Proposed Rules

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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–2014–0095]

RIN 0579–AE08

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

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. The 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 the findings of the fourth biennial review of the list. In addition, we are proposing several amendments to the regulations, including the addition of provisions to address the inactivation of select agents, provisions addressing biocontainment and biosafety, and clarification of regulatory language concerning security, training, incident response, and records. These changes would increase the usability of the select agent regulations as well as provide for enhanced program oversight.

DATES: We will consider all comments that we receive on or before March 21, 2016.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0095.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2014–0095, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0095* or in our reading room, which is located in room 1141 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) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Freeda Isaac, National Director, Agriculture Select Agent Services, APHIS, 4700 River Road Unit 2, Riverdale, MD 20737–1231; (301) 851–3300, Option 3.

SUPPLEMENTARY INFORMATION: 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 that have the potential to pose a severe threat to both human and animal health, to animal health, to plant health, or to animal and plant products. The Animal and Plant Health Inspection Service (APHIS) has the primary responsibility for implementing the provisions of the Act within the United States Department of Agriculture (USDA). Veterinary Services (VS) select agents and toxins 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 are those that have the potential to pose a severe threat to plant health or plant products. Overlap select agents and toxins are those that have been determined to pose a severe threat to both human and animal health or to human health and 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 Bioterrorism Response Act for the Department of Health and Human Services (HHS).

Subtitle B (which is cited as the ''Agricultural Bioterrorism Protection Act of 2002'' and referred to below as the Act), section 212(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. Paragraph (a)(2) of section 212 requires the Secretary to review and republish the list every 2 years and to revise the list as necessary. In this document, we are proposing to amend and republish the list of select agents and toxins based on the findings of our fourth biennial review of the list.

In determining whether to include an agent or toxin on the list, the Act requires that the following criteria be considered:

- The effect of exposure to the agent or the toxin on animal and plant health, and on the production and marketability of animal or plant products;
- The pathogenicity of the agent or 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; and
- Any other criteria that the Secretary considers appropriate to protect animal or plant health, or animal or plant products.

We use the term ''select agents and toxins'' throughout the preamble of this proposed rule. Unless otherwise specified, the term ''select agents and toxins'' will refer to all agents or toxins listed by APHIS. When it is necessary to specify the type of select agent or toxin, we will use the following terms: ''PPQ select agents and toxins'' (for the plant agents and toxins listed in 7 CFR 331.3), ''VS select agents and toxins'' (for the animal agents and toxins listed in 9 CFR 121.3), or ''overlap select agents and toxins'' (for the overlap agents and toxins listed in both 9 CFR 121.4 and 42 CFR 73.4).

On February 27, 2015, we published in the **Federal Register** (80 FR 10627, Docket No. APHIS–2014–0095) an advance notice of proposed rulemaking

and request for comments (ANPR) [1] in order to announce our intention to review the select agent list. We solicited comments regarding potential additions and deletions from the list of select agents and toxins for 60 days ending April 28, 2015. We received 20 comments by that date. They were from scientists, scientific organizations, a State government, private individuals, and industry groups. Suggestions in these comments were used in order to inform our discussions on the content of the select agent list.

PPQ Select Agents and Toxins

APHIS's PPQ program convened an interagency working group to review the list of PPQ select agents and toxins and develop recommendations regarding possible changes to that list. Using the four criteria for listing found in the Act, economic crop data, current Federal quarantine notices, and new scientific information, the working group revisited the currently listed PPQ select agents and toxins and evaluated a number of new plant pathogens for inclusion on the list. Based on this review, APHIS is proposing to amend the list of PPQ select agents and toxins listed in 7 CFR 331.3 by removing three PPQ select agents and toxins from the list. Specifically, we are proposing to remove the following:

- *Peronosclerospora philippinensis* (*Peronosclerospora sacchari*) and *Sclerophthora rayssiae:* There are no viable cultures of these corn pathogens currently held in U.S. laboratories, they are difficult to grow or maintain, difficult to keep viable during transport, and would require a large amount of inoculum to infect fields by artificial means due to the fact that they must spread via infected plant material; and
- *Phoma glycinicola* (formerly *Pyrenochaeta glycines*): This soybean pathogen's natural distribution is limited to two countries in Africa, it does not spread rapidly in the field, soybean importation pathways into the United States by which the pathogen might enter are limited, and while no U.S. soybean variety is immune to this pathogen, Environmental Protection Agency-approved fungicides are available to treat any infestation.

VS Select Agents and Toxins

APHIS' VS program also convened an interagency working group to review the list of VS select agents and toxins and the list of overlap select agents and toxins in 9 CFR part 121 in order to consider changes to the lists. Based on the review, APHIS is proposing to remove three overlap select agents and toxins from the list set out in § 121.4(b):

- *Bacillus anthracis* (Pasteur strain): Historically, the *B. anthracis* Pasteur strain has been retained as a select agent to allow for continued oversight of laboratories in which the accidental (or intentional) combination of this strain with the excluded Sterne strain could occur to produce the wild type phenotype *B. anthracis* de novo. However, a recent study [2] indicates that bacterial transformation of *B. subtilis* with plasmid DNA is inefficient; indicating that transformation with bacteria such as *B. anthracis* (e.g., pXO1 into *B. anthracis* Pasteur strain) would also be inefficient. Given that *B. anthracis* Pasteur strain does not encode the plasmid which carries the pathogenic toxin genes, analogous to the Sterne strain which was excluded from Select Agent oversight in 2003, we believe there is no potential for high animal mortality rates or for misuse that might result in social or economic disruption. Therefore, we are proposing that the Pasteur strain be removed from the overlap select agent list.
- *Brucella abortus* and *Brucella suis:* While both of these organisms have been eradicated from the domestic livestock industry, they are currently endemic in wildlife and feral swine populations in the United States. However, there is an extensive regulatory control program in place for *B. abortus* in the remaining affected Designated Surveillance Area. APHIS has also recently enacted a national program to control feral swine that will include surveillance and disease monitoring for swine brucellosis. Therefore, we believe the effect of exposure to these agents on animal health and on the production and marketability of animal products is minimized. We are proposing that these two *Brucella* species be removed from the overlap select agent list. However, *Brucella melitensis,* as a foreign animal disease agent not currently found in the United States, would be kept as a VS select agent.

Accordingly, CDC will also be proposing a parallel change to its overlap select agent regulations.

Additional Changes

We are proposing to make several changes to the regulations, including the addition of provisions to address the inactivation of select agents, provisions addressing biocontainment and biosafety, and clarification of regulatory language concerning security, training, incident response, and records. These changes, which are described in detail below, would increase the usability of the select agent regulations as well as provide for enhanced program oversight.

Definitions

In 7 CFR 331.1 and 9 CFR 121.1, we are proposing to add definitions for *inactivation* and *kill curve.* We believe these definitions are necessary as they are included in the additional biocontainment and biosafety language we are proposing to add to the regulations.

The definition of *inactivation* would be established as ''a method to render a select agent non-viable but retain characteristic 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.'' This definition draws a distinction between inactivation for waste treatment and inactivation of regulated material for future purposes such as research. The definition of *kill curve* would be established as ''the results of a dose-response experiment where a select agent is subjected to increasing amounts of the inactivating treatment to determine the minimum conditions required to render it non-viable or to render any nucleic acids that can produce infectious forms of any select agent virus as non-infectious.''

Exclusions and Inactivation

We are proposing to amend 7 CFR 331.3(d)(2), 9 CFR 121.3(d)(2), and 9 CFR 121.4(d)(2), which currently exclude nonviable select agents or nonfunctional toxins from the requirements of the regulations, in order to clarify our policy that an entity must use a validated method to render a select agent nonviable or regulated nucleic acids non-infectious for future use. This means that the method must be scientifically sound and that it will produce consistent results each time it is used.

We are proposing that inactivation include the use of one of the following: The exact conditions of a commonly accepted method that has been validated as applied (*e.g.,* autoclaving), a published method with adherence to the exact published conditions (*i.e.,* extrapolations or deductions are to be avoided), or in-house methods, only if validation testing includes the specific conditions used and appropriate controls.

[1] To view the ANPR and the comments we received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0095.*

[2] C. Johnston, B. Martin, G. Fichant, P. Polard, and J.P. Claverys. ''Bacterial transformation: distribution, shared mechanisms and divergent control.'' *Nature Reviews Microbiology.* 2014. 12: 181–196.

We are also proposing that the entity develop a site-specific kill curve in order to define conditions of inactivation for each select agent or regulated nucleic acid. If there are strain-to-strain variations in the resistance of a select agent to the inactivation procedure, then a specific kill curve would have to be developed for each strain that undergoes the inactivation procedure. A new kill curve would have to be created upon any change in procedure or inactivation equipment. In addition, a validated sterility testing protocol would have to be conducted in order to ensure that the inactivation method has rendered a select agent nonviable or regulated nucleic acids non-infectious.

In addition, we are proposing that an entity be required to report any viability of a select agent or infectivity of regulated nucleic acids that can produce infectious forms of any select agent virus that was subjected to a validated inactivation protocol to APHIS or CDC.

We are also proposing to require that an entity review annually, and revise as necessary, the following: (1) The kill curve procedure and results; (2) site-specific standard operating procedures to ensure that select agents or regulated nucleic acids that can produce infectious forms of any select agent virus are inactivated by a safety margin; and (3) the validated sterility testing protocol used to ensure that the inactivation method has rendered a select agent non-viable or regulated nucleic acids that can produce infectious forms of any select agent viruses non-infectious.

Finally, we are proposing that written records be kept for any select agent that has been rendered nonviable or regulated nucleic acids that have been rendered non-infectious. We are particularly requesting comments regarding whether there are more specific measures available to demonstrate that a select agent has been rendered nonviable, or a regulated infectious nucleic acid has been rendered non-infectious.

We are also proposing to add to 7 CFR 331.3(e), 9 CFR 121.3(e), and 9 CFR 121.4(e) a paragraph stating that an individual or entity may make a written request to the Administrator for reconsideration of a decision denying an exclusion application. The written request for reconsideration would have to state the facts and reasoning upon which the individual or entity relies to show the decision was incorrect. The Administrator would grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision. This language was included in previous versions of the regulations and was erroneously removed by an earlier rulemaking.

Exemptions for Select Agents and Toxins

Sections 7 CFR 331.5, 9 CFR 121.5, and 9 CFR 121.6 concern conditions under which entities may be exempted from the requirements of the regulations. Paragraph (a) requires that the identification of the agent or toxin be reported to APHIS or CDC. Since select agents and toxins have the potential to pose a severe threat to both human and animal health, to animal health, to plant health, or to animal and plant products, clinical and diagnostic laboratories typically have their initial results confirmed by a registered or certified reference laboratory. We are proposing to require that in addition to notifying APHIS or CDC, the reference laboratory inform the specimen provider upon confirmation of the identification of a select agent or toxin. This change would clarify our expectations regarding communication and notification between the reference laboratory and the specimen provider.

We are also proposing to add language to paragraph (a) in sections 7 CFR 331.5, 9 CFR 121.5, and 9 CFR 121.6 that specifies that entities may be required to report identification of agents or toxins to other appropriate authorities when required by Federal, State, or local law. This language was added to the CDC select agent regulations in a previous rulemaking, but not to the APHIS regulations and this change is necessary in order to achieve uniformity across all regulations associated with the diagnosis and care for individuals infected with a select agent or toxin. Specifically, we are proposing to add provisions that state that we do not regulate material containing select agents or toxins when it is in a patient care setting and is not being collected or otherwise tested or retained, nor do we regulate waste generated during delivery of patient care. However, once delivery of patient care for the select agent or toxin infection has concluded, these specimens would become subject to the requirements of the regulations. If an entity cannot meet these requirements, then the material may be transferred to another entity according to the select agent regulations or destroyed using an approved method. The decision to retain, transfer, or destroy any specimens must be made within 7 calendar days of the conclusion of patient care. These requirements would be set out in new paragraphs 9 CFR 121.3(d)(4) and 9 CFR 121.4(d)(4).

Registration and Related Security Risk Assessments

The regulations in 7 CFR 331.7 and 9 CFR 121.7 set out registration requirements for those entities that wish to work with select agents and toxins and stipulates the individuals within those entities that must undergo a security risk assessment by the Attorney General.

We are proposing to state that an entity registered to possess, use, or transfer a select agent or toxin would have to meet the requirements of the regulations for those select agents and toxins listed on the entity's official registration regardless of whether the entity is in possession of those select agents or toxins and without regard to the amount of select agents or toxins in the entity's possession. This change would serve to codify existing policy and would be added as a new paragraph (b).

Responsible Official

The regulations in 7 CFR 331.9 and 9 CFR 121.9 set out requirements for entities requesting to work with select agents and toxins to designate a responsible official, who ensures that the entity continues to meet the requirements of the regulations.

Paragraph (a)(6) requires the responsible official to ensure that annual inspections are conducted for each location where select agents or toxins are stored or used in order to determine compliance with the regulations. The responsible official also must document the results of each inspection and identify and address any deficiencies.

We are proposing to require that any corrections of deficiencies found must also be documented. This change is necessary to improve recordkeeping practices and to provide a more complete account of facility containment and security procedures. We are also proposing to replace the word ''laboratory'' with the phrase ''registered space.'' This terminology is more accurate, as registered spaces are not always laboratories.

We are also proposing to add a new paragraph (a)(7), which would require the entity's responsible official to provide contact information for the USDA or HHS Office of Inspector General Hotline, so that employees and other individuals may anonymously report any containment or security concerns they may have. Although the select agent program has established a whistleblower portal on its Web site, there is currently no requirement for employees at registered entities to be

made aware of its existence or how to use it. Adding this requirement would allow for increased worker involvement in biosafety/biocontainment and security programs at registered entities and may also enhance the quality of Federal oversight in this area.

Security Risk Assessments

We are proposing to amend the regulations in 7 CFR 331.10 and 9 CFR 121.10. These regulations establish parameters for restricting access to select agents and toxins and the process by which individuals may be approved for access to select agents and toxins after the completion of a security risk assessment by the Attorney General.

Paragraph (e) states that a person with valid approval from the HHS Secretary or Administrator to have access to select agents or toxins may request, through his or her responsible official, that the HHS Secretary or APHIS Administrator provide their approved access status to another registered individual or entity for a specified period of time. We are proposing to also require that the responsible official at the visiting person's home entity notify the host entity if that person's approved access to select agents or toxins has been terminated. This would ensure that an individual whose permissions have been terminated would not be allowed further access to select agents and toxins.

Security, Biocontainment/Biosafety, and Incident Response Plans

The regulations require registered entities to develop and implement a number of plans in order to ensure the safety and security of the select agents they handle. These are:

- A security plan, as described by the regulations in 7 CFR 331.11 and 9 CFR 121.11, that provides for measures sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss, or release;
- A biocontainment plan, in the case of PPQ select agents, or a biosafety plan, in the case of VS and overlap select agents, as described in the regulations in 7 CFR 331.12 and 9 CFR 121.12, that provides for measures sufficient to contain the select agent or toxin (*e.g.,* physical structure and features of the entity, and operational and procedural safeguards); and
- An incident response plan, as described in the regulations in 7 CFR 331.14 and 9 CFR 121.14, that provides for measures that the registered entity will implement in the event of theft, loss, or release of a select agent or toxin; inventory discrepancies; security breaches (including information systems); severe weather and other natural disasters; workplace violence; bomb threats and suspicious packages; and emergencies such as fire, gas leak, explosion, power outage, etc. The response procedures must account for hazards associated with the select agent or toxin and appropriate actions to contain such agent or toxin.

All of these plans require annual review and revision as necessary. Drills or exercises must also be conducted at least annually to test and evaluate the effectiveness of the plans. The plans must be reviewed and revised, as necessary, after any drill or exercise and after any incident. We are proposing to require that these drills or exercises be documented to include how the drill or exercise tested and evaluated the plan, any problems identified, any corrective action taken, and the names of the individuals who participated in the drill or exercise. This will provide a more thorough accounting of required activities as well as increasing the efficacy of the plans via testing and entity-directed improvements. We are proposing to add these requirements to 7 CFR 331.11(h), 331.12(e), 331.14(f), 9 CFR 121.11(h), 121.12(e), and 121.14(f).

We are also proposing to add a requirement that the biocontainment, biosafety, and incident response plans be submitted for initial registration, renewal of registration, or when requested. These additions would be located in 7 CFR 331.12(a), 331.14(a), 9 CFR 121.12(a), and 121.14(a). This change is necessary in order to bring the requirements for these plans in line with existing requirements for the security plan.

Details of the changes we are proposing to the security, biosecurity, and biosafety plans individually may be found below.

Security Plan

Paragraph (c)(5) of 7 CFR 331.11 and 9 CFR 121.11 requires that the security plan describe procedures for addressing loss or compromise of keys, passwords, combinations, etc. and protocols for changing access numbers or locks following staff changes. We are proposing to add keycards to that list as they are commonly used. We are also proposing to use the term ''access permissions'' instead of the term ''access numbers,'' as it covers a broader range of topics.

We are also proposing to add a new paragraph (c)(11) to the regulations in 7 CFR 331.11 and 9 CFR 121.11. This would require that the security plan contain a description of how the entity authorizes the means of entry into areas where select agents or toxins are stored or used, which would include a description of all centralized access control management systems (*e.g.,* keycards) and/or mechanical key management. This requirement would allow us to directly ascertain the way in which entities allow individuals entry to areas containing select agents and toxins and potentially identify any weaknesses in that process.

In the same sections, paragraphs (d)(7)(i) through (d)(7)(v) encompass a list of activities that individuals with access approval from the Administrator or the HHS Secretary must immediately report to the responsible official. We are proposing to add a new paragraph (d)(7)(vi) to require that the responsible official must be notified of any loss of computer, hard drive, or other data storage device containing information that can be used to gain access to select agents or toxins. Such notification will facilitate notification of the Federal Bureau of Investigation if deemed necessary by the responsible official as the loss of such equipment may be criminal in nature.

Biocontainment/Biosafety Plan

Paragraph (a) of 7 CFR 331.12 and 9 CFR 121.12 requires that the biocontainment or biosafety plan contain sufficient information and documentation to describe the biosafety and containment procedures for each select agent or toxin that the registered entity will possess. The plan must also include a description of the biosafety and containment procedures for any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent. We are proposing to additionally require that laboratory-specific biocontainment and/or biosafety manuals must be accessible to individuals working in those laboratories. This change would help to foster an enhanced culture of responsibility by ensuring that appropriate biocontainment and/or biosafety resources are available to all staff with access to select agents and toxins within a select agent laboratory.

In the aftermath of recent biosafety incidents involving an unintentional release of potentially viable anthrax within the CDC's Roybal Campus, in Atlanta, GA, and the inadvertent cross-contamination and shipment of a laboratory specimen of low-pathogenic avian influenza virus with the VS select agent highly pathogenic avian influenza virus, we believe that the biocontainment and biosafety plans should be designed according to a site-specific risk assessment in accordance with the risk posed by a select agent or toxin. Therefore, we are proposing to

add specific provisions to the biocontainment and biosafety plans that would require completion of a written risk assessment for each procedure. This risk assessment would have to include the following elements: A description of the safeguards in place to protect entity personnel, the public, and the environment from exposure to the select agent or toxin; decontamination procedures; waste management procedures; and procedures for handling select agents and toxins in the same spaces as non-select agents and toxins in order to prevent unintentional cross-contamination.

We are specifically requesting comments regarding any specific biocontainment or biosafety measures to prevent laboratory acquired infections or accidental or intentional release of the select agents and toxins from an entity into the community.

Finally, paragraph (c)(2) of 9 CFR 121.12 requires that entities should consider the guidance found in the Occupational Safety and Health Administration regulations in 29 CFR 1910.1200 and 1910.1450. We are proposing to remove this reference as the information in those regulations is also contained in the CDC/National Institutes of Health publication, ''Biosafety in Microbiological and Biomedical Laboratories,'' which is referenced in paragraph (c)(1) and a second reference is therefore duplicative.

Training

We are proposing to amend the regulations in 7 CFR 331.15 and 9 CFR 121.15, which concern provision of mandatory training for staff and visitors who work in or visit areas where select agents or toxins are handled or stored. We are proposing to require that all individuals who have received approval to have access to select agents and toxins must undergo training regardless of whether they have access to those select agents or toxins. The training would have to be completed within a year of that individual's approval or prior to entry into an area where select agents and toxins are used or stored, whichever occurs first. This change is necessary in order to codify our position regarding which individuals at registered entities are required to receive training.

Transfers

We are proposing to amend the regulations in 7 CFR 331.16 and 9 CFR 121.16, which concern the transfer of select agents and toxins to a registered entity. Specifically, paragraph (b) states that select agents and toxins may need a permit issued in accordance with 7 CFR part 330 or 9 CFR part 122. We have determined that a permit for the importation or interstate movement of a select agent or toxin listed in 7 CFR 331.3, 9 CFR 121.3, or 121.4 is not required for such importation and/or interstate movement provided that the select agent or toxin is authorized for transfer in accordance with 7 CFR 331.16(b) or 9 CFR 121.16(b).

Records

The regulations in 7 CFR 331.17 and 9 CFR 121.17 concern required recordkeeping procedures for regulated entities as those records relate to select agents and toxins. Paragraph (a)(3)(x) requires that registered entities record the destruction of any toxins by specifically noting the quantity of toxin destroyed, the date of such action, and by whom. However, there is not an equivalent requirement regarding the destruction of select agents. We are proposing to add this requirement in order to ensure consistency with the toxin provisions and ensure proper tracking of select agents from acquisition to destruction. These requirements would be added in a new paragraph (a)(1)(ix).

We are also proposing to require that regulated entities maintain records concerning those select agents that have been rendered nonviable or regulated nucleic acids that have been rendered non-infectious. These records would specifically capture the activities detailed under the heading ''Exclusions and Inactivation'' above. Such recordkeeping is necessary in order to confirm that an entity has performed the procedures necessary. The select agent program would then have the ability to review those records in order to ensure that the entity is performing all procedures necessary for nonviability or inactivation. The requirements would be added in a new paragraph (a)(8) in 7 CFR 331.17 and 9 CFR 121.17.

We are also proposing to state that any records created that contain information related to an entity's registration or its select agents and toxins must be provided promptly upon request. This requirement would be added to revised paragraph (c). Given the wide variety of entities regulated under the Federal Select Agent Program, the scope of records readily available for program review will enhance the ability of the program to evaluate entity biosafety, biocontainment, security, and incident response programs. Paragraph (c) in both 7 CFR 331.17 and 9 CFR 121.17 would also be revised to specify that such records may include, but are not limited to, biocontainment certifications, laboratory notebooks, institutional biosafety and/or animal use committee minutes and approved protocols, and records associated with occupational health and suitability programs.

Finally, paragraph (b) in both 7 CFR 331.17 and 9 CFR 121.17 requires that regulated entities implement a system to ensure that all records and databases created under this part are accurate, have controlled access, and that their authenticity may be verified. To ensure the accuracy of handwritten records, we are proposing to specify that such records must be legible.

Records for Select Agents in Long-Term Storage

Paragraph (a)(1) in both 7 CFR 331.17 and 9 CFR 121.17 requires entities to maintain 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. We continue to receive comments critical of that portion of the regulations. Criticism is typically focused on the belief that a container-based inventory requirement is not a useful mechanism to track inventory of biological agents, since small amounts could be stolen without detection and used to grow larger quantities.

However, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 obliges APHIS and CDC to include a requirement for ''the prompt notification of the Secretary, and appropriate Federal, State, and local law enforcement agencies, of the theft or loss of listed agents and toxins'' in the regulations. We are therefore soliciting comment regarding what regulatory requirement or requirements should be implemented such that a registered entity could quickly determine whether a select agent had been lost or stolen from long-term storage without that registered entity first having an accurate, current inventory for each select agent held in long-term storage. Additionally, we are soliciting ideas concerning ways in which the current regulations could be amended to address the possibility of theft of a select agent from a container held in long-term storage.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities. The analysis is summarized below. Copies of the full analysis are available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT** or on the Regulations.gov Web site (see **ADDRESSES** above for instructions for accessing Regulations.gov).

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. APHIS has completed its fourth biennial review of select agent regulations and is proposing changes that would increase their usability as well as provide for enhanced program oversight. The proposed amendments include provisions to address the inactivation of select agents, provisions addressing biosafety, and clarification of regulatory language concerning security, training, incident response, and records.

The proposed rule would require that entities develop an agent-specific *kill curve* in order to define conditions of inactivation for each select agent or regulated infectious nucleic acid and maintain written records of having done so.[3] Costs of complying with this amendment are therefore expected to be modest.

Currently, there are 291 entities registered with APHIS and CDC. Of these entities, there are 240 registered to possess Tier 1 select agents and toxins, including 78 academic, 29 commercial, 80 State government, 37 Federal government, and 16 private (non-profit) institutions, most of which are considered to be small entities. Based on proposed record keeping and reporting requirements, an additional 10 to 20 hours per year may be required. At an imputed cost of $33.40 per hour (GS–12, step 2), this additional time requirement per entity would cost between $334 and $668 per year, or in total for all registered entities between $80,000 and $160,000.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

[3] The definition of *kill curve* would be ''the results of a dose-response experiment where a select agent is subjected to increasing amounts of the inactivating treatment to determine the minimum conditions required to render it non-viable or to render any nucleic acids that can produce infectious forms of any select agent virus as non-infectious.''

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. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), we have determined that there is burden associated with this action. We will publish a separate document in the **Federal Register**, announcing our determination of burden and soliciting comments on it.

E-Government Act Compliance

The Animal and Plant Health Inspection Service 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. For information pertinent to E-Government Act compliance related to this proposed rule, please contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2727.

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. Section 331.1 is amended by adding, in alphabetical order, definitions of *inactivation* and *kill curve* to read as follows:

§ 331.1 Definitions.

* * * * *

Inactivation. A method to render a select agent non-viable but retain characteristic 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.

* * * * *

Kill curve. The results of a dose-response experiment where a select agent is subjected to increasing amounts of the inactivating treatment to determine the minimum conditions required to render it non-viable, or to render any nucleic acids that can produce infectious forms of any select agent virus as non-infectious.

* * * * *

■ 3. Section 331.3 is amended as follows:

■ a. In paragraph (b), by removing the words ''*Peronosclerospora philippinensis* (*Peronosclerospora sacchari*);'', ''*Phoma glycinicola* (formerly *Pyrenochaeta glycines*);'', and ''*Sclerophthora rayssiae;*''

■ b. By revising paragraph (d)(2).

■ c. By adding paragraph (e)(3).

The addition and revision read as follows:

§ 331.3 PPQ select agents and toxins.

* * * * *

(d) * * *

(2) Nonviable select agents or nonfunctional toxins.

(i) Unless waived by the Administrator, 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 process to remove viability or infectious form (*i.e.,* the ability to reproduce or produce disease, while maintaining cellular structure) is not excluded from the requirements of this part until an individual or entity:

(A) Develops a site-specific kill curve to define conditions of inactivation for each select agent or regulated nucleic acids that can produce infectious forms

of any select agent virus. If there are strain-to-strain variations in resistance of a select agent to the inactivation procedure, then a specific kill curve must be developed for each strain that undergoes the inactivation procedure. A new kill curve must be created upon any change in procedure or inactivation equipment.

(B) Develops site-specific standard operating inactivation procedures to ensure that the material is inactivated by a safety margin determined by the kill curve.

(C) Subjects representative samples of inactivated select agents or any nucleic acids that can produce infectious forms of any select agent viruses to a validated sterility testing protocol to ensure that the inactivation method has rendered the select agent non-viable or regulated nucleic acids non-infectious.

(D) Any viability of a select agent or infectivity of regulated nucleic acids that can produce infectious forms of any select agent virus that was subjected to a validated inactivation protocol is reported to APHIS.

(E) Reviews annually, and revises as necessary, the following:

(*1*) The kill curve procedure and results;

(*2*) Site-specific standard operating procedures to ensure that select agents or regulated nucleic acids that can produce infectious forms of any select agent virus are inactivated by a safety margin; and

(*3*) The validated sterility testing protocol used to ensure that the inactivation method has rendered a select agent non-viable or regulated nucleic acids that can produce infectious forms of any select agent virus sample non-infectious.

(F) Reviews, and revises as necessary, documents listed in paragraph (d)(2)(i)(E) of this section after any change in principal investigator, change in protocol, or any reported viability of a select agent or infectivity of regulated nucleic acids that can produce infectious forms of any select agent viruses previously assessed as inactive.

(ii) Unless waived by the Administrator, an extract from a select agent is not excluded from the requirements of this part until an individual or entity meets the following requirements:

(A) Any extract is subjected to a process that removes all viable cells, spores, or virus particles.

(B) Any extract is subjected to a validated sterility testing protocol to ensure that the inactivation method has rendered the extract free of a select agent.

(C) Any viability of an extract that was subjected to a validated inactivation protocol is reported to the responsible official.

(D) Any viability of a select agent or infectivity of regulated nucleic acids that can produce infectious forms of any select agent virus that was previously assessed as inactive by their validated sterility testing protocol is reported to APHIS.

* * * * *

(e) * * *

(3) An individual or entity may make a written request to the Administrator for reconsideration of a decision denying an application for the exclusion of an attenuated strain of a select agent or a select toxin modified to be less potent or toxic. The written request for reconsideration must state the facts and reasoning upon which the individual or entity relies to show the decision was incorrect. The Administrator will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision.

* * * * *

■ 4. In § 331.5, paragraph (a)(3) is revised to read as follows:

§ 331.5 Exemptions.

(a) * * *

(3) The identification of the agent or toxin is reported to APHIS, the specimen provider, and to other appropriate authorities when required by Federal, State, or local law by telephone, facsimile, or email. This report must be followed by submission of APHIS/CDC Form 4 to APHIS within 7 calendar days after identification.

* * * * *

■ 5. Section 331.7 is amended as follows:

■ a. By redesignating paragraphs (b) through (k) as paragraphs (c) through (l), respectively.

■ b. By adding a new paragraph (b).

The addition reads as follows:

§ 331.7 Registration and related security risk assessments.

* * * * *

(b) As a condition of registration, each entity is required to be in compliance with the requirements of this part for select agents and toxins listed on the registration regardless of whether the entity is in actual possession of the select agent or toxin. In regard to toxins, the entity registered for possession, use, or transfer of toxins must be in compliance with the requirements of this part regardless of the amounts of toxins currently in possession.

* * * * *

■ 6. Section 331.9 is amended as follows:

■ a. In paragraph (a)(6), by removing the word ''laboratory'' and adding the words ''registered space'' in its place and by adding the words ''and the corrections documented'' at the end of the second sentence after the words ''must be corrected''.

■ b. By adding paragraph (a)(7).

The addition reads as follows:

§ 331.9 Responsible official.

(a) * * *

(7) Ensure that individuals are provided the contact information for the USDA or HHS Office of Inspector General Hotline so that they may anonymously report any biosafety/biocontainment or security concerns related to select agents and toxins.

* * * * *

■ 7. In § 331.10, paragraph (e) is amended by adding a sentence at the end of the paragraph to read as follows:

§ 331.10 Restricting access to select agents and toxins; security risk assessments.

* * * * *

(e) * * * A responsible official must immediately notify the responsible official of the visiting entity if the person's access to select agents or toxins has been terminated.

* * * * *

■ 8. Section 331.11 is amended as follows:

■ a. In paragraph (c)(5), by adding the word ''keycards,'' after the word ''keys,'' and by removing the word ''numbers'' and adding the word ''permissions'' in its place.

■ b. By adding paragraph (c)(11).

■ c. In paragraph (d)(7)(iv), by removing the word ''and''.

■ d. By adding paragraph (d)(7)(vi).

■ e. By adding a sentence at the end of paragraph (h).

The additions read as follows:

§ 331.11 Security.

* * * * *

(c) * * *

(11) Describe how the entity authorizes the means of entry into areas where select agents or toxins are stored or used to include centralized access control management systems (*e.g.,* keycards) and/or mechanical key management.

(d) * * *

(7) * * *

(vi) Any loss of computer, hard drive or other data storage device containing information that can be used to gain access to select agents or toxins.

* * * * *

(h) * * * Drills or exercises must be documented to include how the drill or

exercise tested and evaluated the plan, any problems that were identified and corrective action(s) taken, and all individuals who participated in the drill or exercise.

■ 9. Section 331.12 is amended as follows:

■ a. By revising paragraph (a).

■ b. By adding a sentence at the end of paragraph (e).

The addition and revision read as follows:

§ 331.12 Biocontainment.

(a) An individual or entity required to register under this part must develop and implement a written biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use.[4] The biocontainment plan must contain sufficient information and documentation to describe the biocontainment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent. The biocontainment procedures specific to each registered laboratory must be available to each individual working in that laboratory. The current biocontainment plan must be submitted for initial registration, renewal of registration, or when requested. The biocontainment plan must include the following provisions:

(1) A written risk assessment for each prescribed procedure involving a select agent or toxin.

(i) The hazardous characteristics of the agent or toxin listed on the entity's registration, including probable routes of transmission in the laboratory and in the environment, infective dose (if known), stability in the environment, host range, contribution of any genetic manipulations, and endemicity.

(ii) Hazards associated with laboratory procedures related to the select agent or toxin.

(2) Safeguards in place with associated containment procedures to protect registered entity personnel, the public, and the environment from exposure to the select agent or toxin including, but not limited to: Safety training requirements for registered entity personnel performing the procedure; required personal protective equipment; required containment equipment including, but not limited to, biological safety cabinets, arthropod caging systems, and centrifuge safety containers; and required physical plant engineering controls.

(3) Written procedures for decontamination, with a validated method, of all contaminated or potentially contaminated materials including, but not limited to: Cultures and other materials related to the propagation of select agents or toxins, items related to the analysis of select agents or toxins, personal protective equipment, arthropod caging systems and extracted plant and/or arthropod tissues.

(4) Written procedures for decontamination, with a validated method, of laboratory surfaces and equipment using manufacturer's specification.

(5) Effluent decontamination procedures, with a validated method, that describe the treatment of effluent material contaminated with select agents or toxins.

(6) Procedures to respond to emergencies such as spills, sharps injury, or any other incident involving select agents and toxins.

(7) Procedures for handling of select agents and toxins in the same spaces as non-select agents and toxins in order to prevent unintentional contamination.

* * * * *

(e) * * * Drills or exercises must be documented to include how the drill or exercise tested and evaluated the plan, any problems that were identified and corrective action(s) taken, and all individuals who participated in the drill or exercise.

■ 10. Section 331.14 is amended as follows:

■ a. By adding a sentence at the end of paragraph (a).

■ b. By adding a sentence at the end of paragraph (f).

The additions read as follows:

§ 331.14 Incident response.[5]

(a) * * * The current incident response plan must be submitted for initial registration, renewal of registration, or when requested.

* * * * *

(f) * * * Drills or exercises must be documented to include how the drill or exercise tested and evaluated the plan, any problems that were identified and corrective action(s) taken, and all individuals who participated in the drill or exercise.

■ 11. Section 331.15 is amended as follows:

■ a. By revising paragraph (a), introductory text.

■ b. By revising paragraph (a)(1).

The revisions read as follows:

§ 331.15 Training.

(a) An individual or entity required to register under this part must provide information and training on biocontainment, security (including security awareness), incident response, and agent- and toxin-specific training to:

(1) Each individual with access approval from the Administrator, within 12 months of that individual's anniversary of receiving such approval or prior to his or her entry into an area where select agents or toxins are used or stored, whichever occurs first; and

* * * * *

■ 12. In § 331.16, paragraph (b), introductory text, is revised as follows:

§ 331.16 Transfers.

* * * * *

(b) A transfer may be authorized if:

* * * * *

■ 13. Section 331.17 is amended as follows:

■ a. In paragraph (a)(1)(iii), by adding the words ''or other storage container'' after the word ''freezer''.

■ b. By adding paragraph (a)(1)(ix).

■ c. In paragraph (a)(3)(v), by adding the words ''or other storage container'' after the word ''freezer''.

■ d. By adding paragraph (a)(8).

■ e. By adding a sentence at the end of paragraph (b).

■ f. By revising paragraph (c).

The additions and revision read as follows:

§ 331.17 Records.

(a) * * *

(1) * * *

(ix) If destroyed, the quantity (*e.g.,* containers, vials, tubes, etc.) of select agent destroyed, the date of such action, and by whom.

* * * * *

(8) For a select agent or an extract from a select agent that has been rendered nonviable or regulated nucleic acids that have been rendered non-infectious:

(i) A written description of the inactivation process used for rendering a select agent or an extract from a select agent nonviable or regulated nucleic acids non-infectious;

(ii) The sterility testing protocol used to verify nonviability of a select agent or an extract from a select agent or non-infectivity of regulated nucleic acids and the results of the test, including investigation, of any inactivation process failures and the corrective actions taken;

(iii) The name of each individual performing the inactivation method and sterility testing protocols;

(iv) The date(s) the inactivation method and sterility testing protocols were completed;

[4] Technical assistance and guidance may be obtained by contacting APHIS.

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

(v) The location where the inactivated method and sterility testing protocols were performed; and

(vi) An inactivation certificate that includes the date of inactivation, method of inactivation, date of final sterility testing protocol result, and the name of the person performing the inactivation. A copy of the inactivation certificate must accompany any transfer of inactivated material.

(b) * * * All written records created under this part are legible.

(c) Any records that contain information related to the requirements of the regulations. Such records may include, but are not limited to, biocontainment certifications, laboratory notebooks, institutional biosafety and/or animal use committee minutes and approved protocols, and records associated with occupational health and suitability programs. All records created under this part must be maintained for 3 years.

TITLE 9—ANIMALS AND ANIMAL PRODUCTS

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

■ 14. 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.

■ 15. Section 121.1 is amended by adding, in alphabetical order, definitions of *inactivation* and *kill curve* to read as follows:

§ 121.1 Definitions.

* * * * *

Inactivation. A method to render a select agent non-viable but retain characteristic 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.

* * * * *

Kill curve. The results of a dose-response experiment where a select agent is subjected to increasing amounts of the inactivating treatment to determine the minimum conditions required to render it non-viable, or to render any nucleic acids that can produce infectious forms of any select agent virus as non-infectious.

* * * * *

■ 16. Section 121.3 is amended as follows:

■ a. By revising paragraphs (d)(2) and (d)(3).

■ b. By adding paragraph (d)(4).

■ c. By adding paragraph (e)(3).

The additions and revisions read as follows:

§ 121.3 VS select agents and toxins.

* * * * *

(d) * * *

(2) Nonviable VS select agents or nonfunctional VS toxins.[3]

(i) Unless waived by the Administrator, 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 process to remove viability or infectious form (*i.e.,* the ability to reproduce or produce disease, while maintaining cellular structure) is not excluded from the requirements of this part until an entity:

(A) Develops a site-specific kill curve to define conditions of inactivation for each select agent or regulated nucleic acids that can produce infectious forms of any select agent virus. If there are strain-to-strain variations in resistance of a select agent to the inactivation procedure, then a specific kill curve must be developed for each strain that undergoes the inactivation procedure. A new kill curve must be created upon any change in procedure or inactivation equipment.

(B) Develops site-specific standard operating inactivation procedures to ensure that the material is inactivated by a safety margin determined by the kill curve.

(C) Subjects representative samples of inactivated select agents or any nucleic acids that can produce infectious forms of any select agent viruses to a validated sterility testing protocol to ensure that the inactivation method has rendered the select agent non-viable or regulated nucleic acids non-infectious.

(D) Any viability of a select agent or infectivity of regulated nucleic acids that can produce infectious forms of any select agent virus that was subjected to a validated inactivation protocol is reported to APHIS or CDC.

(E) Reviews annually, and revises as necessary, the following:

(*1*) The kill curve procedure and results;

(*2*) Site-specific standard operating procedures to ensure that select agents or regulated nucleic acids that can produce infectious forms of any select agent virus are inactivated by a safety margin; and

(*3*) The validated sterility testing protocol used to ensure that the inactivation method has rendered a select agent non-viable or regulated nucleic acids that can produce infectious forms of any select agent viruses non-infectious.

(F) Reviews, and revises as necessary, documents listed in paragraph (d)(2)(i)(E) of this section after any change in principal investigator, change in protocol, or any reported viability of a select agent or infectivity of regulated nucleic acids that can produce infectious forms of any select agent viruses previously assessed as inactive.

(ii) Unless waived by the Administrator, an extract from a select agent is not excluded from the requirements of this part until an individual or entity meets the following requirements:

(A) Any extract is subjected to a process that removes all viable cells, spores, or virus particles.

(B) Any extract is subjected to a validated sterility testing protocol to ensure that the inactivation method has rendered the extract free of a select agent.

(C) Any viability of an extract that was subjected to a validated inactivation protocol is reported to the responsible official.

(D) Any viability of a select agent or infectivity of regulated nucleic acids that can produce infectious forms of any select agent virus that was previously assessed as inactive by their validated sterility testing protocol is reported to APHIS or CDC.

(E) Reviews annually, and revises as necessary, the following:

(*1*) The kill curve procedure and results;

(*2*) Site-specific standard operating procedures to ensure that select agents or regulated nucleic acids that can produce infectious forms of any select agent viruses are inactivated by a safety margin; and

(*3*) The validated sterility testing protocol used to ensure that the inactivation method has rendered a select agent non-viable or regulated nucleic acids that can produce infectious forms of any select agent viruses non-infectious.

(F) Reviews, and revises as necessary, documents listed in paragraph (d)(2)(ii)(E) of this section after any change in principal investigator, change in protocol, or any reported viability of a select agent or infectivity of regulated nucleic acids that can produce infectious forms of any select agent virus previously assessed as inactive.

(3) Any low pathogenic strains of avian influenza virus, avian paramyxovirus serotype-1 (APMV–1) viruses which do not meet the criteria

[3] However, the importation and interstate movement of these nonviable select agents may be subject to the permit requirements under part 122 of this subchapter.

for Newcastle disease virus,[4] including those identified as pigeon paramyxovirus-12 [5] isolated from a non-poultry species, all subspecies *Mycoplasma capricolum* except subspecies *capripneumoniae* (contagious caprine pleuropneumonia), and all subspecies *Mycoplasma mycoides* except subspecies *mycoides* small colony (*Mmm* SC) (contagious bovine pleuropneumonia), provided that the individual or entity can identify that the agent is within the exclusion category.

(4) Waste generated during the delivery of patient care from a patient infected with a select agent that is decontaminated with a validated method within 7 calendar days of the conclusion of patient care.

(e) * * *

(3) An individual or entity may make a written request to the Administrator for reconsideration of a decision denying an application for the exclusion of an attenuated strain of a select agent or a select toxin modified to be less potent or toxic. The written request for reconsideration must state the facts and reasoning upon which the individual or entity relies to show the decision was incorrect. The Administrator will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision.

* * * * *

■ 17. Section 121.4 is amended as follows:

■ a. In paragraph (b), by removing the words ''*Bacillus anthracis* (Pasteur strain);'', ''*Brucella abortus*;'', and ''*Brucella suis*;''.

■ b. In paragraph (c)(1), by redesignating footnote 4 as footnote 6.

■ c. By revising paragraph (d)(2).

■ d. By adding paragraph (d)(4).

■ e. By adding paragraph (e)(3).

The additions and revision read as follows:

§ 121.4 Overlap select agents and toxins.

* * * * *

(d) * * *

(2) Nonviable overlap select agents or nonfunctional overlap toxins.[7]

(i) Unless waived by the APHIS Administrator or HHS Secretary, 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 process to remove viability or infectious form (*i.e.,* the ability to reproduce or produce disease, while maintaining cellular structure) is not excluded from the requirements of this part until an individual or entity:

(A) Develops a site-specific kill curve to define conditions of inactivation for each select agent or regulated nucleic acids that can produce infectious forms of any select agent virus. If there are strain-to-strain variations in resistance of a select agent to the inactivation procedure, then a specific kill curve must be developed for each strain that undergoes the inactivation procedure. A new kill curve must be created upon any change in procedure or inactivation equipment.

(B) Develops site-specific standard operating inactivation procedures to ensure that the material is inactivated by a safety margin determined by the kill curve.

(C) Subjects representative samples of inactivated select agents or any regulated nucleic acids that can produce infectious forms of any select agent viruses to a validated sterility testing protocol to ensure that the inactivation method has rendered the select agent non-viable or regulated nucleic acids non-infectious.

(D) Reports any viability of a select agent or infectivity of regulated nucleic acids that can produce infectious forms of any select agent virus that was subjected to a validated inactivation protocol to the responsible official.

(E) Reviews annually, and revises as necessary, the following:

(*1*) The kill curve procedure and results;

(*2*) Site-specific standard operating procedures to ensure that select agents or regulated nucleic acids that can produce infectious forms of any select agent virus are inactivated by a safety margin; and

(*3*) The validated sterility testing protocol used to ensure that the inactivation method has rendered a select agent non-viable or regulated nucleic acids that can produce infectious forms of any select agent viruses non-infectious.

(F) Reviews, and revises as necessary, documents listed in paragraph (d)(2)(i)(E) of this section after any change in principal investigator, change in protocol, or any reported viability of a select agent or infectivity of regulated nucleic acids that can produce infectious forms of any select agent virus previously assessed as inactive.

(ii) Unless waived by the APHIS Administrator or HHS Secretary, an extract from a select agent is not excluded from the requirements of this part until an individual or entity meets the following requirements:

(A) Any extract is subjected to a process that removes all viable cells, spores, or virus particles.

(B) Any extract is subjected to a validated sterility testing protocol to ensure that the inactivation method has rendered the extract free of a select agent.

(C) Any viability of an extract that was subjected to a validated inactivation protocol is reported to the responsible official.

(D) Any viability of a select agent or infectivity of regulated nucleic acids that can produce infectious forms of any select agent virus that was previously assessed as inactive by the validated sterility testing protocol is reported to APHIS or CDC.

* * * * *

(4) Waste generated during the delivery of patient care from a patient infected with a select agent that is decontaminated with a validated method within 7 calendar days of the conclusion of patient care.

(e) * * *

(3) An individual or entity may make a written request to the Administrator or HHS Secretary for reconsideration of a decision denying an application for the exclusion of an attenuated strain of a select agent or a select toxin modified to be less potent or toxic. The written request for reconsideration must state the facts and reasoning upon which the individual or entity relies to show the decision was incorrect. The Administrator or HHS Secretary will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision.

* * * * *

■ 18. Section 121.5 is amended as follows:

■ a. By revising paragraphs (a)(2) and (a)(3).

■ b. By adding paragraph (a)(4).

The addition and revisions read as follows:

§ 121.5 Exemptions for VS select agents and toxins.

(a) * * *

[4] An APMV–1 virus 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 site that is consistent with virulent strains of Newcastle disease virus. A failure to detect a cleavage site that is consistent with virulent strains does not confirm the absence of a virulent virus.

[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 monoclonal antibody testing and demonstration of their characteristic amino acid signature at the fusion gene cleavage site.

[7] However, the importation and interstate movement of these nonviable overlap select agents may be subject to the permit requirements under part 122 of this subchapter.

(2) The agent or toxin is secured against theft, loss, or release during the period between identification of the agent or toxin and transfer or destruction of such agent or toxin, and any theft, loss, or release of such agent or toxin is reported;

(3) Unless directed otherwise by the Administrator, the clinical or diagnostic specimens collected from a patient infected with a select agent are transferred in accordance with § 121.16 or destroyed on-site by a recognized sterilization or inactivation process within 7 calendar days after delivery of patient care has concluded; and

(4) The identification of the agent or toxin is reported to APHIS or CDC, the specimen provider, and to other appropriate authorities when required by Federal, State, or local law by telephone, facsimile, or email. This report must be followed by submission of APHIS/CDC Form 4 to APHIS or CDC within 7 calendar days after identification.

* * * * *

■ 19. Section 121.6 is amended as follows:

■ a. In paragraph (a)(2), by removing the word ''and'' at the end of the paragraph.

■ b. By redesignating paragraph (a)(3) as paragraph (a)(4).

■ c. By adding new paragraph (a)(3).

■ d. By revising newly redesignated paragraph (a)(4).

The addition and revision read as follows:

§ 121.6 Exemptions for overlap select agents and toxins.

(a) * * *

(3) Unless directed otherwise by the Administrator or HHS Secretary, the clinical or diagnostic specimens collected from a patient infected with a select agent are transferred in accordance with § 121.16, or destroyed on-site by a recognized sterilization or inactivation process within 7 calendar days after delivery of patient care has concluded;

(4) The identification of the agent or toxin is reported to APHIS or CDC, the specimen provider, and to other appropriate authorities when required by Federal, State, or local law by telephone, facsimile, or email. This report must be followed by submission of APHIS/CDC Form 4 to APHIS within 7 calendar days after identification.

* * * * *

■ 20. Section 121.7 is amended as follows:

■ a. By redesignating paragraphs (b) through (k) as paragraphs (c) through (l), respectively.

■ b. By adding a new paragraph (b).

■ c. In paragraph (c)(3), introductory text, by redesignating footnote 6 as footnote 8.

■ d. In paragraph (h)(1), by redesignating footnote 7 as footnote 9.

The addition reads as follows:

§ 121.7 Registration and related security risk assessments.

* * * * *

(b) As a condition of registration, each entity is required to be in compliance with the requirements of this part for select agents and toxins listed on the registration regardless of whether the entity is in actual possession of the select agent or toxin. With regard to toxins, the entity registered for possession, use, or transfer of a toxin must be in compliance with the requirements of this part regardless of the amount of toxin currently in possession.

* * * * *

§ 121.8 [Amended]

■ 21. In § 121.8, footnote 8 is redesignated as footnote 10.

■ 22. Section 121.9 is amended as follows:

■ a. In paragraph (a)(6), by removing the word ''laboratory'' and adding the words ''registered space'' in its place and by adding the words ''and the corrections documented'' at the end of the second sentence after the words ''must be corrected''.

■ b. By adding paragraph (a)(7).

The addition reads as follows:

§ 121.9 Responsible official.

(a) * * *

(7) Ensure that individuals are provided the contact information for the USDA or HHS Office of Inspector General Hotline so that they may anonymously report any safety or security concerns related to select agents and toxins.

* * * * *

■ 23. In § 121.10, paragraph (e) is amended by adding a sentence at the end of the paragraph to read as follows:

§ 121.10 Restricting access to select agents and toxins; security risk assessments.

* * * * *

(e) * * * A responsible official must immediately notify the responsible official of the visited entity if the person's access to select agents and toxins has been terminated.

* * * * *

■ 24. Section 121.11 is amended as follows:

■ a. In paragraph (c)(5), by adding the word ''keycards,'' after the word ''keys,'' and by removing the word ''numbers'' and adding the word ''permissions'' in its place.

■ b. By adding paragraph (c)(11).

■ c. In paragraph (d)(7)(iv), by removing the word ''and''.

■ d. By adding paragraph (d)(7)(vi).

■ e. By adding a sentence at the end of paragraph (h).

The additions read as follows:

§ 121.11 Security.

* * * * *

(c) * * *

(11) Describe how the entity authorizes the means of entry into areas where select agents or toxins are stored or used to include centralized access control management systems (*e.g.,* keycards) and/or mechanical key management.

(d) * * *

(7) * * *

(vi) Any loss of computer, hard drive or other data storage device containing information that could be used to gain access to select agents or toxins.

* * * * *

(h) * * * Drills or exercises must be documented to include how the drill or exercise tested and evaluated the plan, any problems that were identified and corrective action(s) taken, and all individuals who participated in the drill or exercise.

■ 25. Section 121.12 is amended as follows:

■ a. By revising paragraph (a).

■ b. By removing paragraph (c)(2).

■ c. By redesignating paragraph (c)(3) as paragraph (c)(2), and removing the words ''NIH Guidelines for Research Involving Recombinant DNA Molecules'' and replacing them with the words ''NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules''.

■ d. By adding a sentence at the end of paragraph (e).

The addition and revision read as follows:

§ 121.12 Biosafety.

(a) An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the select agent or toxin, given its intended use.[11] The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent. Biosafety and containment procedures specific to

[11] Technical assistance and guidance may be obtained by contacting APHIS.

each registered laboratory must be available to each individual working in that laboratory. The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested. The biosafety plan must include the following provisions:

(1) A written risk assessment for each procedure involving a select agent or toxin that addresses the hazards associated with the agent or toxin.

(i) The hazardous characteristics of each agent or toxin listed on the entity's registration, including probable routes of transmission in the laboratory and in the environment, infective dose (if known), stability in the environment, host range, contribution of any genetic manipulations, and endemicity.

(ii) Hazards associated with laboratory procedures related to the select agent or toxin.

(2) Safeguards in place with associated work practices to protect registered entity personnel, the public, and the environment from exposure to the select agent or toxin including, but not limited to: Safety training requirements for registered entity personnel performing the procedure; required personal protective equipment and other safety equipment; required containment equipment including, but not limited to, biological safety cabinets, animal caging systems, and centrifuge safety containers; and required engineering controls and other facility safeguards.

(3) Written procedures for decontamination, with a validated method, of all contaminated or potentially contaminated materials including, but not limited to: Cultures and other materials related to the propagation of select agents or toxins, items related to the analysis of select agents and toxins, personal protective equipment, animal caging systems and bedding, and animal carcasses or extracted tissues.

(4) Written procedures for decontamination, with a validated method, of laboratory surfaces and equipment using manufacturer's specification.

(5) Effluent decontamination procedures, with a validated method, that describe the treatment of effluent material contaminated with select agents and toxins.

(6) Procedures to respond to emergencies such as spills, sharps injury, or animal bites involving select agents and toxins.

(7) Procedures for the handling of select agents and toxins in the same spaces with non-select agents and toxins in order to prevent unintentional contamination.

* * * * *

(e) * * * Drills or exercises must be documented to include how the drill or exercise tested and evaluated the plan, any problems identified and corrective action(s) that were taken, and all individuals who participated in the drill or exercise.

■ 26. Section 121.14 is amended as follows:

■ a. In paragraph (a), by redesignating footnote 11 as footnote 13, and by adding a sentence at the end of the paragraph.

■ b. In paragraph (f), by adding a sentence at the end of the paragraph.

The additions read as follows:

§ 121.14 Incident response.[12]

(a) * * * The current incident response plan must be submitted for initial registration, renewal of registration, or when requested.

* * * * *

(f) * * * Drills or exercises must be documented to include how the drill or exercise tested and evaluated the plan, any problems identified and corrective action(s) that were taken, and all individuals who participated in the drill or exercise.

■ 27. Section 121.15 is amended as follows:

■ a. By revising paragraphs (a), introductory text, and (a)(1).

■ b. By adding paragraph (e).

The addition and revisions read as follows:

§ 121.15 Training.

(a) An individual or entity required to register under this part must provide information and training on biocontainment, biosafety, security (including security awareness), incident response, and agent- and toxin-specific training to:

(1) Each individual with access approval from the HHS Secretary or Administrator, within 12 months of that individual's anniversary of receiving such approval or prior to his or her entry into an area where select agents or toxins are used or stored, whichever occurs first; and

* * * * *

(e) The responsible official must ensure and document that individuals are provided the contact information of the HHS or USDA Office of Inspector General Hotline so that they may anonymously report any safety or security concerns related to select agents and toxins.

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

■ 28. Section § 121.16 is amended as follows:

■ a. In paragraph (a), by redesignating footnote 12 as footnote 14.

■ b. By revising paragraph (b), introductory text.

■ c. By adding paragraph (l).

The addition and revision read as follows:

§ 121.16 Transfers.

* * * * *

(b) A transfer may be authorized if:

* * * * *

(l) Transfer the amounts only after the transferor uses due diligence and documents that the recipient has a legitimate need (*i.e.,* prophylactic, protective, bona fide research, or other peaceful purpose) to handle or use such toxins. Information to be documented includes, but is not limited, to the recipient information, toxin and amount transferred, and declaration that the recipient has legitimate purpose to store and use such toxins.

■ 29. Section 121.17 is amended as follows:

■ a. In paragraph (a)(1)(iii), by adding the words ''or other storage container'' after the word ''freezer''.

■ b. By adding paragraph (a)(1)(ix).

■ c. In paragraph (a)(3)(v), by adding the words ''or other storage container'' after the word ''freezer''.

■ d. By adding paragraph (a)(8).

■ e. By adding a sentence at the end of paragraph (b).

■ f. By revising paragraph (c).

The additions and revision read as follows:

§ 121.17 Records.

(a) * * *

(1) * * *

(ix) If destroyed, the quantity (*e.g.,* containers, vials, tubes, etc.) of select agent destroyed, the date of such action, and by whom.

* * * * *

(8) For a select agent or an extract from a select agent that has been rendered non-viable or regulated nucleic acids that can produce infectious forms of any select agent virus that have been rendered non-infectious through inactivation:

(i) A written description of the inactivation process used for rendering a select agent non-viable or regulated nucleic acids that can produce infectious forms of any select agent virus non-infectious;

(ii) The sterility testing protocol used to verify non-viability of a select agent or non-infectivity of regulated nucleic acids that can produce infectious forms of any select agent virus and the results of the test, including investigation, of

any inactivation process failures and the corrective actions taken;

(iii) The name of each individual performing the inactivation method and sterility testing protocols;

(iv) The date(s) the inactivation method and sterility testing protocols were completed;

(v) The location where the inactivated method and sterility testing protocols were performed; and

(vi) An inactivation certificate that includes the date of inactivation, method of inactivation, date of final sterility testing protocol result, and the Principal Investigator. A copy of the inactivation certificate must accompany any transfer of inactivated material.

(b) * * * All written records created under this part are legible.

(c) Any records that contain information related to the requirements of the regulations. Such records may include, but are not limited to, certifications, laboratory notebooks, institutional biosafety and/or animal use committee minutes and approved protocols, and records associated with occupational health and suitability programs. All records created under this part must be maintained for 3 years.

Done in Washington, DC, this 8th day of January 2016.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2016–00681 Filed 1–14–16; 4:15 pm]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Grain Inspection, Packers and Stockyards Administration

7 CFR Part 810

United States Standards for Sunflower Seed

AGENCY: Grain Inspection, Packers and Stockyards Administration, USDA.

ACTION: Request for information.

SUMMARY: The United States Department of Agriculture's (USDA) Grain Inspection, Packers, and Stockyards Administration (GIPSA) is seeking comment from the public regarding the United States (U.S.) Standards for Sunflower Seed under the United States Grain Standards Act (USGSA). To ensure that standards and official grading practices remain relevant, GIPSA invites interested parties to comment on whether the current sunflower seed standards and grading practices need to be changed.

DATES: We will consider comments we receive by April 18, 2016.

ADDRESSES: You may submit written or electronic comments on this proposed rule to:

- *Mail:* Irene Omade, GIPSA, USDA, STOP 3642, 1400 Independence Avenue SW., Room 2530–B, Washington, DC 20250–3604.
- *Fax:* (202) 690–2173
- *Internet:* Go to *http://www.regulations.gov* and follow the on-line instruction for submitting comments.

All comments will become a matter of public record and should be identified as ''U.S. Standards for Sunflower Seed request for information comments,'' making reference to the date and page number of this issue of the **Federal Register**. All comments received become the property of the Federal government, are a part of the public record, and will generally be posted to *www.regulations.gov* without change. If you send an email comment directly to GIPSA without going through *www.regulations.gov,* or you submit a comment to GIPSA via fax, the originating email address or telephone number will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. Also, all personal identifying information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

Electronic submissions should avoid the use of special characters, avoid any form of encryption, and be free of any defects or viruses, since these may prevent GIPSA from being able to read and understand, and thus consider your comment.

GIPSA will post a transcript or report summarizing each substantive oral comment that we receive. This would include comments made at any public meetings hosted by GIPSA during the comment period, unless GIPSA publically announces otherwise.

All comments will also be available for public inspection at the above address during regular business hours (7 CFR 1.27(b)). Please call the GIPSA Management and Budget Services support staff (202) 720–8479 for an appointment to view the comments.

FOR FURTHER INFORMATION CONTACT: Andrew Greenfield at GIPSA, USDA, 1400 Independence Avenue SW., Washington. DC 20250; Telephone (202) 720–0277; Fax Number (202) 720–1015; email *Andrew.S.Greenfield@usda.gov.*.

SUPPLEMENTARY INFORMATION: Under the authority of the USGSA (7 U.S.C. 76), GIPSA establishes standards for sunflower seed and other grains regarding kind, class, quality and condition. The sunflower seed standards, established by USDA on September 1, 1984, were last revised in 1988 and appear in the USGSA regulations at 7 CFR 810.1801 through 810.1804. The standards facilitate sunflower seed marketing and define U.S. sunflower seed quality in the domestic and global marketplace. The standards define commonly used industry terms; contain basic principles governing the application of standards, such as the type of sample used for a particular quality analysis; the basis of determination; and specify grades and grade requirements. Official procedures for determining grading factors are provided in GIPSA's Grain Inspection Handbook, Book II, Chapter 11, ''Sunflower Seed'' which also includes standardized procedures for additional quality attributes not used to determine grade, such as moisture content and official criteria. Together, the grading standards and testing procedures allow buyers and sellers to communicate quality requirements, compare sunflower seed quality using equivalent forms of measurement and assist in price discovery.

GIPSA's grading and inspection services are provided through a network of federal, state, and private laboratories that conduct tests to determine the quality and condition of sunflower seed. These tests are conducted in accordance with applicable standards using approved methodologies and can be applied at any point in the marketing chain. Furthermore, the tests yield rapid, reliable and consistent results. In addition, GIPSA-issued certificates describing the quality and condition of graded sunflower seed are accepted as *prima facie* evidence in all Federal courts. U.S. Standards for Sunflower Seed and the affiliated grading and testing services offered by GIPSA verify that a seller's sunflower seed meets specified requirements, and ensure that customers receive the quality of sunflower seed they purchased.

In order for U.S. standards and grading procedures for sunflower seed to remain relevant, GIPSA is issuing this request for information to invite interested parties to submit comments, ideas, and suggestions on all aspects of the U.S. Standards for Sunflower Seed and inspection procedures.