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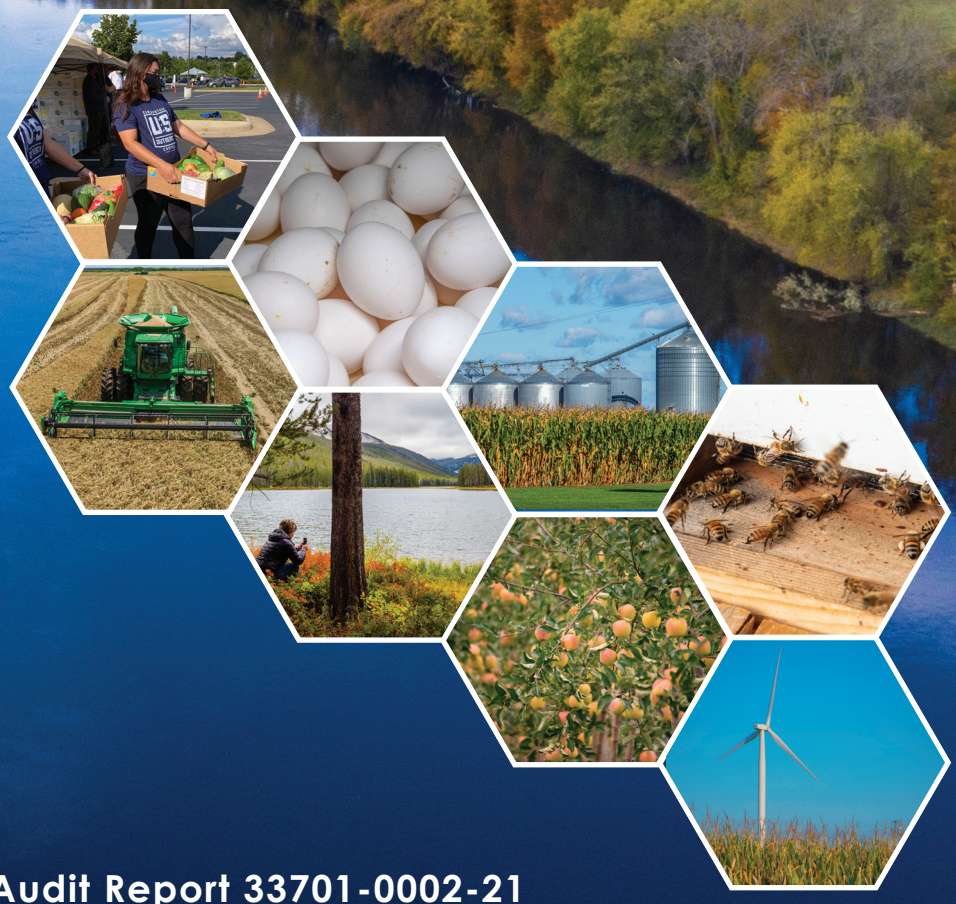
United States Department of Agriculture

Controls Over Select Agents



Audit Report 33701-0002-21

July 2021

OFFICE OF INSPECTOR GENERAL

Controls Over Select Agents

Audit Report 33701-0002-21

OIG evaluated whether APHIS' controls over select agents adequately reduced the threat to public, animal, and plant safety, and animal and plant products.

OBJECTIVE

To evaluate the effectiveness of APHIS' controls over select agents as part of FSAP to adequately reduce the threat to animal and plant products and public, animal, and plant safety. Additionally, we followed up on prior audit recommendations from Audit 33701 0001 AT to determine whether corrective actions were adequately implemented and operating effectively.

REVIEWED

We performed fieldwork at APHIS headquarters, interviewed APHIS officials responsible for the oversight of FSAP, and reviewed FSAP inspections conducted between 2017 and 2019. We also non-statistically selected 10 of the 34 entities registered with APHIS to possess, use, and transfer select agents and toxins between 2017 and 2019.

RECOMMENDS

Develop and implement guidance, including to periodically review and update information in eFSAP; verify and validate that entities remove access of individuals with expired select agent credentials; and establish oversight controls to monitor entities' corrective actions. Formalize and document in Federal regulations the definitions of and the reporting requirements for "discoveries," "losses," "thefts," and "releases" of select agents and toxins. Require entities to verify that select agents are appropriately registered, inventoried, disposed of, and stored.

WHAT OIG FOUND

The Federal Select Agent Program (FSAP) is jointly administered by the Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service (APHIS). FSAP oversees the possession, use, and transfer of biological select agents and toxins, which have the potential to pose a severe threat to public, animal, or plant health, or to animal or plant products.

We found several areas of FSAP that APHIS needs to improve. First, the Electronic FSAP (eFSAP) system, which APHIS uses to monitor entities' compliance with Federal regulations, did not always include accurate and complete information. As a result, APHIS may not be able to ensure select agents and toxins are adequately secured by registered entities.

Second, we identified two deficiencies in APHIS' oversight process. APHIS does not require its inspectors to support "pass" determinations that entities complied with Federal regulations. Additionally, APHIS officials did not ensure that entities timely resolved non-compliances identified during prior inspections.

Finally, from 2017 to 2019, the Office of Inspector General (OIG) determined that APHIS did not report to Congress 13 losses and 3 releases of select agents or toxins. This occurred because APHIS officials do not consider it a loss when an entity cannot account for but eventually finds select agents or toxins. OIG concluded that, without accurate reports, Congress cannot make informed decisions concerning APHIS' oversight of registered entities' handling of dangerous select agents and toxins.

We accepted management decision on 3 of the 11 recommendations. Further action from the agency is needed before management decision can be reached on the remaining recommendations.

USDA OFFICE OF INSPECTOR GENERAL
United States Department of Agriculture

DATE: July 27, 2021

AUDIT NUMBER: 33701-0002-21

TO: Kevin Shea
Administrator
Animal and Plant Health Inspection Service

ATTN: Robert Huttenlocker
Deputy Administrator
Marketing and Regulatory Program Business Services

FROM: Gil H. Harden
Assistant Inspector General for Audit

SUBJECT: Controls Over Select Agents

This report presents the results of the subject review. Your written response to the official draft is included in its entirety at the end of the report. We have incorporated excerpts from your response, and the Office of Inspector General's (OIG) position, into the relevant sections of the report. Based on your written response, we are accepting management decision for 3 of the 11 audit recommendations in the report. However, we are unable to reach management decision on Recommendations 1, 3, 4, 6, 7, 8, 10, and 11. The information needed to reach management decision is set forth in the OIG Position section following the recommendation.

In accordance with Departmental Regulation 1720-1, please furnish a reply within 60 days describing the corrective actions taken or planned, and timeframes for implementing the recommendations for which management decisions have not been reached. Please note that the regulation requires management decision to be reached on all recommendations within 6 months from report issuance, and final action needs to be taken within 1 year of each management decision to prevent being listed in the Department's annual Agency Financial Report. Please follow your internal agency procedures in forwarding final action correspondence to Office of the Chief Financial Officer.

We appreciate the courtesies and cooperation extended to us by members of your staff during our audit fieldwork and subsequent discussions. This report contains publicly available information and will be posted in its entirety to our website (http://www.usda.gov/oig) in the near future.

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Background and Objectives

Background

The Federal Select Agent Program (FSAP) is jointly administered by the Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service (APHIS). FSAP oversees the possession, use, and transfer of biological select agents and toxins (BSAT), which have the potential to pose a severe threat to public, animal, or plant health, or to animal or plant products. Biological select agents and toxins that pose a potential severe risk to plant and animal health or to animal and plant products, such as foot-and-mouth disease and potato wart,[1, 2] are regulated by the United States Department of Agriculture (USDA) as "select agents or toxins" (select agents).[3] The Agricultural Bioterrorism Protection Act of 2002 (the Act) gives USDA authority to designate certain plant and animal biological agents and toxins as select agents by listing them in the Federal Register on a biennial basis.[4]

The Act requires the Secretary of Agriculture to establish and maintain a list of each select agent that the Secretary determines has the potential to pose a severe threat to animal or plant health, or to animal or plant products. The Act also requires the Secretary to establish and enforce standards and procedures governing the possession and use of select agents. Persons possessing, using, or transferring select agents must register with the Secretary to verify that they have a lawful purpose to possess, use, or transfer select agents. In USDA, APHIS' Agriculture Select Agent Services (AgSAS) enforces the Act.[5] Further, the Act requires the national database to include the name of select agents; the names of personnel and location of registered entities authorized to possess, use, and transfer select agents; and the type of select agents the registered entities possessed, used, or transferred. To accomplish this, APHIS uses the Electronic Federal Select Agent Program (eFSAP) database.

APHIS regulates select agents by establishing and enforcing:

- safety procedures for transferring listed agents, including measures to ensure proper training and appropriate skills to handle select agents, and proper laboratory facilities to contain and dispose of select agents;
- security measures to prevent access to select agents for use in domestic or international terrorism or for any other criminal purpose; and

[1] Foot-and-mouth disease is a severe, highly contagious viral disease that causes illness in cows, pigs, sheep, goats, deer, and other animals with divided hooves.
[2] Potato wart disease is caused by the soil borne select agent *Synchytrium endobioticum*. Potato wart soil can be transferred by machinery, footwear, and manure from animals that have fed on infested plant products, causing the spread of the disease.
[3] The regulatory agency is either APHIS or CDC, depending on the type of select agents the entity possesses.
[4] Title II, Subtitle B of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 is cited as the Agricultural Bioterrorism Protection Act of 2002.
[5] Effective January 2021, AgSAS was renamed as Division of Agricultural Select Agents and Toxins.

- procedures to protect public safety and animal and plant health and products if select agents are transferred or potentially transferred in violation of the established safety procedures, safeguards, and security measures.

All entities that possess, use, or transfer select agents must register with the appropriate regulatory agency.[6] Currently, 34 entities—including Government agencies, State and local governments, academic institutions, private non-profit corporations, and commercial entities—are registered with APHIS to possess, use, and transfer select agents.[7] Registered entities are defined as facilities at one physical location (such as a room, a building, or a group of buildings) where the responsible official (RO) will be able to perform all the responsibilities of the select agent program.

Each entity must designate an RO who is responsible for day-to-day program administration and compliance. The entity may also designate one or more alternate ROs, who may act in the absence of the RO. As part of the registration process, an entity's RO, the alternate RO, the entity, and the individual who owns or controls the entity,[8] must undergo a security risk assessment (SRA) by the Criminal Justice Information Service (CJIS) Division of the Federal Bureau of Investigation (FBI).[9] Moreover, all individuals who handle or use select agents must undergo an SRA by the FBI's CJIS Division.

Executive Order 13546 states that a robust and productive scientific enterprise that utilizes select agents is essential to national security. This directive states that heads of executive departments and agencies must take security measures in a coordinated manner, through consistent policies and practices to secure select agents. Further, select agents must be secured in a manner appropriate to their risk of misuse, theft, loss, and accidental release. As part of this coordinated approach, select agents must be tiered to identify those that pose the greatest risk of deliberate misuse and to establish physical security standards for those select agents.[10, 11]

When an entity registers with APHIS, it submits a security plan based on a site-specific risk assessment detailing the physical security of the select agents and the laboratories that house them.[12] In addition, the entity submits biosafety, biocontainment, and incident response plans.[13] As a part of the registration process, APHIS reviews these plans and inspects the entity's relevant facility and laboratories. Once approved, the entity's certificate of registration is approved for a

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[6] Registration with both agencies is not required.
[7] As of December 2019.
[8] Owning or controlling individuals undergo an SRA, when applicable.
[9] CJIS performs SRAs to determine whether individuals meet any of the statutory restrictors that would prohibit or limit their access to select agents.
[10] Exec. Order No.13546, *Optimizing the Security of Biological Select Agents and Toxins in the United States* (July 2, 2010).
[11] Select agents that pose the greatest risk are designated as tier 1, as they present the greatest risk of deliberate misuse with the most significant potential for mass casualties or devastating effects to the economy, critical infrastructure, or public confidence.
[12] 7 C.F.R. § 331.11(c)(d) and 9 C.F.R. § 121.11(c)(d) establish security plan requirements.
[13] 7 C.F.R. § 331.12(a)(b) and 9 C.F.R. § 121.12(a)(b) provide requirements for biosafety/biocontainment plans. Similarly, 7 C.F.R. § 331.14(a)(b) and 9 C.F.R. § 121.14(a)(b) provide requirements for incident response plans.

maximum of 3 years. To ensure entities comply with Federal regulations and biosafety standards, APHIS conducts various categories of inspections.[14] APHIS inspectors complete inspections of entities using standardized checklists to certify that laboratories have the appropriate safety and security measures in place. APHIS inspectors use their professional judgment to make determinations based on checklist questions related to Federal regulations by selecting "pass," "fail," "not applicable," or "not assessed." Once an inspection is scheduled, APHIS' eFSAP database automatically creates the relevant checklists for the inspection when the inspection category is selected.[15] eFSAP is programmed to automatically select the appropriate questions related to the inspection category and eliminate questions that are not relevant. For instance, if the entity is not a tier 1 entity, questions related to tier 1 select agents would automatically be marked "not applicable" by the eFSAP database.[16] During the inspection process, if an inspector does not assess a question, it will be marked "not assessed."

Prior Audits

In 2012, we reported that APHIS needed to strengthen its internal controls over the critical program areas related to monitoring the movement of select agents to alternate facilities, controlling access to select agents, ensuring that individuals handling select agents have up-to-date security clearances, and ensuring that ROs are adequately trained. As part of the objectives of our current audit, we planned to evaluate the actions APHIS implemented to address the 12 recommendations from the 2012 report.

Objectives

The objective of this audit was to evaluate the effectiveness of APHIS' controls over select agents as part of FSAP to adequately reduce the threat to public, animal, and plant safety, and animal and plant products. Additionally, we followed up on prior audit recommendations from Audit 33701-0001-AT to determine whether corrective actions were adequately implemented and operating effectively.

We found APHIS' FSAP oversight and internal controls processes need to be improved to effectively reduce the threat of select agents and toxins to the public, animal, and plant safety, and animal and plant products. However, due to a scope limitation, we are not reporting on the implementation and operating effectiveness of prior audit recommendations.[17]

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[14] APHIS has six categories of inspections: compliance, maximum containment, new entity, new space, renewal, and verification. APHIS can schedule inspections as needed, announced or unannounced, for five of the six categories; APHIS typically conducts a renewal inspection every 3 years to determine if it will renew an entity's certificate to participate in FSAP.

[15] eFSAP is APHIS' database, used to administer FSAP and maintain information regarding entities' select agent registration.

[16] A tier 1 select agent or toxin is a subset of select agents and toxins that have been designated as tier 1 because these BSAT present the greatest risk of deliberate misuse with significant potential for mass casualties or devastating effect to the economy, critical infrastructure, or public confidence, and pose a severe threat to public health and safety.

[17] For more information on the scope limitations, see the Scope and Methodology section of this report.

Section 1: Information System Accuracy

Finding 1: APHIS Needs to Ensure Information in eFSAP is Accurate and Complete

APHIS' database, eFSAP, did not always include accurate and complete information, which is critical for APHIS' monitoring of entities' compliance with Federal regulations. Although APHIS stated that it requires file managers to review information uploaded to eFSAP and approve the possession, use, or transfer of select agents, APHIS lacked oversight control procedures to ensure that file managers performed these reviews and that information was complete and accurate. As a result, APHIS may not be able to proactively take action to ensure select agents and toxins are secure within approved registered entities.

The Agricultural Bioterrorism Protection Act of 2002 states, "the Secretary shall maintain a national database that includes…the listed agents and toxins such persons are possessing, using, or transferring, and information regarding the characterization of such agents and toxins." The purpose of this database is to ensure the United States Government is aware of entities that possess potentially dangerous material and allow for proactive action to ensure select agents and toxins are secure within entities.

eFSAP is APHIS' database, used to administer FSAP and maintain information regarding entities' select agent registration, including:

- the list of select agents and toxins entities possess, use and/or transfer and information regarding the characterization of such agents and toxins;
- records of individuals with approved access and laboratory inspection information; and
- information about the location where entities conduct select agent work.

We noted four deficiencies in eFSAP. First, we determined that one entity's eFSAP list of select agents and toxins and the specific strain designation[18] related to each approved select agent and toxin was inaccurate. Similarly, eFSAP did not include sufficient support for APHIS' approval of amendments to entities' registration to possess, use, or transfer select agents and toxins. The Office of Inspector General (OIG) concluded this information is necessary for agency officials to provide effective oversight of FSAP.

Third, one individual's access to possess, use, and transfer select agents and toxins was inaccurately listed as "unrestricted" in eFSAP, even though the individual's required SRA had expired. Finally, templates based on Office of Management and Budget (OMB)-approved forms used to electronically collect information within eFSAP were incomplete. The templates did not list required expiration dates or explain why it would not be appropriate to include an expiration date on the information collection forms in eFSAP.

[18] "Strain" refers to a group of organisms of the same species which share certain hereditary characteristics atypical of the entire species, but minor enough not to warrant classification as a separate breed or variety.

Inaccurate or Incomplete Records of Select Agents and Toxins in eFSAP

We found that APHIS did not ensure that eFSAP information for one entity contained an accurate listing of select agents and toxins and the associated strain designation. We compared records listed in eFSAP with an entity's records and found the entity's select agent records listed 15 strains of select agents not in eFSAP. Conversely, that entity's eFSAP information listed 23 strains of select agents that were not listed in records.

An APHIS official stated that eFSAP should contain complete, accurate, and up-to-date information regarding select agents and toxins and associated strain designations maintained by entities and that eFSAP is a database that entities continuously update. Because external entities are continuously updating the system, and to provide reasonable assurance that information about select agents and associated strains maintained by registered entities is accurate and complete, OIG recommends APHIS establish controls or policies to ensure that APHIS officials consistently review or verify the accuracy of the information within eFSAP. An APHIS official agreed that eFSAP information should be up-to-date, stating that APHIS' goal is to ensure eFSAP maintains an accurate listing of select agents and the associated strains possessed by registered entities.

Inconsistently Supported Approvals of Amendments to Entity Registration in eFSAP

In order for an entity to possess, use, or transfer select agents and toxins, it must obtain a certificate of registration.[19] The registration process includes submitting APHIS/CDC Form 1, *Application for Registration for Possession, Use, and Transfer of Select Agents and Toxins*, which requests information about the entity such as:

- the facility and laboratory information;
- the select agents and toxins to be possessed, used, or transferred by the entity;
- the individuals who will have access to select agents and toxins; and
- the strain designation of select agents and toxins maintained by the entity.

After initial registration approval, entities can update their registration in eFSAP through an amendment. APHIS file managers must review and approve the amendment before the entity can implement the changes to its certificate of registration.

However, we identified that APHIS file managers did not always ensure entities documented support for approval of entity amendment requests. Although APHIS file managers reviewed information uploaded to eFSAP to approve amendment requests, file managers had not supported the basis for their approval of amendments for 1 of the 10 entities in our sample. For example, one entity recorded in eFSAP the entity's specific room where select agent research would be conducted to be amended and its

[19] According to 7 C.F.R. § 331.7(a) and 9 C.F.R. § 121.7(a), "unless exempted, an individual or entity shall not possess, use, or transfer any select agent or toxin without a certificate of registration issued by the [APHIS] Administrator."

location within the entity. It also documented that the entity uploaded supporting information into eFSAP and the date the entity uploaded that information. By contrast, another entity simply documented "adding to space" in eFSAP without specifying what the file manager reviewed to support an entity's amendment request approval. APHIS officials stated that, while file managers should document the basis for their decision to approve amendments in greater detail, ultimately file managers have the discretion to determine what documentation submitted by entities is sufficient to approve amendment requests.

We understand APHIS' position that file managers should use professional judgment when reviewing and approving amendments. However, per APHIS guidance, amendments should be documented in eFSAP with as much information as possible to ensure changes made to certificates of registration meet Federal regulations.[20, 21] Currently, APHIS does not have a policy or guidance that details its documentation requirements in eFSAP to justify a file manager's review and approval of an entity's amendment to a certificate of registration. Accordingly, OIG recommends APHIS develop and implement such requirements to ensure that file managers adequately document their review and approval of amendments to registrations for entities that possess, use, or transfer select agents.

Inadequate Verification of Approval to Access Select Agents

According to Federal requirements, an individual may not access select agents or toxins unless the APHIS Administrator or the Secretary of the Department of Health and Human Services (HHS) approves the individual, following a SRA.[22] We analyzed SRA data in eFSAP for each of the 10 entities in our sample. We identified that an entity listed an individual in eFSAP as eligible to access and use select agents and toxins even though the individual's SRA was expired at the time of our audit.[23]

APHIS officials informed us that they have a process in place to identify and correct any SRA lapses. However, we found that APHIS had not documented the process in a formal policy. Additionally, we determined that APHIS officials did not follow the process as explained to us; had they done so, OIG concluded they would have been able to identify and resolve the issue timely. First, APHIS officials stated that an APHIS official reviews eFSAP SRA data daily and identifies individuals with expired or soon-to-be expired SRAs. APHIS then documents and maintains this analysis in a log outside of eFSAP. Once APHIS identifies an expired SRA, an agency official contacts the entity's RO to

[20] *Instructions for Completion of APHIS/CDC Form 1, Application for Registration for Possession, Use, and Transfer of Select Agents and Toxins* (Jan. 18, 2017).
[21] An amendment is a request to update a registered entity's certificate of registration for the possession, use, and transfer of select agents and toxins. Amendment requests should be as descriptive as possible and will not be approved until they are reviewed and it is determined that sufficient documentation has been submitted. Lastly, amendment requests will be considered pending until final approval has been officially communicated to the entity.
[22] 7 C.F.R. § 331.10 and 9 C.F.R. § 121.10.
[23] During the course of our review, we discovered that the individual's SRA expired on January 12, 2020, and was not reauthorized until 2 months later on March 12, 2020. APHIS was not aware that the SRA had lapsed or had been reauthorized to work with select agents.

verify the individual's access has been removed. Although APHIS did email the entity's RO, the email was sent on March 5, 2020—2 months after the SRA in question expired and did not include any detail pertaining to whether the individual was removed from accessing select agents and toxins, as required by program regulation.

APHIS stated that it tracks SRA approval dates in eFSAP and relies on entities' ROs both to ensure SRAs are updated and control access to select agents and toxins. However, as the responsible oversight agency, APHIS must also design controls to ensure entities adequately address expired or expiring SRAs. During our audit, APHIS updated eFSAP to capture SRA approval and expiration dates. APHIS officials stated they also implemented a required, weekly report that notifies APHIS of entities with individuals with SRAs set to expire in 60 days. Further, APHIS intends to use this report to identify expiring SRAs and ensure action is taken to re-authorize or remove access to select agents and toxins. We commend APHIS for the steps it has taken to improve oversight of the SRA process and recommend that it document these controls in guidance, so personnel understand agency policy and procedures. We also suggest that APHIS develop oversight controls, such as supervisory reviews, to ensure personnel and entities implement these procedures.

OMB Form Expiration Date in eFSAP

OMB reviews agency forms at least every 3 years, then assigns an approval and expiration date to the forms, which ensures that agencies do not use expired or unapproved forms.[24] If an agency collects information using an OMB-approved form, it must display the form's expiration date on that form; if the agency determines it is not appropriate to include the expiration date, it must provide an explanation.

APHIS allows entities to electronically submit information into eFSAP using templates, based on OMB-approved forms. However, we noted that, while eFSAP captured the information required on OMB paper forms, eFSAP did not include the OMB form expiration dates or justification for the omission, as required, on all electronic versions of OMB forms within eFSAP—such as the electronic version of its *APHIS/CDC Form 2 Request to Transfer Select Agents and Toxins*. APHIS officials agreed that eFSAP should be updated to include the expiration date of the OMB-approved forms. OIG concluded that doing so will provide assurance that APHIS does not use outdated requirements to collect eFSAP electronic requests.

Overall, OIG concluded that APHIS needs to improve its oversight of eFSAP to ensure controls are in place to maintain complete and accurate data. Information contained in eFSAP helps determine who has access to select agents and toxins; where they are stored; and how entities will secure, contain, and respond to incidents involving select agents and toxins. As a result, it is vital that this information be accurate and thoroughly documented in the database. Because APHIS is the oversight body for select agents and toxins within USDA, it must maintain records that allow APHIS officials to make proactive decisions to ensure select agents and toxins are

[24] 5 C.F.R. § 1320.

properly secured. In general, APHIS officials recognized the issues identified and generally agreed with the recommended corrective actions.

Recommendation 1

Develop and implement policy and procedures requiring file managers and supervisors to periodically review eFSAP to provide reasonable assurance that information about select agents and associated strains maintained by registered entities is accurate and complete.

Agency Response

In its June 14, 2021, response, APHIS stated:

It appears the program and OIG differ in the need for eFSAP information system periodic reviews. The eFSAP clearly shows which select agents are in the possession of a registered entity and enough characterization about those agents to satisfy regulations and allows FSAP to have effective oversight.

Sole review of eFSAP data would not provide any additional assurances that information about select agents and associated strains maintained by registered entities is accurate and complete. Only physical inspection of the facility and review of the inventory records (required by 7 CFR §331.17 and 9 CFR §121.17) can provide reasonable assurance information about select agents and associated strains maintained by registered entities is accurate and complete. During inspections, FSAP verifies whether the entity's records reflect an accurate, current inventory for each select agent and toxin listed on its' certificate of registration maintained in eFSAP.

APHIS proposes that OIG delete this recommendation.

OIG Position

We do not accept management decision for this recommendation. Federal standards require APHIS to design control activities to respond to risks. Because external entities are continuously updating eFSAP, it is essential that APHIS establish controls or policies to ensure that APHIS officials consistently review or verify the accuracy of the information within eFSAP. As APHIS mentioned in its response, APHIS inspectors verify if the inventory of select agents maintained by the registered entity is accurate and current during the inspection process. However, APHIS's inspection process does not include steps to verify the accuracy of select agent strain information maintained in eFSAP. Periodic reviews of strain information required to be documented in eFSAP would provide APHIS assurance that entities are continuously updating strain information in eFSAP. These reviews could be included as part of APHIS' inspection process. To achieve management decision, APHIS needs to develop and implement policies and procedures to periodically review eFSAP to provide reasonable assurance that information about select agents and associated strains maintained by registered

entities is accurate and complete. In addition, APHIS needs to provide an estimated completion date for this action.

Recommendation 2

Develop policies and procedures requiring file managers to review and document the verification and approval of detailed amendment documentation submitted by entities within eFSAP.

Agency Response

In its June 14, 2021, response, APHIS stated:

APHIS disagrees with this recommendation as written; however, APHIS agrees with the intent of this recommendation and proposes to rephrase it to: Develop policies and procedures for file managers to review and document that information submitted by registered entities is sufficient to approve an amendment.

It is unnecessary to further document verification of documents already in the record. The registered entities are required to submit sufficient information to process an amendment. The required information that registered entities must submit for registration amendments is available to the public at eFSAP Form 1 Amendment Instructions (selectagents.gov).

If OIG concurs, APHIS will implement the rephrased recommendation by June 30, 2022.

OIG Position

We accept management decision for this recommendation. OIG's acceptance is based on APHIS' response that they plan to develop policies and procedures for file managers to review and document that information submitted by registered entities is sufficient to approve an amendment by June 30, 2022. We do not agree to change the wording of the recommendation.

Recommendation 3

Develop and implement policies that require file managers to collaborate with entities to verify and obtain documentation that individuals with expired SRAs have been timely removed from accessing select agents.

Agency Response

In its June 14, 2021, response, APHIS stated:

APHIS disagrees with this recommendation as written; however, APHIS agrees with the intent of this recommendation and proposes to rephrase it to: Develop, implement, and

document a collaboration process with the registered entities to ensure that individuals with expired SRAs are timely removed from access to select agents.

APHIS will follow up with the registered entities when an individual's SRA expires to verify with the RO that the individual's access has been removed and no additional documentation is required. Please also see the response to Recommendation 4.

If OIG concurs, APHIS will implement the rephrased recommendation by June 30, 2022.

OIG Position

We do not accept management decision for this recommendation. We agree with APHIS' proposed action to develop, implement, and document a collaboration process with registered entities to ensure individuals with expired SRAs are timely removed from access to select agents. However, Federal standards require APHIS to document the results of internal control issues they identify and document the completion of the corrective actions they implemented. Therefore, to achieve management decision, APHIS needs to obtain and document verification from the RO that actions have been taken when APHIS notifies the RO that an individual SRA has expired. Additionally, APHIS needs to provide an estimated completion date for this action.

Recommendation 4

Modify eFSAP to capture and retain SRA expiration dates and to notify agency officials when SRAs have expired.

Agency Response

In its June 14, 2021, response, APHIS stated:

APHIS agrees with the recommendation.

On May 16, 2019, FSAP modified eFSAP to capture and retain SRA expiration dates. eFSAP has been modified to have access approvals automatically expire at midnight on the expiration date. eFSAP automatically posts a message on the registered entity's homepage notification list. APHIS staff can view the same notifications as entity officials. In addition, before the final expiration notification, the entity receives notice of expiring access for an individual at 90, 45, and 7 days prior to expiration.

OIG Position

We do not accept management decision for this recommendation. Federal standards require APHIS to implement its control activities through policy. The modifications that APHIS described, which required APHIS staff to review entity homepages to check the entity's SRA status, were described in the audit finding. APHIS stated that they have a

process where an official reviews the entity's SRA information daily and identifies entities with officials with an expired SRA and documents this information in a log outside of eFSAP. However, APHIS did not formalize this process through written policy. Additionally, APHIS could not provide evidence that its officials followed the process they described and kept logs of entities with expired SRAs. As a result, we found an individuals' SRA had expired. APHIS had not contacted the entity's responsible official to update the SRA or ensure that the expired individuals' access to handle select agents had been removed. Instead, APHIS contacted the entity's responsible official two months after the official's SRA expired. Although registered entity's responsible officials are responsible for ensuring SRA data for personnel approved to work with select agents is updated, it is also APHIS' responsibility, as the oversight agency, to ensure the updates occur or entities remove access. To achieve management decision, APHIS needs to make additional modifications to eFSAP to notify agency officials of individuals with expired SRAs to ensure entities take appropriate action to remove the expired individuals' access. In addition, APHIS needs to provide an estimated completion date for these actions.

Recommendation 5

Modify eFSAP to update and display the expiration date on required OMB forms.

Agency Response

In its June 14, 2021, response, APHIS stated:

APHIS agrees with the recommendation.

On May 12, 2021, the modification to eFSAP was completed and the expiration date is now displayed in the system.

OIG Position

We accept management decision for this recommendation.

Section 2: APHIS Oversight Controls

Finding 2: APHIS Needs to Improve its Oversight Controls

We identified two deficiencies in APHIS' oversight process. First, although APHIS has designed multiple checklists for inspectors to evaluate compliance, APHIS inspectors do not document their justification for "pass" determinations. This occurred because APHIS has not established controls that require its inspectors to document the information reviewed to support "pass" determinations made during their inspections.[25] Second, APHIS officials did not ensure an entity timely resolved non-compliances identified during prior inspections.[26] Although APHIS has a procedure in place, APHIS did not have oversight controls to ensure personnel followed this procedure. Until APHIS develops and requires oversight mechanisms, APHIS cannot reasonably: (1) ensure its inspectors consistently identify all non-compliance issues and (2) ensure these issues are corrected in a timely manner.

To protect program resources from waste, fraud, and mismanagement, APHIS must design controls to effectively monitor and evaluate performance and support management's decisions.[27] Federal regulations state APHIS must be allowed to inspect any site which possesses, uses, or transfers select agents and toxins.[28]

FSAP inspections are APHIS' control to verify that entities comply with the select agent and toxin regulations including biosafety and biocontainment, security, and incident response requirements.[29] These requirements ensure those working in laboratories and living in surrounding communities are safe and secure. To administer inspections, APHIS has established checklists that contain questions inspectors should answer to assess entities' compliance with Federal regulations. Inspectors must answer each checklist question with either "pass," "fail," "not applicable," or "not assessed." Inspectors must document and discuss the non-compliance issues with the entity during an inspection close out meeting. After the inspection is concluded, APHIS prepares a report to provide to entities formally notifying them of the non-compliances identified, if any. The report includes instructions for entities to provide a response to APHIS within 30 days of the specific actions or changes to be adopted to correct the non-compliances identified. Entities that fail to adequately respond may be subject to further compliance actions. In addition, entities may choose to participate in APHIS's corrective action program to address non-compliances. Participating entities must submit a corrective action plan that addresses how they will correct the non-compliances and the timeframe proposed to complete it. However, if

[25] "Determinations" are inspectors' conclusions to questions during the inspection process to determine if entities complied with FSAP regulatory requirements.
[26] "Non-compliances" are departures from regulatory requirements that inspectors identify during the inspection process.
[27] Government Accountability Office (GAO), *Standards for Internal Controls in the Federal Government* (Sept. 2014).
[28] 7 C.F.R. § 331.18; 9 C.F.R. § 121.18; and Public Health and Security and Bioterrorism Preparedness and Response Act of 2002 (Jan. 2002).
[29] APHIS has six categories of inspections: compliance, maximum containment, new entity, new space, renewal, and verification. APHIS can schedule inspections as needed, announced or unannounced, for five of the six categories; APHIS typically conducts a renewal inspection every 3 years to determine if it will renew an entity's certificate to participate in FSAP.

an entity declines to participate in the corrective action plan (CAP) program the entity has 30 days to correct non-compliances or APHIS can implement actions to suspend or revoke the entity's registration.

However, OIG concluded that APHIS needs to require its inspectors to document their conclusions for "pass" determinations and also establish guidance to follow up on non-compliances that APHIS does identify to ensure that entities timely resolve them.

Insufficient Documentation of Inspectors' Review

Although APHIS has established processes to perform inspections to determine whether entities are in compliance, APHIS inspectors do not document their justification for determinations of "pass." APHIS also has not defined the required terms its inspectors use (for example, "pass," "fail," "not applicable," and "not assessed") to determine if entities complied with Federal regulations.

In fiscal year (FY) 2019, APHIS inspectors conducted inspections for 8 of the 10 entities in our sample. We found that inspectors did not describe what they reviewed to support their determination of "pass" for each inspection checklist question. For example, inspectors gave seven sampled entities a "pass" rating for maintaining complete records, such as an accurate and current inventory for each select agent held in long-term storage. However, the inspectors did not provide details, such as the date they reviewed inventory records, the quantity of inventory on hand, and the numbers or percentages of inventory tested (such as, a sampling methodology). OIG concluded such information would be useful for APHIS officials to evaluate if inspectors identified all non-compliance issues during inspections.

APHIS officials explained that they do not require inspectors to document the basis for their "pass" determinations because they have other processes in place to ensure all non-compliance issues are identified, including training and supervisory review of non-compliances. First, APHIS officials stated that when inspectors identify non-compliances, supervisors review and discuss the non-compliances with APHIS' compliance, security, and facility specialist before entering them into eFSAP. These individuals provide an additional level of expertise to evaluate the inspectors' determinations and, when necessary, can add insight to non-compliance determinations. However, APHIS could not describe how it evaluates whether inspectors adequately conducted the inspections with "pass" determinations.

In addition, APHIS has not defined the terms used on their inspection checklists (for example, "pass," "fail," "not applicable," and "not assessed"). For example, the following regulatory checklist question was marked "not assessed": entities must implement a system to ensure that all records and databases are accurate and legible, have controlled access and authenticity verified. The inspector provided no further explanation which would allow a third party or supervisor to determine why this question was not assessed.

However, APHIS has not formally documented any of these terms in guidance or policies related to the inspection process. Therefore, it is unclear why inspectors mark questions as "pass," "fail," "not applicable," and "not assessed." To address this issue, we recommend that APHIS clearly define and document the terms used to answer inspection checklist questions.

APHIS officials also noted that they provide training to their inspectors and rely on inspectors' experience to complete the inspections and checklists accurately. Further, inspectors use their professional judgment and assess entities based on the entity's risk level identified during pre-inspection briefings. Finally, APHIS officials expressed concern that requiring inspectors to maintain documentation to support their determinations would be burdensome.

We agree that training is essential to APHIS' effective administration of Federal regulations. The pre-inspection briefings and post-inspection supervisory review of non-compliance determinations are a helpful oversight control to ensure issues identified are accurately reported. However, these controls alone are not sufficient to protect program resources from fraud, waste, or mismanagement. Federal guidance requires oversight controls to monitor and evaluate performance to support decisions made.[30] Therefore, OIG concluded it is critical for inspectors to document their determinations to allow supervisors and third parties to verify the inspectors' results of inspections for "pass" as well as "non-compliant" determinations, as needed. Similarly, APHIS should define in guidance the meaning of "pass," "fail," "non-applicable," and "not assessed" determinations. While we agree that APHIS should rely on inspectors' professional judgment and experience, APHIS should establish controls that will enable APHIS officials and external parties, including supervisors, to determine if the inspections are properly conducted and the determinations are valid. OIG concluded these oversight controls will help inform APHIS where additional training is needed to improve the inspection process.

Insufficient Monitoring of Non-Compliance Resolution

We also found that APHIS needs to ensure that entities timely resolve non-compliances identified during inspections. For example, APHIS issued 21 non-compliances in 2018 and 3 non-compliances in 2019 to a tier 1 entity that housed the highest risk select agents and toxins.[31] On both occasions, the entity had 30 days to provide a response of the actions the entity planned to take to address the non-compliances identified and the option to participate in the corrective action program. Although in 2018 the entity provided a response to APHIS within 30 days of APHIS notifying the entity of specific non-compliances identified during its review, OIG identified that the entity did not elect to participate in APHIS's corrective action program and did not resolve some of the

[30] GAO, *Standards for Internal Controls in the Federal Government* (Sept. 2014).

[31] A tier 1 select agent or toxin is a subset of select agents and toxins that have been designated as tier 1 because these BSAT present the greatest risk of deliberate misuse with significant potential for mass casualties or devastating effect to the economy, critical infrastructure, or public confidence, and pose a severe threat to public health and safety.

2018 non-compliances until January 2020. In 2019, the entity did not respond within 30 days on the actions it planned to implement to address the non-compliances APHIS reported during their 2019 review. Again, the entity did not choose to participate in APHIS's CAP program and did not resolve all of the non-compliance APHIS reported in 2019, until August 2020.

APHIS officials stated they did not have concerns with the entity's ability to comply with FSAP regulations, despite the identified non-compliances. Therefore, APHIS officials renewed the entity's 2019 registration on the condition that the entity adequately addressed all non-compliances from the 2018 inspections. APHIS officials explained that they issue contingency registration renewals to ensure that entities possessing select agents and toxins are registered even if they have outstanding non-compliances.

We agree that entities should not go without registration; however, program non-compliances should not be allowed to go unaddressed for extended periods without accountability. We note that FSAP has a corrective action program that entities may choose to participate in to allow for additional time to address non-compliances. Participating entities must submit a CAP that addresses how they will correct the non-compliances and the timeframe proposed to complete it. However, if an entity declines to participate in the CAP program, APHIS guidance states that the entity has 30 days to correct non-compliances, or APHIS can implement actions to suspend or revoke the entity's registrations. Ultimately, because APHIS allowed a tier 1 entity to go 2 years without providing evidence that it had addressed non-compliances, APHIS has reduced assurance that these unresolved issues did not pose a threat to the safety of animals, plants, and the public.

OIG recommends APHIS establish oversight controls that will enable its personnel to bring registered entities into compliance when they have not implemented corrective actions within the 30-day response period. As part of this guidance, APHIS should consider making the corrective action mandatory instead of voluntary for entities unable to timely resolve issues. By establishing such controls, such as reports to track open corrective actions, OIG concluded APHIS can better monitor entities' progress in implementing corrective actions. APHIS should also establish procedures for personnel detailing how to bring registered entities into compliance when entities do not take action to timely resolve non-compliances.

Overall, we understand APHIS' concerns that additional documentation requirements can be burdensome and acknowledge APHIS' willingness to work with entities to ensure they are in compliance with Federal regulations. However, select agents and toxins have the potential to pose a severe threat to public, animal, or plant health, or to animal or plant products. OIG recommends APHIS continue to enhance its oversight to ensure the safety and security of select agents and toxins. Specifically, APHIS should design controls to ensure that: (1) APHIS effectively evaluates all inspection determinations; and (2) entities timely resolve non-compliances and protect program resources from waste, fraud, and mismanagement.[32]

[32] GAO, *Standards for Internal Controls in the Federal Government* (Sept. 2014).

APHIS officials did not agree that "pass" determinations should be documented to allow for a third party or a supervisor to arrive at the same determinations. However, APHIS officials did agree that they need to ensure non-compliance issues are resolved in a timely manner.

Recommendation 6

Develop and implement guidance that details how inspectors should document their justifications for determinations that entities complied with Federal regulations. Specifically, APHIS guidance should: (1) describe the information reviewed that led to a "pass" determination of compliance; (2) define the meaning of "pass" statements, "fail" statements, "non-applicable" statements, and "not assessed" determinations.

Agency Response

In its June 14, 2021, response, APHIS stated:

It appears the program and OIG differ in the methodology for the program's inspection process. APHIS differs with OIG up to and including part (1) of this recommendation. APHIS agrees with the intent of the part (2) of this recommendation. APHIS proposes to rephrase part (2) of this recommendation to: Develop the definitions of "pass," "fail," "not applicable," and "not assessed" determinations in the standard operating procedure.

APHIS already complies with part 1 of this recommendation by using a comprehensive inspection checklist which describes all information required be reviewed during inspections. All inspectors undergo extensive training to teach them how to evaluate items listed on the checklists with emphasis on when to pass and when to fail an item. In addition, inspectors take internal and external continuous training to maintain and enhance their inspection skills. On the inspection checklist, when the inspector selects "pass," it means the registered entity met the select agent regulatory standard listed on the checklist and no additional information is needed.

Adding description of the information reviewed by the inspectors that led to a "pass" determination of compliance with the Federal regulations, would not benefit the program, nor the supervisors but only third-party reviewers.

Please also see answer to recommendation 7.

If OIG concurs, APHIS will implement this rephrased recommendation. If OIG concurs, APHIS will implement the rephrased recommendation by June 30, 2022.

OIG Position

We do not accept management decision for this recommendation. Federal standards require APHIS to design controls to effectively monitor and evaluate performance and support management's decisions. APHIS was unable to describe how they effectively monitored and evaluated the performance of its inspectors to complete the inspection

checklist accurately. APHIS described a process of how they evaluate non-compliances identified before reporting the non-compliance to the entity but could not explain how they monitored the performance of its inspectors to ensure other determinations made by inspectors during inspections were correct. Establishing effective monitoring controls would benefit APHIS supervisors and third parties, such as OIG, because monitoring can provide reasonable assurance that the controls they established are effective. Although APHIS conducts training to teach its inspectors how to complete its checklist, without effective monitoring, APHIS cannot evaluate how effective their training is or inform them of areas where additional training is needed. To achieve management decision, APHIS needs to develop and implement procedures describing its processes to periodically review all determinations made during inspections. In addition, APHIS needs to provide an estimated completion date for these actions.

Recommendation 7

Develop and implement oversight controls to periodically review a sample of inspections completed by inspectors to ensure all conclusions and responses are adequately supported and accurate.

Agency Response

In its June 14, 2021, response, APHIS stated:

It appears the program and OIG differ in control validation methods.

For each inspection, APHIS has pre-and post-inspection staff meetings and supervisory reviews and approvals that provide oversight controls to monitor and evaluate performance and to support decisions made on each and every inspection. Performing secondary inspection evaluations would be redundant. APHIS always reviews all inspection reports to ensure that all conclusions and responses are adequately supported and accurate. Multiple APHIS staff members review findings during inspections and at the post-inspection debrief, with input from inspectors and specialists (as needed). Additionally, the proposed final report is reviewed by a supervisor prior to releasing the inspection report to the registered entity. This process is described in the inspection report procedures.

APHIS proposes that OIG delete this recommendation.

OIG Position

We do not accept management decision for this recommendation. Federal standards require that effective controls must be designed to monitor and evaluate performance and support decisions. While we agree that APHIS does assess non-compliances identified during inspections, no further review or assessment of the overall inspection process is documented. To fulfill Federal requirements, APHIS needs to implement oversight controls to periodically review a sample of inspections to ensure all conclusions and

responses are adequately supported and accurate. This is a control that APHIS does not already have in place. To achieve management decision, APHIS needs to develop and implement monitoring controls that APHIS can use to ensure all determinations made by inspectors during inspections are accurate. These controls can include a description of the information reviewed that led to the inspectors' conclusion followed by periodic review of a sample of completed inspection checklists or periodic on-site monitoring by supervisors documenting its evaluation of inspectors' performance to complete APHIS' inspection checklist. In addition, APHIS needs to provide an estimated completion date for these actions.

Recommendation 8

Establish oversight controls, such as a tracking report, to monitor the status of registered entities' progress to implement corrective actions. Establish procedures APHIS personnel should take to bring registered entities into compliance when corrective actions have not been timely resolved.

Agency Response

In its June 14, 2021, response, APHIS stated:

It appears the program and OIG differ in corrective actions; however, APHIS agrees with the intent of the first part of this recommendation. APHIS proposes to rephrase this recommendation to: Establish oversight controls, such as the use of a tracking report, and monitor the status of registered entities' progress to implement corrective actions.

There is no mandatory timeline to implement corrective actions. The timeline of corrective actions is contingent on the extent of the repairs or mitigations needed to comply with the select agent and toxin regulations. APHIS collaborates with registered entities to ensure that during the implementation of corrective actions (regardless of the duration), the entity remains in compliance with the select agent regulations. eFSAP allows tracking of inspections pending closure.

If OIG concurs, APHIS will implement the rephrased recommendation by June 30, 2022.

OIG Position

We do not accept management decision for this recommendation. In addition to tracking the status of registered entities' progress to implement corrective actions, APHIS should also establish procedures that its personnel should follow if corrective actions are not implemented based on the timeframes agreed to by APHIS and the registered entity. These actions can include approving extensions of the timeframe agreed, warning notifications of potential removal, and removal if necessary. Federal standards require APHIS to implement its control activities through policy. Currently, APHIS has not established policy that documents the responsibility of its officials to ensure corrective actions are timely implemented. To achieve management decision, APHIS needs to establish oversight controls to monitor the status of registered entities' progress to

implement corrective actions and procedures to bring registered entities into compliance when entities do not timely implement corrective actions. In addition, APHIS needs to provide an estimated completion date for these actions.

Recommendation 9

Train personnel on how to implement the new guidance established in Recommendations 6 through 8.

Agency Response

In its June 14, 2021, response, APHIS stated:

APHIS agrees with the recommendation. APHIS will provide training to staff as needed for any revisions to the new guidance.

APHIS will implement this recommendation by June 30, 2022.

OIG Position

We accept management decision for this recommendation.

Section 3: Improper Reporting

Finding 3: APHIS' Annual Report to Congress Needs Improvement

APHIS did not report to Congress all select agent and toxin notifications reported by entities from 2017 through 2019. Specifically, OIG determined that 13 notifications of a loss and 3 notifications of a release of select agents or toxins fit APHIS' definition of a loss and, consequently, should have been included in its report to Congress.[33] This occurred because APHIS officials do not consider it a loss when an entity cannot account for select agents or toxins but those agents/toxins are eventually discovered or found. Therefore, APHIS did not report these instances to Congress. As a result, APHIS did not provide Congress with accurate information to assess APHIS' administration of FSAP. OIG concluded that, without accurate reports, Congress cannot fully determine the effectiveness of APHIS' administration of FSAP or make informed decisions concerning APHIS' oversight of registered entities' handling of dangerous select agents and toxins.

APHIS defines a loss as "a failure to account for a select agent or toxin."[34, 35] Entities are required to immediately notify APHIS upon discovering the loss of a select agent or toxin.[36] Entities must report losses to APHIS even if the select agent or toxin is subsequently recovered. The Agricultural Bioterrorism Protection Act of 2002 requires the Secretary of Agriculture to report to Congress annually on the number and nature of notifications received related to any theft, loss, and release of select agents and toxins reported by entities.[37]

We identified seven entities that notified APHIS of 16 instances where they did not account for select agents or toxins that APHIS did not include in its annual reports to Congress. For example, in 2017, APHIS reported 11 instances of releases and 1 instance of a loss in its calendar year (CY) 2017 Annual Report to Congress. While we determined that three entities notified APHIS of releases of select agents, the notifications actually met APHIS' definition of a loss and should have been included in the annual report to Congress. Specifically, three entities reported that they discovered or found vials of select agents in a freezer in space not registered with APHIS to store select agents and vials of select agents in long-term storage that the entity was unaware it possessed.

In 2018, APHIS reported no losses and four releases in its CY 2018 Annual Report to Congress. However, we identified one notification of loss from one entity that APHIS did not include in its

[33] None of the reported losses or releases resulted in a risk to public or agricultural health.
[34] APHIS and CDC Guidance Document, *Reporting Potential Theft, Loss, Release, or Occupational Exposure* (June 2016).
[35] Types of loss include, but are not limited to: (1) "Inventory/Recordkeeping error" if there was an error in the inventory records that misrepresented the amount or type of select agent or toxin that are present at the entity; and (2) "Sample lost/discarded at entity" if a select agent or toxin was intentionally or unintentionally misplaced or disposed of at the entity.
[36] The regulatory agency is either APHIS or CDC, depending on the type of select agents the entity possesses.
[37] Agricultural Bioterrorism Protection Act of 2002, Title II, Subtitle B Sec. 212. Regulations of Certain Biological Agents and Toxins.

Annual Report to Congress. The entity discovered a select agent it had not accounted for in the entity's inventory records outside of the space registered to store select agents and toxins.

In 2019, APHIS reported no losses and eight releases in its CY 2019 Annual Report to Congress. However, we identified 12 notifications of loss reported to APHIS by four entities that APHIS did not report to Congress.[38] One entity reported nine instances where it found select agents in its facility that were not accounted for in its inventory records when conducting an inventory review. Additionally, three entities reported instances where they discovered select agents they were unaware they possessed, which were unsecured in a secondary freezer and comingled with non-select agent strains.

Each of the notifications identified above described an instance where an entity did not account for a select agent and toxin it possessed and eventually discovered the existence of the select agent or toxin within its facility. OIG concluded that these notifications met APHIS' definition of a loss and should have been reported by APHIS in its annual report to Congress. However, APHIS stated that it did not consider these notifications a "true" loss. As an example, APHIS described a hypothetical instance in which it would have received a notification where a retired scientist from a registered entity stored a select agent in their home refrigerator. Hypothetically, the entity would have notified APHIS of this discovery, which was reported as a loss. APHIS does not consider this situation to be a "true" loss because the select agent was found and reported to APHIS.

APHIS described another hypothetical example that included an instance where an entity would have reported that it discovered a select agent that it was unaware of due to the select agent being stored in a lab freezer since 1932. The entity discovered the select agent in the freezer and took steps to secure the select agent and report the incident to APHIS. APHIS officials determined that these instances should be identified as a "discovery" and not a "true" loss. APHIS officials stated the finding of a select agent or toxin by an individual or entity that is unaware of its existence is interpreted as a "discovery." APHIS stated that instances where an entity finds a select agent they were unaware existed should not be reported to Congress as a loss because APHIS interprets these instances to be a "discovery." However, this interpretation is not consistent with APHIS' own definition of a loss, which is "a failure to account for a select agent or toxin." As a result, APHIS should have reported these losses to Congress.

APHIS officials stated that they plan to draft language to define a "discovery," develop a new form to track the discoveries, and publish in the Federal Register a notice of proposed rulemaking to receive approval for requested changes to Federal regulations. OIG recommends that, until APHIS has taken the necessary actions to seek approval and redefine instances where an entity finds a select agent it was unaware it possessed as a "discovery" instead of a loss, APHIS should report all notifications of theft, loss, and releases in accordance with its guidance to Congress in its annual report.

When select agents or toxins are unaccounted for, there are health risks to personnel who work at entities that possess select agents or toxins and the surrounding community. Due to the

[38] An entity that submitted a theft, loss, and release notification in CY 2017 also submitted a notification in CY 2019.

seriousness of the risk, APHIS must report to the FBI, for further investigation, instances where select agents or toxins are unaccounted for by entities and reported as a loss. In 2014, due to lapses in biosafety practices in Federal laboratories, the Assistant to the President for Homeland Security and Counterterrorism and the Assistant to the President for Science and Technology issued a memorandum urging all Federal departments and agencies that possess, use, or transfer human, animal, or plant infectious agents or toxins to perform an immediate sweep of their facilities to verify that all BSAT was appropriately registered, stored, and disposed of in accordance with regulations.[39] The departments and agencies identified 27 instances in which BSAT materials were not properly accounted for and registered with FSAP. The call for the sweep and the identification of unaccounted for select agents and toxins demonstrated the importance of constant vigilance in implementing biosafety and FSAP regulations. Although the stand-down is not a required control, OIG concludes that this would be a beneficial practice to implement to ensure entities periodically conduct sweeps of all inventory on-hand to identify select agents and toxins that they are unaware are in their possession.

OIG determined that accurately reporting losses, including the nature of each loss, could help Congress make informed decisions to strengthen guidance for FSAP. Although APHIS officials did not agree that they should report to Congress as a loss instances where select agents are unaccounted for but eventually found, APHIS officials stated that they are developing language to define these instances as "discoveries" and a new form for entities to report such instances. While we understand APHIS' overall position, until this new definition has been approved, OIG recommends that APHIS report all theft, losses, and releases as required by the Agricultural Bioterrorism Protection Act of 2002.

Recommendation 10

Establish procedures to report all notifications of all theft, loss, and releases that meet APHIS' definition of theft, loss, and release in APHIS' annual report to Congress.

Agency Response

In its June 14, 2021, response, APHIS stated:

It appears the program and OIG differ in procedural requirements. The establishment of any additional procedures is not warranted. APHIS and CDC provide a joint FSAP report to Congress that accurately reports all thefts, losses, and releases as required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and the Agricultural Bioterrorism Protection Act of 2002. These Acts outline what must be reported to Congress annually. Every report of theft, loss, or release is carefully reviewed by FSAP before it is reported, so that Congress already has the most accurate reports.

APHIS proposes that OIG delete this recommendation.

[39] Enhancing Biosafety and Biosecurity in the United States (Aug. 2014).

OIG Position

We do not accept management decision for this recommendation. As mentioned in the finding, APHIS guidance defines a loss as "a failure to account for a select agent or toxin." The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and the Agricultural Bioterrorism Protection Act of 2002 require APHIS to report all notifications of a loss in its annual report to Congress. Based on APHIS' definition of a loss and the Acts, APHIS' report to Congress should include notifications where an entity reported its failure to account for select agent or toxin inventory. Our finding shows that APHIS did not report to Congress all losses in 2018 and 2019 reported by entities that fit APHIS' definition of a loss. To achieve management decision, APHIS needs to establish procedures to report all notifications of all thefts, losses, and releases that meet APHIS's current definition of theft, loss, and release in their annual report to Congress and provide an estimated completion date for this action.

Recommendation 11

Evaluate, formalize, and document in the select agent and toxin regulations the definitions of and the reporting requirements for the "discovery," "loss," "theft," and "release" of select agents and toxins.

Agency Response

In its June 14, 2021, response, APHIS stated:

APHIS disagrees with the recommendation as currently drafted. APHIS agrees with the intent of this recommendation. APHIS proposes to rephrase this draft recommendation to: Evaluate and formalize in the select agent and toxin regulations the definitions of the "discovery," "loss," "theft," and "release" of select agents and toxins.

We have deleted the verb "document" from the recommendation because the formal rulemaking process will satisfy this point. In addition, FSAP does not control the rulemaking process and will have to coordinate it with CDC and OMB as the CDC's and APHIS's rules must be published in the *Federal Register* simultaneously.

If OIG concurs, APHIS publish the final rule and implement the rephrased recommendation by December 31, 2023.

OIG Position

We do not accept management decision for this recommendation. The purpose of adding the word "document" is to ensure APHIS updates all of their internal documentation once APHIS completes the rule making process to formalize and update the definitions and requirements to report discoveries, losses, thefts, and releases of select agents. To achieve management decision, APHIS needs to evaluate and formalize the definitions of the reporting requirements for "discovery," "loss", "theft," and "release." In addition,

APHIS needs to document in the select agent and toxin regulations the definitions of and the reporting requirements for the "discovery;" "loss;" "theft;" and "release" of select agents and toxins and provide an estimated completion date for this action within 1 year of the date of management decision.

Scope and Methodology

We conducted this audit to evaluate the effectiveness of APHIS' controls over select agents as part of FSAP to adequately reduce the threat to public, animal, and plant safety, and animal and plant products. The scope of our audit covered CYs 2017 through 2019. Additionally, we planned to review prior audit recommendations to determine whether corrective actions were adequately implemented and operating effectively.[40] However, due to the Coronavirus Disease 2019 pandemic, we were unable to complete all scheduled site visits after February 20, 2020, obtain sensitive non-electronic records from the entities,[41] and obtain electronic files from the ROs because the entities were assisting with the pandemic. These restrictions created a scope limitation beyond the control of APHIS. Therefore, we did not complete our objective to evaluate the implementation and effectiveness of prior recommendations as planned in the engagement program. However, we conducted one site visit prior to February 2020, and the issues identified as a result are included in Finding 1.

We performed fieldwork from October 2019 through January 2021 at APHIS headquarters in Riverdale, Maryland. To accomplish our objective, we interviewed APHIS officials responsible for the oversight of FSAP. Additionally, we reviewed FSAP inspections conducted from 2017 through 2019. We requested and obtained data from APHIS for the universe of entities registered to possess, use, and transfer select agents that APHIS oversaw from CY 2017 through December 17, 2019. We determined that APHIS oversaw 34 registered entities and non-statistically selected 10 to evaluate.[42]

In developing findings for this report, we:

- Obtained and reviewed laws, regulations, and directives that provide statutory requirements and guidance on FSAP.
- Interviewed APHIS officials responsible for the development and oversight of FSAP.
- Interviewed APHIS officials to determine agency procedures for coordinating with the CDC for activities such as entity registration and certification, inspection, and enforcement activities.
- Interviewed APHIS officials to determine registration, renewal, and amendment policies; inspection types and policies; and theft, loss, and release policies.

[40] Audit Report 33701-0001-AT, *Follow Up on APHIS Implementation of the Select Agent or Toxin Regulations*, Nov. 2012.
[41] Certain entities maintain hardcopy logs and records and store documentation within approved registered space.
[42] We created pivot tables for each of the five entity types (Federal Government; State/local government; academic; private non-profit; and commercial). We then generated random numbers and selected the top four entities based on the largest random numbers from each entity type (two initial and two alternates), if applicable. We selected two entities from each entity type to ensure that each entity covered a variety of select agents and toxins and biosafety laboratory levels. Lastly, we verified the entities' certificate expiration dates to validate the entities' eligibility to possess, use, or transfer select agents. Using a non-statistical judgmental selection process, we selected a total of 10 entities to visit. Nine entities were selected via random number generator by entity type. (Because State/local government only had 1 entity, we selected an additional Federal Government entity to bring the total to 10). In addition, we selected six alternate entities in case we were not able to gain access to certain entities because of security requirements. In total, we selected 16 entities for our sample—10 initial and 6 alternates.

- Interviewed an RO and alternate RO to gain an understanding of each entity's implementation of select agent program regulations, as well as compliance with the regulations.
- Evaluated the entity's guidance for restricting access to select agents, inventory control, transferring select agents, and notifying APHIS in the event of a theft, loss, or release.
- Evaluated the physical security measures implemented to protect select agents and toxins from potential theft, loss, and release at locations where select agents and toxins were stored and/or used.
- Assessed the accuracy, adequacy, and completeness of the records the RO is required to maintain per Federal regulations to ensure the registered entity is in compliance with FSAP, including:
    - security, biocontainment/biosafety, and incident response plans;
    - site-specific risk assessments;
    - training records;
    - authorized individuals;
    - security records (for example, transactions from access control systems, visitor logs, etc.);
    - inventory records (including select agent source and characteristic data); and
    - transfer documents issued by APHIS or CDC.

To assess the reliability of data, we interviewed agency officials knowledgeable about APHIS' information system used to administer FSAP and eFSAP. Through these interviews, we gained an understanding of the existence, relationship, impact, and pervasiveness of the information system. We obtained APHIS-registered entity data from eFSAP to use for selecting our non-statistical sample of registered entities to visit. We also obtained eFSAP data to verify the FSAP performance of non-statistically selected registered entities. We assessed the reliability of data by: (1) reviewing existing information about the data and the system that produced them; and (2) verifying the number of theft, loss, and release notifications submitted, number and approval of amendment notifications submitted, entity inspection documentation, and select agent inventory strain designations by comparing data within eFSAP to an entity's internal records. Based on our analysis and discussions with agency officials, we concluded that information within the system was not always accurate or complete (see Finding 1). However, we determined that the data were sufficiently reliable for the purposes of this report.

We assessed internal controls that were deemed significant to our audit objective, including, but not limited to, controls defined in GAO *Standards for Internal Control in the Federal Government*. For specific controls we reviewed, see the table below.[43]

[43] GAO, *Standards for Internal Control in the Federal Government* (Sept. 2014).

Internal Control Standard	GAO Definition
Control Environment Principle 2	The oversight body should oversee the entity's internal control system.
Control Activities Principle 1	Management should design control activities to achieve objectives and respond to risks.
Control Activities Principle 3	Management should implement control activities through policies.
Information and Communication Principle 3	Management should externally communicate the necessary quality information to achieve the entity's objectives.
Risk Assessment Principle 6	Management should define objectives clearly to enable the identification of risks and define risk tolerances.

However, because our review was limited to these internal control components and underlying principles, it may not have disclosed all internal control deficiencies that may have existed at the time of this audit.

We conducted this audit in accordance with Generally Accepted Government Auditing Standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. Except for the scope limitation described above, we believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

Abbreviations

AgSAS .....Agriculture Select Agent Services
APHIS .....Animal and Plant Health Inspection Service
BSAT .....Biological Select Agents and Toxins
CAP.....corrective action plan
CDC .....Centers for Disease Control and Prevention
C.F.R. .....Code of Federal Regulations
CJIS.....Criminal Justice Information Service Division
CY .....calendar year
eFSAP .....Electronic Federal Select Agent Program
FBI .....Federal Bureau of Investigation
FSAP.....Federal Select Agent Program
FY .....fiscal year
GAO.....Government Accountability Office
HHS.....Department of Health and Human Services
OIG .....Office of Inspector General
OMB .....Office of Management and Budget
RO.....responsible official
SRA.....security risk assessment
USDA.....United States Department of Agriculture

APHIS'
Response to Audit Report

United States Department of Agriculture

United States Department of Agriculture

Marketing and Regulatory Programs

Washington, DC 20250

TO: Gil H. Harden
Assistant Inspector General for Audit
USDA Office of the Inspector General

FROM: Kevin Shea
Administrator /S/
Animal and Plant Health Inspection Service

SUBJECT: APHIS Response and Request for Management Decisions on OIG Report, "Controls Over Select Agents" (33701-0002-21)

Thank you for the opportunity for the Animal and Plant Health Inspection Service (APHIS) to comment on this report. Although APHIS is proposing responses to some of the recommendations, their implementation affects the operation of the Federal Select Agent Program (FSAP) as a whole and not just APHIS individually. Because FSAP is jointly comprised of the Centers for Disease Control and Prevention's (CDC) Division of Select Agents and Toxins (DSAT) and APHIS' Division of Agricultural Select Agents and Toxins (DASAT), APHIS cannot unilaterally implement changes. Implementation of the OIG recommendations by APHIS DASAT will depend on coordination and further discussion with CDC's DSAT.

Section 1: Information System Accuracy
Finding 1: APHIS Needs to Ensure Information in eFSAP is Accurate and Complete

Recommendation 1
Develop and implement policy and procedures requiring file managers and supervisors to periodically review eFSAP to provide reasonable assurance that information about select agents and associated strains maintained by registered entities is accurate and complete.

It appears the program and OIG differ in the need for electronic Federal Select Agent Program information system (eFSAP) periodic reviews. The eFSAP clearly shows which select agents are in the possession of a registered entity and enough

characterization about those agents to satisfy regulations and allows FSAP to have effective oversight.

Sole review of eFSAP data would not provide any additional assurances that information about select agents and associated strains maintained by registered entities is accurate and complete. Only physical inspection of the facility and review of the inventory records (required by 7 CFR §331.17 and 9 CFR §121.17) can provide reasonable assurance information about select agents and associated strains maintained by registered entities is accurate and complete. During inspections, FSAP verifies whether the entity's records reflect an accurate, current inventory for each select agent and toxin listed on its' certificate of registration maintained in eFSAP.

APHIS proposes that OIG delete this recommendation.

Recommendation 2
Develop policies and procedures requiring file managers to review and document the verification and approval of detailed amendment documentation submitted by entities within eFSAP.

APHIS disagrees with this recommendation as written; however, APHIS agrees with the intent of this recommendation and proposes to rephrase it to: Develop policies and procedures for file managers to review and document that information submitted by registered entities is sufficient to approve an amendment.

It is unnecessary to further document verification of documents already in the record. The registered entities are required to submit sufficient information to process an amendment. The required information that registered entities must submit for registration amendments is available to the public at eFSAP Form 1 Amendment Instructions (selectagents.gov).

If OIG concurs, APHIS will implement the rephrased recommendation by June 30, 2022.

Recommendation 3
Develop and implement policies that require file managers to collaborate with entities to verify and obtain documentation that individuals with expired SRAs have been timely removed from accessing select agents.

APHIS disagrees with this recommendation as written; however, APHIS agrees with the intent of this recommendation and proposes to rephrase it to: Develop, implement, and document a collaboration process with the registered entities to ensure that individuals with expired security risk assessments (SRAs) are timely removed from access to select agents.

APHIS will follow up with the registered entities when an individual's SRA expires to verify with the Responsible Official (RO) that the individual's access has been removed and no additional documentation is required. Please also see the response to recommendation 4.

If OIG concurs, APHIS will implement the rephrased recommendation by June 30, 2022.

Recommendation 4
Modify eFSAP to capture and retain SRA expiration dates and to notify agency officials when SRAs have expired.

APHIS agrees with the recommendation.

On May 16, 2019, FSAP modified eFSAP to capture and retain SRA expiration dates. eFSAP has been modified to have access approvals automatically expire at midnight on the expiration date. eFSAP automatically posts a message on the registered entity's homepage notification list. APHIS staff can view the same notifications as entity officials. In addition, before the final expiration notification, the entity receives notice of expiring access for an individual at 90, 45, and 7 days prior to expiration.

Recommendation 5
Modify eFSAP to update and display the expiration date on required OMB forms.

APHIS agrees with the recommendation.

On May 12, 2021, the modification to eFSAP was completed and the expiration date is now displayed in the system.

Section 2: APHIS Oversight Controls
Finding 2: APHIS Needs to Improve its Oversight Controls

Recommendation 6
Develop and implement guidance that details how inspectors should document their justifications for determinations that entities complied with Federal regulations. Specifically, APHIS guidance should: (1) describe the information reviewed that led to a "pass" determination of compliance; (2) define the

meaning of "pass" statements, "fail" statements, "non-applicable" statements, and "not assessed" determinations.

It appears the program and OIG differ in the methodology for the program's inspection process. APHIS differs with OIG up to and including part (1) of this recommendation. APHIS agrees with the intent of the part (2) of this recommendation. APHIS proposes to rephrase part (2) of this recommendation to: Develop the definitions of "pass," "fail," "not applicable," and "not assessed" determinations in the standard operating procedure.

APHIS already complies with part 1 of this recommendation by using a comprehensive inspection checklist which describes all information required be reviewed during inspections. All inspectors undergo extensive training to teach them how to evaluate items listed on the checklists with emphasis on when to pass and when to fail an item. In addition, inspectors take internal and external continuous training to maintain and enhance their inspection skills. On the inspection checklist, when the inspector selects "pass," it means the registered entity met the select agent regulatory standard listed on the checklist and no additional information is needed.

Adding description of the information reviewed by the inspectors that led to a "pass" determination of compliance with the Federal regulations, would not benefit the program, nor the supervisors but only third-party reviewers.

All inspections have hundreds of checklist items that inspectors evaluate. Inspectors are professionals, highly trained in assessing entity compliance with the select agent regulations. Inspections are team efforts with multiple layers of review and represent only a snapshot of conditions at the entity at the time of inspection. For example, one joint inspection entailed 477 separate checklist items to which "comments" would potentially need to be added. If inspectors spend 5 minutes to justify "pass" determinations on each of the 477 items, then the inspectors would have to spend an estimated additional 40 hours documenting the inspection findings.

Please also see answer to recommendation 7.

If OIG concurs, APHIS will implement this rephrased recommendation. If OIG concurs, APHIS will implement the rephrased recommendation by June 30, 2022.

Recommendation 7
Develop and implement oversight controls to periodically review a sample of inspections completed by inspectors to ensure all conclusions and responses are adequately supported and accurate.

It appears the program and OIG differ in control validation methods.

For each inspection, APHIS has pre-and post-inspection staff meetings and supervisory reviews and approvals that provide oversight controls to monitor and evaluate performance and to support decisions made on each and every inspection. Performing secondary inspection evaluations would be redundant. APHIS always reviews all inspection reports to ensure that all conclusions and responses are adequately supported and accurate. Multiple APHIS staff members review findings during inspections and at the post-inspection debrief, with input from inspectors and specialists (as needed). Additionally, the proposed final report is reviewed by a supervisor prior to releasing the inspection report to the registered entity. This process is described in the inspection report procedures.

APHIS proposes that OIG delete this recommendation.

Recommendation 8
Establish oversight controls, such as a tracking report, to monitor the status of registered entities' progress to implement corrective actions. Establish procedures APHIS personnel should take to bring registered entities into compliance when corrective actions have not been timely resolved.

It appears the program and OIG differ in corrective actions; however, APHIS agrees with the intent of the first part of this recommendation. APHIS proposes to rephrase this recommendation to: Establish oversight controls, such as the use of a tracking report, and monitor the status of registered entities' progress to implement corrective actions.

There is no mandatory timeline to implement corrective actions. The timeline of corrective actions is contingent on the extent of the repairs or mitigations needed to comply with the select agent and toxin regulations. APHIS collaborates with registered entities to ensure that during the implementation of corrective actions (regardless of the duration), the entity remains in compliance with the select agent regulations. eFSAP allows tracking of inspections pending closure.

If OIG concurs, APHIS will implement the rephrased recommendation by June 30, 2022.

Recommendation 9
Train personnel on how to implement the new guidance established in Recommendations 6 through 8.

APHIS agrees with the recommendation. APHIS will provide training to staff as needed for any revisions to the new guidance.

APHIS will implement this recommendation by June 30, 2022.

Section 3: Improper Reporting
Finding 3: APHIS' Annual Report to Congress Needs Improvement

Recommendation 10
Establish procedures to report all notifications of all theft, loss, and releases that meet APHIS' definition of theft, loss, and release in APHIS' annual report to Congress.

It appears the program and OIG differ in procedural requirements. The establishment of any additional procedures is not warranted. APHIS and CDC provide a joint FSAP report to Congress that accurately reports all thefts, losses, and releases as required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and the Agricultural Bioterrorism Protection Act of 2002. These Acts outline what must be reported to Congress annually. Every report of theft, loss, or release is carefully reviewed by FSAP before it is reported, so that Congress already has the most accurate reports.

APHIS proposes that OIG delete this recommendation.

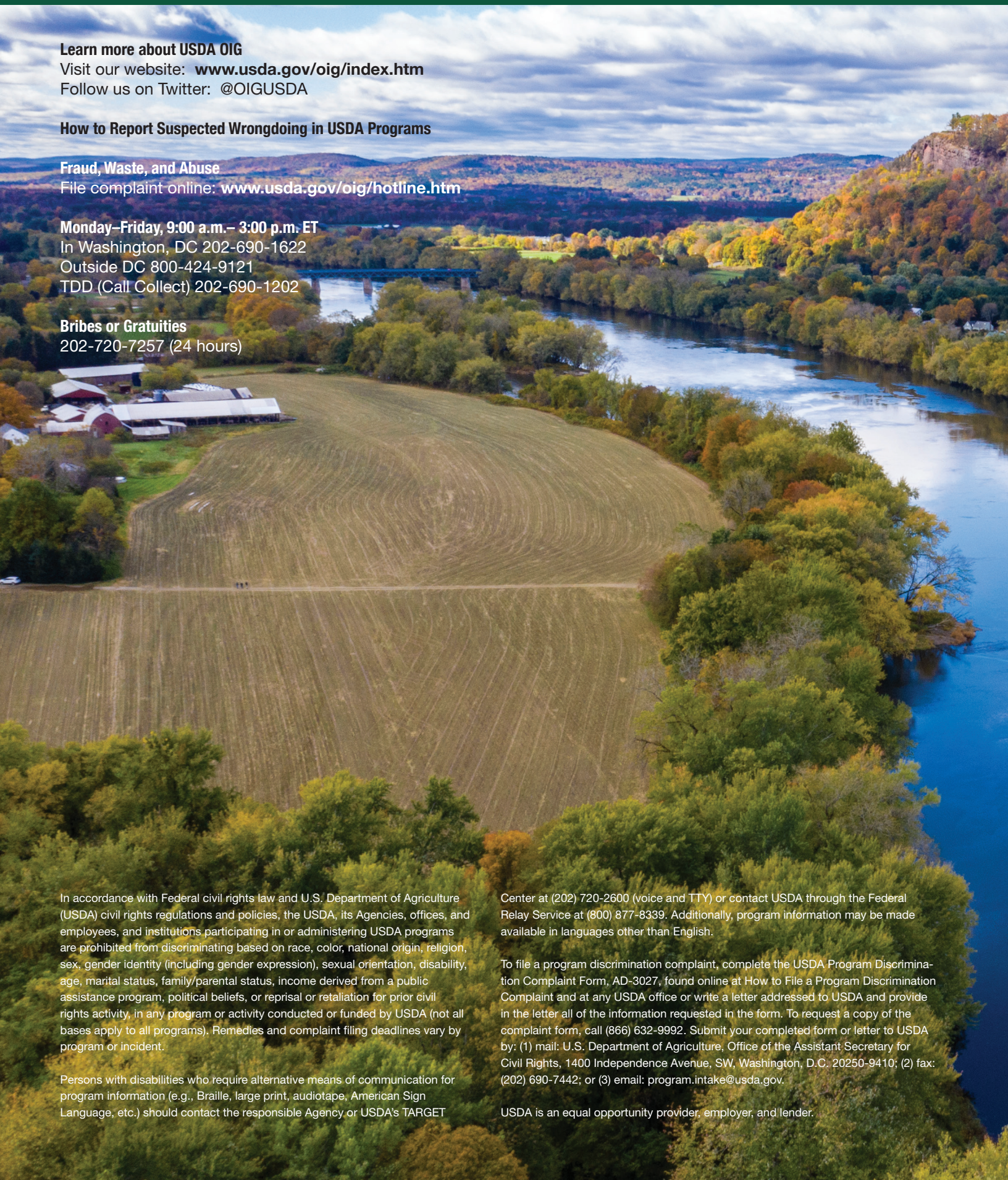
Recommendation 11
Evaluate, formalize, and document in the select agent and toxin regulations the definitions of and the reporting requirements for the "discovery;" "loss;" "theft;" and "release" of select agents and toxins.

APHIS disagrees with the recommendation as currently drafted. APHIS agrees with the intent of this recommendation. APHIS proposes to rephrase this draft recommendation to: Evaluate and formalize in the select agent and toxin regulations the definitions of the "discovery," "loss," "theft," and "release" of select agents and toxins.

We have deleted the verb "document" from the recommendation because the formal rulemaking process will satisfy this point. In addition, FSAP does not control the rulemaking process and will have to coordinate it with CDC and OMB as the CDC's and APHIS's rules must be published in the *Federal Register* simultaneously.

If OIG concurs, APHIS publish the final rule and implement the rephrased recommendation by December 31, 2023.

Thank you for the opportunity to respond. If you would like to discuss this response further, please contact Dr. Narda Huyke, at narda.huyke@usda.gov.



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