Proposed Rules

Federal Register
Vol. 89, No. 20
Tuesday, January 30, 2024

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 331

9 CFR Part 121

[Docket No. APHIS–2019–0018]

RIN 0579–AE52

Agricultural Bioterrorism Protection Act of 2002; Biennial Review and Republication of the Select Agent and Toxin List

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: In accordance with the Agricultural Bioterrorism Protection Act of 2002, we are proposing to amend and republish the list of select agents and toxins that have the potential to pose a severe threat to animal or plant health, or to animal or plant products. This Act requires the biennial review and republication of the list of select agents and toxins and the revision of the list as necessary. This action would implement findings from the biennial review for the list. The biennial review was initiated within 2 years of the completion of the previous biennial review. In addition, we are proposing to add definitions for several terms; codify policies regarding the role of responsible officials and alternate responsible officials, conclusion of patient care, and annual internal inspections; and revise or clarify provisions related to validated inactivation procedures and viable select agent removal methods, recordkeeping, non-possession of select agents and toxins, electronic Federal Select Agent Programs, registration, Tier 1 enhancements, and exclusion of naturally infected animals. We are also proposing to add requirements for reporting discoveries of select agents and toxins, provisions regarding effluent decontamination system, biosafety provisions for facility verification requirements for registered biosafety level 3 and animal biosafety level 3 laboratories, a new requirement related to restricted experiments, and to correct editorial errors. These proposed changes would economically benefit producers, research and reference laboratories, and State and Federal oversight agencies, while also maintaining adequate program oversight of select agents and toxins.

DATES: We will consider all comments that we receive on or before April 1, 2024.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov.* Enter APHIS–2019–0018 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2019–0018, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Commenters should not include any information in their comments or supporting materials that they consider confidential or inappropriate for public disclosure. APHIS will carefully consider all comments submitted in preparation of a final rule.

Supporting documents and any comments we receive on this docket may be viewed at *www.regulations.gov* or in our reading room, which is located in Room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 7997039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Jacek Taniewski, DVM, Director, Division of Agricultural Select Agents and Toxins, ERCS, APHIS, 4700 River Road, Riverdale, MD 20737; (301) 851–3352; *jacek.taniewski@usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (referred to below as the Bioterrorism Response Act) provides for the regulation of certain biological agents and toxins that have the potential to pose a severe threat to human, animal, and plant health, or to animal and plant products. The Animal and Plant Health Inspection Service (APHIS) has the responsibility for implementing the provisions of the Bioterrorism Response Act within the U.S. Department of Agriculture (USDA). Veterinary Services (VS) select agents and toxins, listed in 9 CFR 121.3, are those that have been determined to have the potential to pose a severe threat to animal health or animal products. Plant Protection and Quarantine (PPQ) select agents and toxins, listed in 7 CFR 331.3, are those that have been determined to have the potential to pose a severe threat to plant health or plant products. Overlap select agents and toxins, listed in 9 CFR 121.4, are those that have been determined to pose a severe threat to public health and safety, to animal health, or to animal products. Overlap select agents are subject to regulation by both APHIS and the Centers for Disease Control and Prevention (CDC), which has the primary responsibility for implementing the provisions of the Act for the U.S. Department of Health and Human Services (HHS). Together, APHIS and CDC comprise the Federal Select Agent Program (FSAP).

Title II, Subtitle B of the Bioterrorism Response Act (which is cited as the ''Agricultural Bioterrorism Protection Act of 2002'' and referred to below as the Act), section 212(a)(1)(A) (7 U.S.C. 8401(a)(1)(A)), provides, in part, that the Secretary of Agriculture (the Secretary) must establish by regulation a list of each biological agent and each toxin that the Secretary determines has the potential to pose a severe threat to animal or plant health, or to animal or plant products.

In determining whether to include an agent or toxin in the list, the Act (7 U.S.C. 8401(a)(1)(B)) requires that the following criteria be considered:

- The effect of exposure to the agent or toxin on animal or plant health, and on the production and marketability of animal or plant products;
- The pathogenicity of the agent or the toxicity of the toxin and the methods by which the agent or toxin is transferred to animals or plants;

• The availability and effectiveness of pharmacotherapies and prophylaxis to treat and prevent any illness caused by the agent or toxin;

• Whether such inclusion would have a substantial negative impact on the research and development of solutions for the animal and plant disease caused by the agent or toxin and whether the negative impact on research and development would substantially outweigh the risk posed by the agent or toxin to animal or plant health if it is not included on the list (added by the 2018 Farm Bill); and

• Any other criteria that the Secretary considers appropriate to protect animal or plant health, or animal or plant products.

Paragraph (a)(2) of section 212 of the Act (7 U.S.C. 8401(a)(2)) requires the Secretary to review and republish the list of select agents and toxins every 2 years and to otherwise revise the list as necessary. To fulfill this statutory mandate, APHIS convenes separate interagency working groups in order to review the lists of PPQ and VS select agents and toxins, as well as any overlap select agents and toxins, and develop recommendations regarding possible changes to the list using the five criteria for listing found in the Act.

Advance Notice of Proposed Rulemaking

Pursuant to this same paragraph of the Act, on March 17, 2020, we issued an advance notice of proposed rulemaking (ANPR) in the **Federal Register** (85 FR 15078–15079, Docket No. APHIS–2019–0018) in which we solicited public comment on the possible delisting of one PPQ select agent, *Peronosclerospora philippinensis,* formerly known as *Peronosclerospora sacchari,* one VS select agent, African horse sickness virus, and five overlap select agents, *Bacillus anthracis* (Pasteur strain), *Brucella abortus, B. suis,* and *B. melitensis,* and Venezuelan equine encephalitis virus. We took comment on the ANPR for 60 days, ending May 18, 2020. We received 224 comments by that time. They were from private citizens and stakeholders. We discuss the comments on the ANPR below.

Commenters overwhelmingly supported delisting of *B. abortus, B. suis,* and *B. melitensis.* We did not receive any comments relative to delisting *P. philippinensis* or African horse sickness virus. Additionally, we did receive adverse comments regarding our proposed possible removal of Venezuelan equine encephalitis virus (VEEV) and *Bacillus anthracis* (Pasteur strain).

Finally, we received two comments suggesting the delisting of *Ralstonia solanacearum* Race 3 biovar 2 and several comments suggesting delisting of other agents from the list of select agents and toxins. We acknowledge these requests but before we propose to delist or list an agent, it is reviewed by the Agricultural Interagency Select Agents and Toxins Technical Advisory Committee, or Ag-ISATTAC. In that regard, it is beneficial to clarify how those reviews take place. On a biannual basis, the Ag-ISATTAC, a Federal interagency committee of subject matter experts in domestic and transboundary animal diseases and toxins, reviews existing USDA select agents and toxins and makes recommendations regarding their continued listing, possible delisting, or addition of new agents/toxins, according to several risk categories. Until such time as the Ag-ISATTAC has recommended listing or delisting, we do not propose to do so. In the case of the additional changes to the list recommended by commenters, we have not received recommendations from the Ag-ISATTAC in support of the changes.

Based upon the subject matter expert scientific assessment conducted during the biennial review, the conclusions of which were referenced in the ANPR, along with consideration of the accompanying public comments received on the ANPR, we are proposing to delist *P. philippinensis,* African horse sickness virus, *B. abortus, B. suis,* and *B. melitensis* as select agents. As we discussed in the ANPR, the technical justification for the agents we are proposing to delist is the following:

• *Peronosclerospora philippinensis:* This agent is only able to survive and reproduce in the host plant and requires specific environmental conditions to become infectious, for which mitigations exist. (Food and Agriculture Organization of the United Nations, cited October 19, 2017; Murray, G.M. 2009; Purdue University Extension, cited October 20, 2017; USDA, 2013.)

• *African horse sickness virus:* This virus is difficult to successfully disseminate and effectively transmit. An effective vaccine exists. (Alberca, B, et al., 2014; Braverman, Y, 1996; Lulla, V., et al., 2017; Sanchez-Vizcaino, J.M., 2004; Spickler, 2015.)

• *Brucella abortus:* This agent presents little economic or animal health risk as it is unlikely to result in large-scale population introduction due to the high concentration of the agent necessary to produce disease as well as modern cattle production processes that limit animal-to-animal transmission routes. There is an efficacious vaccine, moderate immunity status within vulnerable populations, limited farm-to-farm transmission risk, and effective quarantine procedures. (Center for Food Security and Public Health, 2009; Moreno, E., 2014; Olsen, S.C., 2011.)

• *Brucella melitensis:* This agent, which primarily affects goats and sheep, is of lesser concern because the low farm-to-farm transmission risk due to modern production practices limits the chance of introduction on a scale large enough to impact domestic production. (The Center for Food Security and Public Health, 2009; Moreno, E., 2014; Olsen, S.C., 2011.)

• *Brucella suis:* This agent presents a low to moderate animal health risk due to limited farm-to-farm transmission risk as a result of modern production practices which reduce the risk of a large-scale introduction. (The Center for Food Security and Public Health, 2009; Stoffregen, W.C., 2006; World Organizsation for Animal Health (OIE), 2017; Zhu, L., et al., 2016.)

In addition, we are proposing to retain Venezuelan equine encephalitis virus and *Bacillus anthracis* (Pasteur strain) as select agents.

We appreciate all comments received from the ANPR and will consider these comments in future deliberations.

We are also proposing additional changes to the regulations beyond those discussed in the ANPR. Certain of these would be codifications of existing operational policy. These include provisions related to: Discovery of a select agent or toxin, disposal of select agent waste after conclusion of patient care, the exclusion of animals naturally infected with select agents from the requirements of the regulations, allowing individuals other than the responsible official (*e.g.,* principal investigators) to revise inactivation procedure documentation, removal procedures, and the content of annual internal inspections.

Many of the proposed revisions are intended to clarify existing provisions of the regulations. These include proposed definitions of *loss, release,* and *theft;* clarifying reporting requirements for ''discovered'' select agents or toxins, a clarification regarding what constitutes an acceptable ''validated inactivation procedure,'' clarifications related to the existing reporting requirements, clarifying that certificates must accompany transfers of a select agent or toxin, including intra-entity transfers, clarifying that the documentation in the IT system for the FSAP program serves as official records required by the regulations, clarifying the documentation that may be needed for the issuance of a certificate of

registration, clarifying that a responsible official cannot be approved as the responsible official at more than one registered entity and cannot be the sole alternate responsible official at another registered entity, clarifying requirements related to restricted experiments, clarifying the notification requirements for changes to the application for registration, and clarifying the scope of pre-access suitability assessments.

Lastly, there are certain provisions that would be new. They include: Provisions regarding effluent decontamination system, biosafety provisions for facility verification requirements for registered biosafety level 3 and animal biosafety level 3 laboratories, and a new requirement related to restricted experiments.

We discuss the codifications of existing policy, the proposed clarifications, and the new provisions immediately below, by topic.

Discovery of Select Agents or Toxins

Since 2003, the FSAP has received at least 100 instances of reports from entities that ''discovered'' a select agent or toxin in their possession for which the entity was not registered to possess and neither an exemption nor an exclusion to compliance with the select agent and toxins regulations applied. Many of the select agents and toxins ''discovered'' were from studies associated with personnel who had left their entity, such as a research institution, and the custodianship of samples was not reassigned. Some of the materials were labeled with obsolete pathogen names, where other ''discovered'' materials were found in laboratories where their active use had ceased, in some cases, decades prior to the establishment of the select agent and toxin regulations. Discovery of a select agent in situations when there is an unexpected finding of the select agent as described above, is mutually exclusive from regulatory applications when instances of a theft, loss, or release of a select agent occur.

Since 2003, unless an exemption applied or the select agent was excluded from the requirements of the select agent and toxin regulations, unregistered possession of a select agent or toxin on the HHS or USDA select agent and toxin list is a regulatory violation that could subject an individual or entity to civil and/or criminal penalties.

APHIS continues to receive reports from registered and non-registered entities who find themselves in possession of select agents and toxins that they are not registered to possess and to which neither an exemption nor exclusion applies. We are proposing to revise 9 CFR 121.2 and 7 CFR 331.2 of the regulations to codify this longstanding operational policy by clarifying that any individual or entity in possession of a select agent or toxin, for which an exclusion or exemption listed in 9 CFR part 121 or 7 CFR part 331 does not apply, and that is not included on a certificate of registration issued by the HHS Secretary or APHIS Administrator for that individual or entity, must immediately report such possession to either the APHIS Administrator or the HHS Secretary.

To date, when registered and non-registered entities have reported such ''discoveries,'' they have often done so on an APHIS/CDC Form 3. However, the APHIS/CDC Form 3 is for reporting of thefts, losses, and releases, and not for discoveries. To facilitate such reporting for discoveries, HHS and USDA plan to create, in compliance with the Paperwork Reduction Act, a new APHIS/CDC Form 6 that will require submission of information regarding the discovery of a select agent or toxin. Establishing a standard form for reporting will enable HHS and USDA to better understand the circumstances and assess regulatory violations related to the possession of a ''discovered'' select agent and/or toxin. We would also add reference to this form in the regulations.

We are also proposing to add a definition for the term *Discovery* to 7 CFR 331.1 and 9 CFR 121.1 of the regulations to distinguish a ''discovery'' from a ''theft,'' ''loss,'' and ''release'' and to clarify the scope of the reporting requirement for discoveries. We would define *Discovery* to mean the finding of a select agent or toxin by an individual or entity that is not aware of the select agent or toxin's existence. Examples would include, but would not be limited to, the following:

- A registered individual or entity finds a select agent or toxin not accounted for in their inventory; or
- A non-registered individual or entity finds a select agent or toxin.

Disposal of Select Agent Waste After Conclusion of Patient Care

In 7 CFR 331.3(d)(8), 9 CFR 121.3(d)(8) and 9 CFR 121.4(d)(8), the regulations provide that waste generated during the delivery of patient care by health care professionals from a patient diagnosed with an illness or condition associated with a select agent is excluded from the requirements of the regulations, provided that the waste is decontaminated or transferred for destruction by complying with State and Federal regulations within 7 calendar days of the conclusion of patient care. Additionally, 9 CFR 121.5(a)(3) and 9 CFR 121.6(a)(3) exempt from the regulations diagnostic laboratories and other entities that collect clinical or diagnostic specimens from a patient infected with a select agent provided that, among other requirements, the specimens are transferred in accordance with § 121.16 or destroyed on-site within 7 calendar days after delivery of patient care by health care professionals has concluded.

In this rulemaking, APHIS is proposing to codify in regulation a current operational policy that, for an individual who has been admitted to a medical facility, that individual's ''conclusion of patient care,'' and the point when ''delivery of patient care by health care professionals has concluded,'' is when an individual is released from the medical facility where treatment was being provided by the medical facility or physician. If the patient is seen by the physician or medical facility for follow-up care (*e.g.,* 6 month follow-up visit), such follow-up care would be considered a new delivery of patient care. The policy that we are codifying further clarifies that the exclusion is intended for select agent waste generated during the treatment of humans and is not intended to apply to animals receiving veterinary care, or plants or plant products submitted for diagnostic purposes.

Exclusion of Animals Naturally Infected With Select Agents

In this rulemaking, we are proposing to codify in regulation the current policy regarding when animals naturally infected with select agents are excluded from the requirements of the regulations. Sections 121.3(d)(1) and 121.4(d)(1) in 9 CFR of the regulations provide for exclusion of select agents occurring in their natural environment. Mere possession of an animal that is naturally infected with a select agent, either within its natural environment or having been transported to an artificially established environment, meets the criteria of this exclusion. However, the removal of an animal that is infected with a select agent from its natural environment to an artificially established environment for the purpose of the intentional exposure or introduction of a select agent to a naïve or experimental animal, or the introduction of a naïve animal to a natural environment where there is an animal that is naturally infected with a select agent for the purpose of the intentional exposure or introduction of a select agent to the naïve or

experimental animal, does not meet the exclusion criteria. To provide an example, avian influenza virus is listed in § 121.3(b) as a VS select agent. When animals within a poultry flock are confirmed to be naturally infected with highly pathogenic avian influenza, the individual infected animals are not subject to the select agent requirements based on possession of the animals. However, if animals from the same flock were sold to a research facility for the purpose of intentionally exposing naïve animals to these naturally infected animals during a disease transmissibility study, that study and the associated animals would be subject to the select agent requirements.

We are proposing to revise the two sections to clarify the scope of the exclusion.

Finally, please note that when such infected animals are involved there may be existing USDA disease control programs and requirements regarding the management, movement, and disposition of infected animals. Additionally, even if an animal is confirmed to be naturally infected with a select agent and is excluded from the select agent and toxin regulations, there may still be transfer and/or transport restrictions placed upon its movement based upon specific Federal and/or State requirements.

Inactivation

The regulations in 7 CFR 331.3(d)(4), 9 CFR 121.3(d)(4), and 9 CFR 121.4(d)(4) provide an exclusion from the requirements of the regulations for a select agent or regulated nucleic acids that can produce infectious forms of any select agent virus that has been subjected to a validated inactivation procedure that is confirmed through a viability testing protocol. The exclusion further specifies that surrogate strains that are known to possess equivalent properties with respect to inactivation can be used to validate an inactivation procedure; however, if there are known strain-to-strain variations in the resistance of a select agent to an inactivation procedure, then an inactivation procedure validated on a lesser resistant strain must also be validated on the more resistant strains.

We are proposing several revisions (discussed in detail below) related to the inactivation exclusion discussed above.

We are clarifying what constitutes an acceptable ''validated inactivation procedure.'' Specifically, we are proposing to revise the exclusion discussed above so that a select agent or regulated nucleic acids that can produce infectious forms of any select agent virus would be excluded from the requirements of the regulations if subjected to a validated inactivation procedure, provided that:

- In-house validation of the inactivation procedure is completed prior to use;
- A certificate of inactivation (discussed below) has been generated in accordance with the regulations;
- For use of a select agent surrogate to validate an inactivation procedure, the select agent surrogate chosen is known to possess equivalent properties with respect to inactivation, and, if there are known variations in the resistance of a select agent to an inactivation procedure, including strain to strain, then the inactivation procedure must also be validated using the most resistant select agent surrogate; and
- For use of a whole tissue or homogenized tissue surrogate to validate a chemical inactivation procedure for other tissues, including those in other animal or plant models, all standardized conditions must be held constant such as the select agent used, the tissue volume, and the ratio of tissue to volume of inactivating material; a safety margin must be incorporated into the final inactivation procedure to ensure the effective inactivation of the select agent; and the tissue surrogate is either expected to have the highest concentration of the specific select agent to be inactivated, or the concentration of the select agent in the tissue is determined and this select agent concentration is not exceeded when applying the validated inactivation procedure on subsequent tissue samples.

The purpose of these revisions is to indicate that the inactivation procedure must have been validated in-house and must have been validated in a manner that provides assurances regarding its general suitability and use within that facility. The regulations in 9 CFR 121.5(a) and 9 CFR 121.6(a) currently also exempt diagnostic laboratories and other entities that possess, use, or transfer a select agent or toxin that is contained in a specimen presented for diagnosis or verification from the requirements of the regulations, if, among other requirements, the select agent or toxin is destroyed on-site within 7 calendar days using an approved inactivation process. We are proposing to revise this exemption so that if an inactivation process is used, it meets the parameters in the above exclusion, as revised. We are also clarifying that such an inactivation process may not necessarily entail physical destruction of the select agent or toxin.

We are also proposing a new exclusion related to inactivation in 7 CFR 331.3(d), 9 CFR 121.3(d), and 9 CFR 121.4(d). Specifically, we propose to exclude from the requirements of the regulations any select agent or regulated nucleic acid that can produce infectious forms of any select agent virus if the material is contained in a formalin-fixed paraffin-embedded tissue that has been effectively inactivated by a recognized method for that particular agent or regulated nucleic acid. This would exclude from the requirements of the regulations, as an example, appropriately prepared histopathology samples that have undergone satisfactory formalin fixation and further paraffin embedding processes that result in a quality sample. In this example, such properly prepared samples that will yield a usable histopathology sample provide assurances that the additional processing steps required to prepare an acceptable formalin-fixed, paraffin-embedded tissue sample will result in agent inactivation.

The regulations in 7 CFR 331.9(a) and 9 CFR 121.9(a) require individuals or entities required to register under the regulations to designate an individual to be the responsible official for the individual or entity. One of the current responsibilities of the responsible official is to review, and revise as necessary, each of the entity's validated inactivation procedures or viable select agent removal methods (7 CFR 331.9(a)(9); 9 CFR 121.9(a)(9)).

We are proposing to codify a policy that allows individuals besides the responsible official (*e.g.,* principal investigators) to revise the inactivation procedures, if necessary. Responsible officials would still be responsible for ensuring the revision occurs but would not necessarily have to revise the procedure themselves. This revision is being proposed because, often, the principal investigators are the subject matter experts when it comes to the procedures and are the most qualified to enact revisions to the inactivation procedures.

Finally, we are proposing to revise the existing definition of *validated inactivation procedure* in 7 CFR 331.1 and 9 CFR 121.1. Currently, we define the term as ''[a] procedure, whose efficacy is confirmed by data generated from a viability testing protocol, to render a select agent non-viable but allows the select agent to retain characteristics of interest for future use; or to render any nucleic acids that can produce infectious forms of any select agent virus non-infectious for future use.'' As revised, to be consistent with

its use in our proposed revisions to the exclusion and exemption noted above, we would specify that the validated inactivation procedure must be conducted in-house and must have its efficacy confirmed by an in-house viability test, and would clarify that, if used on nucleic acids of a select agent virus, it must render the nucleic acids incapable of producing infectious virus.

Removal

In addition to inactivation, the regulations in 7 CFR 331.3(d)(5), 9 CFR 121.3(d)(5), and 9 CFR 121.4(d)(5) also provide for an exclusion from the requirements of the regulations for material containing a select agent that is subjected to a procedure that removes all viable select agent cells, spores, or virus particles if the material is subjected to a viability testing protocol to ensure that the removal method has rendered the material free of all viable select agent. We are proposing to revise this exclusion to reflect current operational practices and policies. As revised, it would exclude from the requirements of the regulations material containing a select agent that is subjected to a validated viable select agent removal procedure, provided that all of the following conditions are met:

- In-house validation of the viable select agent removal procedure is completed prior to use;
- A certificate of viable select agent removal (discussed below) has been generated in accordance with § 121.17(a)(8) or § 331.17(a)(8);
- For use of a surrogate to validate a viable select agent removal procedure, only surrogates known to possess equivalent properties with respect to removal are used; and
- A portion of each subsequent sample has been subjected to a verification viability testing protocol to ensure that the validated viable select agent removal procedure has rendered the material free of all viable select agent.

In a similar manner to our proposed revisions to the exclusion based on inactivation in 7 CFR 331.3(d)(4), 9 CFR 121.3(d)(4), and 9 CFR 121.4(d)(4), the intent of these revisions is to indicate that the removal procedure must be validated in-house as appropriate and effective for the facility's particular circumstances. We are also proposing to add to the definitions in 7 CFR 331.1 and 9 CFR 121.1 the term *Validated removal procedure,* which we propose to define as ''a procedure, whose efficacy has been confirmed by data generated in-house from a viability testing protocol, to confirm removal of all viable select agent, or nucleic acids of any select agent virus capable of producing infectious virus.''

Currently, the definition of *Viability testing protocol* in 7 CFR 331.1 and 9 CFR 121.1 does not include reference to removal procedures. However, given that we are proposing to include viability testing protocols in our proposed revision to the removal procedures, it is correspondingly necessary to revise the definition of *Viability testing protocol* to include such reference. We would also specify that it must be conducted in-house. We would also add to the definitions in 7 CFR 331.1 and 9 CFR 121.1 a definition of the term *Verification viability testing protocol.* We would define this term as ''a protocol, used on samples that have been subjected to a validated inactivation or removal procedure, to confirm the material is free of all viable select agent, or nucleic acids of any select agent virus capable of producing infectious virus.''

Finally, wherever the exclusion related to removal is currently discussed in other provisions of the regulations, we are proposing harmonizing changes to ensure the terminology remains consistent with our proposed revisions to that exclusion.

Loss, Release, and Theft

The terms *loss, release,* and *theft* are used in several instances in the existing regulations. For example, 7 CFR 331.19 and 9 CFR 121.19 discuss the notification requirements for loss, release, and theft. Additionally, 7 CFR 331.3(f) and 9 CFR 121.3(f) also contain an exclusion from the requirements of the regulations for any select agent or toxin seized by a Federal law enforcement agency during the period between seizure of the agent or toxin and the transfer or destruction of such agent or toxin provided that, among other requirements, the Federal law enforcement agency safeguards and secures the seized agent or toxin against theft, loss, or release, and reports any theft, loss, or release of such agent or toxin. However, the terms *loss, release,* and *theft* are not currently defined within the regulations. We are proposing definitions for each of these terms in 7 CFR 331.1 and 9 CFR 121.1 to clarify their meaning.

We are proposing to define *loss* as ''the inability to account for a select agent or toxin known to be in the individual or entity's possession.''

We are proposing to define *release* as any of the following:

- An incident resulting in occupational exposure to a select agent or toxin;
- An incident resulting in animal/plant exposure to a select agent or toxin;
- The failure of equipment used to contain a select agent or toxin such that it is reasonably anticipated that a select agent or toxin was released;
- The failure of or breach in personal protective equipment in the presence of a select agent or toxin; or
- The failure of biosafety procedures such that it is reasonably anticipated that a select agent or toxin was outside of containment.

Finally, we are proposing to define *theft* as the unauthorized taking and removing of a select agent or toxin from the possession of an entity or individual.

Recordkeeping

The regulations in 7 CFR 331.17 and 9 CFR 121.17 contain recordkeeping requirements for individuals and entities required to register pursuant to the regulations. We are proposing amendments to these sections to ensure an accurate, current inventory is maintained for all select agents and toxins held in long-term storage. Specifically, the section is being modified to add more specific language regarding from whom material is acquired and the date the agent was removed and returned from the storage locations to more specifically define required recordkeeping information.

We are proposing to require that records contain:

- The quantity acquired and the name of the individual by whom it was acquired. The quantity acquired is currently one of the recordkeeping requirements; the name of the individual by whom it was acquired would be new.
- The location where the select agent or toxin is stored (*e.g.,* building, room number or name, and freezer identification or other storage container). This is an existing requirement, but we are clarifying that the salient information is not the manner in which it is stored (*e.g.,* freezer versus non-refrigerated unit) but where in the facility it is stored.
- The date the agent was removed and returned, the purpose for using the agent, the name of the individual who removed and returned the agent, and when applicable, date of final disposition of the agent and by whom. This would clarify the existing recordkeeping requirement to keep records of when an agent is removed or returned; we require a record of the calendar date, but not specific times within that day.
- For intra-entity transfers (sender and the recipient are covered by the

same certificate of registration), name of the select agent or toxin, the date of the transfer, the number of items transferred or number of vials or quantity of toxin transferred, the name of the sender, and the name of the recipient. The current recordkeeping requirement is substantially similar but only specifically refers to select agents, whereas the intent is that it applies both to select agents and toxins.

The regulations in 7 CFR 331.17(a)(8)(vii) and 9 CFR 121.17(a)(8)(vii) also currently require individuals and entities to maintain, for select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or a procedure for removal of viable select agent, a certificate, signed by the principal investigator, that includes the date of inactivation or viable select agent removal, the validated inactivation or viable select agent removal method used, and the name of the principal investigator. The regulations further specify that a copy of the certificate must accompany any transfer of inactivated or select agent removed material.

We are proposing several revisions to the records needed for inactivated or select agent-free material created by an entity. We are proposing to allow a designee to sign the certificate of inactivation on behalf of a principal investigator, so that certificates may be signed during the principal investigator's absence. We are further proposing that certificates must be signed within 7 days after completion of the validated inactivation or validated viable select agent removal, so that a significant amount of time does not elapse between when the inactivation or removal occurs and when the certificate is issued. We are also proposing that records must be maintained for as long as the material is in the possession of the registered individual or entity plus an additional 3 years, and clarifying the requirement that certificates must accompany any transfers, and that such transfers include intra-entity transfers. Principal investigator is defined in the regulations as the one individual who is designated by the entity to direct a project or program and who is responsible to the entity for the scientific and technical direction of that project or program. When a principal investigator is unavailable (such as out of the office) to review the results of a select agent that has been subjected to a validated inactivation or removal procedure, a temporary designee (appointed by the principal investigator and approved of by the responsible official) may sign the inactivation certificate to allow for work to continue. The temporary designee must be listed on the entity's registration and have the knowledge and expertise to provide scientific and technical direction regarding the validated inactivation procedure or the procedure for removal of viable select agent to which the certificate refers. The appointment of a designee to sign certificates is not for regular substitution of the principal investigator, such as the principal investigator relinquishing this requirement to other individuals in the laboratory due to normal work demands or general unavailability.

Non-Possession of Select Agent or Toxin

When an individual or entity registers to possess a select agent or toxin, they agree to comply with the standards in the regulations regardless of whether they currently possess or plan on possessing the agent or toxin. Registration is a choice, and indicates readiness to possess, use, or transfer select agents or toxins; the specific select agents or toxins for which the facility is registered are listed on its registration certificate. Although an entity does not need to have intent to possess a select agent or toxin to be registered, in most cases, registered entities for a select agent or toxin possess or are in the process of acquiring the select agent or toxin.

Should these plans change, prior to registration, an individual or entity may ask FSAP to hold review and processing of their registration application at any point. They may, also, choose to terminate their registration certificate at any time, if they no longer possess a select agent or toxin and no longer wish to be registered. Lastly, prior to required annual inspections and triannual renewal of registration, FSAP will ask a non-possessing entity if they desire to continue to be registered since there are agency and entity-related regulatory compliance costs associated with maintaining registration.

Despite the foregoing considerations, there are a few registered entities, primarily academic institutions, who have never possessed the select agent or toxin for which they are registered and have no current plans to obtain it, yet still wish to remain registered. We propose to revise the regulations in order to clarify that these entities must meet all regulatory requirements for registered entities should they continue to desire to maintain registration.

Electronic Federal Select Agent Program (eFSAP) Information System

As discussed previously in this document, the regulations sometimes require individuals and entities to submit reports and maintain records pursuant to the terms of the regulations. The regulations currently do not provide, however, how such reports may be submitted or how such records are to be maintained.

APHIS currently utilizes a highly secure information system, the eFSAP information system, to conduct all select agent program activities. The eFSAP information system is a two-way communication portal, which is accessible by both CDC and APHIS staff and the regulated community. For users at registered entities, benefits of the system include reduced paperwork, increased ease of validating and submitting information, and reduced processing time for requests (as real-time information exchange allows for increased responsiveness). Based on the implementation of the eFSAP information system, APHIS is proposing to update the regulations to indicate that reports (*e.g.,* APHIS/CDC Forms 2, 3, and 4) and requests (*e.g.,* amendments to registration) can be submitted via the eFSAP information system (or successor IT system as specified by APHIS in guidance). In addition, APHIS is proposing to update the regulations to clarify that the electronic documentation in the eFSAP information system serves as official records required by the select agent and toxin regulations, and once submitted in the eFSAP information system, there is no requirement for entities to retain a separate copy.

Registration

Unless exempted by the regulations, individuals and entities are required to have a certificate of registration issued by the APHIS Administrator to possess, use, or transfer select agents or toxins (7 CFR 331.7(a); 9 CFR 121.7(a)). This certificate of registration denotes approval for the select agents and/or toxins that an individual or entity is authorized to possess, use, and/or transfer; the specific activities the individual or entity is approved to conduct related to the registered select agents and/or toxins; the persons authorized to access the select agents and/or toxins; and the locations (buildings, rooms, suites of rooms, storage facilities, etc.) where select agents and/or toxins are authorized to be present as described in the entity's APHIS/CDC Form 1.

The regulations currently indicate that issuance of a certificate of registration may be contingent upon inspection or submission of additional information, such as the security plan, biosafety plan, incident response plan, or any other documents required to be prepared to meet the requirements of the select agent and toxin regulations (7 CFR 331.7(g) and 9 CFR 121.7(g)). This provision could be construed to suggest that the security plan, biosafety plan, and incident response plan are each mutually exclusive, illustrative examples of additional information that APHIS may request, but that we would not request more than one of the examples. This is, however, not the case. Depending on the circumstances of the facility, we may request any or all of the documents listed in this provision. We are proposing to clarify that this may be the case.

Additionally, currently, the regulations in 7 CFR 331.7(i) and 9 CFR 121.7(i) state that a certificate of registration may be amended to reflect changes in circumstances (*e.g.,* replacement of the responsible official or other personnel changes, changes in ownership or control of the entity, changes in the activities involving any select agents or toxins, or the addition or removal of select agents or toxins). However, this amendment is not discretionary. Each of the illustrative examples currently provided in the regulations could have a direct, material adverse impact on the possession and use of the select agents and toxins at the entity, and the entity's certificate of registration must be amended to reflect those changes. We are proposing to clarify that such an amendment is not discretionary.

Responsible Official and Alternate Responsible Official

As we mentioned previously in this document, the regulations in 7 CFR 331.9(a) and 9 CFR 121.9(a) require individuals or entities required to register under the regulations to designate an individual to be the responsible official for the individual or entity. The regulations require the responsible official to have a physical, and not merely telephonic or audio/visual, presence at the registered entity to ensure compliance with the regulations and respond in a timely manner to onsite incidents (7 CFR 331.9(a)(5); 9 CFR 121.9(a)(5)). This requirement effectively precludes a responsible official from serving as the primary responsible official for two separate registered entities, because the responsible official cannot be physically present at both entities simultaneously. Likewise, although the regulations allow the responsible official for one registered entity to serve as an alternate responsible official for another registered entity, the regulations do not currently provide that the official cannot be the sole alternate responsible official at the other entity; such an allowance would, again, run the risk of requiring the official to be physically present at two entities simultaneously. Accordingly, we are proposing to amend the regulations to clarify that a responsible official cannot be approved as the responsible official at more than one registered entity and cannot be the sole alternate responsible official at another registered entity. We are, however, proposing to allow an individual who has been approved as an alternate responsible official at one entity to also be able to be approved to be an alternate responsible official at another registered entity.

Annual Internal Inspections

The regulations at 7 CFR 331.9(a)(6) and 9 CFR 121.9(a)(6) currently require responsible officials to ensure that annual inspections are conducted of each registered space where select agents or toxins are stored or used to ensure compliance with the requirements of the regulations. The results of each inspection must be documented, and any deficiencies identified during an inspection must be corrected and the corrections documented. However, the content of the inspections themselves is not specified. We are therefore proposing to codify the current policy that an entity's annual internal inspections must address whether:

- The entity's biosafety/biocontainment plan is being effectively implemented as outlined in the regulations (7 CFR 331.12 and 9 CFR 121.12, respectively).
- The entity's security plan is being effectively implemented as outlined in the regulations (7 CFR 333.11 and 9 CFR 121.11, respectively).
- The entity's incident response plan is implemented to ensure whether the entity is able to respond, as outlined in the regulations (7 CFR 331.14 and 9 CFR 121.14, respectively).
- Each individual with access approval from the Administrator or HHS Secretary has received the appropriate training as outlined in the regulations (7 CFR 331.15 and 9 CFR 121.15, respectively).

Tier 1 Security Enhancements

Currently, the regulations in 9 CFR 121.3 specify that certain VS select agents and toxins are Tier 1; the current VS Tier 1 select agents are foot-and-mouth disease virus and rinderpest virus. The regulations further specify that Tier 1 select agents are subject to additional requirements relative to other VS select agents and toxins. Currently, among these additional requirements is a requirement that registered entities with Tier 1 select agents must have procedures for screening visitors, including their property, and vehicles, at the entry and exit points to the registered space or at other designated points of entry to the building, facility, or compound that are based on the entity's site-specific risk assessment (9 CFR 121.11(f)(4)(iii)).

This requirement could be construed to suggest that the facility must authorize visitors to enter the facility, whereas the intent is to specify that, if the facility does allow visitors, they must be screened at an appropriate checkpoint. Accordingly, we propose to revise the provision to require procedures for screening any visitors, their property, and, where appropriate, vehicles at entry points to registered space based on the entity's site-specific risk assessment.

Biosafety—Facility Verification

The CDC has established guidelines for four biosafety levels for laboratories engaged in microbiological and biomedical laboratories (Biosafety in Microbiological & Biomedical Laboratories (BMBL), current edition). Biosafety level 3 facilities are facilities that possess an agent with a known potential for aerosol transmission and that may cause serious or potentially lethal disease in humans. The CDC has also established parallel animal biosafety level 3 biosafety guidelines for facilities that possess an agent with a known potential for aerosol transmission and that may cause lethal disease in animals.

Because of the unique and significant biosafety risks at such facilities, we are proposing to amend 7 CFR 331.12 and 9 CFR 121.12 to require facility verification every 12 months for registered entities that maintain biosafety level 3 and animal biosafety level 3 laboratories. The verifications would also have to be documented to confirm that systems are in place to monitor, maintain, and validate performance of the facility's containment functions, such as inward directional airflow, decontamination systems, as well as preventative maintenance conducted to ensure all systems are functioning appropriately to maintain containment during normal operations. Therefore, we also are proposing to amend 7 CFR 331.12 and

9 CFR 121.12 to require the entity to document facility verification and require the entity to verify the facility's containment functions.

APHIS does not believe that the new provisions will create an additional burden to entities that maintain biosafety level 3 and animal biosafety level 3 laboratories because we believe these entities are already performing such annual facility verifications. However, if a registered entity has not been performing annual facility verifications for biosafety level 3 and animal biosafety level 3 laboratories, we would be interested in comments concerning the cost and burden of annual facility verifications, especially if the entity is considered a small business.

Biosafety—Effluent Decontamination Systems

Biosafety level 3 and biosafety level 4 facilities are highly sophisticated facilities built to contain biological agents and toxins with the highest potential to threaten agricultural, plant, and public health and safety. Any defect, such as a crack or leaky pipe, could have severe consequences. For example, in August 2007, foot-and-mouth disease virus was discovered at farms in the United Kingdom. The source of the contamination was determined to be long-term damage and leakage of a drainage system used by a high-containment laboratory working with the foot-and-mouth disease virus. As such, APHIS is proposing to amend the security (7 CFR 331.11 and 9 CFR 121.11), biosafety (7 CFR 331.12 and 9 CFR 121.12), and incident response (7 CFR 331.14 and 9 CFR 121.14) sections of the select agent and toxin regulations to address risks posed by the effluent decontamination systems used by biosafety level 3 and biosafety level 4 facilities.

If an effluent decontamination system is used by an entity possessing and using select agents and toxins, to comply with the regulations, the entity would have to include in its plans how it will address security, biosafety, and incident response as it relates to the system. Specifically, the biosafety plan, to ensure it contains adequate biosafety and containment procedures, would have to provide for verification that the liquid waste generated from registered space is sufficiently treated to prevent the release of a select agent or toxin prior to discharge of the waste from the facility. The security plan, to ensure it contains adequate safeguards for select agents and toxins for any space not listed on the entity's registration that contains a portion of an effluent decontamination system, would have to describe procedures to prevent the theft, loss, release, or unauthorized access to a select agent or toxin. The incident response plan, to ensure it contains adequate response procedures, would have to fully describe the entity's response procedures for the theft, loss, or release of a select agent or toxin; the failure of an effluent decontamination system resulting in a release of a select agent or toxin; and how personnel will access an area potentially containing a select agent or toxin due to the failure of an effluent decontamination system.

Restricted Experiments

The regulations in 7 CFR 331.13 and 9 CFR 121.13 place restrictions on the experiments that registered entities or individuals may conduct and on their possession of products resulting from such experiments. Under the regulations, restricted experiments are experiments that involve the deliberate transfer of, or selection for, a drug or chemical resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture, and experiments that involve the deliberate formation of synthetic or recombinant nucleic acids containing genes for the biosynthesis of select toxins lethal for vertebrates at an $LD_{50} < 100$ ng/kg body weight.

Due to heightened biosafety concerns of research involving potential pandemic pathogens and emerging diseases, increased emphasis on oversight of products of restricted experiments is being proposed. To ensure that an entity has the appropriate safeguards to work with the product of a select agent or toxin resulting from a restricted experiment, APHIS is proposing to clarify the provision that the receiving entity of a transfer must amend their certificate of registration and receive approval by CDC or APHIS to possess the products of a restricted experiment. Entities are currently required to obtain approval to conduct restricted experiments and possess the product of a select agent or toxin resulting from a restricted experiment.

Training

The regulations in 9 CFR 121.15 require individuals or entities registered to possess, use or transfer select agents or toxins to provide information and training on biocontainement, biosafety, security, and incident response to individuals with access to select agents or toxins. APHIS is proposing revisions to the training requirements in accordance with the new mandate in the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (42 U.S.C. 262a(k)(1); Pub. L. 117–328) amendment of subsection (b)(1). These revisions have been made in an effort to comply with the statutory amendment that states training requirements for (1) unapproved individuals whose responsibilities routinely place them in close proximity to laboratory facilities and (2) those individuals who perform administrative or oversight functions. Trainings must be completed within 6 months after publication of a final rule for this proposed rulemaking.

Miscellaneous

We are proposing to remove the definition of the term *permit* from 7 CFR 331.1. We currently define the term as ''a written authorization by the Administrator to import or move interstate select agents or toxins, under conditions prescribed by the Administrator.'' However, the term is only used once in 7 CFR part 331, specifically in 7 CFR 331.11(c)(9)(i) and is used as a verb. Additionally, it is used in that one instance with the dictionary definition of allowing or authorizing an action to occur. For these reasons, the definition of the term *permit* serves no function and its removal is appropriate.

In 7 CFR 331.3(b), *Ralstonia solanacearum* is listed as a select agent. However, only *Ralstonia solanacearum* Race 3 biovar 2 poses a severe threat to plant health or plant products and merits inclusion on the list of select agents; other races and biovars are less pathogenic. We propose to amend this section accordingly.

The regulations in 7 CFR 331.3(e)(1), 9 CFR 121.3(e)(1), and 9 CFR 121.4(e)(1) currently refer to exclusions being posted to ''the National Select Agent Registry website.'' However, the name of the website has changed to ''the Federal Select Agent Program website.'' We propose to update the regulations accordingly.

Multiple regulations currently indicate that APHIS can receive reports received via facsimile. Due to the implementation of the eFSAP information system for official recordkeeping, this is no longer the case. We are proposing to amend the regulations accordingly.

Prior to issuance of a certificate of registration, we currently require that the responsible official must provide notification of any changes to the application for registration by submitting the relevant pages of the registration application (7 CFR 331.7(f); 9 CFR 121.7(f)). We propose to clarify that the submission should be the

relevant information that needs to be updated, rather than a particular page citation.

The regulations in 7 CFR 331.11(d)(4) and 9 CFR 121(d)(4) currently require registered individuals and entities to inspect all suspicious packages before they are brought into or removed from an area where select agents or toxins are used or stored. However, the presence of a suspicious package in any registered space, and not just the area where the select agents or toxins are used or stored, could represent a significant biosecurity and personal safety risk, and therefore, the presence of a suspicious package in any registered space should be inspected. We propose to amend the regulations accordingly.

In § 121.3, we are proposing revisions to footnotes 1, 4, and 5 to reflect the current understanding of the genomic structure and advancements in molecular characterization of infectious Newcastle disease virus and pigeon paramyxovirus in columbid birds.

Currently, § 121.11(f) requires pre-access suitability assessments and ongoing assessments of suitability for persons who will have access to a Tier 1 select agent or toxin at a registered entity. We are proposing to clarify that such assessments are needed for all employees authorized to have access to the Tier 1 select agent or toxin, whether or not they ever actually access the select agent or toxin. The current language can be interpreted that an ongoing assessment is only required for those who do access a Tier 1 select agent or toxin and not necessarily applicable to those individuals authorized for access but not currently accessing the Tier 1 agent space. This updated language will ensure all those authorized to have access will have ongoing assessments. The section is also updated to more clearly define requirements for visitor screening for security enhancements.

In that same section of the regulations (9 CFR 121.11(f)(5)(iii)), we currently require entities that possess foot-and-mouth disease virus and rinderpest virus to have closed circuit television, or CCTV. We are proposing to revise this to video surveillance, which may or may not be by CCTV. With the advances in video surveillance and options available, a broader video surveillance provision is being proposed.

Although we previously updated paragraph (b) of 9 CFR 121.3 to list avian influenza virus as a select agent, without reference to particular strains or pathogenicity, two references later in the regulations, in paragraph (f)(3)(i) of that same section and paragraph (c)(1) of 9 CFR 121.9, were not updated at that time to conform with that revised listing. We are proposing to update them accordingly.

Finally, although Newcastle disease virus is listed as a select agent regardless of virulence, in certain instances within part 121, requirements are stated to pertain to ''virulent'' Newcastle disease virus. To clarify that the requirements pertain to Newcastle disease virus in the broad sense, we are proposing to delete the word ''virulent'' in those instances.

Executive Orders 12866 and 13563 and Regulatory Flexibility Act

This proposed rule has been determined to be significant for the purposes of Executive Order 12866 as amended by Executive Order 14094, ''Modernizing Regulatory Review,'' and, therefore, has been reviewed by the Office of Management and Budget.

We have prepared an economic analysis for this proposed rule. The economic analysis provides a cost-benefit analysis, as required by Executive Orders 12866 and 13563, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The economic analysis also examines the potential economic effects of this rulemaking on small entities, as required by the Regulatory Flexibility Act.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107–188) provides for the regulation of certain biological agents and toxins that have the potential to pose a severe threat to human, animal, or plant health, or to animal or plant products. The Animal and Plant Health Inspection Service (APHIS), Division of Agricultural Select Agents and Toxins (DASAT) has the primary responsibility for implementing the provisions of the Act with the United States Department of Agriculture (USDA). Within APHIS, Veterinary Services (VS) select agents and toxins, listed in 9 CFR 121.3, are those that have been determined to have the potential to pose a severe threat to animal health or animal products, and Plant Protection and Quarantine (PPQ) select agents and toxins, listed in 7 CFR 331.3, are those that have been determined to have the potential to pose a severe threat to plant health or plant products. Overlap select agents and toxins, listed in 9 CFR 121.4, are those that have been determined to pose a severe threat to public health and safety, to animal health, or to animal products. Overlap select agents and toxins are subject to regulation by both APHIS DASAT and the Centers for Disease Control and Prevention (CDC), Division of Regulatory Science and Compliance (DRSC), which has the primary responsibility for implementing the provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 for the Department of Health and Human Services (HHS). Together, APHIS' DASAT and CDC's DRSC comprise the Federal Select Agent Program (FSAP).

Title II, Subtitle B of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (which is cited as the ''Agricultural Bioterrorism Protection Act of 2002'' and referred to below as the Act), section 212(a) (7 U.S.C. 8401(a)(1)), provides, in part, that the Secretary of Agriculture (the Secretary) must establish by regulation a list of each biological agent and each toxin that the Secretary determines has the potential to pose a severe threat to animal or plant health, or to animal or plant products. Paragraph (a)(2) of section 212 of the Act (7 U.S.C. 8401(a)(2)) requires the Secretary to review and republish the list of select agents and toxins every two years and to otherwise revise the list as necessary. To fulfill this statutory mandate, APHIS convenes separate interagency working groups to review the list of PPQ and VS select agents and toxins, as well as any overlap select agents and toxins, and develop recommendations regarding possible changes to the list using the five criteria for listing found in the Act. APHIS and CDC coordinate on the biennial review for overlap select agents and toxins that have been determined to pose a severe threat to human and animal health or animal products.

Description of Proposed Rule

Pursuant to the Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. 8401(a)(2)), APHIS has completed its required biennial review of the current list of select agents and toxins in 7 CFR 331.3 (PPQ select agents), 9 CFR 121.3 (VS select agents), and 9 CFR 121.4 (overlap select agents overseen jointly with CDC). This proposed rule would implement the recommendations of the interagency working groups with respect to the list of select agents and toxins. APHIS, in conjunction with CDC, proposes removing the following overlap select

agents: *Brucella abortus, Brucella suis,* and *Brucella melitensis.* APHIS proposes removing one VS select agent, African horse sickness virus. APHIS also proposes removing one PPQ select agent, *Peronosclerospora philippinensis,* also known as *Peronosclerospora sacchari.*

Public response showed overwhelming support for the proposed delisting, particularly for the Brucella agents. Therefore, for reasons set forth in the ANPR and further articulated in the proposed rule that this economic analysis accompanies, we consider it appropriate to propose to delist the agents.

In addition to the delisting of some select agents, APHIS is also proposing several amendments to the select agent and toxin regulations and several corrections to fix editorial errors. The amendments are summarized as follows:

- *Discovery of Select Agents and Toxins:* We are proposing a definition for the term *Discovery,* clarifying that an individual or entity in possession of a select agent or toxin for which an exclusion or exemption listed in 9 CFR part 121 or 7 CFR part 331 does not apply, and that is not included on a certificate of registration, must immediately report such possession to either the APHIS Administrator or HHS Secretary, and creating a new APHIS/CDC Form 6 to facilitate reporting of discoveries.
- *Disposal of Select Agent Waste After Conclusion of Patient Care:* This proposes to codify a current operational policy that, for an individual who has been admitted to a medical facility, that individual's ''conclusion of patient care'' and the point when ''delivery of patient care by health care professionals has concluded'' is when an individual is released from the medical facility where treatment was being provided by the medical facility or physician.
- *Exclusion of Animals Naturally Infected with Select Agents:* We are proposing to codify the current operational policy regarding when animals naturally infected with select agents are excluded from the requirements of the regulations.
- *Inactivation:* We are proposing to clarify what constitutes an acceptable ''validated inactivation procedure,'' including revising the existing definition of the term; add a new exclusion 7 CFR 331.3(d), 9 CFR 121.3(d), and 9 CFR 121.4(d) that would exclude any select agent or regulated nucleic acid that can produce infectious forms of any select agent virus if the material is contained in a formalin-fixed paraffin-embedded tissue or fixed to slides (*e.g.,* Gram stain) that has been effectively inactivated by a recognized method; and codify a policy that allows individuals besides the responsible official to revise the inactivation procedures.
- *Removal:* We are proposing to codify an operational exclusion in 7 CFR 331.3(d)(5), 9 CFR 121.3(d)(5), and 9 CFR 121.4(d)(5) regarding material containing a select agent that is subjected to a validated viable select agent removal procedure, revise the definition of *Viability testing protocol,* and add a definition for the term *Verification viability testing protocol.*
- *Loss, Release, and Theft:* APHIS proposes to add definitions for the terms *Loss, Release,* and *Theft.*
- *Recordkeeping:* We are proposing amendments to the recordkeeping requirements in 7 CFR 331.17 and 9 CFR 121.17 to ensure an accurate, current inventory is maintained for all select agents and toxins held in long-term storage and address intra-agency transfer. APHIS is also proposing several revisions to the records needed for inactivated or select agent-free material created by an entity and to clarify throughout the regulations that whenever an entity is registered to possess, use, or transfer a select agent or toxin, the entity is required to meet all of the regulatory requirements for those select agents and toxins listed on the entity's certificate of registration regardless of whether the select agent or toxin is in the actual possession of the entity and without regard to the amount of toxin in possession.
- *Electronic Federal Select Agent Program (eFSAP) Information System:* We are proposing to add references to eFSAP's electronic data submission and management procedures throughout the regulations.
- *Registration:* We are clarifying the conditions under which issuance of a certificate of registration may be contingent and that amendment of a certification of registration to reflect changes in circumstances is mandatory.
- *Responsible Official and Alternate Responsible Official:* We are proposing to clarify that a responsible official is precluded from serving as the primary responsible official for two separate registered entities. We are also clarifying that a responsible official cannot be the sole alternate responsible official at another registered entity, but that an alternate responsible official at one entity may be approved to be an alternate responsible official at another registered entity.
- *Annual Internal Inspections:* We are proposing to codify current policy on what an entity's annual internal inspections must address.
- *Tier 1 Security Enhancements:* We are proposing to clarify that registered entities that possess Tier 1 select agents must have procedures for screening any visitors, their property, and, where appropriate, vehicles at entry points to registered space based on the entity's site-specific risk assessment.
- *Biosafety—Facility Verification:* We are proposing to amend 7 CFR 331.12 and 9 CFR 121.12 to require facility verification every 12 months for registered entities that maintain biosafety level 3 and animal biosafety level 3 laboratories.
- *Biosafety—Effluent Decontamination System:* We are proposing to amend the security (7 CFR 331.11 and 9 CFR 121.11), biosafety (7 CFR 331.12 and 9 CFR 121.12), and incident response (7 CFR 331.14 and 9 CFR 121.14) sections of the select agent and toxin regulations to address risks posed by the effluent decontamination systems used by high and maximum-containment laboratories.
- *Restricted Experiments:* We are proposing to add a provision that an individual or entity must submit a written request to CDC or APHIS prior to the transfer or possession of the products of restricted experiments.

Overview of the Action and Affected Entities

There are 236 entities registered with APHIS and CDC. Of these entities, there are 13 Private entities, 30 Federal entities, 42 Commercial entities, 84 Academic entities, and 67 State entities. Of these, less than 4 percent of all entities within these NAICS categories are considered to be small entities. The delisting of several select agents and the proposed amendments to the select agent and toxins regulations are anticipated to economically benefit producers, research and reference laboratories, and State and Federal oversight agencies, while also maintaining adequate program oversight of select agents and toxins, while minimizing additional costs to adherence. Below we provide a benefit-cost analysis, as required by Executive Orders 12866, 13563, and 14094, to examine the potential economic effects of the rule on small entities.

Expected Benefits and Costs of the Proposed Rule

Costs for regulated entities to implement the changes contemplated in this proposed rule are expected to be very modest. For example, APHIS is proposing to add a provision that an individual or entity must submit a written request to CDC or APHIS prior to the transfer or possession of the

products of restricted experiments. (Restricted experiments are experiments that involve the deliberate transfer of, or selection for, a drug or chemical resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture, and experiments that involve the deliberate formation of synthetic or recombinant nucleic acids containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50] < 100 ng/kg body weight.)

This request is likely to take minimal time, less than a few minutes per request for these entities to provide, but could inform and result in a rapid mitigation if the products are accidently exposed to the natural environment. The written request is simply checking a box on a form that has already been readily available to them.

Additionally, there are benefits of reducing the risks of the unintended release of select of select agents and toxins. For example, Kaufman et. al., 1997 estimated the economic impacts of a bioterrorist attack at approximately $26.2 billion per 100,000 people exposed to the release of the anthrax select agent. Additionally, many regulated entities have been requesting some of the amendments, particularly the delisting of *Brucella* species. State Veterinarians have expressed concern regarding the limitation on *brucellosis* research because of the designation of *Brucella* as a select agent.

Livestock producer organizations and the United States Animal Health Association (USAHA) have emphasized the need for continued research on an improved *B. abortus* vaccine and development of a *B. suis* vaccine, as well as improved diagnostics for both agents. Regulatory restrictions prohibit vaccine trials using natural transmission models, limit the opportunity for large animal studies, inhibit available surveillance, and prohibit studies that would evaluate vaccine or diagnostic product efficacy through comingling vaccinated and naturally infected animals. These limitations increase disease management costs for State and Federal governments as well as livestock producers.

One previous example of the public requesting delisting of a select agent for research purposes was Valley Fever or *Coccidiodes spp.* Until October 2012, Valley Fever or *Coccidiodes spp.* had been listed as a select agent by both USDA and HHS as a level 3 pathogen, but due to financial difficulties for researchers to provide a biosafety three laboratory to conduct desperately needed clinical and environmental research, research was limited. Now research is taking place, and doctors and medical personnel are more familiar with it and understand that climate change is contributing to this disease in California, and research is ongoing along with outreach to inform potential infected citizens. Again, due to the high cost of laboratory requirements for select agents as mentioned above for Valley fever and other select agents, the appropriate research and field studies could not take place, thus hampering new information and research to limit or stop the spread of the disease or at least inform the public of its method of infection. Very few laboratories have the resources or ability to do research on select agents due to costs of containment and facility needs required by the regulations.

There is currently limited courier availability for these five select agent shipments, which has resulted in prohibitive shipment costs for many laboratories. The increased shipment costs have inhibited isolate sharing between reference and research laboratories, thus leading to decreased advancements from researchers and laboratories involved in diagnostic improvements and disease eradication efforts. Removing the three Brucella agents (*B. abortus, B. suis,* and *B. melitensis*), as overlap select agents and one VS agent, African horse sickness virus, along with one plant agent, *Peronosclerospora philippinensis,* from the list of select agents and toxins would thus economically benefit producers, research and reference laboratories, and State and Federal oversight agencies. We welcome comments from the public if there are any reasons we should not be delisting these select agents.

APHIS' proposed amendment to require facility verification every 12 months for registered entities that maintain biosafety level 3 and animal biosafety level 3 laboratories is not anticipated to create an additional burden to entities that maintain biosafety level 3 and animal biosafety level 3 laboratories. APHIS reached this conclusion as we understand that these entities are already performing such annual facility verifications. Level 3 facilities are a highly regulated industry (at the Federal, State, and local level) with significant start-up and maintenance costs. It is highly likely that these are being monitored multiple times a week, if only for safety reasons. Also, many of the facilities operate, at least in part, on grants that are conditioned on demonstrating routine maintenance checks. However, APHIS has specifically requested comments concerning the cost and burden of annual facility verifications, especially if the entity is considered a small business, and will reevaluate as appropriate.

APHIS has proposed several amendments to the select agent and toxin regulations related to security, biosafety, and incident response to address risks posed by the effluent decontamination systems used by Level 3 and level 4-containment laboratories. Level 3 and level 4-containment laboratories are highly sophisticated facilities built to contain biological agents and toxins with the highest potential to threaten agricultural, plant, and public health and safety. Any defect, such as a crack or leaky pipe, could have severe consequences. For example, in August 2007, foot-and-mouth disease virus was discovered at farms in the United Kingdom. The source of the contamination was determined to be long-term damage and leakage of a drainage system used by a high-containment laboratory working with the foot-and-mouth disease virus. APHIS does not believe this proposal will cause an undue burden to regulated entities. The regulations already require that entities prepare a security plan that is sufficient to safeguard the select agent or toxin against theft, loss, or release and unauthorized access, a biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use, and an incident response plan based upon a site-specific risk assessment. These facilities are well versed in the security, biocontainment, and incident response measures that are necessary.

Therefore, making changes to their current security, biocontainment, and incident response plans, as applicable, is not expected to cause a burden to these facilities other than the time it takes to develop the plans—if not previously done—and clearly describe the procedures to address the risks posed by the effluent decontamination systems. We have estimated that adherence to future security, biocontainment, and incident response plans could take as little as a few hours to no longer than a day. Additionally, the procedures needed are, in most cases, well-known and currently being implemented by entities with these effluent decontamination systems because lack of such procedures could potentially result in millions/billions of dollars in damages if a select agent or toxin was accidentally released into the natural environment. Once again, APHIS would be interested in comments concerning the cost and

burden of annual security plans, especially if the entity is considered a small business.

APHIS is also proposing that an entity must submit a written request to APHIS or CDC prior to the transfer or possession of products of restricted experiments. Restricted experiments are experiments that involve the deliberate transfer of, or selection for, a drug or chemical resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture, and experiments that involve the deliberate formation of synthetic or recombinant nucleic acids containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50] < 100 ng/kg body weight. Again, we do not believe this proposed requirement will negatively impact these highly sophisticated entities other than the time requirement it takes to send a written request for the transfer or possession of products of restricted experiments. APHIS would once again welcome feedback regarding the burden of providing written requests prior to the transfer of restricted items, especially if the entity is considered a small business.

Lastly, as described above, this proposed rule will codify several current policies that entities have already implemented, specifically, policies related to the disposal of select agent waste after conclusion of patient care, the exclusion appliable to animals naturally infected with a select agent, who can revise inactivation procedures, and matters that an entity's annual internal inspection must address. APHIS has no reason to believe that continued adherence to these polices would negatively impact regulated entities going forward. In contrast, APHIS believes codification of the current policies adds clarity and consistency across facilities, which benefits the security of select agents and toxins.

As described, any impacts of the proposed changes to the list of select agents and toxins are expected to be beneficial for the affected industries.

Small-Entity Prevalence

Entities that possess, use, or transfer certain plant, animal, or human select agents or toxins would either benefit or be unaffected by this rulemaking. Potentially affected entities include laboratories, other research institutions, and related entities in possession of select agents or toxins. Affected entities (other than Federal and State governmental entities) are likely found within the following North American Industry Classification System (NAICS) categories:

541714, Research and Development in Biotechnology.

541715, Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology);

325412, Pharmaceutical Preparation Manufacturing;

325413, In-Vitro Diagnostic Substance Manufacturing;

325414, Biological Product (except Diagnostic) Manufacturing;

541940, Veterinary Services;

611310, Colleges, Universities and Professional Schools;

621511, Medical Laboratories;

622110, General Medical and Surgical Hospitals.

The Small Business Administration (SBA) has established small-entity size standards based on the NAICS categories. An entity classified within NAICS 541714 or NAICS 541715 is considered small with 1,000 or fewer employees, and one within NAICS 325412, 325413, or 325414 is considered small with 1,250 or fewer employees. An entity in NAICS 541940 is considered small with annual receipts of $8 million or less, and an entity in NAICS 611310 is considered small with annual receipts of not more than $30 million. Entities classified within NAICS 621511 are considered to be small if they have annual receipts of not more than $35 million. An entity classified within NAICS 622110 is considered to be small with annual receipts of not more than $41.5 million.

While the breakdown of the size of the establishments, as reported by the 2017 Economic Census, does not precisely fit the SBA guidelines, the data indicate that the vast majority of the entities in industries potentially affected by this proposed rule, other than post-secondary institutions, can be considered large entities. In other words, over 96 percent of all firms included in the above mentioned NAICS codes are large entities meaning only approximately 4 percent of these firms are small entities. According to the 2017 Economic Census, the most recent census data available for all entities, 96 percent of entities in NAICS 541714 and 541715, 49 percent of entities in NAICS 325412, 19 percent of entities in NAICS 325413, 25 percent of entities in NAICS 325414, 100 percent of entities in NAICS 541940, 87 percent of entities in NAICS 621511, 93 percent of entities in NAICS 611310, and 97 percent of entities in NAICS 622110 and can be classified as large.

TABLE 1—PREVALENCE OF SMALL/LARGE ENTITIES WITHIN AFFECTED INDUSTRIES

NAICS code	Number of firms		Annual revenue, receipts, or value of shipments	
SBA Small-entity Standard based on Employment.	<1,000 Employees small entities.	1,000+ Employees large entities.	<1,000 Employees small entities.	1,000+ Employees large entities.
541714 R&D in Biotechnology (commercial and non-profit) 3,109 firms.	438	2,671	$20.6 m	$24.5b.
541715 R&D in the Life Sciences (commercial and non-profit) 8,019 firms.	0	8,019	$0	$96.8.
	<1,250 Employees	1,250+ Employees	<1,250 Employees	1,250+ Employees.
325412 Pharmaceutical Preparation	494	513	$1.9b	$152.7b.
325413 In-vitro Diagnostic Substance.	153	35	$1b	$12.6b.
325414 Biological Product (except Diagnostic).	197	67	$1.4b	$29.2b.
SBA Small-entity Standard based on Annual Receipts.	<$8 million in Receipts employees.	$8 million+ in Receipts employees.	<$8 million in Receipts	$8 million+ in Receipts.
541940 Veterinary Services 42 b receipts.	0	28,291	$0	$42.1 b.
SBA Small-entity Standard based on Annual Receipts.	<$35 million in Receipts employees.	$35 million+ in Receipts employees.	<$35 million in Receipts	$35 million+ in Receipts.
621511 Medical Laboratories 35.6b	438	2,927	$22.m	$35.6b.
SBA Small-entity Standard based on Annual Receipts.	<$30 million in Receipts employees.	$30 million+ in Receipts employees.	<$30 million in Receipts	$30 million+ in Receipts.
611310 Colleges, Universities, and Professional Schools.	168	2,265	7.9 m	255.6 b.
SBA Small-entity Standard based on Annual Receipts.	<$41.5 million in Receipts employees.	$41.5 million+ in Receipts employees.	<$41.5 million in Receipts	$41.5 million+ in Receipts.
622110 General Medical and Surgical Hospitals.	65	2,495	$35.5 m	$997.3 b.

The analysis above shows the potential costs of the proposed rule to be slight. The benefits will of the proposed rule will accrue to all firms, most of which (96 percent) included in the above mentioned NAICS codes are large entities meaning only approximately 4 percent of these firms are small entities. Very few entities registered for select agents and toxins are considered small and because there are so few small entities, the proposed rule is not expected to have a significant economic impact on small entities.

Alternatives to the Rule

Status Quo—Not Delisting

APHIS convenes separate interagency working groups in order to review the list of PPQ and VS select agents and toxins, as well as any overlap select agents and toxins, and develop recommendations regarding possible changes to the list using the five criteria for listing found in the Act. APHIS and CDC coordinate on the biennial review for overlap select agents and toxins that have been determined to pose a severe threat to human and animal health or animal products. The proposed changes are based on the recommendations of the interagency working groups.

Maintaining the status quo would mean foregoing continued research on an improved *B. abortus* vaccine and development of a *B. suis* vaccine, as well as improved diagnostics for both agents. Regulatory restrictions prohibit vaccine trials using natural transmission models, limit the opportunity for large animal studies, inhibit available surveillance, and prohibit studies that would evaluate vaccine or diagnostic product efficacy through comingling vaccinated and naturally infected animals. These limitations increase disease management costs for State and Federal governments as well as livestock producers.

Not Codifying Policies

One alternative to the proposed rule considered by APHIS was not to propose to codify the current operational policies listed above and just delist the proposed select agents. However, we decided to propose codification for the sake of consistency with CDC and transparency with our stakeholders. The proposed changes are currently operationalized, and codification of the policies has been recommended by various governmental entities.

Without codification we would not have transparency and consistency throughout agencies which is important when requiring strict adherence to our proposed regulatory policies for select agents; thus we have rejected the alternative to not codify our operational policies that are closely coordinated between APHIS and CDC.

APHIS convenes separate interagency working groups in order to review the list of PPQ and VS select agents and toxins, as well as any overlap select agents and toxins, and develop recommendations regarding possible changes to the list using the five criteria for listing found in the Act. APHIS and CDC coordinate on the biennial review for overlap select agents and toxins that have been determined to pose a severe threat to human and animal health or animal products. The proposed changes are based on the recommendations of the interagency working groups.

Maintaining the status quo would mean foregoing continued research on an improved *B. abortus* vaccine and development of a *B. suis* vaccine, as well as improved diagnostics for both agents. Regulatory restrictions prohibit vaccine trials using natural transmission models, limit the opportunity for large animal studies, inhibit available surveillance, and prohibit studies that would evaluate vaccine or diagnostic product efficacy through comingling vaccinated and naturally infected animals. These limitations increase disease management costs for State and Federal governments as well as livestock producers.

The analysis above shows the potential costs of the proposed rule to

be slight. The benefits of the proposed rule will accrue to all firms, most of which (96 percent) included in the above mentioned NAICS codes are large entities, meaning only approximately 4 percent of these firms are small entities. Very few entities registered for select agents and toxins are considered small and because there are so few small entities, the proposed rule is not expected to have a significant economic impact on small entities.

Objectives of and Legal Basis for the Rule

Pursuant to the Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. 8401(a)(2)), APHIS has completed its required biennial review of the current list of select agents and toxins in 7 CFR 331.3 (PPQ select agents), 9 CFR 121.3 (VS select agents), and 9 CFR 121.4 (overlap select agents overseen jointly with CDC). This proposed rule will implement the recommendations of the interagency working groups with respect to the list of select agents and toxins. APHIS, in conjunction with CDC, proposes removing the following overlap select agents: *Brucella abortus, Brucella suis, and Brucella melitensis.* APHIS proposes removing one VS select agent, African horse sickness virus. APHIS also proposes removing one PPQ select agent, *Peronosclerospora philippinensis,* also known as *Peronosclerospora sacchari.*

Projected Reporting, Recordkeeping, and Other Compliance Requirements

New regulatory compliance, reporting and recordkeeping requirements associated with the information collection in this proposed rule are discussed above in the section on expected benefits and costs of the proposed rule. Those requirements are also discussed in the rule under the heading ''Paperwork Reduction Act.''

Executive Order 13175

This proposed rule has been reviewed in accordance with the requirements of Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments.'' Executive Order 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. What follows is a summary of such coordination to date.

The Animal and Plant Health Inspection Service (APHIS) has assessed the impact of this proposed rule on Indian Tribes by soliciting tribal feedback on its provisions. On April 8, 2022, APHIS sent tribal nations a letter outlining the provisions of the proposed rule and soliciting their feedback. On May 5, 2022, the Sac and Fox Tribe of the Mississippi in Iowa submitted a response expressing concerns regarding whether possible *Brucella abortus* delisting would materially adversely impact APHIS' domestic quarantine program for the control and eradication of brucellosis in cattle and bison. In response, APHIS clarified that the two issues were distinct, and no adverse operational impacts were anticipated. On June 6, 2022, the Tribe indicated that they have no further comments or concerns. To date, no other Tribes have expressed concerns regarding the proposed rule. Therefore, the Agency has determined that this proposed rule does not, to our knowledge, have Tribal implications that require formal Tribal consultation under Executive Order 13175. If a Tribe requests consultation, the Animal and Plant Health Inspection Service will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions and modifications identified herein are not expressly mandated by Congress.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR Chapter IV.)

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule (1) preempts all State and local laws and regulations that are in conflict with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

FSAP is the collaboration of the CDC's Division of Regulatory Science and Compliance (DRSC) and the APHIS Division of Agricultural Select Agents and Toxins (DASAT) to administer the select agent and toxin regulations in a manner to minimize the administrative burden on persons subject to the select agent and toxin regulations. The Federal select agent activities managed by APHIS are described in 7 CFR part 331 and 9 CFR part 121; otherwise, they are managed by the CDC in 42 CFR part 73.

Both agencies are concurrently publishing proposed rules in this issue of the **Federal Register** [1] with changes to the select agent and toxin regulations, and the changes are uniform, as applicable, across all three sets of regulations. In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the CDC is reporting, as the sponsoring agency, information collection requirements to the Office of Management and Budget under OMB control number 0920–0576, Possession, Use, and Transfer of Select Agents and Toxins. Reportable activities include requests for exclusions, reports of identification of a select agent or toxin, requests of exemption, applications for registration, amendments to a certificate of registration, documentation of self-inspection, requests for expedited review, security plans, biosafety plans, requests regarding restricted experiments, incident response plans, training, requests to transfer select agents and toxins, recordkeeping, notifications of theft, loss, or release; and administrative reviews. There are no new activities in this proposed rule. There are an estimated 3,656 hours of burden associated with this program.

Information about information collection 0920–0576 may be obtained from the *www.reginfo.gov* website or from Ms. Lori Bane, Deputy Director, Division of Select Agents and Toxins, Center for Preparedness and Response, Centers for Disease Control and Prevention, at (404) 718–2006. APHIS and CDC will respond to any ICR-related comments in the final rule. All comments will also become a matter of public record.

E-Government Act Compliance

APHIS is committed to compliance with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. FSAP utilizes a highly secure eFSAP information system to conduct select agent and toxin program activities and the information system is a two-way communication portal accessible by both CDC and APHIS staff and the regulated community. APHIS estimates 100 percent of the total responses can be

[1] Go to *www.regulations.gov* and enter CDC–2020–0024 in the Search field.

processed electronically. For users at registered entities, benefits of the system include reduced paperwork, increased ease of validating and submitting information, and reduced processing time for requests (as real-time information exchange allows for increased responsiveness). Both APHIS and CDC collect information from reports (*e.g.,* APHIS/CDC Forms 2, 3, and 4) and requests (*e.g.,* amendments to registration) submitted via the eFSAP information system.

For assistance with E-Government Act compliance related to this proposed rule, please contact Mr. Joseph Moxey, APHIS' Paperwork Reduction Act Coordinator, at (301) 851–2483, or the individual listed under **FOR FURTHER INFORMATION CONTACT**.

References

Alberca, B., et al. *Vaccination of horses with a recombinant modified vaccinia Ankara virus (MVA) expressing African horse sickness (AHS) virus major capsid protein VP2 provides complete clinical protection against challenge.* Vaccine, 2014. 32(29): p. 3670–3674.

Braverman, Y. and A. Chizov-Ginzburg. *Role of dogs (Canis domesticus) as hosts for African horse sickness virus.* Vet Microbiol, 1996. 51(1–2): p. 19–25.

Center for Food Security and Public Health. *Brucellosis fact sheet.* July 19, 2009. Available from: *http://www.cfsph.iastate.edu/Factsheets/pdfs/brucellosis.pdf.*

Center for Food Security and Public Health. *Porcine and Rangiferine Brucellosis: Brucella suis Fact Sheet.* July 2009. Available from: *http://www.cfsph.iastate.edu/Factsheets/pdfs/brucellosis_suis.pdf.*

Food and Agriculture Organization of the United Nations. *List of Regulated Pests. International Plant Protection Convention.* Cited October 19, 2017. Available from: *https://www.ippc.int/en/countries/all/regulatedpests/.*

Kajon, A.E., et al. *Molecular epidemiology and brief history of emerging adenovirus 14-associated respiratory disease in the United States.* J Infect Dis, 2010. 202(1): p. 93–103.

Lulla, V., et al. *Protective efficacy of multivalent replication-abortive vaccine strains in horses against African horse sickness virus challenge.* Vaccine, 2017. 35(33): p. 4262–4269.

Moreno, E. *Retrospective and prospective perspectives on zoonotic brucellosis.* Frontiers in Microbiology, 2014. 5. Available from: *https://pubmed.ncbi.nlm.nih.gov/24860561/.*

Murray, G.M. *Industry Biosecurity Plan for the Grains Industry: Threat Specific Contingency Plan Philippine downy mildew of maize (Perenosclerospora philippensis) and Downy mildew of sorghum (P. sorghi).* Plant Health Australia 2009 [cited 2017 Oct 20]; Available from: *http://www.planthealthaustralia.com.au/wp-content/uploads/2013/03/Downy-mildew-of-maize-and-sorghum-CP-2009.pdf.*

Olsen, S.C. and C. Johnson. *Comparison of Abortion and Infection after Experimental Challenge of Pregnant Bison and Cattle with Brucella abortus Strain 2308.* Clinical and Vaccine Immunology, 2011. 18(12): p. 2075–2078. Available from: *https://pubmed.ncbi.nlm.nih.gov/21976222/.*

Purdue University Extension. *Peronosclerospora philippinensis Fact Sheet.* Cited Oct 20, 2017. Available from: *http://download.ceris.purdue.edu/file/3117.*

Sanchez-Vizcaino, J.M., *Control and eradication of African horse sickness with vaccine.* Dev Biol (Basel), 2004. 119: p. 255–8.

Spickler, A.R. *African Horse Sickness.* Center for Food Security and Public Health Technical Factsheets February 2015. Available from: *http://www.cfsph.iastate.edu/Factsheets/pdfs/african_horse_sickness.pdf.*

Stoffregen, W.C. *Brucella infection and vaccine studies in feral and domestic swine.* 2006.

The Center for Food Security and Public Health. *Ovine and Caprine Breucellosis: Brucella melitensis.* 2009, Iowa State University: Ames, Iowa.

USDA. *Recovery Plan for Philippine Downy Mildew and Brown Stripe Downy Mildew of Corn.* Cited Oct 20, 2017. Available from: *https://www.ars.usda.gov/ARSUserFiles/opmp/CornDownyMildewsRecoveryPlanRevised2013.pdf.*

World Organizsation for Animal Health (OIE). *Terrestrial Animal Health Code (2017).* [cited 2017 Oct 11]; Available from: *http://www.oie.int/en/international-standard-setting/terrestrial-code/access-online/.*

Zhu, L., et al., *Brucella suis strain 2 vaccine is safe and protective against heterologous Brucella spp. infections.* Vaccine, 2016. 34(3): p. 395–400. Available at: *https://pubmed.ncbi.nlm.nih.gov/26626213/.*

List of Subjects

7 CFR Part 331

Agricultural research, Laboratories, Plant diseases and pests, Reporting and recordkeeping requirements.

9 CFR Part 121

Agricultural research, Animal diseases, Laboratories, Medical research, Reporting and recordkeeping requirements.

Accordingly, we propose to amend 7 CFR part 331 and 9 CFR part 121 as follows:

TITLE 7—AGRICULTURE

PART 331—POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS

■ 1. The authority citation for part 331 continues to read as follows:

Authority: 7 U.S.C. 8401; 7 CFR 2.22, 2.80, and 371.3.

■ 2. Amend § 331.1 by:
■ a. Adding in alphabetical order definitions for ''Discovery'' and ''Loss'';
■ b. Removing the definition for ''Permit'';
■ c. Adding in alphabetical order definitions for ''Release'' and ''Theft'';
■ d. Revising the definition for ''Validated inactivation procedure'';
■ e. Adding in alphabetical order definitions for ''Validated removal procedure'' and ''Verification viability testing protocol''; and
■ f. Revising the definition for ''Viability testing protocol''.

The additions and revisions read as follows:

§ 331.1 Definitions.

* * * * *

Discovery. The finding of a select agent or toxin by an individual or entity that is not aware of the select agent or toxin's existence. Examples include, but are not limited to the following:

(1) A registered individual or entity finds a select agent or toxin not accounted for in their purpose inventory; or

(2) A non-registered individual or entity finds a select agent or toxin.

* * * * *

Loss. The inability to account for a select agent or toxin known to be in the individual or entity's possession.

* * * * *

Release means any of the following:

(1) An incident resulting in occupational exposure to a select agent or toxin;

(2) An incident resulting in animal/plant exposure to a select agent or toxin;

(3) The failure of equipment used to contain a select agent or toxin such that it is reasonably anticipated that a select agent of toxin was released;

(4) The failure of or breach in personal protective equipment in the presence of a select agent or toxin; or

(5) The failure of biosafety procedures such that it is reasonably anticipated that a select agent or toxin was outside of containment.

* * * * *

Theft. The unauthorized taking and removing of a select agent or toxin from the possession of an entity or individual.

* * * * *

Validated inactivation procedure. A procedure, whose efficacy has been confirmed by data generated from an in-house viability testing protocol, to render a select agent non-viable but allows the select agent to retain characteristics of interest for future use;

or to render any nucleic acids that can produce infectious forms of any select agent virus non-infectious for future use.

Validated removal procedure. A procedure, whose efficacy has been confirmed by data generated in-house from a viability testing protocol, to confirm removal of all viable select agent, or nucleic acids of any select agent virus capable of producing infectious virus.

* * * * *

Verification viability testing protocol. A protocol, used on samples that have been subjected to a validated inactivation or removal procedure, to confirm the material is free of all viable select agent, or nucleic acids of any select agent virus capable of producing infectious virus.

Viability testing protocol. A protocol, used on samples that have been subjected to a validated inactivation or removal procedure, to confirm the material is free of all viable select agent, or nucleic acids of any select agent virus capable of producing infectious virus.

■ 3. Revise § 331.2 to read as follows:

§ 331.2 Purpose and scope.

(a) This part implements the provisions of the Agricultural Bioterrorism Protection Act of 2002 setting forth the requirements for possession, use, and transfer of select agents and toxins. The biological agents and toxins listed in this part have the potential to pose a severe threat to plant health or plant products.

(b) Any individual or entity in possession of a select agent or toxin, for which an exclusion or exemption listed in this part does not apply, and that is not included on a certificate of registration issued by the Administrator for that individual or entity, must immediately report such possession to the Administrator by the submission of an APHIS/CDC Form 6.

■ 4. Amend § 331.3 by:

■ a. Revising paragraphs (b) and (d)(4) through (6);

■ b. Redesignating paragraphs (d)(7) through (9) as paragraphs as (d)(8) through (10) and adding a new paragraph (d)(7);

■ c. In newly redesignated paragraph (d)(9), removing the words ''of the conclusion of patient care'' and adding the words ''from when the individual has been released from the medical facility where treatment was being provided'' in their place;

■ d. Revising newly redesignated paragraph (d)(10);

■ e. In paragraph (e)(1), removing the words ''National Select Agent Registry website'' and adding the words ''Federal Select Agent Program website'' in their place; and

■ f. In paragraph (f)(3), removing the words ''telephone, facsimile, or email'' and adding the words ''eFSAP information system, telephone, or email'' in their place in the second sentence.

The revisions and addition read as follows:

§ 331.3 PPQ select agents and toxins.

* * * * *

(b) PPQ select agents and toxins:

Coniothyrium glycines, (formerly *Phoma glycinicola, Pyrenochaeta glycines*);

Ralstonia solanacearum Race 3 biovar 2;

Rathayibacter toxicus;

Sclerophthora rayssiae;

Synchytrium endobioticum; and

Xanthomonas oryzae.

* * * * *

(d) * * *

(4) A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus that has been subjected to a validated inactivation procedure, provided that:

(i) In-house validation of the inactivation procedure is completed prior to use;

(ii) A certificate of inactivation has been generated in accordance with § 331.17(a)(8);

(iii) For use of a select agent surrogate is used to validate an inactivation procedure:

(A) Select agent surrogates must be known to possess equivalent properties with respect to inactivation;

(B) If there are known variations in the resistance of a select agent to an inactivation procedure, including strain to strain, then an inactivation procedure must also be validated using the most resistant select agent surrogate;

(iv) For use of whole plant tissue or homogenized plant tissue surrogate to validate a chemical inactivation procedure for other tissues including those in other plant models:

(A) All standardized conditions must be held constant such as the select agent used, plant tissue volume, and ratio of plant tissue to volume of inactivating chemical;

(B) A safety margin must be incorporated into the final chemical inactivation procedure to ensure the effective inactivation of the select agent;

(C) The tissue surrogate must meet the following criteria:

(*1*) The plant tissue is expected to have the highest concentration of the specific select agent to be inactivated; or

(*2*) The concentration of the select agent in the plant tissue must be determined and this select agent concentration must not be exceeded when applying the validated inactivation procedure on subsequent plant tissue samples.

(5) Material containing a select agent that is subjected to a validated viable select agent removal procedure that has rendered the material free of all viable select agent provided that:

(i) In-house validation of the viable select agent removal procedure is completed prior to use;

(ii) A certificate of viable select agent removal has been generated in accordance with § 331.17(a)(8);

(iii) For use of a surrogate to validate a viable select agent removal procedure, only surrogates known to possess equivalent properties with respect to removal are used;

(iv) A portion of each subsequent sample has been subjected to a verification viability testing protocol to ensure that the validated viable select agent removal procedure has rendered the material free of all viable select agent.

(6) A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus not subjected to a validated inactivation procedure or material containing a select agent not subjected to a validated viable select agent removal procedure that removes all viable select agent cells, spores, or virus particles if the material is determined by the Administrator or HHS Secretary to be effectively inactivated or effectively removed. To apply for a determination, an individual or entity must submit a written request and supporting scientific information to APHIS. A written decision granting or denying the request will be issued.

(7) Any select agent or regulated nucleic acids that can produce infectious forms of any select agent virus contained in a formalin-fixed paraffin-embedded (FFPE) tissue if the FFPE process used is a recognized procedure for that particular select agent or regulated nucleic acids.

* * * * *

(10) All subspecies of *Sclerophthora rayssiae* except var. *zeae,* provided that the individual or entity can identify that the agent is within the exclusion category.

* * * * *

■ 5. Amend § 331.5 by:

■ a. Revising paragraphs (a) introductory text and (a)(1); and

■ b. In paragraph (a)(3), removing the words ''by telephone, facsimile, or email'' and adding the words ''through the eFSAP information system, telephone, or email'' in their place in the first sentence.

The revisions read as follows:

§ 331.5 Exemptions.

(a) Clinical or diagnostic laboratories and other entities that possess, use, or transfer a PPQ select agent or toxin that is contained in a specimen presented for diagnosis or verification will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the Administrator, within 7 calendar days after identification of the select agent or toxin, the select agent or toxin is transferred in accordance with § 331.16 or destroyed on-site by a recognized sterilization process or inactivated for future use in accordance with § 331.3(d)(4).

* * * * *

■ 6. Amend § 331.7 by:

■ a. In paragraph (f), removing the words ''the relevant page(s) of'' and adding the words ''information related to'' in their place;

■ b. Revising paragraph (g);

■ c. In paragraph (i) introductory text, removing the word ''may'' and adding the word ''must'' in its place, and removing the word ''circumstances'' and adding the words ''the possession and use of the select agents and toxins'' in its place;

■ d. In paragraph (i)(1), removing the words ''the relevant page(s) of'' and adding the words ''information related to'' in their place and removing footnote 2.

The revision reads as follows:

§ 331.7 Registration and related security risk assessments.

* * * * *

(g) The issuance of a certificate of registration may be contingent upon inspection and submission of additional information to include any or all of the following: The security plan, biosafety plan, incident response plan, or any other documents related to the requirements of this part.

* * * * *

§ 331.8 [Amended]

■ 7. Amend § 331.8, in paragraph (a)(3), by redesignating footnote 3 as footnote 1.

■ 8. Amend § 331.9 by:

■ a. Redesignating paragraphs (a)(5) through (9) as paragraphs (a)(6) through (10) and adding a new paragraph (a)(5);

■ b. Revising newly redesignated paragraphs (a)(7), (9), and (10);

■ c. Adding a new second sentence to paragraph (b); and

■ d. Revising paragraph (c)(1).

The addition and revisions read as follows:

§ 331.9 Responsible official.

(a) * * *

(5) Not be approved as Responsible Official or alternate Responsible Official at another registered entity.

* * * * *

(7) Ensure that annual inspections are conducted for each registered space to determine compliance with the requirements in accordance with the regulations of this part. The results of each inspection must be documented, and any deficiencies identified during an inspection must be corrected and the corrections documented. The annual inspection must address whether:

(A) The entity's biosafety/biocontainment plan is being effectively implemented as outlined in § 331.12.

(B) The entity's security plan is being effectively implemented as outlined in § 331.11.

(C) The entity's incident response plan is implemented to ensure whether the entity is able to respond, as outlined in § 331.14.

(D) Each individual with access approval from the Administrator or HHS Secretary has received the appropriate training as outlined in § 331.15.

* * * * *

(9) Investigate to determine the reason for any failure of a validated inactivation or validated viable select agent removal procedure to render material free from viable select agent. If the responsible official is unable to determine the cause of the failure from a validated inactivation or validated viable select agent removal procedure or receives a report of any inactivation failure after the movement of material to another location, the responsible official must report immediately through the eFSAP information system, telephone, or email the inactivation or viable select agent removal procedure failure to APHIS or CDC.

(10) Review each of the entity's validated select agent inactivation procedure or validated viable select agent removal procedure and ensure they are revised as necessary. The review must be conducted annually or after any change in principal investigator, change in the validated inactivation or validated viable select agent removal procedure, or failure of the validated inactivation or validated viable select agent removal procedure. The review must be documented, and training must be conducted if there are any changes to the validated select agent inactivation or validated viable select agent removal procedure, or viability testing protocol.

(b) * * * An alternate responsible official can serve at multiple registered entities. * * *

* * * * *

(c) * * *

(1) The identification of the select agent or toxin must be immediately reported through the eFSAP information system, telephone, or email. The final disposition of the agent or toxin must be reported by submission of APHIS/CDC Form 4 within 7 calendar days after identification. A copy of the completed form not submitted through eFSAP information system must be maintained for 3 years.

* * * * *

§ 331.10 [Amended]

■ 9. Amend § 331.10, in paragraph (c), by removing the words ''access to select agents or toxins'' and adding the words ''approval from the Administrator or HHS Secretary'' in their place.

■ 10. Amend § 331.11 by:

■ a. Redesignating paragraphs (c)(9) and (10) as (c)(10) and (11) and adding a new paragraph (c)(9);

■ b. In paragraph (d)(4), removing the words ''an area where select agents or toxins are used or stored'' and adding the words ''registered space'' in their place; and

■ c. Removing paragraph (g) and redesignating paragraph (h) as paragraph (g).

The addition reads as follows:

§ 331.11 Security.

* * * * *

(c) * * *

(9) Describe procedures to prevent the theft, loss, release, or unauthorized access to a select agent or toxin from an effluent decontamination system originating from a registered laboratory.

* * * * *

■ 11. Amend § 331.12 by:

■ a. In paragraph (a) introductory text, redesignating footnote 4 as footnote 1.

■ b. Removing paragraph (c)(1) and redesignating paragraph (c)(2) as paragraph (c)(1);

■ c. Adding a new reserved paragraph (c)(2); and

■ d. Adding paragraphs (f), (g), and (h).

The additions read as follows:

§ 331.12 Biocontainment.

* * * * *

(c) * * *

(2) [Reserved]

* * * * *

(f) When an effluent decontamination system is used, the plan must provide for verification that the liquid waste generated from registered space is sufficiently treated to prevent the

release of a select agent or toxin prior to discharge of the waste from the facility.

(1) For a new effluent decontamination system, verification is required before initial use.

(2) For an effluent decontamination system in place, verification is required at least once every 12 months and following any major change to the effluent decontamination system.

(3) The verification must be documented.

(g) When an effluent decontamination system is used, the plan must provide that monthly routine maintenance is conducted of the effluent decontamination system, including at a minimum verification that:

(1) Alarms are functioning according to established specifications;

(2) Piping, pumps, valves, and tanks are not leaking; and

(3) Methods used to monitor and record performance measurements are functioning according to established specifications.

(h) An individual or entity must document every 12 months the following facility verification requirements for registered biosafety level 3 and animal biosafety level 3 laboratories.

(1) Accuracy of devices that monitor directional air-flow;

(2) Confirmation that decontamination systems (*e.g.,* autoclave, room decontamination systems, digesters, liquid effluent decontamination systems) are operating to ensure the containment of the select agent and toxin;

(3) Confirmation that systems are in place to monitor, maintain, and validate performance of mechanical systems to ensure that airflows and differential pressures are appropriate to maintain containment during normal/operational conditions;

(4) Verification that the facility mechanical, electrical, and drain waste and ventilation systems responsible for containment are inspected, maintained, and function as designed by the manufacturer specifications;

(5) Verification that the facility systems perform as intended in response to failure conditions as defined and tested during commissioning to prevent the release of a select agent or toxin and verification of secondary containment:

(i) Evaluate using work objectives, use of space, and facility infrastructure systems against the verified original design and standards (*e.g.,* Biosafety in Microbiological and Biomedical Laboratories, NIH Design Requirements Manual).

(ii) Implement controls and alarms to identify and alert personnel when systems fail, malfunction, or are unable to maintain containment during such an event.

(6) Certification of laboratory ventilation system HEPA filters, if present;

(7) Confirmation that room integrity has been evaluated and repairs are addressed (*e.g.,* sealed penetrations);

(8) Primary containment equipment is certified based on manufacturer's specifications (or recommendations) (*e.g.,* biological safety cabinets, flexible film isolators, animal caging);

(9) Seals on centrifuges not used in primary containment have been checked and replaced if needed; and

(10) Showers, eye wash stations, and hands-free sinks are operating properly.

§ 331.13 [Amended]

■ 12. Amend § 331.13, in paragraph (a) introductory text, by adding the words ''or transfer'' after the word ''possess''.

■ 13. Amend § 331.14 by:

■ a. In the section heading, redesignating footnote 5 as footnote 1;

■ b. In paragraph (a), redesignating footnote 6 as footnote 2;

■ c. In paragraph (b), adding the words ''the failure of an effluent decontamination system resulting in a release of a select agent or toxin;'' after the words ''a select agent or toxin;''; and

■ d. Revising paragraph (c).

The revision reads as follows:

§ 331.14 Incident response [1].

* * * * *

(c) The response procedures must account for hazards associated with the select agent or toxin and appropriate actions to contain such select agent or toxin in registered space including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent, or an effluent decontamination system originating from registered space.

* * * * *

[1] Nothing in this section is meant to supersede or preempt incident response requirements imposed by other statutes or regulations.

■ 14. Amend § 331.15 by:

■ a. In paragraph (d), revising the last sentence; and

■ b. In paragraph (e), removing the words ''and document.''

The addition reads as follows:

§ 331.15 Training.

* * * * *

(d) * * * The record must include the name of the individual who received the training, the date of the training, a description of the training provided, and the means used to verify that the individual understood the training.

* * * * *

§ 331.16 [Amended]

■ 15. Amend § 331.16, in paragraph (a), by redesignating footnote 7 as footnote 1.

■ 16. Amend § 331.17 by:

■ a. Revising paragraphs (a)(1), (3), and (8);

■ b. Removing the last sentence in paragraph (c); and

■ c. Adding paragraph (d).

The revisions and addition read as follows:

§ 331.17 Records.

(a) * * *

(1) An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and organisms containing recombinant and/or synthetic nucleic acids) held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials), including:

(i) The name and characteristics (*e.g.,* strain designation, GenBank Accession number);

(ii) The quantity acquired from another individual or entity (*e.g.,* containers, vials, tubes), date of acquisition, by whom, and the source;

(iii) Location where it is stored (*e.g.,* building, room number or name, and freezer identification or other storage container);

(iv) The date the agent was removed and returned, the purpose for using the agent, the name of the individual who removed and returned the agent, and when applicable, date of final disposition of the agent and by whom;

(v) Records created under § 331.16;

(vi) For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), name of the select agent, the date of the transfer, the number of items transferred, the name of the sender, and the name of the recipient; and

(vii) Records created under § 331.19.

* * * * *

(3) Accurate, current inventory for each toxin held, including:

(i) The name and characteristics;

(ii) The quantity acquired from another individual or entity (*e.g.,* containers, vials, tubes, volume including concentration), date of acquisition, by whom, and the source;

(iii) The initial and current amount (*e.g.,* milligrams, milliliters, grams);

(iv) Location where the toxin is stored (*e.g.,* building, room number or name, and freezer identification or other storage container);

(v) When the toxin was accessed, the name of the toxin, the location where the toxin was accessed, the date the toxin was accessed, the purpose for accessing the toxin, the name of the individual accessing the toxin, the date the toxin was returned back to storage, the name of the individual returning the toxin back to storage, and date of final disposition of the toxin and by whom;

(vi) Records created under § 331.16;

(vii) For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), name of the toxin, the date of the transfer, the number of vials or quantity of toxin transferred, the name of the sender, and the name of the recipient; and

(viii) Records created under § 331.19.

* * * * *

(8) For select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or a validated viable select agent removal procedure:

(i) A written description of the validated inactivation procedure or validated viable select agent removal procedure used, including validation data;

(ii) A written description of the viability testing protocol used;

(iii) A written description of the investigation conducted by the entity's responsible official involving a validated inactivation or validated viable select agent removal failure and the corrective actions taken;

(iv) The name of each individual performing the validated select agent inactivation or validated viable select agent removal;

(v) The date(s) the validated inactivation or validated viable select agent removal was completed;

(vi) The location where the validated inactivation or validated viable select agent removal was performed; and

(vii) A signed certificate that must:

(A) Include the date(s) the validated inactivation or validated viable select agent removal was completed.

(B) Include the validated inactivation procedure or validated viable select agent removal procedure used.

(C) Include the name of the principal investigator.

(D) Include an attestation statement certifying that the information on the certificate is true, complete, and accurate, and that the validated inactivation or validated viable select agent removal was performed as described in paragraph (a)(8)(i) of this section.

(E) Be signed by the principal investigator or designee within 7 days after completion of the validated inactivation or validated viable select agent removal. Such designee must be listed on the entity's registration and have the knowledge and expertise to provide scientific and technical direction regarding the validated inactivation procedure or the validated viable select agent removal procedure to which the certificate refers.

(F) Be maintained for as long as the material is in the possession of the registered individual or entity plus an additional 3 years.

(G) A copy of the certificate must accompany all transfers of inactivated or select agent removed material including intra-entity transfers.

* * * * *

(d) All records created in accordance with the regulations of this part must be maintained for 3 years unless otherwise stated.

§ 331.19 [Amended]

■ 17. Amend § 331.19, in paragraphs (a)(1) introductory text and (b)(1) introductory text, by removing the words ''telephone, facsimile, or e-mail'' and adding the words ''eFSAP information system, telephone, or email'' in their place.

TITLE 9—ANIMALS AND ANIMAL PRODUCTS

PART 121—POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS

■ 18. The authority citation for part 121 continues to read as follows:

Authority: 7 U.S.C. 8401; 7 CFR 2.22, 2.80, and 371.4.

■ 19. Amend § 121.1 by:

■ a. Adding in alphabetical order definitions for ''Discovery'', ''Loss'', ''Release'', and ''Theft'';

■ b. Revising the definition of ''Validated inactivation procedure'';

■ c. Adding in alphabetical order definitions for ''Validated removal procedure'' and ''Verification viability testing protocol''; and

■ d. Revising the definition of ''Viability testing protocol''.

The additions and revisions read as follows:

§ 121.1 Definitions.

* * * * *

Discovery. The finding of a select agent or toxin by an individual or entity that is not aware of the select agent or toxin's existence. Examples include, but are not limited to the following:

(1) A registered individual or entity finds a select agent or toxin not accounted for in their inventory; or

(2) A non-registered individual or entity finds a select agent or toxin.

* * * * *

Loss. The inability to account for a select agent or toxin known to be in the individual or entity's possession.

* * * * *

Release means any of the following:

(1) An incident resulting in occupational exposure to a select agent or toxin;

(2) An incident resulting in animal/plant exposure to a select agent or toxin;

(3) The failure of equipment used to contain a select agent or toxin such that it is reasonably anticipated that a select agent of toxin was released;

(4) The failure of or breach in personal protective equipment in the presence of a select agent or toxin; or

(5) The failure of biosafety procedures such that it is reasonably anticipated that a select agent or toxin was outside of containment.

* * * * *

Theft. The unauthorized taking and removing of a select agent or toxin from the possession of an entity or individual.

* * * * *

Validated inactivation procedure. A procedure, whose efficacy has been confirmed by data generated from an in-house viability testing protocol, to render a select agent non-viable but allows the select agent to retain characteristics of interest for future use; or to render any nucleic acids that can produce infectious forms of any select agent virus non-infectious for future use.

Validated removal procedure. A procedure, whose efficacy has been confirmed by data generated in-house from a viability testing protocol, to confirm removal of all viable select agent, or nucleic acids of any select agent virus capable of producing infectious virus.

* * * * *

Verification viability testing protocol. A protocol, used on samples that have been subjected to a validated inactivation or removal procedure, to confirm the material is free of all viable select agent, or nucleic acids of any select agent virus capable of producing infectious virus.

Viability testing protocol. A protocol to confirm the efficacy of the inactivation or removal procedure by demonstrating the material is free of all viable select agent.

* * * * *

■ 20. Revise § 121.2 to read as follows:

§ 121.2 Purpose and scope.

(a) This part implements the provisions of the Agricultural Bioterrorism Protection Act of 2002 setting forth the requirements for possession, use, and transfer of select agents and toxins. The biological agents and toxins listed in this part have the potential to pose a severe threat to public health and safety, to animal health, or to animal products. Overlap select agents and toxins are subject to regulation by both APHIS and CDC.

(b) Any individual or entity in possession of a select agent or toxin, for which an exclusion or exemption listed in this part does not apply, and that is not included on a certificate of registration issued by the Administrator or HHS Secretary for that individual or entity, must immediately report such possession to the either the Administrator or HHS Secretary by the submission of an APHIS/CDC Form 6.

■ 21. Amend § 121.3 by:

■ a. Revising paragraphs (b) and (d)(1), (4), (5), and (6);

■ b. Redesignating paragraphs (d)(7) through (9) as paragraphs as (d)(8) through (10) and adding a new paragraph (d)(7);

■ c. In newly redesignated paragraph (d)(9), removing the words ''of the conclusion of patient care'' and adding the words ''from when the individual has been released from the medical facility where treatment was being provided'' in their place;

■ d. In newly redesignated paragraph (d)(10), revising footnotes 4 and 5;

■ e. In paragraph (e)(1), removing the words ''National Select Agent Registry website'' and adding the words ''Federal Select Agent Program website'' in their place; and

■ f. In paragraph (f)(3)(i), removing the words ''telephone, facsimile, or email'' and adding the words ''eFSAP information system, telephone, or email'' in their place, and removing the words ''(highly pathogenic)'' and ''virulent''.

The revisions and addition read as follows:

§ 121.3 VS select agents and toxins.

* * * * *

(b) VS select agents and toxins: African swine fever virus; Avian influenza virus; Classical swine fever virus; * Foot-and-mouth disease virus; Goat pox virus; Lumpy skin disease virus; *Mycoplasma capricolum; Mycoplasma mycoides;* Newcastle disease virus; [1] Peste des petits ruminants virus; * Rinderpest virus; Sheep pox virus; Swine vesicular disease virus.

* * * * *

(d) * * *

(1) Any VS select agent or toxin that is in its naturally occurring environment, provided that the agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source. Except for,

(i) Removal of an animal which is naturally infected with a select agent from its natural environment to an artificially established environment for the purpose of the intentional exposure or introduction of a select agent to a naïve or experimental animal; or

(ii) the introduction of a naïve animal to a natural environment where there is an animal which is naturally infected with a select agent for the purpose of the intentional exposure or introduction of a select agent to the naïve or experimental animal.

* * * * *

(4) A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus that has been subjected to a validated inactivation procedure, provided that:

(i) In-house validation of the inactivation procedure is completed prior to use;

(ii) A certificate of inactivation has been generated in accordance with § 121.17(a)(8).

(iii) For use of a select agent surrogate to validate an inactivation procedure:

(A) Select agent surrogates must be known to possess equivalent properties with respect to inactivation;

(B) If there are known variations in the resistance of a select agent to an inactivation procedure, including strain to strain, then an inactivation procedure must also be validated using the most resistant select agent surrogate.

(iv) For use of whole tissue or homogenized tissue surrogate to validate a chemical inactivation procedure for other tissues including those in other animal models:

(A) All standardized conditions must be held constant such as the select agent used, tissue volume, and ratio of tissue to volume of inactivating chemical;

(B) A safety margin must be incorporated into the final chemical inactivation procedure to ensure the effective inactivation of the select agent;

(C) The tissue surrogate must meet one of the following criteria:

(*1*) The tissue is expected to have the highest concentration of the specific select agent to be inactivated; or

(*2*) The concentration of the select agent in the tissue must be determined and this select agent concentration must not be exceeded when applying the validated inactivation procedure on subsequent tissue samples.

(5) Material containing a select agent that is subjected to a validated viable select agent removal procedure that has rendered the material free of all viable select agent provided that:

(i) In-house validation of the viable select agent removal procedure is completed prior to use;

(ii) A certificate of viable select agent removal has been generated in accordance with § 121.17(a)(8);

(iii) For use of a surrogate to validate a viable select agent removal procedure, only surrogates known to possess equivalent properties with respect to removal are used;

(iv) A portion of each subsequent sample has been subjected to a verification viability testing protocol to ensure that the validated viable select agent removal procedure has rendered the material free of all viable select agent.

(6) A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus not subjected to a validated inactivation procedure or material containing a select agent not subjected to a validated viable select agent removal procedure that removes all viable select agent cells, spores, or virus particles if the material is determined by the Administrator to be effectively inactivated or effectively free of select agents. To apply for a determination, an individual or entity must submit a written request and supporting scientific information to APHIS. A written decision granting or denying the request will be issued.

(*7*) Any select agent or regulated nucleic acids that can produce infectious forms of any select agent virus contained in a formalin-fixed paraffin-embedded (FFPE) tissue if the FFPE process used is a recognized procedure for that particular select agent or regulated nucleic acids.

* * * * *

[1] A virulent Newcastle disease virus (avian paramyxovirus type 1) has an intracerebral pathogenicity index in day-old chicks (*Gallus gallus*) of 0.7 or greater, or has an amino acid sequence at the fusion (F) protein cleavage that is consistent with virulent strains of Newcastle disease virus and phenylalanine at residue 117 of the F1 protein N-terminus, except for genotype VI viruses from columbid birds.

* * * * *

[4] An avian paramyxovirus type 1 virus (APMV–1) isolated from poultry which has an intracerebral pathogenicity index in day-old chicks (*Gallus gallus*) of 0.7 or greater or has an amino acid sequence at the fusion (F) protein cleavage that is consistent with

virulent strains of Newcastle disease virus and phenylalanine at residue 117 of the F1 protein N-terminus, except for genotype VI viruses from columbid birds.

[5] Pigeon paramyxovirus (PPMV–1) is a species-adapted APMV–1 virus which is endemic in pigeons and doves in the United States and can be identified through demonstration of the characteristic amino acid signature at the fusion gene cleavage site along with accompanying phylogenetic analysis confirming classification as a PPMV–1.

■ 22. Amend § 121.4 by:
■ a. Revising paragraph (b);
■ b. In paragraph (c)(1), redesignating footnote 6 as footnote 1;
■ c. Revising paragraph (d)(1);
■ d. In paragraph (d)(2), redesignating footnote 7 as footnote 2;
■ e. Revising paragraphs (d)(4) through (6);
■ f. Redesignating paragraphs (d)(7) through (9) as paragraphs as (d)(8) through (10) and adding a new paragraph (d)(7);
■ g. In newly redesignated paragraph (d)(9), removing the words ''of the conclusion of patient care'' and adding the words ''from when the individual has been released from the medical facility where treatment was being provided'' in their place;
■ h. In paragraph (e)(1), removing the words ''National Select Agent Registry website'' and adding the words ''Federal Select Agent Program website'' in their place in the last sentence;
■ i. Revising paragraph (f)(3)(i);
■ j. In paragraph (f)(3)(iii), adding the words ''not submitted through eFSAP Information System'' between the words ''APHIS/CDC Form 4'' and ''must''; and
■ k. In paragraph (f)(4), adding the words ''not submitted through eFSAP information system'' between the words ''form'' and ''must'' in the last sentence.

The revisions and addition read as follows:

§ 121.4 Overlap select agents and toxins.

* * * * *

(b) Overlap select agents and toxins: ** Bacillus anthracis; Bacillus anthracis* (Pasteur strain); ** Burkholderia mallei; * Burkholderia pseudomallei;* Hendra virus; * Nipah virus; and Rift Valley fever virus; and Venezuelan equine encephalitis virus.

* * * * *

(d) * * *

(1) Any overlap select agent or toxin that is in its naturally occurring environment, provided that the agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source. Except for,

(i) Removal of an animal which is naturally infected with a select agent from its natural environment to an artificially established environment for the purpose of the intentional exposure or introduction of a select agent to a naïve or experimental animal; or

(ii) The introduction of a naïve animal to a natural environment where there is an animal which is naturally infected with a select agent for the purpose of the intentional exposure or introduction of a select agent to the naïve or experimental animal.

* * * * *

(4) A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus that has been subjected to a validated inactivation procedure, provided that:

(i) In-house validation of the inactivation procedure is completed prior to use;

(ii) A certificate of inactivation has been generated in accordance with § 121.17(a)(8);

(iii) For use of a select agent surrogate to validate an inactivation procedure:

(A) Select agent surrogates must be known to possess equivalent properties with respect to inactivation;

(B) If there are known variations in the resistance of a select agent to an inactivation procedure, including strain to strain, then an inactivation procedure must also be validated using the most resistant select agent surrogate.

(iv) For use of a whole tissue or homogenized tissue surrogate to validate a chemical inactivation procedure for other tissues, including those in other animal models:

(A) All standardized conditions must be held constant, such as the select agent used, tissue volume, and ratio of tissue to volume of inactivating chemical;

(B) A safety margin must be incorporated into the final chemical inactivation procedure to ensure the effective inactivation of the select agent;

(C) The tissue surrogate must meet the following criteria:

(*1*) The tissue is expected to have the highest concentration of the specific select agent to be inactivated; or

(*2*) The concentration of the select agent in the tissue must be determined and this select agent concentration must not be exceeded when applying the validated inactivation procedure on subsequent tissue samples.

(5) Material containing a select agent that is subjected to a validated viable select agent removal procedure that has rendered the material free of all viable select agent provided that:

(i) In-house validation of the viable select agent removal procedure is completed prior to use;

(ii) A certificate of viable select agent removal has been generated in accordance with § 121.17(a)(8);

(iii) For use of a surrogate to validate a viable select agent removal procedure, only surrogates known to possess equivalent properties with respect to removal are used;

(iv) A portion of each subsequent sample has been subjected to a verification viability testing protocol to ensure that the validated viable select agent removal procedure has rendered the material free of all viable select agent.

(6) A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus not subjected to a validated inactivation procedure or material containing a select agent not subjected to a validated viable select agent removal procedure that removes all viable select agent cells, spores, or virus particles if the material is determined by the Administrator or HHS Secretary to be effectively inactivated or effectively removed. To apply for a determination, an individual or entity must submit a written request and supporting scientific information to APHIS or CDC. A written decision granting or denying the request will be issued.

(7) Any select agent or regulated nucleic acids that can produce infectious forms of any select agent virus contained in a formalin-fixed paraffin-embedded (FFPE) tissue if the FFPE process used is a recognized procedure for that particular select agent or regulated nucleic acids.

* * * * *

(f) * * *

(3) * * *

(i) The seizure of any Tier 1 overlap select agents and toxins must be reported within 24 hours by eFSAP information system, telephone, or email, or email. This report must be followed by submission of APHIS/CDC Form 4 within 7 calendar days after seizure of the overlap select agent or toxin.

* * * * *

■ 23. Amend § 121.5 by:
■ a. Revising paragraphs (a) introductory text and (a)(1);
■ b. In paragraph (a)(3), removing the words ''delivery of patient care by health care professionals has concluded'' and adding the words ''the individual has been released from the medical facility where treatment was being provided'' in their place;
■ c. In paragraph (a)(4), removing the words ''by telephone, facsimile, or email'' and adding the words ''through the eFSAP information system, telephone, or email'' in their place in the first sentence;

■ d. Adding paragraphs (a)(4)(i) and (ii);
■ e. Revising paragraph (b)(1); and
■ f. In paragraph (b)(3), adding the words ''not submitted through eFSAP information system'' between the words ''form'' and ''must'' in the last sentence.

The revisions and additions read as follows:

§ 121.5 Exemptions for VS select agents and toxins.

(a) Clinical or diagnostic laboratories and other entities that possess, use, or transfer a VS select agent or toxin that is contained in a specimen presented for diagnosis or verification will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the Administrator, within 7 calendar days after identification of the select agent or toxin, the select agent or toxin is transferred in accordance with § 121.16 or destroyed on-site by a recognized sterilization process or inactivated for future use in accordance with § 121.3(d)(4).

* * * * *

(4) * * *

(i) The identification of VS Tier 1 select agents or toxins must be immediately reported through the eFSAP information system, telephone, or email. This report must be followed by submission of APHIS/CDC Form 4 within 7 calendar days after identification.

(ii) [Reserved]

(b) * * *

(1) Unless directed otherwise by the Administrator, within 90 calendar days of receipt, the select agent or toxin is transferred in accordance with § 121.16 or destroyed on-site by a recognized sterilization process or inactivated for future use in accordance with § 121.3(d)(4).

* * * * *

■ 24. Amend § 121.6 by:
■ a. Revising paragraph (a)(1);
■ b. In paragraph (a)(3), removing the words ''delivery of patient care by health care professionals has concluded'' and adding the words ''the individual has been released from the medical facility where treatment was being provided'' in their place;
■ c. In paragraph (a)(4), removing the words ''by telephone, facsimile, or email'' and adding the words ''through the eFSAP information system, telephone, or email'' in their place in the first sentence;
■ d. Adding paragraphs (a)(4)(i) through (iv);
■ e. Revising paragraph (b)(1); and
■ f. In paragraph (b)(3), adding the words ''not submitted through eFSAP information system'' between the words ''form'' and ''must'' in the last sentence.

The revisions and additions read as follows:

§ 121.6 Exemptions for overlap select agents and toxins.

(a) * * *

(1) Unless directed otherwise by the Administrator or HHS Secretary, within 7 calendar days after identification, the select agent or toxin is transferred in accordance with § 121.16 or 42 CFR 73.16 or destroyed on-site by a recognized sterilization process, or inactivated for future use in accordance with § 121.4(d)(4);

* * * * *

(4) * * *

(i) The identification of any of the following overlap select agents or toxins must be immediately reported by telephone or email: *Bacillus anthracis, Burkholderia mallei* and *Burkholderia pseudomallei.* This report must be followed by submission of APHIS/CDC Form 4 within 7 calendar days after identification.

(ii) For all other overlap select agents or toxins, APHIS/CDC Form 4 must be submitted within 7 calendar days after identification.

(iii) Less stringent reporting may be required during agricultural emergencies or outbreaks, or in endemic areas.

(iv) A copy of APHIS/CDC Form 4 must be maintained for 3 years.

(b) * * *

(1) Unless directed otherwise by the Administrator or HHS Secretary, within 90 calendar days of receipt, the select agent or toxin is transferred in accordance with § 121.16 or 42 CFR 73.16 or destroyed on-site by a recognized sterilization process or inactivated for future use in accordance with § 121.4(d)(4);

* * * * *

■ 25. Amend § 121.7 by:
■ a. In paragraph (d)(3) introductory text, redesignating footnote 8 as footnote 1;
■ b. In paragraph (f), removing the words ''the relevant page(s) of'' and adding the words ''information related to'' in their place;
■ c. Revising paragraph (g);
■ d. In paragraph (i) introductory text, removing the word ''may'' and adding the word ''must'' in its place, and removing the word ''circumstances'' and adding the words ''the possession and use of the select agents and toxins'' in its place; and
■ e. In paragraph (i)(1), removing the words ''the relevant page(s) of'' and adding the words ''information related to'' in their place and removing footnote 9.

The revision reads as follows:

§ 121.7 Registration and related security risk assessments.

* * * * *

(g) The issuance of a certificate of registration may be contingent upon inspection and submission of additional information to include any or all of the following: the security plan, biosafety plan, incident response plan, or any other documents related to the requirements of this part.

* * * * *

§ 121.8 [Amended]

■ 26. Amend § 121.8, in paragraph (a)(3), by redesignating footnote 10 as footnote 1.
■ 27. Amend § 121.9 by:
■ a. Redesignating paragraphs (a)(5) through (9) as paragraphs (a)(6) through (10) and adding a new paragraph (a)(5);
■ b. Revising newly redesignated paragraphs (a)(7), (9), and (10);
■ c. Adding a new second sentence to paragraph (b);
■ d. Revising paragraph (c)(1); and
■ e. In paragraphs (c)(2) and (d), adding the words ''not submitted through eFSAP information system'' between the words ''form'' and ''must'' in the last sentence.

The addition and revisions read as follows:

§ 121.9 Responsible official.

(a) * * *

(5) Not be approved as responsible official or alternate responsible official at another registered entity.

* * * * *

(7) Ensure that annual inspections are conducted for each registered space to determine compliance with the requirements in accordance with the regulations of this part. The results of each inspection must be documented, and any deficiencies identified during an inspection must be corrected and the corrections documented. The annual inspection must address whether:

(A) The entity's biosafety/biocontainment plan is being effectively implemented as outlined in § 121.12.

(B) The entity's security plan is being effectively implemented as outlined in § 121.11.

(C) The entity's incident response plan is implemented to ensure whether the entity is able to respond, as outlined in § 121.14.

(D) Each individual with access approval from the Administrator or HHS Secretary has received the appropriate training as outlined in § 121.15.

* * * * *

(9) Investigate to determine the reason for any failure of a validated inactivation or validated viable select agent removal procedure to render material free from viable select agent. If the responsible official is unable to determine the cause of the failure from a validated inactivation or validated viable select agent removal procedure or receives a report of any inactivation failure after the movement of material to another location, the responsible official must report immediately through the eFSAP information system, telephone, or email the inactivation or viable select agent removal procedure failure to APHIS or CDC.

(10) Review each of the entity's validated select agent inactivation procedure or validated viable select agent removal procedure and ensure they are revised as necessary. The review must be conducted annually or after any change in principal investigator, change in the validated inactivation or validated viable select agent removal procedure, or failure of the validated inactivation or validated viable select agent removal procedure. The review must be documented, and training must be conducted if there are any changes to the validated select agent inactivation or validated viable select agent removal procedure, or viability testing protocol.

(b) * * * An alternate responsible official can serve at multiple registered entities. * * *

* * * * *

(c) * * *

(1) The identification of any of the following select agents or toxins must be immediately reported through the eFSAP information system, telephone, or email: African swine fever virus, avian influenza virus, *Bacillus anthracis, Burkholderia mallei, Burkholderia pseudomallei,* classical swine fever virus, foot-and-mouth disease virus, Newcastle disease virus, rinderpest virus, or swine vesicular disease virus. The final disposition of the agent or toxin must be reported by submission of APHIS/CDC Form 4 within 7 calendar days after identification. A copy of the completed form must be maintained for 3 years.

* * * * *

§ 121.10 [Amended]

■ 28. Amend § 121.10 by:

■ a. In paragraph (c), removing the words ''to select agents or toxins'' and adding the words ''approval from the Administrator or HHS Secretary'' in their place; and

■ b. In paragraph (h), removing the text ''(f)(2) through (f)(3)'' and adding the text ''(g)(2) through (3)'' in its place.

■ 29. Amend § 121.11 by:

■ a. Redesignating paragraphs (c)(9) and (10) as paragraphs (c)(11) and (12) and adding new paragraphs (c)(9) and (10);

■ b. In paragraph (d)(4), removing the words ''an area where select agents or toxins are used or stored'' and adding the words ''registered space'' in their place;

■ c. In paragraph (f) introductory text, removing the word ''possessing'' and adding the words ''registered for'' in their place;

■ d. Revising paragraph (f)(4)(iii);

■ e. In paragraph (f)(5)(iii), removing the ''CCTV'' and adding the word ''Video'' in its place; and

■ f. Removing paragraph (g) and redesignating paragraph (h) as paragraph (g).

The additions and revision read as follows:

§ 121.11 Security.

* * * * *

(c) * * *

(9) Describe procedures for conducting a pre-access suitability assessment of persons prior to seeking access approval for a Tier 1 select agent or toxin;

(10) Describe procedures to prevent the theft, loss, release, or unauthorized access to a select agent or toxin from an effluent decontamination system originating from a registered laboratory.

* * * * *

(f) * * *

(4) * * *

(iii) Procedures for screening any visitors, their property, and, where appropriate, vehicles at entry points to registered space based on the entity's site-specific risk assessment;

* * * * *

■ 30. Amend § 121.12 by:

■ a. In paragraph (a) introductory text, redesignating footnote 11 as footnote 1;

■ b. In paragraph (c)(1), removing the words ''National Select Agent Registry'' and adding the words ''Federal Select Agent Program website'' in their place;

■ c. In paragraph (c)(2), removing the words ''the internet'' and adding the words ''the Federal Select Agent Program website'';

■ d. Revising paragraph (d); and

■ e. Adding paragraphs (f), (g), and (h).

The revision and additions read as follows:

§ 121.12 Biosafety.

* * * * *

(d) The biosafety plan must include an occupational health plan for individuals listed on the entity's registration for access to Tier 1 select agents and toxins, and those individuals must be enrolled in the occupational health plan.

* * * * *

(f) When an effluent decontamination system is used, the plan must provide for verification that the liquid waste generated from registered space is sufficiently treated to prevent the release of a select agent or toxin prior to discharge of the waste from the facility.

(1) For a new effluent decontamination system, verification is required before initial use.

(2) For an effluent decontamination system in place, verification is required at least once every 12 months and following any major change to the effluent decontamination system.

(3) The verification must be documented.

(g) When an effluent decontamination system is used, the plan must provide that monthly routine maintenance is conducted of the effluent decontamination system, including at a minimum verification that:

(1) Alarms are functioning according to established specifications;

(2) Piping, pumps, valves, and tanks are not leaking; and

(3) Methods used to monitor and record performance measurements are functioning according to established specifications.

(h) An individual or entity must document every 12 months the following facility verification requirements for registered biosafety level 3 and animal biosafety level 3 laboratories.

(1) Accuracy of devices that monitor directional air-flow;

(2) Confirmation that decontamination systems (*e.g.,* autoclave, room decontamination systems, digesters, liquid effluent decontamination systems) are operating to ensure the containment of the select agent and toxin;

(3) Confirmation that systems are in place to monitor, maintain, and validate performance of mechanical systems to ensure that airflows and differential pressures are appropriate to maintain containment during normal/operational conditions;

(4) Verification that the facility mechanical, electrical, and drain waste and ventilation systems responsible for containment are inspected, maintained, and function as designed by the manufacturer specifications;

(5) Verification that the facility systems perform as intended in response to failure conditions as defined and tested during commissioning to prevent the release of a select agent or

toxin and verification of secondary containment:

(i) Evaluate using work objectives, use of space, and facility infrastructure systems against the verified original design and standards (*e.g.,* Biosafety in Microbiological and Biomedical Laboratories, NIH Design Requirements Manual).

(ii) Implement controls and alarms to identify and alert personnel when systems fail, malfunction, or are unable to maintain containment during such an event.

(6) Certification of laboratory ventilation system HEPA filters, if present;

(7) Confirmation that room integrity has been evaluated and repairs are addressed (*e.g.,* sealed penetrations);

(8) Primary containment equipment is certified based on manufacturer's specifications (or recommendations) (*e.g.,* biological safety cabinets, flexible film isolators, animal caging);

(9) Seals on centrifuges not used in primary containment have been checked and replaced if needed; and

(10) Showers, eye wash stations, and hands-free sinks are operating properly.

§ 121.13 [Amended]

■ 31. Amend § 121.13, in paragraph (a) introductory text, by adding the words ''or transfer'' after the word ''possess''.

■ 32. Amend § 121.14 by:

■ a. In the section heading, redesignating footnote 12 as footnote 1;

■ b. In paragraph (a), redesignating footnote 13 as footnote 2;

■ c. In paragraph (b), adding the words ''the failure of an effluent decontamination system resulting in a release of a select agent or toxin;'' after the words ''a select agent or toxin;'';

■ d. Revising paragraph (c); and

■ e. In paragraph (e) introductory text, removing the words ''Entities with'' and adding the words ''An individual or entity registered for'' in their place.

The revision reads as follows:

§ 121.14 Incident response[1].

* * * * *

(c) The response procedures must account for hazards associated with the select agent or toxin and appropriate actions to contain such select agent or toxin in registered space including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent, or an effluent decontamination system originating from registered space.

* * * * *

[1] Nothing in this section is meant to supersede or preempt incident response requirements imposed by other statutes or regulations.

■ 33. Amend § 121.15 by:

■ a. Adding paragraphs (a)(3) and (4);

■ b. In paragraph (b), removing the words ''Entities with'' and adding the words ''An individual or entity registered for'' in their place;

■ c. Revising paragraph (d); and

■ d. In paragraph (e), by removing words ''and document''.

The additions and revision read as follows:

§ 121.15 Training.

(a) * * *

(3) Each individual not approved for access to HHS and overlap select agents and toxins by the HHS Secretary or APHIS Administrator whose responsibilities routinely place them in close proximity (*e.g.,* shared laboratory space) to areas where select agents or toxins are transferred, possessed, or used. The training must be based on the particular needs of the individual and risks associated with working near areas where select agents and toxins are handled or stored. The training must also instruct each individual on the notification requirements related to select agents and toxins. Training must be accomplished prior to the individual's close proximity to areas where select agents or toxins are handled or stored and refresher training must be provided annually.

(4) Each individual not approved for access to HHS and overlap select agents and toxins by the HHS Secretary or APHIS Administrator who performs administrative or oversight functions of the facility related to the transfer, possession or use of such agents or toxins on behalf of the entity (*e.g.,* administrative professionals, facility managers, etc.). The training must instruct each individual on the regulatory requirements relevant to their administrative or oversight functions. The training must also instruct each individual on the notification requirements related to select agents and toxins. Training must be accomplished prior to the individual performing these functions and refresher training must be provided annually.

* * * * *

(d) The Responsible Official must ensure a record of the training provided for each individual listed in paragraph (a) of this section is maintained. The record must include the name of the individual who received the training, the date of the training, a description of the training provided, and the means used to verify that the individual understood the training.

* * * * *

§ 121.16 [Amended]

■ 34. Amend § 121.16, in paragraph (a), by redesignating footnote 14 as footnote 1.

■ 35. Amend § 121.17 by:

■ a. Revising paragraphs (a)(1), (3), and (8);

■ b. Removing the last sentence in paragraph (c); and

■ c. Adding paragraph (d).

The revisions and addition read as follows:

§ 121.17 Records.

(a) * * *

(1) An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and organisms containing recombinant and/or synthetic nucleic acids) held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials), including:

(i) The name and characteristics (*e.g.,* strain designation, GenBank Accession number);

(ii) The quantity acquired from another individual or entity (*e.g.,* containers, vials, tubes), date of acquisition, by whom, and the source;

(iii) Location where it is stored (*e.g.,* building, room number or name, and freezer identification or other storage container);

(iv) The date the agent was removed and returned, the purpose for using the agent, the name of the individual who removed and returned the agent, and when applicable, date of final disposition of the agent and by whom;

(v) Records created under § 121.16;

(vi) For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), name of the select agent, the date of the transfer, the number of items transferred, the name of the sender, and the name of the recipient; and

(vii) Records created under § 121.19.

* * * * *

(3) Accurate, current inventory for each toxin held, including:

(i) The name and characteristics;

(ii) The quantity acquired from another individual or entity (*e.g.,* containers, vials, tubes, volume including concentration), date of acquisition, by whom, and the source;

(iii) The initial and current amount (*e.g.,* milligrams, milliliters, grams);

(iv) Location where the toxin is stored (*e.g.,* building, room number or name, and freezer identification or other storage container);

(v) When the toxin was accessed, the name of the toxin, the location where the toxin was accessed, the date the

toxin was accessed, the purpose for accessing the toxin, the name of the individual accessing the toxin, the date the toxin was returned back to storage, the name of the individual returning the toxin back to storage, and date of final disposition of the toxin and by whom;

(vi) Records created under § 121.16;

(vii) For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), name of the toxin, the date of the transfer, the number of vials or quantity of the toxin transferred, the name of the sender, and the name of the recipient; and

(viii) Records created under § 121.19.

* * * * *

(8) For select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or a validated viable select agent removal procedure:

(i) A written description of the validated inactivation procedure or validated viable select agent removal procedure used, including validation data;

(ii) A written description of the viability testing protocol used;

(iii) A written description of the investigation conducted by the entity's responsible official involving a validated inactivation or validated viable select agent removal failure and the corrective actions taken;

(iv) The name of each individual performing the validated select agent inactivation or validated viable select agent removal;

(v) The date(s) the validated inactivation or validated viable select agent removal was completed;

(vi) The location where the validated inactivation or validated viable select agent removal was performed; and

(vii) A signed certificate that must:

(A) Include the date(s) the validated inactivation or validated viable select agent removal was completed.

(B) Include the validated inactivation procedure or validated viable select agent removal procedure used.

(C) Include the name of the principal investigator.

(D) Include an attestation statement certifying that the information on the certificate is true, complete, and accurate, and that the validated inactivation or validated viable select agent removal was performed as described in paragraph (a)(8)(i) of this section.

(E) Be signed by the principal investigator or designee within 7 days after completion of the validated inactivation or validated viable select agent removal. Such designee must be listed on the entity's registration and have the knowledge and expertise to provide scientific and technical direction regarding the validated inactivation procedure or the validated viable select agent removal procedure to which the certificate refers.

(F) Be maintained for as long as the material is in the possession of the registered individual or entity plus an additional 3 years.

(G) A copy of the certificate must accompany all transfers of inactivated or select agent removed material including intra-entity transfers.

* * * * *

(d) All records created in accordance with the regulations of this part must be maintained for 3 years unless otherwise stated.

§ 121.19 [Amended]

■ 36. Amend § 121.19, in paragraphs (a)(1) introductory text and (b)(1) introductory text, by removing the words ''telephone, facsimile, or email'' and adding the words ''eFSAP information system, telephone, or email'' in their place.

Done in Washington, DC, this 19th day of January 2024.

Jennifer Moffitt,

Undersecretary, Marketing and Regulatory Programs, USDA.

[FR Doc. 2024–01501 Filed 1–26–24; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 172

[FHWA Docket No. FHWA–2023–0046]

RIN 2125–AG12

Procurement, Management, and Administration of Engineering and Design Related Services

AGENCY: Federal Highway Administration (FHWA), U.S. Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM); request for comments.

SUMMARY: This proposed rule would update the regulations governing the procurement, management, and administration of engineering and design related services directly related to a highway construction project that is funded through a discretionary grant administered by FHWA. The intent of the proposed rule is to clarify how the regulations apply to recipients other than State transportation agencies (STA). This proposed rulemaking would also make technical changes and corrections to improve the administration of these regulations.

DATES: Comments must be received on or before April 1, 2024. Late comments will be considered to the extent practicable.

ADDRESSES: You may submit comments by any of the following methods:

- *Fax:* (202) 493–2251;
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590;
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays; or
- *Electronically through the Federal eRulemaking Portal: www.regulations.gov.* Follow the online instructions for submitting comments.

FOR FURTHER INFORMATION CONTACT: Mr. John McAvoy, Consultant Services Program Manager, FHWA Office of Preconstruction, Construction, and Pavements, (202) 853–5593, or via email at *john.mcavoy@dot.gov,* or Mr. Lev Gabrilovich, Senior Attorney Advisor, FHWA Office of the Chief Counsel, (202) 366–3813, or via email at *lev.gabrilovich@dot.gov.* Office hours for the FHWA are from 8 a.m. to 4:30 p.m., ET, Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

This document and all comments received may be viewed online through the Federal eRulemaking portal at *www.regulations.gov.* The website is available 24 hours each day, 366 days this year. Please follow the instructions. Electronic submission and retrieval help and guidelines are available under the help section of the website.

An electronic copy of this document may also be downloaded by accessing the Office of the Federal Register's home page at *www.FederalRegister.gov,* or the Government Printing Office's website at *www.GovInfo.gov.*

All comments received before the close of business on the comment closing date indicated above will be considered and will be available for examination in the docket at the above address. Comments received after the comment closing date will be filed in the docket and will be considered to the extent practicable. In addition to late