

THEFT, LOSS OR RELEASE OF SELECT AGENTS

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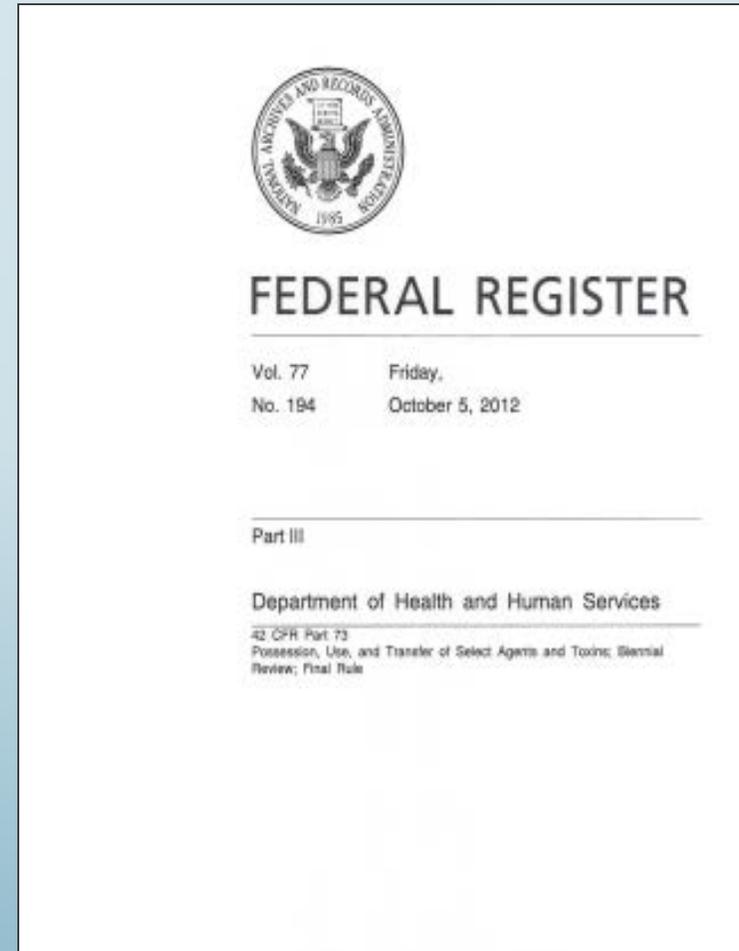
TOPICS

1. *HHS Select Agent Regulation (42 CFR Part 73)*
2. *Select Agent Theft, Loss, or Release (TLR) reporting requirements (42 CFR § 73.19)*
3. *TLR report process*

HHS SELECT AGENT REGULATION

42 CFR PART 73

- *Identifies regulated 'select agents'*
- *Delineates requirements for possession, use and transfer of SA including:*
 - *Security*
 - *Biosafety*
 - *Incident response*
- *Parallel regulations enacted for agricultural select agents (USDA)*
- *Security Risk Assessments by DOJ*



42 CFR 73.19(a) THEFT OR LOSS OF BSAT

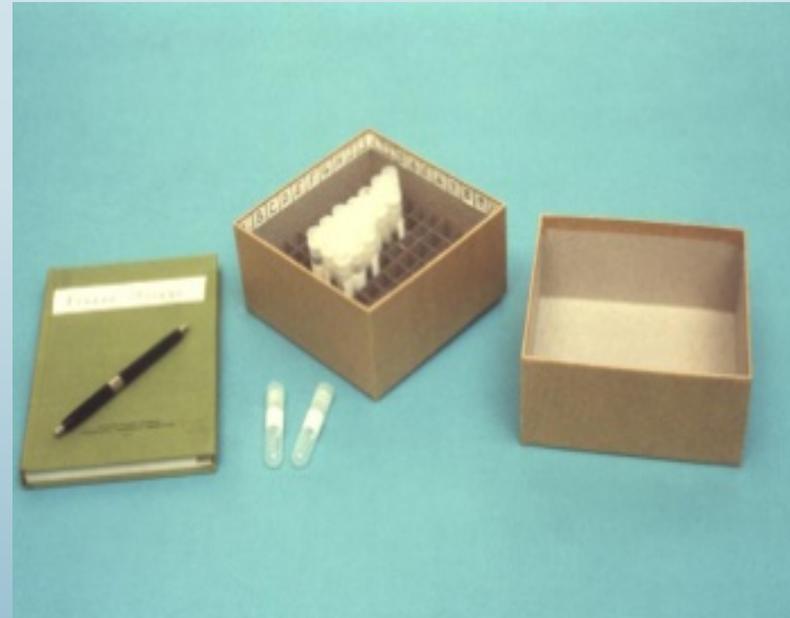
Notification of Theft or Loss

“ 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 or losses must be reported even if the select agent or toxin is subsequently recovered or the responsible parties are identified.”



INFORMATION TO BE REPORTED TO FSAP FOR THEFTS OR LOSSES OF BSAT

- *name and any identifying information (e.g., strain)*
- *estimate of the quantity lost or stolen*
- *time when theft or loss occurred*
- *location where theft or loss occurred*
- *Federal, State, or local law enforcement agencies notified*



42 CFR 73.19(b) RELEASES OF BSAT

Occupational Exposures

“Upon discovery of a release of an agent or toxin causing occupational exposure,..... an individual or entity must immediately notify CDC or APHIS.”

“Occupational exposure means any reasonably anticipated skin, eye, mucous membrane, parenteral contact, or respiratory aerosol exposure to select agents or toxins that may result from the performance of an employee's duties.”



42 CFR 73.19(b) RELEASES OF BSAT

Primary Containment Breaks

“Upon discovery of a release of a select agent or toxin... outside of the primary barriers of the biocontainment area, an individual or entity must immediately notify CDC or APHIS.”

“A discharge of a select agent or toxin outside the primary containment barrier due to a failure in the containment system, an accidental spill, occupational exposure, or a theft. Any incident that results in the activation of a post exposure medical surveillance/prophylaxis protocol should be reported as a release.”

[http://www.selectagent.gov/resources/CDCAPHIS_Theft_Loss_Release_Information_Document.](http://www.selectagent.gov/resources/CDCAPHIS_Theft_Loss_Release_Information_Document)

pdf



EVENT DISCOVERY

- *by the entity*

- *by law enforcement*

- *by the media*

- *during inspection*



NOTIFICATION OF THE FSAP

There are two reporting requirement steps for TLR events:

1) immediate notification of event by email, fax, phone

Centers for Disease Control and Prevention

Division of Select Agents and Toxins
1600 Clifton Road, NE, Mailstop A-46
Atlanta, GA 30329

Fax: 404-471-8375_

Email: LRSAT@cdc.gov

Phone: 404-718-2000

or

Animal and Plant Health Inspection Service

Agriculture Select Agent Services
4700 River Road, Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737

Fax: 301-734-3652_

Email: AgSAS@aphis.usda.gov

Phone: 301-851-3300_ option 3 (voice only)

NOTIFICATION OF THE FSAP

2) submit a completed Form 3 within 7 calendar days

Fillable PDF: [APHIS/CDC Form 3](#) (PDF 207KB) (Adobe Reader 6.0 or greater required)

Print Only PDF: [APHIS/CDC Form 3](#) (PDF 78KB)

[Guidance Document for the Completion of APHIS/CDC Form 3](#) (PDF 412KB)

<http://www.selectagents.gov/form3.html>



REPORT OF THEFT, LOSS, OR RELEASE OF SELECT AGENTS AND TOXINS (APHIS/CDC FORM 3)

FORM APPROVED
OMB NO. 0678-0213
OMB NO. 0920-0676
EXP DATE 12/31/2008

Read all instructions carefully before completing the report. Answer all items completely and type or print in ink. The report must be signed and submitted to either APHIS or CDC:

Animal and Plant Health Inspection Service
Agricultural Select Agent Program
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
FAX: 301-734-3652

Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road NE, Mailstop A-46
Atlanta, GA 30333
FAX: 404-718-2096

SECTION 1 - TO BE COMPLETED BY ALL ENTITIES			
1. Entity name:		2. Entity registration number (if applicable):	
3. Entity address (NOT a post office address):		4. City:	5. State: 6. Zip Code:
7. Responsible Official (RO) or facility director First: M: Last:		8. Telephone:	9. FAX: 10. E-mail:
11. RO or facility director address (NOT a post office address):		12. City:	13. State: 14. Zip Code:
15. Type of incident: <input type="checkbox"/> Theft <input type="checkbox"/> Loss <input type="checkbox"/> Release		16. Immediate notification provided to: <input type="checkbox"/> APHIS <input type="checkbox"/> CDC	
		17. Date of immediate notification:	
		18. Type of immediate notification: <input type="checkbox"/> E-mail <input type="checkbox"/> Fax <input type="checkbox"/> Telephone	
19. An internal review of laboratory procedures and policies has been initiated to prevent recurrences of loss of select agents and toxins at this entity: <input type="checkbox"/> No <input type="checkbox"/> Yes (If yes, please provide additional details in an attachment.)			

NOTIFICATION OF THE FSAP

FAX Notification of TLR incident

From: RightFax E-mail Gateway
Sent: Tuesday, November 03, 2015 4:10:41 PM (UTC-05:00) Eastern Time (US & Canada)
To: Form 3 (CDC)
Subject: A new fax has arrived from 5----- (Part 1 of 1) on Channel 4

11/3/2015 4:07:09 PM Transmission Record
Received from remote ID: 5-----
Inbound user ID FORM3, routing code 18375
Result: (0/352;0/0) Successful Send
Page record: 1 - 5
Elapsed time: 02:56 on channel 4

FSAP RESPONSE TO TLR REPORTS

Information Collection

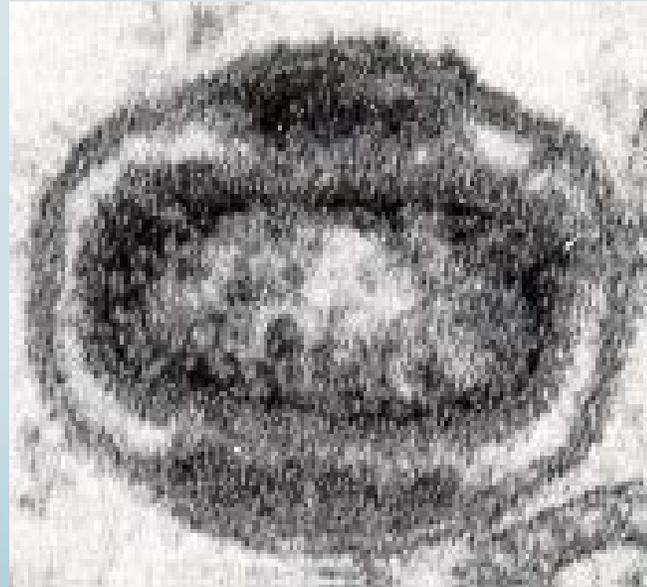
- *agent*
- *dates (event, discovery, report)*
- *contact information*
- *circumstances*
- *amount stolen, lost or released*
- *duration and location of release*
- *number of persons potentially exposed*
- *actions taken to mitigate release*
- *specific hazards of release*

FSAP RESPONSE TO TLR REPORTS

Classification and Evaluation

- *Determine event category*
 - a) *theft*
 - b) *loss*
 - c) *release*

- *Evaluate public health risk*
 - a) *urgent*
 - b) *potentially serious*
 - c) *low risk*



FSAP RESPONSE TO TLR REPORTS

Information Sharing

Determine who needs to be contacted

- a) FBI*
- b) CDC response elements*
- c) APHIS*
- d) other Feds (HHS, DHS, DOT)*

Verify that entity has contacted local and state law enforcement, if needed

- State and/ local DOH*
- FSAP is not first responder, but has capability to enter all BSLs*



FSAP RESPONSE TO TLR REPORTS

Incident Investigations

Urgent cases (time sensitive)

- a) conference call*
- b) assess immediate needs*
- c) hazard / public health issues*
- d) select site visit team*
- e) deployment plans*

Partners may include:

- a) state and/ local DOH*
- b) SMEs*
- c) CDC EOC*
- d) APHIS, FBI*
- e) other Feds*



Monkeypox

FSAP RESPONSE TO TLR REPORTS

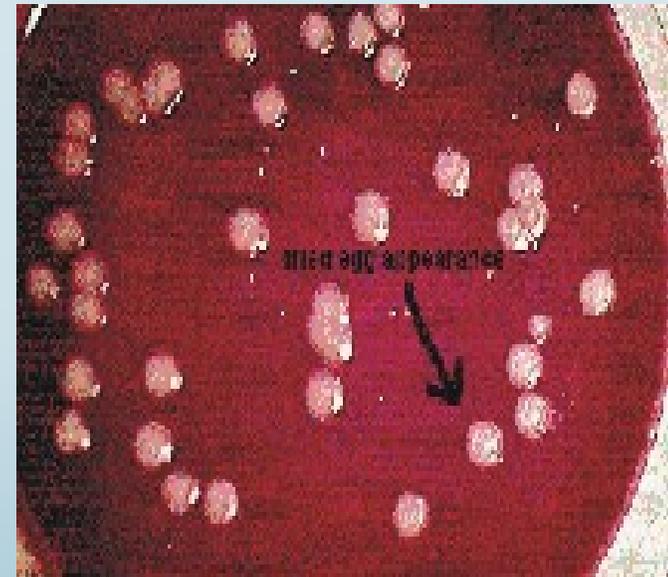
Incident Investigations

Potentially serious cases

- less time sensitive
- a) assess immediate needs
- b) occupational health issues
- c) contact SMEs for advice or assistance to entity
- d) determine if site visit is necessary

Partners may include:

- a. Local health departments
- b. SMEs
- c. FBI



Yersinia pestis

FSAP RESPONSE TO TLR REPORTS

Entity/ FSAP interactions

- verbal and written communications
- identification of root cause(s)
- mitigation plans
- resolution of issues
- follow up (weeks to months)

Event Outcome(s)

- improvements in security, biosafety
- possible referral to HHS-OIG, USDA-IES, FBI



Castor beans

SUMMARY

- 1. Federal Regulations require persons and entities in possession of select agents and toxins to report the theft, loss or release of these materials immediately to CDC or APHIS.***
- 2. CDC/ DSAT and APHIS have developed a system for tracking TLR reports that allows for rapid assessment and response to events that may pose significant threats to public health and the health of laboratory workers.***
- 3. This tracking system also provides a resource for biosafety and biosecurity consultations with entities, links medical care givers with CDC subject matter experts and ensures that TLRs are investigated by laboratory safety and security experts and law enforcement personnel if necessary.***

ACKNOWLEDGEMENTS

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(DSAT)