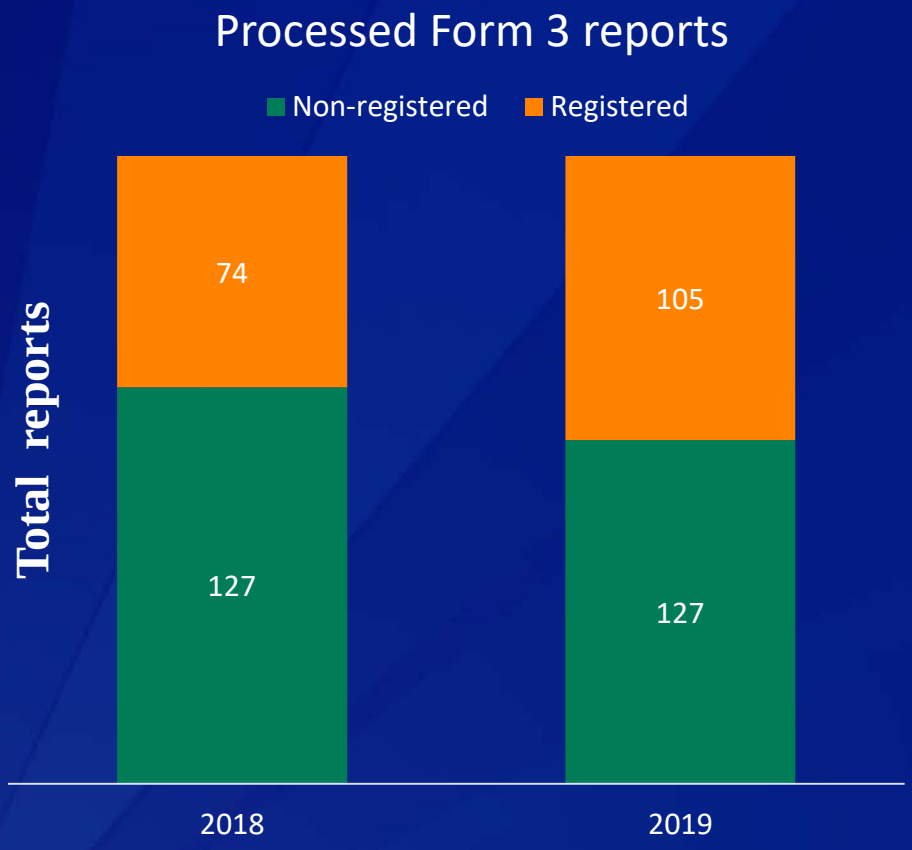
APHIS/CDC Forms 2, 3, and 4 Statistical Overview

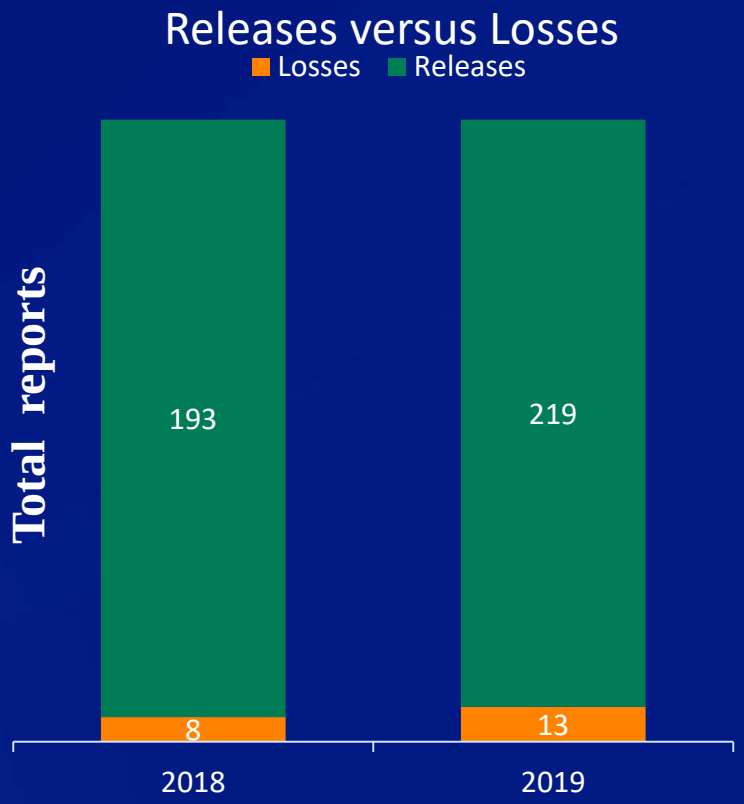
- **APHIS/CDC Form 2**
  - 2018 -2019 Comparisons
- **APHIS/CDC Form 3**
  - 2018-2019 Comparisons
- **APHIS/CDC Form 4A Sections A/B**
  - 2018- 2019 Comparisons

APHIS/CDC Form 2 Statistics 2018-2019



APHIS/CDC Form 3 Statistics 2018-2019

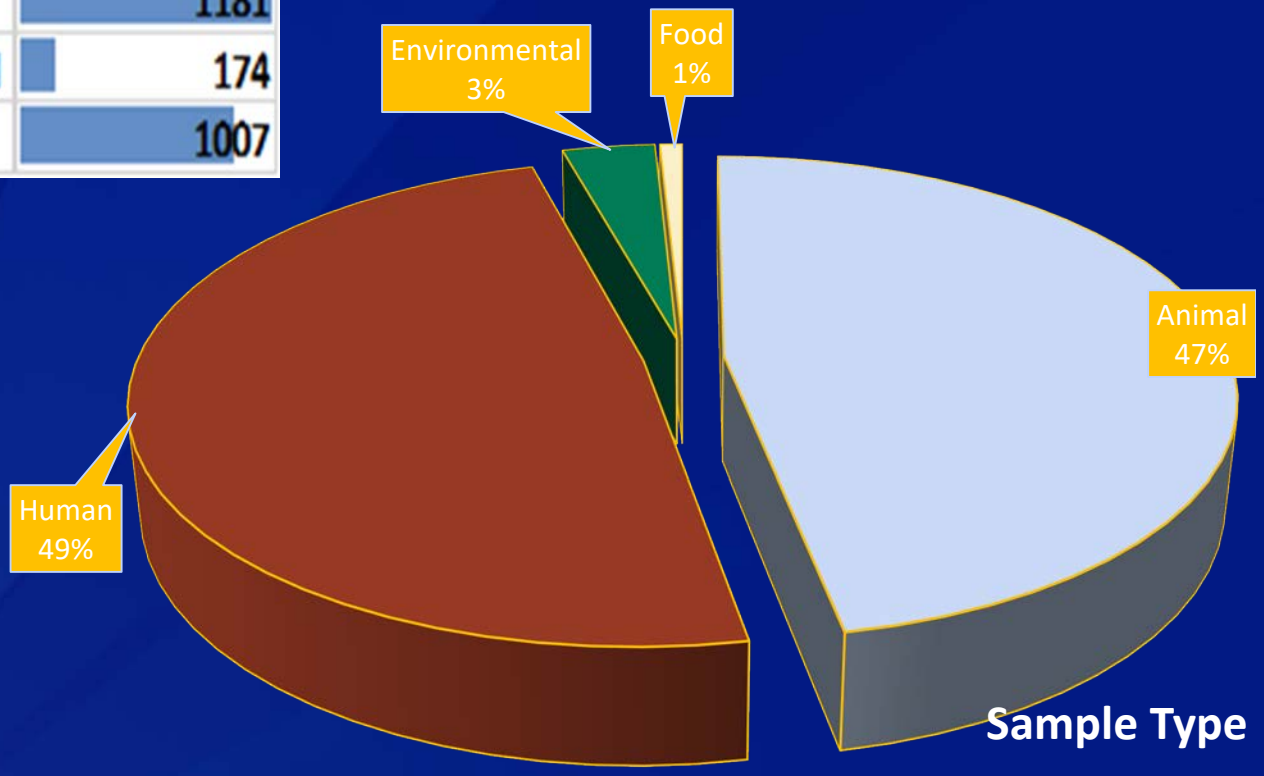




Note: No thefts reported in 2018 or 2019.

APHIS/CDC Form 4A A/B 2018 Statistics

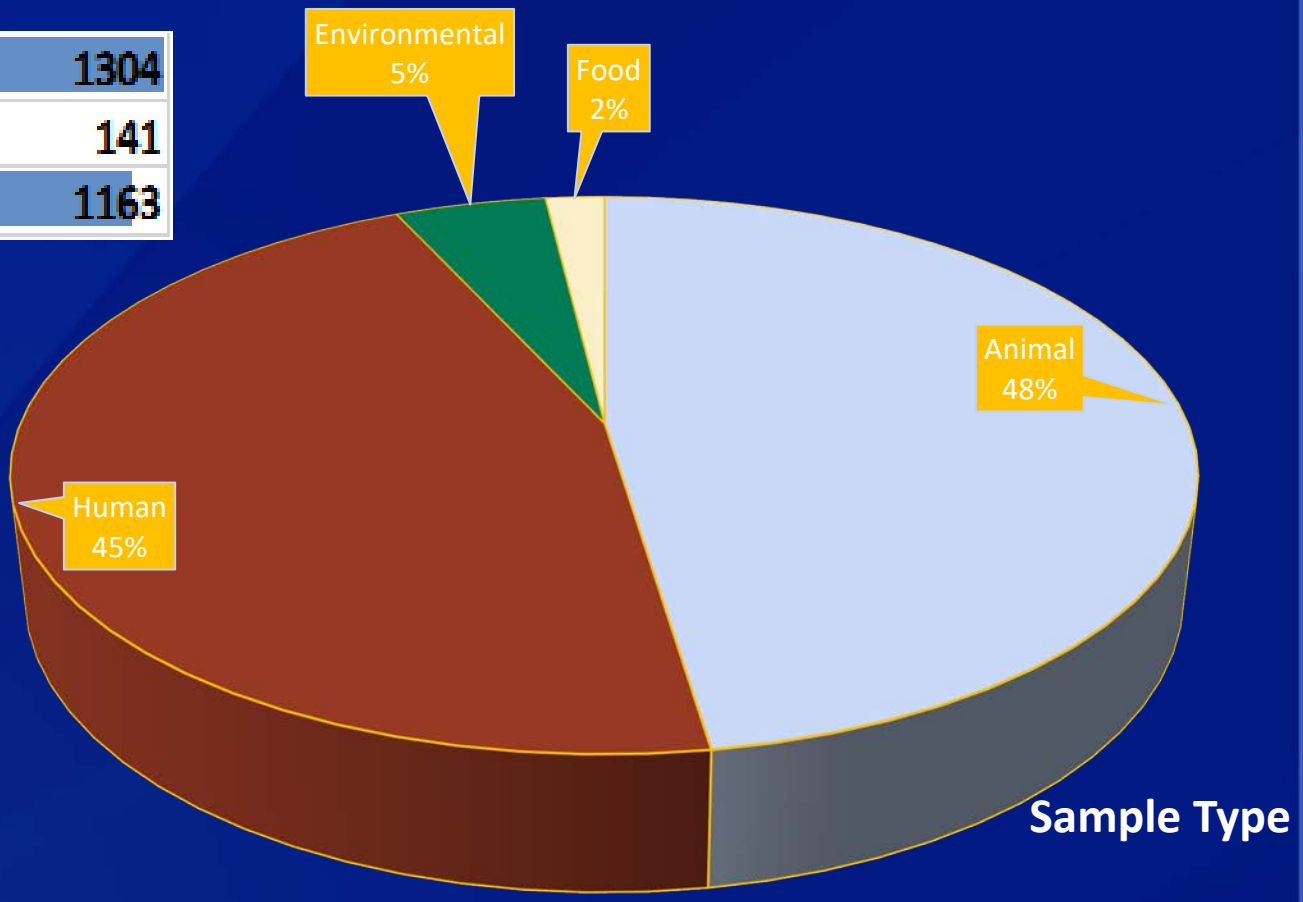
Total received	1181
Non-registered	174
Registered	1007



Note: Plant sample type was <1%.

APHIS/CDC Form 4A A/B 2019 Statistics

Total Received	1304
Non-registered	141
Registered	1163



Note: Plant sample type was <1%.

APHIS/CDC Form 2

APHIS/CDC Form 2
Request to Transfer Select Agents and Toxins

- **Most common submission concerns**
  - Missing carrier information
  - Unable to add select agent or toxin for question 16 in Section C
  - Completion and submission of Section 2
  - Incorrect select agent or toxin amount on Section 2
- **Scenarios**
  - Exports
  - Extensions

APHIS/CDC Form 2 – Most Common Submission Concerns – #1

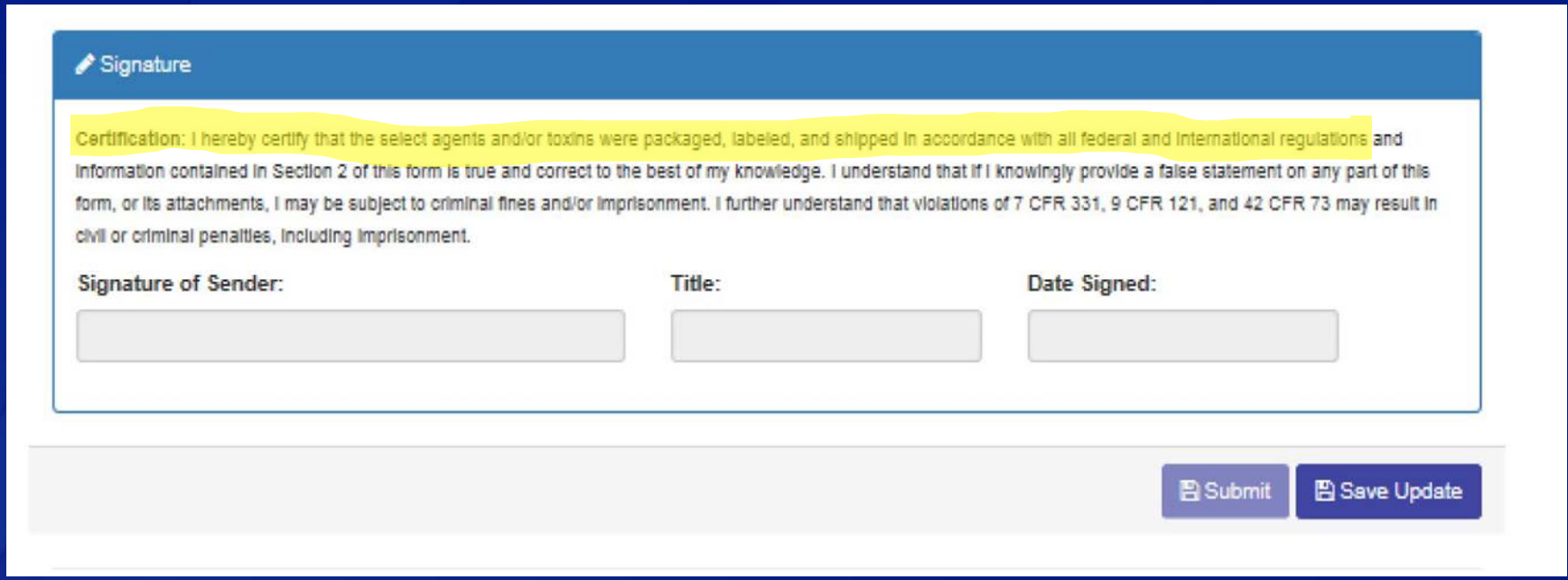
- **Missing Carrier Information**
  - Incomplete information for question 15 in section B
    - Missing Commercial Carrier Name
    - Missing Department of Transportation (DOT) Number

APHIS/CDC Form 2 – Most Common Submission Concerns – #2

- **Unable to add select agent or toxin**
  - **"Disappearing Agent and toxin List"**
    - Entity begins APHIS/CDC Form 2 and saves as a draft
    - When entity returns to complete Section 1, the agents and toxins are no longer on the dropdown list for question 16 in Section C.
  - Solution:
    - Entity must re-select the Principal Investigator (PI) from the dropdown list for question 1 in Section A, then the list of select agents and toxins associated with the PI will show for question 16 in Section C.

APHIS/CDC Form 2 – Most Common Submission Concerns – #3

- **Section 2 should be submitted the day of transfer**
  - Unexpected changes to request
  - Shipment delays
  - Certification Statement



APHIS/CDC Form 2 – Most Common Submission Concerns – #4

- **Incorrect amount of select agent or toxin**
  - Amount received is more than listed on form
    - Notification to FSAP Form 2 Team through General Discussion
    - Notification to sender
  - Amount received is less than listed on form
    - Notification to FSAP Form 2 Team through General Discussion
    - Notification to FSAP Form 3 by submission of APHIS/CDC Form 3
    - Notification to sender

APHIS/CDC Form 2 – Scenarios

- **Scenario 1 - Export**
  - An international collaborator requests a registered entity to send a select agent.

- **Is APHIS/CDC Form 2 required for this transaction?**

  A) Yes

  B) No

Polls are open…Submit your answer now!

APHIS/CDC Form 2 – Scenarios

- **Scenario 1 – Export**

  Is APHIS/CDC Form 2 required for this transaction?

  B) No – transfer authorization is not required.

  - **The exportation of a select agent or toxin requires an export license issued by the Department of Commerce (DOC). For more information, contact the DOC Bureau of Export Administration at the Bureau of Industry and Security.**
  - **(202) 482-4811**
  - **ECDOEXS@bis.doc.gov**

APHIS/CDC Form 2 – Scenarios

- **Scenario 2 – Extension**
  - A registered entity requests a select agent from an international collaborator for a research project. However, the registered entity requests an extension to the transfer because the international collaborator was unable to ship the select agent within the 30-day authorization.

- **When does the new 30-day transfer approval period begin?**

  A) Day of the request

  B) Day the extension for the transfer is approved

  C) Day of original expiration date

Polls are open…Submit your answer now!

APHIS/CDC Form 2 – Scenarios

- **Scenario 2 – Extension**

  When does the new 30-day transfer approval period begin?

  B) Day the extension for the transfer is approved

  - **Written request should be in eFSAP or sent by email**
  - **The transfer is completed when the recipient has received, signed, dated and submitted Section 3 in eFSAP.**
    - Must be completed by the end of the approved 30 days.

APHIS/CDC Form 3

APHIS/CDC Form 3 Incident Notification and Reporting (Theft, Loss, Release)

- **Overview**
  - **Most common submission concerns**
    - Immediate Notification
    - Incident Date
    - Responding to a Request for Information
  - **Root causes**
  - **Scenarios**
    - Release
    - Inventory Discrepancy
    - Theft

APHIS/CDC Form 3 – Most Common Submission Concerns and Questions - #1

- **Immediate Notification: Block B2: What date should be entered as the Immediate Notification date?**

  A) When incident happens

  B) When RO/entity leadership is notified

  C) When internal investigation is completed

  D) When the entity first informs FSAP of the incident

Polls are open…Submit your answer now!

APHIS/CDC Form 3 – Most Common Submission Concerns and Questions - #1

- **Question 1 – Immediate Notification: Block B2: What date should be inputted as the Immediate Notification date?**

D) When the entity first informs FSAP of the incident

APHIS/CDC Form 3 – How to make an Immediate Notification?

- **eFSAP Immediate Notification**
  - If unclear what select agent or toxin was manipulated, select the select agent or toxin last worked with at time of incident.
- **eFSAP General Discussion**
  - Acknowledgement of immediate notification received by FSAP
  - Initial questions from FSAP
- **Email/Phone Call**
  - Acknowledge by FSAP on entity homepage

APHIS/CDC Form 3 – Most Common Submission Concerns and Questions - #2

- **Incorrect Incident Date: Block B1: Incident date**
  - For release, date of earliest exposure/manipulation outside of primary containment (i.e., environmental sampling date).
  - For loss, date when inability to account for select agent or toxin first identified.

APHIS/CDC Form 3 – Most Common Submission Concerns and Questions - #3

- **Responding to a request for information (RFI): How to best respond to RFI letter?**

  A) Upload to Entity Documents section of specific APHIS/CDC Form 3 report

  B) Upload to main entity landing page

  C) Send response through email or fax

Polls are open…Submit your answer now!

APHIS/CDC Form 3 – Most Common Submission Concerns and Questions - #3

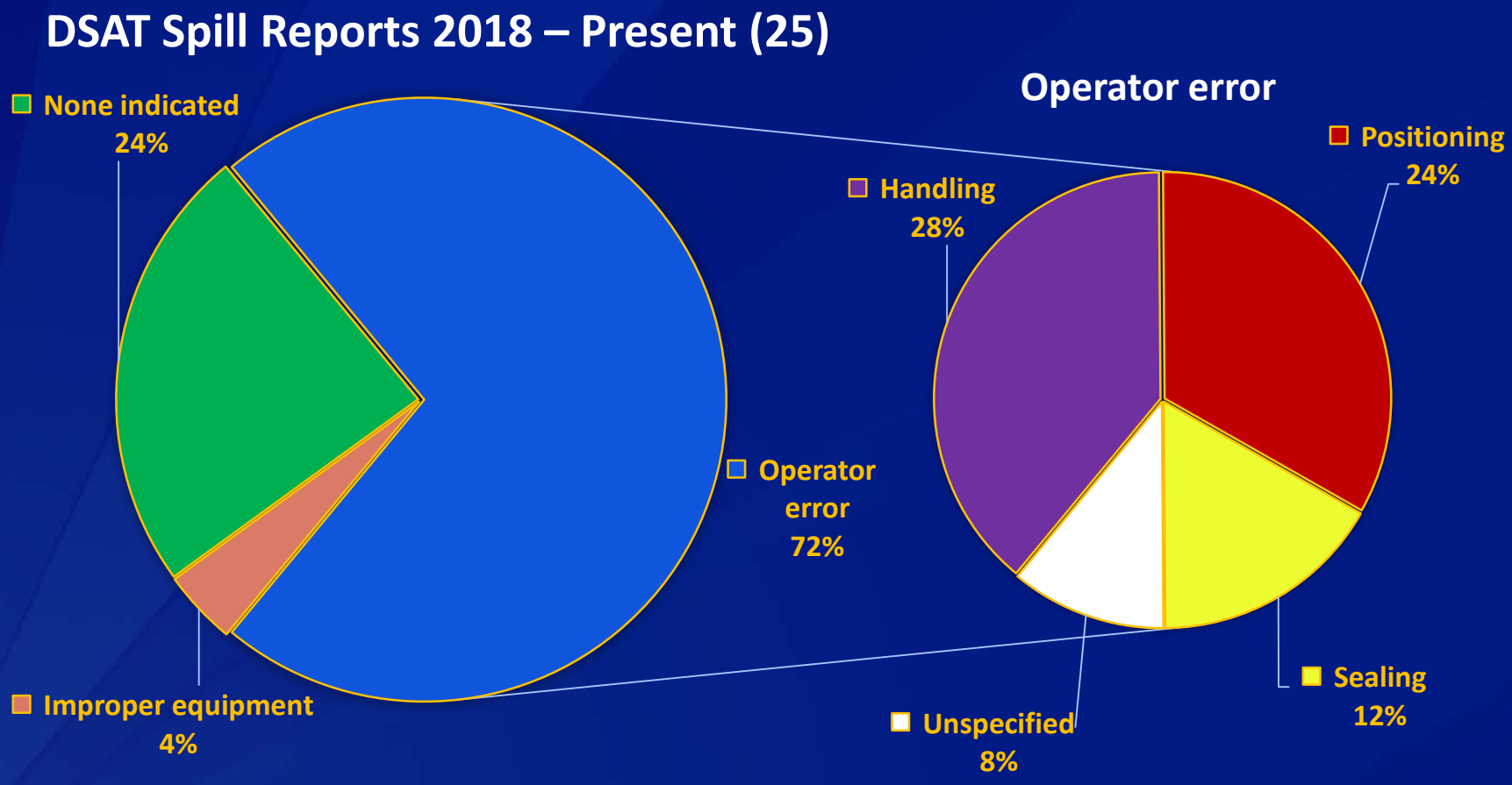
- **Responding to RFI: How to best respond to RFI letter?**

  A) Upload to the Entity Documents section for the specific APHIS/CDC Form 3 report

APHIS/CDC Form 3 – Root Causes

- **Root causes**
  - Please describe any root cause(s) identified in Appendix A or block E8 (Release only) .
  - Closure letters uploaded to eFSAP may provide recommendations to mitigate recurrence (e.g., use thicker gloves when handling taped culture plates) based on assessment of root cause.

APHIS/CDC Form 3 – Root Cause Analysis



APHIS/CDC Form 3 – Scenarios

- **Scenario 1 – Diagnostic work at a non-registered entity**
  - A non-registered diagnostic laboratory reports exposures to presumptive *Yersinia pestis* after sub-culturing of the agent was performed outside of primary containment. In addition, the tape holding stack of plates became loose and resulted in 1 plate falling onto the floor. Two days later, the registered state public health laboratory confirms the identification of *Y. pestis.*
- **Part A: Is this reportable?**

  A) Yes

  B) No

Polls are open…Submit your answer now!

APHIS/CDC Form 3 – Scenarios

- **Scenario 1 – Diagnostic work at a non-registered entity**
- **Part A: Is this reportable?**
  - **A) Yes – upon the identification of the select agent**
- **Part B: Who should submit the APHIS/CDC Form 3?**
  - A) Registered state public health laboratory
  - B) Non-registered diagnostic laboratory

Polls are open…Submit your answer now!

APHIS/CDC Form 3 – Scenarios

- **Scenario 1 - Diagnostic work at a non-registered entity**
- **Part B – Who should submit the Form 3?**

B) Non-registered diagnostic laboratory

- The entity that experiences the release is responsible for completing the APHIS/CDC Form 3 and submitting to form3@cdc.gov.

APHIS/CDC Form 3 – Scenarios

- **Scenario 2 – Needle stick**
  - Registered entity reports that a laboratorian stuck their finger when removing the cap from a clean needle. The laboratorian was preparing to inject a mouse with Japanese encephalitis virus in the registered BSL-3 laboratory.

- **Is this reportable?**

  A) Yes

  B) No

Polls are open…Submit your answer now!

APHIS/CDC Form 3 – Scenarios

- **Scenario 2 – Needle stick**
- **Is this reportable?**

  B) No

  - The incident did not involve a select agent or toxin.

APHIS/CDC Form 3 – Scenarios

- **Scenario 3 – Cage injury**
  - An animal technician scratches their gloved hand on a piece of metal while bagging empty mice cages in an ABSL-3 laboratory. No select agent or toxin work, or infected mice were present at time of incident. All work surfaces and cages were properly disinfected. *Brucella abortus* research was conducted a week prior. The incident was reported to Occupational Health Office where the physician prescribed antibiotics.

- **Is this reportable?**

  A) Yes

  B) No

Polls are open…Submit your answer now!

APHIS/CDC Form 3 – Scenarios

- **Scenario 3 – Cage injury**
- **Is this reportable?**
  - **No**
  - The incident did not involve a select agent or toxin.

APHIS/CDC Form 3 – Scenarios

- **Scenario 4 – Inactivation**
  - A laboratorian performed a validated chemical inactivation procedure on a diagnostic isolate. After treatment, the tube is opened outside of the biosafety cabinet (BSC) and sample loaded onto agarose gel. Viability testing confirms the growth and identification of *Brucella melitensis.*

- **Is this reportable?**

  A) Yes

  B) No

Polls are open…Submit your answer now!

APHIS/CDC Form 3 – Scenarios

- **Scenario 4 – Inactivation**
- **Is this reportable?**

  A) Yes

  - Manipulation of a select agent or toxin outside primary containment is reportable.

Any failure to a previously validated procedure should be investigated and revalidated, as needed.

APHIS/CDC Form 3 – Scenarios

- **Scenario 5 – Inventory Discrepancies**
  - During an inventory audit, the RO notices that there are multiple discrepancies between the records and the physical select agent inventory. Multiple vials of *Bacillus anthracis* are missing. All of the discrepancies involve a specific Principal Investigator (PI).
- **How should this be reported?**

  A) Loss

  B) Theft

  C) Release

  D) Nothing to report

APHIS/CDC Form 3 – Scenarios

- **Scenario 5 – Inventory Discrepancies**
- **How should this be reported?**

A) Loss

- The inability to account for inventory is a loss.

APHIS/CDC Form 3 – Scenarios

- **Scenario 6 – Theft**
  - The RO is notified by campus police that they identified evidence of a forced entry into a select agent laboratory during their patrol. During the inventory verification, the RO discovers that the locks on one of the refrigerators are broken and vials of Venezuelan Equine Encephalitis (VEE) virus are missing.
- **Who does this event get reported to and when?**

  A) Appropriate law enforcement agency and FSAP immediately

  B) FSAP, after an entity internal search

  C) Campus President at the next monthly meeting

  D) Close the lab and do nothing

APHIS/CDC Form 3 – Scenarios

- Scenario 6 – Theft
- Who does this event get reported to and when?

  A) Appropriate law enforcement agency and FSAP immediately

APHIS/CDC Form 4

APHIS/CDC Form 4A Reporting the Identification of a Select Agent or Toxin from a Clinical/Diagnostic Specimen

- **Overview**
  - Most Common Submission Concerns
    - Sample Provider information provided by Reference Laboratory
    - Responsible Official/Alternate Responsible Official not using eFSAP
    - Incorrect form submitted
    - Pending Required Status in eFSAP
    - Linking of forms in eFSAP
  - Scenarios
    - Split Sample – one sample sent to two different laboratories for testing

APHIS/CDC Form 4A – Most Common Submission Concerns

- Sample Provider information provided by Reference Laboratory
  - Laboratory listed did not receive or send sample
  - Incorrect Sample Provider contact information
    - State Epidemiologist listed not state laboratory personnel
    - Incorrect phone numbers
    - Incorrect emails
    - Incorrect person listed
    - Updated entity name

APHIS/CDC Form 4A – Most Common Submission Concerns

- **Responsible Official/Alternate Responsible Official not using eFSAP**
  - APHIS/CDC Form 4 reports and immediate notifications submitted through eFSAP.
  - Inform Select Agent Program Officer or Form 4 Coordinator if issues submitting or entering data.

APHIS/CDC Form 4A – Most Common Submission Concerns

- **Incorrect form submitted**
  - Reference laboratory identifies a select agent or toxin – use APHIS/CDC Form 4A Section A/B
  - Sample provider receives identification from reference laboratory – use APHIS/CDC Form 4A Section C/D
  - Reporting identification of select agent or toxin from proficiency sample – use APHIS/CDC Form 4B

APHIS/CDC Form 4A – Most Common Submission Concerns

- **Pending Required Status in eFSAP**
  - Registered entities cannot create a Form 4A Sections C/D in eFSAP
  - FSAP will open Form 4A Section C/D within 24 hours of when a Reference Laboratory submits the APHIS/CDC Form 4A Section A/B

APHIS/CDC Form 4A – Most Common Submission Concerns

- **Field Collection Samples**
  - Reference Laboratory lists the Sample Provider
    - Veterinary clinic/hospital
    - Veterinary laboratory
    - Farm/wildlife center with veterinary staff
  - Sample Provider reporting
    - Necropsy versus carcass
    - Field collection (soil, water, insects)
    - Mosquito testing

APHIS/CDC Form 4A – Scenario

- **Scenario – Split Sample**
  - A hospital laboratory sends a patient sample to two regional laboratories for testing. The regional laboratories are unable to identify the isolate. Regional laboratory A sends the isolate to the state laboratory while Regional laboratory B sends the isolate to the Centers for Disease Control and Prevention (CDC) for identification. The state laboratory and CDC identify a select agent and notify the sending regional laboratories. The notification of the select agent identification was sent to all Sample Providers. Both the CDC and the state laboratory submitted a Form 4A Sections A/B.
- **Which laboratory is required to submit APHIS/CDC Form 4A Sections C/D?**

  A) Hospital laboratory only

  B) The two regional laboratories that received the sample

  C) All of the above

  D) No one – nothing else to submit

APHIS/CDC Form 4A – Scenario

- Scenario - Split Sample
- Which laboratory is required to submit APHIS/CDC Form 4A Sections C/D?

  C) All of the above – account for each location that is in possession of the sample containing the select agent/toxin upon identification

Discussion

www.selectagents.gov

CDC: lrsat@cdc.gov or 404-718-2000

APHIS: AgSAS@usda.gov or
301-851-3300 option 3 (voice only)