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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; Proposed Rule

DEPARTMENT OF AGRICULTURE**Animal and Plant Health Inspection Service****7 CFR Part 331****9 CFR Part 121**

[Docket No. APHIS–2009–0070]

RIN 0579–AD09

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 third biennial review of the list. In addition, we are proposing to reorganize the list of select agents and toxins based on the relative potential of each select agent or toxin to be misused to adversely affect human, plant, or animal health. Such tiering of the list would allow for the optimization of security measures for those select agents or toxins that present the greatest risk of deliberate misuse with the most significant potential for mass casualties or devastating effects to the economy, critical infrastructure, or public confidence. We are also proposing a number of amendments to the regulations, including the addition of definitions and clarification of language concerning security, training, biosafety, biocontainment, and incident response. 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 December 2, 2011.

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

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#!documentDetail;D=APHIS-2009-0070-0001>.

- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2009–0070, 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-2009-0070> 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) 690–2817 before coming.

FOR FURTHER INFORMATION CONTACT: Mr. Charles L. Divan, Branch Chief, APHIS Agriculture Select Agent Program, APHIS, 4700 River Road Unit 2, Riverdale, MD 20737–1231; (301) 734–5960.

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 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 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 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 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 third 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 agents and toxins listed in both 9 CFR 121.4 and 42 CFR 73.4).

On July 29, 2010, we published in the **Federal Register** (75 FR 44724–44725, Docket No. APHIS–2009–0070) an advance notice of proposed rulemaking and request for comments (ANPR)¹ in order to announce our intention to review and reorganize the select agent list. We solicited comments regarding potential additions and deletions from the list of select agents and toxins as well as comments on reorganization of the list based on the relative potential of each select agent or toxin to be misused to adversely affect human, plant, or animal health. We requested recommendations as to what criteria should be utilized to designate high risk select agents and toxins and incorporated those recommendations

¹ To view the ANPR and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2009-0070>.

into the interagency working group discussions on the matter. We solicited comments for 30 days ending August 30, 2010. We received 30 comments by that date. They were from scientists, scientific organizations, 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 and our determination regarding reorganization of the 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 *Xylella fastidiosa*, citrus variegated chlorosis (CVC) strain, from the list as it no longer meets the criteria for use as an agroterrorism agent. Since CVC was first included on the list, extensive research on this select agent has been completed. New scientific information has led to creation of detection methods that provide for better early response and control methods. These new technologies can be applied regardless of how the agent might be introduced, including purposeful introduction for harmful purposes. Furthermore, the use of geostatistical analysis in citrus production areas using geographic information systems is now well-developed with relation to monitoring and facilitating a response to any purposeful introduction. As a result of this new research, as well as the development of new regulatory systems for CVC, the likelihood that someone would use CVC as an agent of bioterrorism is reduced, and our ability to manage an introduction is increased.

VS Select Agents and Toxins

APHIS's 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 update and revise the lists as necessary.

We are proposing to remove nine VS select agents and toxins from the list set out in § 121.3(b). Specifically, we are proposing to remove the following: Akabane virus; Bluetongue virus

(exotic), Bovine spongiform encephalopathy agent; Camel pox virus; *Ehrlichia ruminantium* (Heartwater); Japanese encephalitis virus; Malignant catarrhal fever virus (Alcelaphine herpesvirus type 1); Menangle virus; and Vesicular stomatitis virus (exotic): Indiana subtypes VSV-IN2, VSV-IN3.

The interagency working group considered each of the VS select agents and toxins with respect to the four criteria for listing found in the Act and based on the group's analysis, APHIS has determined that the nine VS select agents and toxins listed above should be removed from the list. These agents were judged not to pose a significant threat to animal health, either because the disease risk is not significant (e.g., low mortality rate in the event of infection), they affect only minor (i.e., not economically significant) species, or they are not likely to be used as an agroterrorism agent (e.g., difficulty of transmission from animal to animal).

For example, Japanese encephalitis virus primarily affects horses and pigs and is transmitted via a mosquito bite. It is not directly contagious between animals. Horses represent a dead-end host for the disease; mosquitoes biting an infected horse will not pick up virus to transmit to any new animals. Pigs represent an amplifying host, but modern pig husbandry practices in the U.S. minimize exposure of the herd to mosquitoes and make it difficult to establish and sustain a natural transmission cycle.

Likewise, a sustained transmission cycle of malignant catarrhal fever virus (Alcelaphine herpesvirus type 1) requires the presence of the reservoir host (African wildlife) in close physical association with the susceptible domestic species (cattle and bison).

With respect to the remaining agents:

- Camel pox only affects camels, which are a minor species in the US;
- Akabane virus, bluetongue virus (exotic), *Ehrlichia ruminantium* (Heartwater), and vesicular stomatitis virus (exotic): Indiana subtypes VSV-IN2, VSV-IN3 all utilize insect vectors as a mode of transmission and are not usually spread by direct contact between animals;
- Menangle virus transmission is associated with certain species of fruit bats, which are native only to Australia and Southeast Asia; and
- Bovine spongiform encephalopathy agent is only known to be transmitted through the ingestion of infected tissues.

All of these circumstances make transmission from animal-to-animal difficult, which greatly lessens the chance of an outbreak either accidental or intentional. Consequently, the extent

to which Federal, State, and/or local officials need to take special action in planning for a major animal health disaster as a result of any of these organisms is decreased in light of these factors. Therefore, in considering these reasons as well as recommendations provided in previous reports such as "The Report of the Working Group on Strengthening the Biosecurity of the United States"² and the "Federal Experts Security Advisory Panel: Recommendations Concerning the Select Agent Program"³ as well as comments received on the ANPR, APHIS has determined those pathogens listed here are not likely to be used as agroterrorism agents and no longer need to be designated as VS select agents.

Overlap Select Agents and Toxins

We are also proposing to modify the listing for one of the overlap select agents by removing certain subtypes of Venezuelan equine encephalitis virus from the list of overlap select agents and toxins set out in 9 CFR 121.4(b), and to clarify that only Venezuelan equine encephalitis subtypes IAB and IC would remain on the list. These subtypes contain the only recognized strains of Venezuelan equine encephalitis that can suddenly affect a large number of animals over a large area (i.e., epizootic). The remaining subtypes, ID and IE, are strains prevalent among existing animal populations (i.e., enzootic) and do not represent the same type of risk. Other viruses within the Venezuelan equine encephalitis complex (subtypes IF and II through IV) are separate viruses and are not included in the list of overlap select agents and toxins. Accordingly, CDC will also be proposing a parallel change to its overlap select agent regulations.

Reorganization of the Current List of Select Agents and Toxins

We are proposing to establish a number of select agents and toxins as "Tier 1" select agents and toxins within the lists of VS and overlap select agents and toxins. We are not including PPQ select agents and toxins in this proposed reorganization because none of the proposed Tier 1 select agents and toxins are from the plant list. All other select agents and toxins would continue to be subject to the current requirements concerning select agents and toxins. All select agents and toxins were scored against 20 criteria by over 60 subject

² Available on the Internet at <http://www.phe.gov/Preparedness/legal/boards/biosecurity/Documents/biosecurityreportfinal102309.pdf>.

³ Available on the Internet at <http://www.phe.gov/Preparedness/legal/boards/fesap/Documents/fesap-recommendations-101102.pdf>.

matter experts representing the Federal life sciences, public health, law enforcement, security, and intelligence communities. These criteria included:

- The relative ease with which a particular select agent or toxin might be disseminated or transmitted from one animal to another or into the environment where it could produce a deleterious effect upon animal or plant health;

- The potential for high animal or plant mortality rates;
- The potential for a major animal or plant health impact;
- Select agents or toxins whose misuse might result in public panic or other social or economic disruption; and
- Select agents or toxins whose use might require Federal, State, and/or local officials to take special action in planning for major animal or plant health disasters.

APHIS and CDC determined that two VS select agents and three overlap select agents should be given Tier 1 status. Based on the criteria listed above, we are proposing to list foot-and-mouth disease virus and rinderpest virus as Tier 1 VS select agents and toxins and *Bacillus anthracis*, *Burkholderia mallei*, and *Burkholderia pseudomallei* as Tier 1 overlap select agents and toxins. We are also proposing to amend the list of overlap select agents and toxins whose seizure by any Federal law enforcement agency requires reporting to APHIS or CDC within 24 hours (located in 9 CFR 121.4(f)(3)(i)) to include only those overlap agents designated as Tier 1. The current list, which is comprised of *Bacillus anthracis*, *Brucella melitensis*, Hendra virus, Nipah virus, Rift Valley fever virus, and Venezuelan equine encephalitis virus was initially adapted from a different system of threat assessment categorization. The proposed changes would bring the list in line with the listing of Tier 1 agents, which was developed as a result of the experience and expertise of the select agent program. These changes, in tandem with the enhanced practices for physical and information security detailed below, would serve to further mitigate the potential for deliberate misuse of these select agents and toxins that could result in devastating effects to the economy, critical infrastructure, or public confidence.

Accordingly, we are also proposing additions to the VS regulations that would allow for the optimization of security measures for those select agents or toxins that present the greatest risk of deliberate misuse with the most significant potential for mass casualties or devastating effects to the economy, critical infrastructure, or public

confidence, *i.e.*, Tier 1 select agents and toxins. These requirements would include:

- Additions regarding the assessment of persons who will have access to Tier 1 select agents and toxins that would be made to the security plan currently required to be developed by all entities seeking approval for the possession, use, and transfer of select agents and toxins; ongoing oversight of those persons with access to Tier 1 select agents and toxins; and the role of the entity's responsible official in coordinating and assuring the security of Tier 1 select agents and toxins;

- Security enhancements that include provisions for security barriers, intrusion detection and monitoring, delay/response force, access control, and information security;

- Additions to the biosafety plan currently required to be developed by all entities seeking approval for the possession, use, and transfer of select agents and toxins that would describe implementation of an occupational health program for individuals with access to Tier 1 select agents and toxins;

- Development of security policies and procedures describing the entity's response to a failure of an intrusion detection or alarm system and notification procedures for the Federal Bureau of Investigation (FBI) in the event of theft or suspicious activity that may be criminal in nature involving a Tier 1 select agent or toxin. These policies and procedures would be required as part of the entity's incident response plan; and

- Required annual insider threat awareness briefings focused on how to identify and report suspicious behaviors.

These changes would serve to further mitigate the potential for deliberate misuse of these select agents and toxins that could result in devastating effects to the economy, critical infrastructure, or public confidence.

We are also proposing to add required physical security measures in addition to the proposed general Tier 1 required security measures for those entities working with foot-and-mouth disease virus and rinderpest virus due to the particular dangers posed by these two viruses.

Foot-and-mouth disease is an extremely contagious viral disease of domesticated cloven-hoofed animals (*e.g.*, cattle, sheep, goats, and pigs) and many wild animals. It is easily transmissible from infected animals to susceptible animals through contact with contaminated objects, consumption of contaminated meat products or ingestion of contaminated

milk, artificial insemination, and inhalation of infectious aerosols. It is not found in the United States and the U.S. domestic animal population is therefore considered highly susceptible. Foot-and-mouth disease virus can cause infection and disease in close to 100 percent of susceptible animals. The potential exists for severe economic impacts through loss of animal production and products and trade restrictions. Because of these factors, this select agent is considered to have a high potential as a weapon of bioterrorism and we are therefore proposing to require that it be handled only in high containment facilities which provide enhanced biosafety and biosecurity features in order to safeguard its distribution.

Rinderpest is a contagious viral disease of cattle, buffalo, and some wild species of cloven-hoofed animals, such as giraffe and wildebeest. Like foot-and-mouth disease virus, it is not native to the United States and can cause 100 percent illness if susceptible animals come in contact with infected animals or contaminated surfaces. As the result of an extensive international campaign consisting of vaccinations, clinical disease research, serological surveillance sampling, contingency planning, and laboratory support in affected regions, the World Organization for Animal Health declared rinderpest to be globally eradicated in May 2011. Post-eradication efforts will include surveillance of all international laboratories with existing stocks of the virus, consensus regarding laboratories authorized to retain the agent and the type of laboratory work which will continue, and destruction of all other inventoried stocks. Also, conditions for laboratory storage will be developed in order to ensure biosafety and security of the agent. The proposed enhanced security measures are necessary in order to ensure that the United States will be able to maintain inventories of rinderpest virus under secure and safe conditions.

All of these proposed changes are based on established Government and security industry standards with respect to securing high risk material and developed in accordance with the experience and expertise of the Select Agent Program. They are necessary in order to further ensure the safety and security of those select agents and toxins that pose the most potential harm to the animal and human environment. As stated previously, the requirements for working with all other select agents and toxins would remain unchanged with the exception of certain

miscellaneous changes, which are detailed below.

Miscellaneous Changes

We are proposing to make several smaller-scale changes to the regulations, including the addition of definitions and clarification of language concerning security, training, biosafety, biocontainment, and incident response. 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.

In 7 CFR 331.1 and 9 CFR 121.1, we are proposing to add definitions for *adjudicated as a mental defective*, *alien*, *committed to any mental institution*, *controlled substance*, *crime punishable by imprisonment for a term exceeding 1 year*, *indictment*, *lawfully admitted for permanent residence*, *mental institution*, *restricted person*, and *unlawful user of any controlled substance*. We believe that these definitions would assist regulated entities as well as those seeking approval to access select agents and toxins to better understand what status or activities, past or present, might prohibit such access.

Although these terms were undefined in the Bioterrorism Response Act, it is evident that Congress modeled many of them after the disqualifiers that are used by the Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF) when enforcing the Gun Control Act of 1968. Because the purpose of the Select Agent Program differs from ATF's enforcement actions under the Gun Control Act, we do not believe that these terms must be defined exactly the same. The Gun Control Act regulates access to firearms, while the Bioterrorism Response Act regulates access to biological agents and toxins that the government has recognized as having the potential to be used as weapons of mass destruction by the wrong hands.

Nevertheless, we looked at the statutory and regulatory definitions of these terms under the Gun Control Act when drafting our definitions. With the exception of the term "crime punishable by imprisonment for a term exceeding 1 year," we decided to adopt the applicable definitions used by ATF.

The definition of *crime punishable by imprisonment for a term exceeding 1 year* would be established as "any Federal, State, or foreign offense for which the maximum penalty, whether or not imposed, is capital punishment or imprisonment in excess of 1 year. What constitutes a conviction of such a crime shall be determined in accordance with the law of the jurisdiction in which

the proceedings were held. Any conviction which has been set aside or nullified as a matter of law or for which a person has been pardoned shall not be considered a conviction for purposes of this part." Contrary to definition of this term used under the Gun Control Act, we have decided that foreign offenses should be considered a disqualifier. In doing so we are aware of the Supreme Court's decision in *Small v. United States*, 544 US 385 (2005) in which the court, interpreting the provisions of 18 U.S.C. 922(g)(1), held that the phrase "convicted in any court" refers only to U.S. courts, not to foreign courts. In its opinion interpreting the Gun Control Act, the court stated that "the statute itself and its history offer only congressional silence" as to whether Congress considered whether the statutory language included foreign convictions. In the case of the Bioterrorism Response Act, we believe Congress spoke clearly about their desire to limit or deny access to select agents and toxins for those who have committed serious crimes regardless of where those crimes were committed. As a part of the safeguard and security section of the Bioterrorism Response Act, Congress not only put select agents and toxins off limits to a "restricted person," as that term is defined by 18 U.S.C. 175b, but to the those who are "reasonably suspected by any Federal law enforcement or intelligence agency of" (1) Committing a "Federal crime of terrorism" transcending national boundaries (18 U.S.C. 2332b); (2) the knowing involvement with an organization that engages in domestic or international terrorism or with any other organization that engages in international crimes of violence; or (3) being an agent of a foreign power. We believe it would be an inconsistent reading of statutory authority to allow the Secretary to limit or deny access to select agents and toxins to someone identified by the Attorney General as being only reasonably suspected of committing a Federal crime of terrorism transcending national boundaries but to be powerless in cases where a person had actually been convicted of a serious crime in a foreign country. We believe that in light of the threat of bioterrorism attacks, Congress would not want to exclude an individual convicted of a U.S. offense from having access to select agents and toxins, but still allow access to an individual convicted in a foreign court of a similar offense. We also believe that the instances of regulation can be distinguished in that with regard to the Gun Control Act the government is regulating access to guns while, with

respect to the Bioterrorism Response Act, the government is regulating access to biological agents and toxins which the government has recognized as having the potential to be used in the wrong hands as weapons of mass destruction.

We are specifically requesting comments on the use of a foreign conviction as a predicate for denying access to select agents and toxins. We recognize that there can be significant differences between foreign convictions and domestic convictions. For example, foreign legal systems may not provide the same due process safeguards afforded to citizens of the United States, including impartial tribunals and jury trials. Additionally, foreign countries may punish conduct that is permitted under domestic law or may require more severe penalties than under domestic law. We note that in the past, courts have applied the criteria set forth in Section 482 of the Restatement (third) of Foreign Relations Law of the United States (1986) in determining whether a foreign judgment should be recognized in the United States. That Section provides that a court in the United States may not recognize a judgment of the court of a foreign state if the judgment was rendered under a judicial system that does not provide impartial tribunals or procedures compatible with due process of law or the court that rendered the judgment did not have jurisdiction over the defendant in accordance with the law of the rendering state. It further provides that a court in the United States need not recognize a judgment of the court of a foreign state if the court that rendered the judgment did not have jurisdiction of the subject matter of the action, the defendant did not receive notice of the proceedings in sufficient time to enable him to defend, the judgment was obtained by fraud, the cause of action on which the judgment was based, or the judgment itself, is repugnant to the public policy of the United States or of the State where recognition is sought, the judgment conflicts with another final judgment that is entitled to recognition, or the proceeding in the foreign court was contrary to an agreement between the parties to submit the controversy on which the judgment is based to another forum. We are seeking comment on whether these criteria should be applied in considering whether access to select agents and toxins should be denied based on a foreign conviction or whether other criteria or factors would be appropriate to consider.

We are also proposing to add a definition for *information security* to the

regulations in 7 CFR 331.1 and 9 CFR 121.1 as it is used but not defined. This definition would be identical to that used in the "Information Security" subchapter of the U.S. Code (44 U.S.C. 3542).

We are also proposing to add a definition for *occupational exposure* to the VS regulations in 9 CFR 121.1 as it is used in the regulations but not defined. This definition is based on that used in the Occupational Safety and Health Administration regulations in 29 CFR 1910.1030. We are not proposing to add a corresponding definition to the PPQ regulations in 7 CFR 331.1 since PPQ select agents and toxins do not pose a severe threat to human health and, therefore, it is unnecessary to address personnel safety and health.

Finally, we are proposing to add a definition for *recombinant and synthetic nucleic acids*. This addition is necessary, as the term "synthetic nucleic acids" is employed in the proposed changes to the select agent regulations. We are proposing to include synthetic nucleic acids in the regulations because, while synthetic nucleic acids have the same potential for harm as recombinant nucleic acids, the process of production is different.

We are proposing to amend 7 CFR 331.3(e), 9 CFR 121.3(e) and 9 CFR 121.4(e). These paragraphs specify that attenuated strains of select agents or toxins may be excluded from the requirements of the select agent regulations subject to an official request and supporting scientific information. We are proposing to state that the "inactive form of a select toxin" may be excluded from regulation under each respective part subject to the application procedure. This change is necessary because the current term, "attenuated strain of toxin," is scientifically inaccurate. Attenuated is a term that is applied to living organisms, and toxins are not living organisms. "Inactive form of a select toxin" is a more accurate term and we are therefore proposing to amend the regulations to include the correct terminology. We are also proposing to update the Web site address in paragraph (e)(1) of each section as all information concerning the Select Agent Program is now centralized on the National Select Agent Registry Web site at <http://www.selectagents.gov/>. Finally, we are proposing to remove the language stating that exclusions will be published in the **Federal Register**. This change is necessary because, while we anticipated publication of exclusions both in the **Federal Register** and on the Internet at the time the regulations were initially created, we have found that publication

on the select agent Web site only has served to provide the most up-to-date information to the regulated community. We are therefore proposing to update the regulations to accurately reflect the way in which we handle the listing of exclusions.

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. We are proposing to explicitly require that all designated responsible officials possess the appropriate training or expertise to execute their required duties. We are also proposing to clarify the role of alternate responsible official in order to definitively establish that the alternate responsible official must have the knowledge and authority to act for the responsible official in his/her absence. Finally, we are proposing to add a requirement that the responsible official's principal duty station be the physical location of the registered entity. These changes would clarify the requirements that a person must meet in order to serve as a responsible official or alternate responsible official.

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. Specifically, we are proposing to add new provisions by which individuals may have access to select agents at entities other than the individual's "home" entity. We are also proposing to decrease the maximum length of time for which a security risk assessment will be valid from 5 years to 3 years in order to more expeditiously identify individuals who may have fallen into one of the prohibited or restricted categories.

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 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.

Details of the changes we are proposing to each plan individually may be found below. Generally, we are proposing to require that the security plan, biocontainment/biosafety plan, and incident response plan include provisions to address the safeguarding of animals or plants that have been intentionally or accidentally exposed to or infected with select agents against unauthorized access, theft, loss or release. This would enhance the comprehensiveness of the regulations as well as provide necessary guidance regarding handling of animals and plants inoculated with select agents. We would not require the plan to address animals and plants exposed to select toxins, however. Recovering the toxin from within an animal or plant subject is highly difficult and such removal does not produce a reasonable yield of recovery. In addition, there is uncertainty as to whether or not the toxin would remain active when recovered from the animal or plant. For these reasons it is highly unlikely that once introduced into an animal or plant, a sufficient amount of toxin could be recovered to pose a significant hazard to public health, agriculture or agriculture products.

Currently, the security plan described in 7 CFR 331.11 and 9 CFR 121.11 must be developed by all regulated entities and submitted for review only upon request. We are now proposing to require that the security plan be submitted for initial registration and renewals of registration as well as at any other time upon request. We are also proposing to add a requirement that the security plan include procedures that require the responsible official to immediately notify the FBI in order to initiate a threat assessment process in the event that he or she becomes aware

of suspicious activity which is criminal in nature, related to the facility, its personnel, or select agents. This addition would provide for added security and establish a framework for communication between regulated entities and the FBI. We are also proposing to add provisions for information security, including the need for backup measures if the entity relies on information systems for security. These provisions would include network connectivity monitoring, restriction of user permissions so that only mission-specific files and applications may be accessed, measures to prevent network infiltration by malicious code, and configuration management including regular patching and system and software updates. We believe these additions are necessary in order to establish requirements for a more comprehensive security plan. We are also proposing to codify current practices for shipping, receiving, and storage of select agents and toxins to ensure that the entity has documented processes for securing and monitoring the shipment, receipt, and storage of these items. These changes would serve to decrease the chance that such materials would be made available to an unauthorized individual or an individual without a legitimate use for the material. Finally, we are proposing to amend paragraph (e) in 7 CFR 331.11 and 9 CFR 121.11, which currently directs individuals creating a security plan to guidance for developing such documents contained in the "Morbidity and Mortality Weekly Report" from December 2002. Applicants would instead be directed to the "Security Information Document" and the "Security Plan Template" on the select agents Web site.

We are proposing to update the specific Web site address references to various CDC and National Institutes of Health guidance publications found in 9 CFR 331.12(c)(1) and (c)(3). The regulations in 7 CFR 331.13 and 9 CFR 121.13 concern restricted experiments, which are those experiments that may not be performed by regulated entities without the approval of the Administrator. We are proposing to state that, in addition to the existing prohibition on conducting restricted experiments, entities may not possess the products of restricted experiments without the approval of the Administrator. We are also proposing to remove recombinant technology as a determining factor for a restricted experiment. This is because the current regulations regarding restricted experiments focus solely on the use of

recombinant technology in the generation of drug resistant select agents or biosynthesis of toxins lethal to vertebrates. Since synthetic DNA or other methods (*e.g.*, selection in sublethal exposures) may also be used to generate such products, we are proposing to expand the category of restricted experiments to include passive selection, recombinant, and synthetic DNA. Finally, we are proposing to add language in order to clarify the requirement that all experiments involving the creation of drug resistant select agents must be submitted to the Select Agent Program for approval.

Additionally, we are proposing to specify in 7 CFR 331.14 and 9 CFR 121.14 that each entity's incident response plan be based upon a site-specific risk assessment. This change would further ensure the specificity and quality of the plan. In addition, we are proposing that the incident response procedures contain stipulations concerning animals and plants accidentally or intentionally exposed to or infected with a select agent. This change would provide specific guidance and further elaborate our requirements for incident response plans.

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 all registered entities to provide security awareness and incident response training. This is in addition to the existing training requirements, which are concerned with biocontainment and security practices in the case of PPQ select agents, and biosafety and security practices in the case of VS select agents. We are also proposing to establish that training for escorted personnel would be based on the risk associated with accessing areas where select agents and toxins are used and/or stored. Currently, refresher training is required to be provided once a year. We are proposing to require that such training also be provided if a registered entity's security, incident response, biosafety, or biocontainment plans are substantively altered. Finally, we are proposing to specify that the responsible official ensure maintenance of training records. Currently there is no particular person designated as the entity's required record keeper, only that a training record must be kept. The above changes are necessary in order to provide clarity and ease of use to the regulations.

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 from one registered entity to another. The proposed additions would serve to codify practices for shipping, receiving, and storage of select agents and toxins and ensure that all registered entities have documented processes for securing and monitoring the shipment, receipt, and storage of select agents and toxins that make it extremely unlikely that such materials would be made available to an unauthorized individual.

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. We are proposing to add language to address synthetic select agent organisms and animals and plants inoculated with select agents. This change would improve oversight of the select agent program as it relates to synthetic select agent organisms. We are also proposing to add recordkeeping requirements whereby regulated entities maintain an accurate, current inventory of any animals or plants intentionally or accidentally exposed to or infected with a select agent (including number and species, location, and appropriate disposition). As previously stated, we are not proposing to require regulated entities to keep records regarding animals or plants exposed to select toxins.

We are proposing to amend the regulations in 7 CFR 331.19, which concern requirements for notification of theft, loss, or release of select agents. Specifically, we are proposing to remove paragraph (b)(1)(vi), which states that an individual entity must report certain information to APHIS or CDC immediately upon discovery of a release of a select agent or toxin outside of the primary barriers of the biocontainment area. Currently we require that the number of individuals potentially exposed at the entity be reported. We are proposing to remove this requirement as PPQ select agents and toxins do not pose a severe threat to human health and, therefore, it is unnecessary to address personnel safety and health in the same manner as they are addressed in the VS regulations. The notification requirements in 9 CFR 121.19 would remain unchanged.

The regulations in 7 CFR 331.20 and 9 CFR 121.20 concern the guidelines for administrative review of an individual's or entity's denial, revocation, or suspension of registration and access approval. We are proposing to modify the current regulations in order to allow individuals more time to gather the necessary components of their appeal following the denial, limitation, or

revocation of access approval. Currently, this process must be completed in 30 calendar days. We are proposing to extend the deadline to 180 calendar days. This change is necessary because, thus far, all appeal requests from individuals regarding their access approval have been received after the 30-day deadline has passed. Because of specific program procedures, these individuals receive no advance notice of a denial, limitation, or revocation of their access approval. Given this situation and the requirements for submitting a formal appeal, we believe it is appropriate to extend the deadline in order to allow individuals to gather the necessary background data for their appeals. We are not proposing to grant a similar extension for entities which have had their registration denied, revoked, or suspended, as these entities typically have had advance notice of such a determination and are thus able to document and prepare their appeals within the existing 30-day timeframe.

Given that we are reorganizing 7 CFR 331.20 and 9 CFR 121.20 in order to more clearly spell out the way in which an individual or an entity may appeal the denial, revocation, or suspension of registration and access approval, we are also proposing to remove footnote 9 from the regulations in 7 CFR 331.20 and corresponding footnote 15 in 9 CFR 121.20. This proposed change is necessary because these footnotes would offer redundant information concerning the appeals process in light of both sections' reorganization. Finally, we are proposing to remove the provision stating that a request for review of a denial, limitation, or revocation of access approval will be forwarded to the Attorney General by the Administrator for further review. Forwarding a request for review to the Attorney General describes an internal process. This proposed change is necessary because the current language implies a level of decisionmaking on the part of the Attorney General that does not exist and the change would more clearly establish that the decision to grant access approval rests solely with the Administrator.

Guidance Documents

We are specifically requesting comment from the regulated community and any other interested persons on the need for and desirability of guidance documents that would serve to assist regulated entities in preparation of the elements that comprise various aspects of the select agent regulations.

The areas where such guidance documents may be useful include, but are not limited to:

1. Aspects of the required security plan. These may include, but are not limited to:

- Provisions for information security;
- Development of suitability or personnel reliability practices, including pre-access and ongoing assessment of persons who will have access to Tier 1 select agents or toxins;
- Procedures for the method by which an entity's responsible official will coordinate his or her efforts with the entity's safety and security professionals to ensure security of Tier 1 select agents or toxins;
- Development of a self- and peer-reporting program to track incidents or conditions that could affect an individual's ability to safely access or work with Tier 1 select agents and toxins; and
- Layered protection of assets for entities housing Tier 1 select agents and toxins.

2. Aspects of the required biosafety plan, *e.g.*, components of an occupational health program for individuals with access to Tier 1 select agents and toxins; and

3. Aspects of the required training, *e.g.*, best practices for development of a security awareness training program.

We welcome public comment on Web sites, articles, or other sources that may be used to develop such guidance documents, in addition to suggestions as to what elements should be included as useful examples. These documents would serve as a resource to the regulated community as a whole.

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 and, therefore, has been reviewed by the Office of Management and Budget.

We have prepared an economic analysis for this rule. The economic analysis provides a cost-benefit analysis, as required by Executive Orders 12866 and 13563, and an initial regulatory flexibility analysis that examines the potential economic effects of this proposed rule on small entities, as required by the Regulatory Flexibility Act. The economic 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).

Based on the information we have, there is no reason to conclude that adoption of this proposed rule would result in any significant economic effect

on a substantial number of small entities. The entities are those laboratories and other institutions conducting research and related activities entities in possession of Tier 1 select agents or toxins, and, to a somewhat lesser extent, those entities possessing the newly added select agents and toxins. The economic analysis presents categories and information from the Department of Commerce and the Small Business Administration for those entities we have identified as most likely to be affected by this rule. While we believe affected entities are contained within these categories, we are seeking further information regarding how many entities fall specifically into each category, and are therefore, inviting comments on potential effects. In particular, we are interested in determining the number and kind of small entities that may incur benefits or costs from the implementation of this proposed rule.

This proposed rule would update the APHIS, CDC, and overlap select agent and toxin lists. The regulation of select agents and toxins is intended to prevent their misuse and thereby reduce the potential for those pathogens to harm humans, animals, animal products, plants or plant products in the United States. Should any select agent or toxin be intentionally or unintentionally released into the environment, the consequences would be significant. Consequences could include disruption of markets, difficulties in sustaining an adequate food and fiber supply, and the potential spread of disease infestations over large areas. The entities most likely to be affected by this rule would be those laboratories and other institutions conducting research and related activities that involve the use of the newly categorized Tier 1 select agents and toxins. The impact of the changes to the regulations is expected to be minimal, however. Based on information obtained through site-specific inspections, indications are that very few entities would incur significant costs for compliance. Many of the proposed changes to the regulations would impose an added cost of the time spent on documenting measures already required for compliance, with respect to security, biocontainment/biosafety, and incident response plans, information security, and ongoing background checks. While the total costs imposed by the proposed regulations are estimated to range between \$5.30 million and \$6.95 million, including costs to government, we believe many of these costs are incurred through observance of

generally recognized industry standards. Costs actually incurred would depend upon the extent to which current facility practices will need to be enhanced based on the proposed requirements. The expected benefits of strengthened safeguards against the costs associated with unintentional or deliberate release of select agents or toxins would greatly exceed the estimated costs of the proposed measures. The cost associated with a single outbreak have been known to exceed \$100 million as outlined in the Regulatory Impact Analysis. Deliberate introduction greatly increases the probability of a select agent or toxin becoming established and causing wide-ranging and devastating impacts on an economy, loss of market access for consumer goods and services, disruption to society, and diminished confidence in public and private institutions.

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 7 CFR part 3015, subpart V.)

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.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket Nos. APHIS–2009–0070

and CDC–2011–0012. Please send a copy of your comments to: (1) Docket Nos. APHIS–APHIS–2009–0070 and CDC–2011–0012, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238, and (2) Clearance Officer, OCIO, USDA, room 404–W, 14th Street and Independence Avenue, SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

The Bioterrorism Preparedness Act is designed to prevent, prepare for and respond to bioterrorism and other public health emergencies. The law requires individuals possessing agents or toxins deemed a severe threat to human, animal, or plant health, or to animal or plant products, to be registered with the Secretary of Agriculture or the Secretary of Health and Human Services, unless they have been specifically exempted.

This proposed rule entails the use of a number of separate forms designed to obtain critical information concerning individuals or entities in possession of certain agents or toxins, as well as the specific characteristics of the agents or toxins—including name, strain, and genetic information. This data is needed, in part, to allow APHIS and CDC to determine the biosafety level of an entity as well as the entity’s biosecurity situation. This, in turn, helps APHIS and CDC ensure that appropriate safeguard, containment, and disposal requirements commensurate with the risk of the agent or toxin are present at the entity, thus preventing access to such agents and toxins for use in domestic or international terrorism. Facilities containing select agents will be required to maintain records on animals and plants, and revise their Biosafety/Biocontainment Plan and Incident Response Plan for review by APHIS and CDC upon request.

Information to determine that individuals seeking to register have a lawful purpose to possess, use, or transfer agents or toxins will also be requested as part of the registration process. In addition, we will be requesting submission of their Security Plan for our review.

APHIS and CDC are asking OMB to approve, for 3 years, the use of these information collections, associated with its efforts to more closely regulate select agents or toxins that could be used to commit acts of domestic or international terrorism. We are soliciting comments from the public (as well as affected agencies) concerning this information collection activity. APHIS and CDC need this outside input to help accomplish the following:

- (1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency’s functions, including whether the information will have practical utility;
- (2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;
- (3) Enhance the quality, utility, and clarity of the information to be collected; and
- (4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; *e.g.*, permitting electronic submission of responses).

Estimate of burden: Public reporting burden for this collection of information is estimated to average 2.3187883 hours per response.

Respondents: Researchers, universities, research and development organizations, commercial manufacturers, non-profit institutions, diagnostic laboratories and other interested parties who possess, use, or transfer agents or toxins deemed a severe threat to human, animal or plant health, or to animal or plant products.

Estimated annual number of respondents: 386.

Estimated annual number of responses per respondent: 12.230569.

Estimated annual number of responses: 4,721.

Estimated total annual burden on respondents: 10,947 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Section	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
9 CFR 121.5 and 6, 7 CFR 331.5, 43 CFR 73.5 and 6.	Report of Identification of a Select Agent or Toxin.	161	3	1	299
§ 121.7, § 331.7, § 73.7	Application for Registration	7	1	5	35
§ 121.7, § 331.7, § 73.7	Amendment to a Certificate of Registration.	380	7	1	1,955

Section	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
§ 121.11, § 331.11, § 73.11	Security Plan	380	1	5	1,900
§ 121.12, § 331.12, § 73.12	Biosafety/Biocontainment Plan	380	1	8	3,040
§ 121.13, § 331.13, § 73.13	Request Regarding a Restricted Experiment.	160	1	2	320
§ 121.14, § 331.14, § 73.14	Incident Response Plan	380	1	5	1,900
§ 121.15, § 331.15, § 73.15	Training	380	1	1	380
§ 121.16, § 331.16, § 73.16	Request to Transfer Select Agents and Toxins.	290	1	2	580
§ 121.17, § 331.17, § 73.17	Records	295	1	0.5	148
§ 121.19, § 331.19, § 73.19	Notification of Theft, Loss, or Release.	195	1	2	390

Copies of this information collection can be obtained from Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851-2908.

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 Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851-2908.

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—[AMENDED]

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 *adjudicated as a mental defective*, *alien*, *committed to any mental institution*, *controlled substance*, *crime punishable by imprisonment for a*

term exceeding 1 year, *indictment*, *information security*, *lawfully admitted for permanent residence*, *mental institution*, *recombinant and synthetic nucleic acids*, *restricted person*, and *unlawful user of any controlled substance* to read as follows:

§ 331.1 Definitions.

Adjudicated as a mental defective. A determination by a court, board, commission, or other lawful authority that a person, as a result of marked subnormal intelligence, or mental illness, incompetency, condition, or disease is a danger to himself/herself or to others or lacks the mental capacity to contract or manage his/her own affairs. The term includes a finding of insanity by a court in a criminal case and those persons found incompetent to stand trial or found not guilty by reason of lack of mental responsibility pursuant to articles 50a and 72b of the Uniform Code of Military Justice, 10 U.S.C. 850a, 876b.

* * * * *

Alien. Any person not a citizen or national of the United States.

* * * * *

Committed to any mental institution. A formal commitment of a person to any mental institution by a court, board, commission, or other lawful authority. The term includes a commitment to a mental institution involuntarily. The term includes commitment for mental defectiveness or mental illness. It also includes commitments for other reasons, such as for drug use. The term does not include a person in a mental institution for observation or a voluntary admission to a mental institution.

Controlled substance. A drug or other substance, or immediate precursor, as “controlled substance” is defined in section 102 of the Controlled Substances Act, 21 U.S.C. 802. The term includes, but is not limited to, marijuana and scheduled depressants, stimulants, and narcotic drugs. The term does not

include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in Subtitle E of the Internal Revenue Code of 1986, as amended.

Crime punishable by imprisonment for a term exceeding 1 year. Any Federal, State, or foreign offense for which the maximum penalty, whether or not imposed, is capital punishment or imprisonment in excess of 1 year. What constitutes a conviction of such a crime shall be determined in accordance with the law of the jurisdiction in which the proceedings were held. Any conviction which has been set aside or nullified as a matter of law or for which a person has been pardoned shall not be considered a conviction for the purposes of this part.

* * * * *

Indictment. A formal written accusation originating with a prosecutor and issued by a grand jury against a party charged with a crime. For the purpose of these regulations the term indictment includes an “information,” which is a formal accusation of a crime, differing only in that it is being presented by a competent public officer on his oath of office, instead of a grand jury.

Information security. Protecting information and information systems from unauthorized access, use, disclosure, disruption, modification, or destruction in order to provide:

(1) Integrity, which means guarding against improper information modification or destruction, and includes ensuring information nonrepudiation and authenticity;

(2) Confidentiality, which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and

(3) Availability, which means ensuring timely and reliable access to and use of information.

* * * * *

Lawfully admitted for permanent residence. The status of having been lawfully accorded the privilege of residing permanently in the United States as an immigrant in accordance with the immigration laws, such status not having changed.

Mental institution. Includes mental health facilities, mental hospitals, sanitariums, psychiatric facilities, and other facilities that provide diagnoses by licensed professionals of mental retardation or mental illness, including a psychiatric ward in a general hospital.

Recombinant and synthetic nucleic acids. (1) Recombinant nucleic acid molecules that are constructed by joining nucleic acid molecules and that can replicate in a living cell;

(2) Synthetic nucleic acid molecules that are chemically, or by other means, synthesized or amplified nucleic acid molecules that may wholly or partially contain functional equivalents of nucleotides; or

(3) Molecules that result from the replication of those described in paragraph (1) or (2) of this definition.

Restricted person. An individual who: (1) Is under indictment for a crime punishable by imprisonment for a term exceeding 1 year;

(2) Has been convicted in any court of a crime punishable by imprisonment for a term exceeding 1 year;

(3) Is a fugitive from justice;

(4) Is an unlawful user of any controlled substance (as “controlled substance” is defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

(5) Is an alien illegally or unlawfully in the United States;

(6) Has been adjudicated as a mental defective or has been committed to any mental institution;

(7) Is an alien (other than an alien lawfully admitted for permanent residence) who is a national of a country as to which the Secretary of State, pursuant to section 6(j) of the Export Administration Act of 1979 (50 U.S.C. App. 2405(j)), section 620A of chapter 1 of part M of the Foreign Assistance Act of 1961 (22 U.S.C. 2371), or section 40(d) of chapter 3 of the Arms Export Control Act (22 U.S.C. 2780(d)), has made a determination (that remains in effect) that such country has repeatedly provided support for acts of international terrorism; or

(8) Has been discharged from the Armed Services of the United States under dishonorable conditions.

Unlawful user of any controlled substance. For purposes of this

regulation, a person who uses a controlled substance and has lost the power of self-control with reference to the use of that controlled substance; and any person who is a current user of a controlled substance in a manner other than as prescribed by a licensed physician. Such use is not limited to the use of drugs on a particular day, or within a matter of days or weeks before, but rather that the unlawful use has occurred recently enough to indicate that the individual is actively engaged in such conduct. A person may be an unlawful current user of a controlled substance even though the substance is not being used at the precise time the person seeks to have access to a select agent or toxin. An inference of current use may be drawn from evidence of a recent use or possession of a controlled substance or a pattern of use or possession that reasonably covers the present time, e.g., a conviction for use or possession of a controlled substance within the past year; multiple arrests for such offenses within the past 5 years if the most recent arrest occurred within the past year, or persons found through a drug test to use a controlled substance unlawfully, provided that the test was administered within the past year. For a current or former member of the Armed Forces, an inference of current use may be drawn from recent disciplinary or other administrative action based on confirmed drug use, e.g., court-martial conviction, nonjudicial punishment, or an administrative discharge based on drug use or drug rehabilitation failure.

3. Section 331.3 is amended as follows:

a. By revising paragraph (b) to read as set forth below.

b. In paragraph (c) introductory text, by adding the words “and/or synthetic” after the word “recombinant” each time it appears.

c. In paragraph (c)(2) introductory text, by adding the words “and/or synthetic” after the word “Recombinant”.

d. By revising paragraph (e) to read as set forth below.

§ 331.3 PPQ select agents and toxins.

(b) PPQ select agents and toxins:

Peronosclerospora philippinensis

(*Peronosclerospora sacchari*);

Phoma glycinicola (formerly

Pyrenochaeta glycines);

Ralstonia solanacearum, race 3, biovar

2;

Rathayibacter toxicus;

Sclerophthora rayssiae var. *zeae*;

Synchytrium endobioticum;
Xanthomonas oryzae.

(e) An attenuated strain of a select agent or an inactive form of a select toxin may be excluded from the requirements of this part based upon a determination that the attenuated strain or inactivated toxin does not pose a severe threat to plant health or plant products.

(1) To apply for exclusion, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued. An exclusion will be effective upon notification to the applicant. Exclusions will be listed on the National Select Agent Registry Web site at <http://www.selectagents.gov/>.

(2) If an excluded attenuated strain or inactivated toxin is subjected to any manipulation that restores or enhances its virulence or toxic activity, the resulting select agent or toxin will be subject to the requirements of this part.

§ 331.8 [Amended]

4. In § 331.8, paragraph (a)(1) is amended by removing the words “within any of the categories described in 18 U.S.C. 175b” and adding the words “a restricted person” in their place.

5. Section 331.9 is amended as follows:

a. By redesignating paragraphs (a)(3) through (a)(5) as paragraphs (a)(4), (a)(5), and (a)(7) respectively.

b. By adding a new paragraph (a)(3) to read as set forth below.

c. In newly redesignated paragraph (a)(5), by removing the word “and”.

d. By adding a new paragraph (a)(6) to read as set forth below.

e. By revising the first sentence of paragraph (b) to read as set forth below.

§ 331.9 Responsible official.

(3) Have the appropriate training or expertise to competently implement and manage the requirements of this part;

(6) Have their principal duty station at the physical location of the entity; and

(b) An entity may designate one or more individuals to serve as an alternate responsible official who acts for the responsible official in his/her absence.

6. Section 331.10 is amended as follows:

a. By redesignating paragraphs (e) through (i) as paragraphs (f) through (j) respectively.

b. By adding a new paragraph (e) to read as set forth below.

c. In newly redesignated paragraph (g)(1), by removing the words "within any of the categories described in 18 U.S.C. 175b" and adding the words "a restricted person" in their place.

d. In newly redesignated paragraph (i), by removing the number "5" and adding the number "3" in its place.

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

* * * * *

(e) A person who has a valid approval from the HHS Secretary or Administrator for access to a select agent or toxin may request the HHS Secretary or Administrator to provide the person's approval status to another registered individual or entity for a specified period of time.

* * * * *

7. Section 331.11 is amended as follows:

a. By revising paragraph (b) to read as set forth below.

b. By revising paragraph (c)(2) to read as set forth below.

c. In paragraph (c)(6), by removing the word "and".

d. In paragraph (c)(7), by removing the period and adding a semicolon in its place.

e. By adding new paragraphs (c)(8), (c)(9), and (c)(10) to read as set forth below.

f. By revising paragraph (e) to read as set forth below.

§ 331.11 Security.

* * * * *

(b) The security plan must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the risk of the select agent or toxin, given its intended use. A current security plan must be submitted for initial registration, renewal of registration, or when requested.

(c) * * *

(2) Contain provisions for the control of access to select agents and toxins, including the safeguarding of animals or plants intentionally or accidentally exposed to or infected with a select agent, against unauthorized access, theft, loss or release.

* * * * *

(8) Describe procedures for how the responsible official will be informed of suspicious activity that may be criminal in nature and related to the entity, its

personnel, or its select agents or toxins; and how the responsible official will notify the Federal Bureau of Investigation (FBI) of such activity;

(9) Contain provisions for information security that:

(i) Ensure that all external connections to systems which control security of the facility are isolated or have controls that permit and monitor for only authorized and authenticated user access;

(ii) Ensure that authorized and authenticated users are only granted access to select agent and toxin related information, files, equipment (e.g., servers or mass storage devices) and applications as necessary to fulfill their roles and responsibilities, and that access is modified when the user's roles and responsibilities change or when their access to select agent and toxin is suspended or revoked;

(iii) Ensure that controls are in place that are designed to prevent malicious code (such as, but not limited to, computer viruses, worms, and spyware) from compromising the confidentiality, integrity, or availability of information systems;

(iv) Establish a robust configuration management practice for information systems to include regular patching and updates made to operating systems and individual applications; and

(v) Establish procedures that provide backup security measures in the event that access control systems and/or surveillance devices are rendered inoperable.

(10) Contain provisions and policies for shipping, receiving, and storage of select agents and toxins, including documented procedures for receiving, monitoring, and shipping of all select agents and toxins. These provisions must provide that an entity will properly secure containers on site and have a written contingency plan for unexpected shipments.

* * * * *

(e) In developing a security plan, an individual or entity should consider the documents entitled, "Select Agents and Toxins Security Information Document" and "Select Agents and Toxins Security Plan Template." These documents are available on the Internet at <http://www.selectagents.gov/>.

* * * * *

8. Section 331.12 is amended by revising paragraph (a) to 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 containment procedures for the select agent or toxin, including any animals or plants intentionally or accidentally exposed to or infected with a select agent.

* * * * *

§ 331.13 [Amended]

9. Section 331.13 is amended as follows:

a. By removing footnote 5.

b. In paragraph (a) introductory text, by adding the words " , or possess products (i.e., select agents that are not known to acquire the resistance naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture, or recombinant and or synthetic DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50] < 100 ng/kg body weight) resulting from," after the word "conduct".

c. In paragraph (a)(1), by removing the words "Experiments utilizing recombinant DNA that involve the deliberate transfer of" and replacing them with the words "Experiments that involve the deliberate transfer of, or selection for,".

d. In paragraph (a)(2), by adding the words "synthetic or" before the word "recombinant".

10. Section 331.14 is amended as follows:

a. By redesignating footnote 6 as footnote 5.

b. By revising the first sentence in paragraph (a) to read as set forth below.

c. By redesignating footnote 7 as footnote 6.

d. By revising paragraph (b) to read as set forth below.

e. By redesignating paragraphs (c) and (d) as paragraphs (d) and (e), respectively.

f. By adding a new paragraph (c) to read as set forth below.

§ 331.14 Incident response.⁵

(a) An individual or entity required to register under this part must develop and implement a written incident response plan⁶ based upon a site specific risk assessment. * * *

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.

⁶ Technical assistance and guidance may be obtained by contacting APHIS.

(b) The incident response plan must fully describe the entity's response procedures for the 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.

(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, including any animals or plants intentionally or accidentally exposed to or infected with a select agent.

* * * * *

11. Section 331.15 is revised to 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), and incident response to:

(1) Each individual with access approval from the HHS Secretary or Administrator before that individual has such access to select agents and toxins. The training must address the particular needs of the individuals, the work they will do, and the risks posed by the select agents or toxins; and

(2) Each individual not approved for access to select agents and toxins by the HHS Secretary or Administrator before that individual enters areas where select agents or toxins are handled or stored (e.g., laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.). Training for escorted personnel must be based on the risk associated with accessing areas where select agents and toxins are used and/or stored.

(b) Refresher training must be provided annually or at such time as the registered individual or entity significantly amends its security, incident response, or biocontainment plans.

(c) The responsible official must ensure a record of the training provided to each individual with access to select agents and each escorted individual (e.g., laboratory workers, visitors, etc.) is maintained. The record must include the name of the individual, the date of the training, a description of the training provided, and the means used to verify that the employee understood the training.

12. Section 331.16 is amended as follows:

a. By redesignating footnote 8 as footnote 7.

b. By redesignating paragraphs (e) through (h) as paragraphs (h), (i), (j), and (f) respectively.

c. By adding a new paragraph (e) to read as set forth below.

d. In newly redesignated paragraph (f), by removing the words "packaging and".

e. By adding a new paragraph (g) to read as set forth below.

§ 331.16 Transfers.

* * * * *

(e) After authorization is provided by APHIS or CDC, the select agent(s) or toxin(s) are packaged for shipment in compliance with all applicable laws concerning packaging by an individual approved by the HHS Secretary or Administrator to have access to select agents and toxins, following a security risk assessment by the Attorney General.

* * * * *

(g) Transportation in commerce starts when the select agent(s) or toxin(s) are packaged for shipment and ready for receipt by a courier transporting select agent(s) or toxin(s) and ends when the package is received by the intended recipient who is an individual approved by the HHS Secretary or Administrator to have access to select agents and toxins, following a security risk assessment by the Attorney General.

* * * * *

13. Section 331.17 is amended as follows:

a. By revising paragraph (a)(1) introductory text to read as set forth below.

b. By redesignating paragraphs (a)(2) through (a)(6) as paragraphs (a)(3) through (a)(7), respectively.

c. By adding a new paragraph (a)(2) to read as set forth below.

§ 331.17 Records.

(a) * * *

(1) An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and recombinant and/or synthetic organisms) 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:

* * * * *

(2) An accurate, current inventory of any animals or plants intentionally or accidentally exposed to or infected with a select agent (including number and species, location, and appropriate disposition);

* * * * *

§ 331.19 [Amended]

14. Section 331.19 is amended as follows:

a. By removing paragraph (b)(1)(iv).

b. By redesignating paragraphs (b)(1)(v) through (b)(1)(viii) as paragraphs (b)(1)(iv) through (b)(1)(vii), respectively.

15. Section 331.20 is revised to read as follows:

§ 331.20 Administrative review.

(a) An individual or entity may appeal a denial, revocation, or suspension of registration under this part. The appeal must be in writing, state the factual basis for the appeal, and be submitted to the Administrator within 30 calendar days of the decision.

(b) An individual may appeal a denial, limitation, or revocation of access approval under this part. The appeal must be in writing, state the factual basis for the appeal, and be submitted to the Administrator within 180 calendar days of the decision.

(c) The Administrator's decision constitutes final agency action.

TITLE 9—[AMENDED]

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

16. 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.

17. Section 121.1 is amended by adding, in alphabetical order, definitions of *adjudicated as a mental defective*, *alien*, *committed to any mental institution*, *controlled substance*, *crime punishable by imprisonment for a term exceeding 1 year*, *indictment*, *information security*, *lawfully admitted for permanent residence*, *mental institution*, *occupational exposure*, *recombinant and synthetic nucleic acids*, *restricted person*, and *unlawful user of any controlled substance* to read as follows:

§ 121.1 Definitions.

Adjudicated as a mental defective. A determination by a court, board, commission, or other lawful authority that a person, as a result of marked subnormal intelligence, or mental illness, incompetency, condition, or disease is a danger to himself/herself or to others or lacks the mental capacity to contract or manage his/her own affairs. The term includes a finding of insanity by a court in a criminal case and those persons found incompetent to stand trial or found not guilty by reason of lack of mental responsibility pursuant to

articles 50a and 72b of the Uniform Code of Military Justice, 10 U.S.C. 850a, 876b.

* * * * *

Alien. Any person not a citizen or national of the United States.

* * * * *

Committed to any mental institution. A formal commitment of a person to any mental institution by a court, board, commission, or other lawful authority. The term includes a commitment to a mental institution involuntarily. The term includes commitment for mental defectiveness or mental illness. It also includes commitments for other reasons, such as for drug use. The term does not include a person in a mental institution for observation or a voluntary admission to a mental institution.

Controlled substance. A drug or other substance, or immediate precursor, as defined in section 102 of the Controlled Substances Act, 21 U.S.C. 802. The term includes, but is not limited to, marijuana and scheduled depressants, stimulants, and narcotic drugs. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in Subtitle E of the Internal Revenue Code of 1986, as amended.

Crime punishable by imprisonment for a term exceeding 1 year. Any Federal, State, or foreign offense for which the maximum penalty, whether or not imposed, is capital punishment or imprisonment in excess of 1 year. What constitutes a conviction of such a crime shall be determined in accordance with the law of the jurisdiction in which the proceedings were held. Any conviction which has been set aside or nullified as a matter of law or for which a person has been pardoned shall not be considered a conviction for the purposes of this part.

* * * * *

Indictment. A formal written accusation originating with a prosecutor and issued by a grand jury against a party charged with a crime. For the purpose of these regulations the term indictment includes an "information," which is a formal accusation of a crime, differing only in that it is being presented by a competent public officer on his oath of office, instead of a grand jury.

Information security. Protecting information and information systems from unauthorized access, use, disclosure, disruption, modification, or destruction in order to provide:

(1) Integrity, which means guarding against improper information modification or destruction, and

includes ensuring information nonrepudiation and authenticity;

(2) Confidentiality, which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and

(3) Availability, which means ensuring timely and reliable access to and use of information.

* * * * *

Lawfully admitted for permanent residence. The status of having been lawfully accorded the privilege of residing permanently in the United States as an immigrant in accordance with the immigration laws, such status not having changed.

Mental institution. Includes mental health facilities, mental hospitals, sanitariums, psychiatric facilities, and other facilities that provide diagnoses by licensed professionals of mental retardation or mental illness, including a psychiatric ward in a general hospital.

Occupational exposure. Any reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials or toxins that may result from the performance of an employee's duties.

* * * * *

Recombinant and synthetic nucleic acids. (1) Recombinant nucleic acid molecules that are constructed by joining nucleic acid molecules and that can replicate in a living cell;

(2) Synthetic nucleic acid molecules that are chemically, or by other means, synthesized or amplified nucleic acid molecules that may wholly or partially contain functional equivalents of nucleotides; or

(3) Molecules that result from the replication of those described in paragraph (1) or (2) of this definition.

* * * * *

Restricted person. An individual who:

(1) Is under indictment for a crime punishable by imprisonment for a term exceeding 1 year;

(2) Has been convicted in any court of a crime punishable by imprisonment for a term exceeding 1 year;

(3) Is a fugitive from justice;

(4) Is an unlawful user of any controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

(5) Is an alien illegally or unlawfully in the United States;

(6) Has been adjudicated as a mental defective or has been committed to any mental institution;

(7) Is an alien (other than an alien lawfully admitted for permanent residence) who is a national of a country

as to which the Secretary of State, pursuant to section 6(j) of the Export Administration Act of 1979 (50 U.S.C. App. 2405(j)), section 620A of chapter 1 of part M of the Foreign Assistance Act of 1961 (22 U.S.C. 2371), or section 40(d) of chapter 3 of the Arms Export Control Act (22 U.S.C. 2780(d)), has made a determination (that remains in effect) that such country has repeatedly provided support for acts of international terrorism; or

(8) Has been discharged from the Armed Services of the United States under dishonorable conditions.

* * * * *

Unlawful user of any controlled substance. For purposes of this regulation, a person who uses a controlled substance and has lost the power of self-control with reference to the use of that controlled substance; and any person who is a current user of a controlled substance in a manner other than as prescribed by a licensed physician. Such use is not limited to the use of drugs on a particular day, or within a matter of days or weeks before, but rather that the unlawful use has occurred recently enough to indicate that the individual is actively engaged in such conduct. A person may be an unlawful current user of a controlled substance even though the substance is not being used at the precise time the person seeks to have access to a select agent or toxin. An inference of current use may be drawn from evidence of a recent use or possession of a controlled substance or a pattern of use or possession that reasonably covers the present time, e.g., a conviction for use or possession of a controlled substance within the past year; multiple arrests for such offenses within the past 5 years if the most recent arrest occurred within the past year, or persons found through a drug test to use a controlled substance unlawfully, provided that the test was administered within the past year. For a current or former member of the Armed Forces, an inference of current use may be drawn from recent disciplinary or other administrative action based on confirmed drug use, e.g., court-martial conviction, nonjudicial punishment, or an administrative discharge based on drug use or drug rehabilitation failure.

* * * * *

18. Section 121.3 is amended as follows:

a. By adding a new sentence at the end of paragraph (a) to read as set forth below.

b. By revising paragraph (b) to read as set forth below.

c. In paragraph (c) introductory text, by adding the words “and/or synthetic” after the word “recombinant” each time it appears.

d. In paragraph (c)(2), by adding the words “and/or synthetic” after the word “Recombinant”.

e. By revising paragraph (e) to read as set forth below.

f. In paragraph (f)(3)(i), by removing the words “Newcastle disease virus (velogenic)” and adding the words “virulent Newcastle disease virus” in their place.

§ 121.3 VS select agents and toxins.

(a) * * * The select agents and toxins marked with an asterisk (*) are designated as Tier 1 select agents and toxins and are subject to additional requirements as listed in this part.

(b) VS select agents and toxins:

African horse sickness virus;

African swine fever virus;

Avian influenza virus (highly

pathogenic);

Classical swine fever virus;

* Foot-and-mouth disease virus;

Goat pox virus;

Lumpy skin disease virus;

Mycoplasma capricolum subspecies

capripneumoniae (contagious

caprine pleuropneumonia);

Mycoplasma mycoides subspecies

mycoides small colony (*Mmm* SC)

(contagious bovine

pleuropneumonia);

Peste des petits ruminants virus;

* Rinderpest virus;

Sheep pox virus;

Swine vesicular disease virus;

Virulent Newcastle disease virus.¹

* * * * *

* * * * *

(e) An attenuated strain of a select agent or an inactive form of a select toxin may be excluded from the requirements of this part based upon a determination by the Administrator that the attenuated strain or inactivated toxin does not pose a severe threat to animal health or to animal products.

(1) To apply for exclusion, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued. An exclusion will be effective upon notification to the

¹ A virulent Newcastle disease virus (avian paramyxovirus serotype 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 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.

applicant. Exclusions will be listed on the National Select Agent Registry Web site at <http://www.selectagents.gov/>.

(2) If an excluded attenuated strain or inactivated toxin is subjected to any manipulation that restores or enhances its virulence or toxic activity, the resulting select agent or toxin will be subject to the requirements of this part.

* * * * *

19. Section 121.4 is amended as follows:

a. By adding a new sentence at the end of paragraph (a) to read as set forth below.

b. By revising paragraph (b) to read as set forth below.

c. In paragraph (c) introductory text, by adding the words “and/or synthetic” after the word “recombinant” each time it appears.

d. In paragraph (c)(2) introductory text, by adding the phrase “and/or synthetic” after the word “Recombinant”.

e. By revising paragraph (e) to read as set forth below.

f. In paragraph (f)(3)(i), by removing the words “*Brucella melitensis*, Hendra virus, Nipah virus, Rift Valley fever virus, and Venezuelan equine encephalitis virus” and adding the words “*Burkholderia mallei*, and *Burkholderia pseudomallei*” in their place.

§ 121.4 Overlap select agents and toxins.

(a) * * * The select agents and toxins marked with an asterisk (*) are designated as Tier 1 select agents and toxins and are subject to additional requirements as listed in this part.

(b) Overlap select agents and toxins:

* *Bacillus anthracis*;

Brucella abortus;

Brucella melitensis;

Brucella suis;

* *Burkholderia mallei*;

* *Burkholderia pseudomallei*;

Hendra virus;

Nipah virus;

Rift Valley fever virus;

Venezuelan equine encephalitis virus:

Epizootic Subtypes IAB, IC.

* * * * *

(e) An attenuated strain of a select agent or an inactive form of a select toxin may be excluded from the requirements of this part based upon a determination by the HHS Secretary or Administrator that the attenuated strain or inactivated toxin does not pose a severe threat to public health and safety, to animal health or to animal products.

(1) To apply for exclusion, an individual or entity must submit a written request and supporting scientific information. A written

decision granting or denying the request will be issued. An exclusion will be effective upon notification to the applicant. Exclusions will be listed on the National Select Agent Registry Web site at <http://www.selectagents.gov/>.

(2) If an excluded attenuated strain or inactivated toxin is subjected to any manipulation that restores or enhances its virulence or toxic activity, the resulting select agent or toxin will be subject to the requirements of this part.

* * * * *

§ 121.5 [Amended]

20. In § 121.5, paragraph (a)(3)(i) is amended by removing the words “bovine spongiform encephalopathy agent,”.

§ 121.6 [Amended]

21. In § 121.6, paragraph (a)(3)(i) is amended by removing the words “Hendra virus, Nipah virus, Rift Valley fever virus, and Venezuelan equine encephalitis virus” and adding the words “*Burkholderia mallei*, and *Burkholderia pseudomallei*” in their place.

§ 121.8 [Amended]

22. In section 121.8, paragraph (a)(1) is amended by removing the words “within any of the categories described in 18 U.S.C. 175b” and adding the words “a restricted person” in their place.

23. Section 121.9 is amended as follows:

a. By redesignating paragraphs (a)(3) through (a)(5) as paragraphs (a)(4), (a)(5), and (a)(7) respectively.

b. By adding a new paragraph (a)(3) to read as set forth below.

c. In newly redesignated paragraph (a)(5), by removing the word “and”.

d. By adding a new paragraph (a)(6) to read as set forth below.

e. By revising the first sentence of paragraph (b) to read as set forth below.

f. By revising the first sentence of paragraph (c)(1) to read as set forth below.

§ 121.9 Responsible official.

(a) * * *

(3) Have the appropriate training and expertise to competently implement and manage the requirements of this part;

* * * * *

(6) Have their principal duty station at the physical location of the entity; and

* * * * *

(b) An entity may designate one or more individuals to serve as an alternate responsible official who acts for the responsible official in his/her absence.

* * *

(c) * * *

(1) The identification of any of the following select agents or toxins must be immediately reported by telephone, facsimile, or e-mail: African horse sickness virus, African swine fever virus, avian influenza virus (highly pathogenic), *Bacillus anthracis*, *Brucella melitensis*, *Burkholderia mallei*, *Burkholderia pseudomallei*, classical swine fever virus, foot-and-mouth disease virus, virulent Newcastle disease virus, rinderpest virus, and swine vesicular disease virus. * * *

24. Section 121.10 is amended as follows:

a. By redesignating paragraphs (e) through (j) as paragraphs (f) through (k), respectively.

b. By adding a new paragraph (e) to read as set forth below.

c. In newly redesignated paragraph (g)(1), by removing the words "within any of the categories described in 18 U.S.C. 175b" and adding the words "a restricted person" in their place.

d. In newly redesignated paragraph (j), by removing the number "5" and adding the number "3" in its place.

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

* * * * *

(e) A person who has a valid approval from the HHS Secretary or Administrator for access to a select agent or toxin may request the HHS Secretary or Administrator to provide the person's approval status to another registered individual or entity for a specified period of time.

* * * * *

25. Section 121.11 is amended as follows:

a. By revising paragraph (b) to read as set forth below.

b. By revising paragraph (c)(2) to read as set forth below.

c. In paragraph (c)(6), by removing the word "and".

d. By adding new paragraphs (c)(8), (c)(9), and (c)(10) to read as set forth below.

e. By redesignating paragraphs (e) and (f) as paragraphs (f) and (g), respectively.

f. By adding a new paragraph (e) to read as set forth below.

g. By revising newly redesignated paragraph (f) to read as set forth below.

§ 121.11 Security.

* * * * *

(b) The security plan must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the risk of

the select agent or toxin, given its intended use. A current security plan must be submitted for initial registration, renewal of registration, or when requested.

(c) * * *

(2) Contain provisions for the control of access to select agents and toxins, including the safeguarding of animals or plants intentionally or accidentally exposed to or infected with a select agent, against unauthorized access, theft, loss or release.

* * * * *

(8) Describe procedures for how the responsible official will be informed of suspicious activity that may be criminal in nature and related to the entity, its personnel, or its select agents or toxins; and how the responsible official will notify the Federal Bureau of Investigation (FBI) of such activity;

(9) Contain provisions for information security that:

(i) Ensure that all external connections to systems which control security of the facility are isolated or have controls that permit and monitor for only authorized and authenticated user access;

(ii) Ensure that authorized and authenticated users are only granted access to select agent and toxin related information, files, equipment (e.g., servers or mass storage devices) and applications as necessary to fulfill their roles and responsibilities, and that access is modified when the user's roles and responsibilities change or when their access to select agent and toxin is suspended or revoked;

(iii) Ensure that controls are in place that are designed to prevent malicious code (such as, but not limited to, computer viruses, worms, and spyware) from compromising the confidentiality, integrity, or availability of critical information systems;

(iv) Establish a robust configuration management practice for information systems to include regular patching and updates made to operating systems and individual applications; and

(v) Establish procedures that provide backup security measures in the event that access control systems and/or surveillance devices are rendered inoperable.

(10) Contain provisions and policies for shipping, receiving, and storage of select agents and toxins, including documented procedures for receiving, monitoring, and shipping of all select agents and toxins. These provisions must provide that an entity will properly secure containers on site and have a written contingency plan for unexpected shipments.

* * * * *

(e) In addition to the requirements contained in paragraphs (c) and (d) of this section, the security plan for an individual or entity possessing a Tier 1 select agent or toxin must also:

(1) Describe procedures for conducting a pre-access suitability assessment of persons who will have access to a Tier 1 select agent or toxin;

(2) Describe procedures for how an entity's responsible official will coordinate their efforts with the entity's safety and security professionals to ensure security of Tier 1 select agents and toxins and share, as appropriate, relevant information; and

(3) Describe procedures for the ongoing assessment of the suitability of personnel with access to a Tier 1 select agent or toxin. The procedures must include:

(i) Self- and peer-reporting of incidents or conditions that could affect an individual's ability to safely have access to or work with select agents and toxins, or to safeguard select agents and toxins from theft, loss, or release;

(ii) The training of all entity employees on entity policies and procedures for reporting, evaluation, and corrective actions concerning the assessment of personnel suitability to access Tier 1 agents and toxins; and

(iii) The ongoing suitability monitoring of individuals with access to Tier 1 select agents and toxins.

(4) Entities with Tier 1 select agents and toxins must prescribe and/or implement the following security enhancements:

(i) Procedures that limit access to registered space only to those approved by the HHS Secretary or the Administrator and meet the criteria of the entity's program that will ensure individuals with access approval to select agents and toxins are trustworthy and behaving in a manner that upholds public health and safety, the protection of animal or plant health and animal or plant products, security, and the integrity of the scientific enterprise. In developing these procedures, an individual or entity may consider the guidance documents available on the Internet at <http://www.selectagents.gov/>;

(ii) Procedures that limit access to laboratory and storage facilities outside of normal business hours to only those specifically approved by the responsible official or designee;

(iii) Procedures for allowing visitors, 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

based on the entity's site-specific risk assessment;

(iv) A minimum of three barriers where each subsequent barrier is different and adds to the delay in reaching secured areas where select agents and toxins are used or stored. Barriers must be monitored in such a way as to detect and assess intentional and unintentional circumventing of established access control measures under all conditions (day/night, severe weather, etc.);

(v) All registered space or areas that reasonably afford access to the registered space must be protected by an intrusion detection system (IDS) unless physically occupied;

(vi) Personnel monitoring the IDS must be capable of evaluating and interpreting the alarm and alerting the designated security response force or law enforcement;

(vii) Provide backup power and energy sources to power information security networks and integrated access controls and related systems during emergencies;

(viii) Response time for security forces or local police must not exceed 15 minutes from the time of an intrusion alarm or report of a security incident;

(ix) Entities must conduct complete inventory audits of all Tier 1 select agents and toxins in long-term storage when any of the following occur:

(A) Upon the physical relocation of a collection or inventory of select agents or toxins for those Tier 1 select agents or toxins in the collection or inventory;

(B) Upon the departure or arrival of a principal investigator for those Tier 1 select agents or toxins under the control of that principal investigator; or

(C) In the event of a theft or loss of a Tier 1 select agent or toxin.

(5) Entities that possess foot-and-mouth disease virus and rinderpest virus must have the following additional security requirements:

(i) A minimum of four barriers, one of which must be a perimeter security fence or equivalent which is monitored 24 hours a day, 7 days a week (24/7) to detect the presence of unauthorized persons, vehicles, materials, or unauthorized activities;

(ii) Onsite 24/7 armed security response force with roving patrol. Response time must not exceed 5 minutes from the time of an intrusion alarm or report of a security incident;

(iii) CCTV surveillance with 24/7 monitoring and recording; and

(iv) Transport vehicle with GPS tracking designed to serve as a containment vehicle.

(f) In developing a security plan, an individual or entity should consider the

documents entitled "Select Agents and Toxins Security Information Document" and "Select Agents and Toxins Security Plan Template." These documents are available on the Internet at <http://www.selectagents.gov/>.

* * * * *

26. Section 121.12 is amended as follows:

a. By revising paragraph (a) to read as set forth below.

b. By revising paragraph (c)(1) to read as set forth below.

c. In paragraph (c)(3), by removing the address "http://www.aphis.usda.gov/programs/ag_selectagent/index.html" and replacing it with the address "<http://www.selectagents.gov/>".

d. By redesignating paragraph (d) as paragraph (e).

e. By adding a new paragraph (d) to read as set forth below.

§ 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.⁹ 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 or plants intentionally or accidentally exposed to or infected with a select agent.

* * * * *

(c) * * *

(1) The CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories." This document is available on the Internet at <http://www.selectagents.gov/>.

* * * * *

(d) The biosafety plan must include an occupational health program for individuals with access to Tier 1 select agents and toxins, and those individuals must be enrolled in the occupational health program. The occupational health program may also be made available to individuals without access to Tier 1 select agents and toxins.

* * * * *

§ 121.13 [Amended]

27. Section 121.13 is amended as follows:

a. In the section heading, by removing footnote 10.

b. In paragraph (a), by adding the words ", or possess products (*i.e.*, select agents that are not known to acquire the resistance naturally, if such acquisition

⁹Technical assistance and guidance may be obtained by contacting APHIS.

could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture, or recombinant and or synthetic DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD₅₀ < 100 ng/kg body weight) resulting from," after the word "conduct" both times it appears.

c. In paragraph (b)(1), by removing the words "Experiments utilizing recombinant DNA that involve the deliberate transfer of" and adding the words "Experiments that involve the deliberate transfer of, or selection for," in their place.

d. In paragraph (b)(2), by adding the words "synthetic or" before the word "recombinant".

28. Section 121.14 is amended as follows:

a. In the section heading, by redesignating footnote 11 as footnote 10.

b. In paragraph (a), by redesignating footnote 12 as footnote 11 and revising the first sentence to read as set forth below.

c. By revising paragraph (b) to read as set forth below.

d. By redesignating paragraphs (c) and (d) as paragraphs (d) and (f), respectively.

e. By adding a new paragraph (c) to read as set forth below.

f. By adding a new paragraph (e) to read as set forth below.

§ 121.14 Incident response.¹⁰

(a) An individual or entity required to register under this part must develop and implement a written incident response plan¹¹ based upon a site specific risk assessment. * * *

(b) The incident response plan must fully describe the entity's response procedures for the 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.

(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, including any animals or plants intentionally or accidentally exposed to or infected with a select agent.

* * * * *

(e) Entities with Tier 1 select agents and toxins must have the following

¹⁰Nothing in this section is meant to supersede or preempt incident response requirements imposed by other statutes or regulations.

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

additional incident response policies or procedures:

(1) The incident response plan must fully describe the entity's response procedures for failure of intrusion detection or alarm system; and

(2) The incident response plan must describe notification procedures for the FBI in the event of a theft or suspicious activity that may be criminal in nature involving a Tier 1 select agent or toxin.

* * * * *

29. Section 121.15 is revised to read as follows:

§ 121.15 Training.

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

(1) Each individual with access approval from the HHS Secretary or Administrator before that individual has such access to select agents and toxins. The training must address the particular needs of the individuals, the work they will do, and the risks posed by the select agents or toxins; and

(2) Each individual not approved for access to select agents and toxins by the HHS Secretary or Administrator before that individual works in or otherwise enters areas where select agents or toxins are handled or stored (e.g., laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.). Training for escorted personnel must be based on the risk associated with accessing areas where select agents and toxins are used and/or stored.

(b) Entities with Tier 1 select agents and toxins must conduct annual insider threat awareness briefings on how to identify and report suspicious behaviors.

(c) Refresher training must be provided annually or at such time as the registered individual or entity significantly amends its security, incident response, or biosafety plans.

(d) The responsible official must ensure a record of the training provided

to each individual with access to select agents and each escorted individual (e.g., laboratory workers, visitors, etc.) is maintained. The record must include the name of the individual, the date of the training, a description of the training provided, and the means used to verify that the employee understood the training.

30. Section 121.16 is amended as follows:

a. By redesignating footnote 14 as footnote 12.

b. By redesignating paragraphs (f) through (i) as paragraphs (i), (k), and (g), respectively.

c. By adding a new paragraph (f) to read as set forth below.

d. In newly redesignated paragraph (g), by removing the words "packaging and".

e. By adding a new paragraph (h) to read as set forth below.

§ 121.16 Transfers.

* * * * *

(f) After authorization is provided by APHIS or CDC, the select agent(s) and toxin(s) are packaged for shipment in compliance with all applicable laws concerning packaging by an individual approved by the HHS Secretary or Administrator to have access to select agents and toxins, following a security risk assessment by the Attorney General.

* * * * *

(h) Transportation in commerce starts when the select agent(s) or toxin(s) are packaged for shipment and ready for receipt by a courier transporting select agent(s) or toxin(s) and ends when the package is received by the intended recipient who is an individual approved by the HHS Secretary or Administrator to have access to select agents and toxins, following a security risk assessment by the Attorney General.

* * * * *

31. Section 121.17 is amended as follows:

a. By revising paragraph (a)(1) introductory text to read as set forth below.

b. By redesignating paragraphs (a)(2) through (a)(6) as paragraphs (a)(3) through (a)(7), respectively.

c. By adding a new paragraph (a)(2) to read as set forth below.

§ 121.17 Records.

(a) * * *

(1) An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and recombinant and/or synthetic organisms) 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:

* * * * *

(2) An accurate, current inventory of any animals or plants intentionally or accidentally exposed to or infected with a select agent (including number and species, location, and appropriate disposition);

* * * * *

32. Section 121.20 is revised to read as follows:

§ 121.20 Administrative review.

(a) An individual or entity may appeal a denial, revocation, or suspension of registration under this part. The appeal must be in writing, state the factual basis for the appeal, and be submitted to the Administrator within 30 calendar days of the decision.

(b) An individual may appeal a denial, limitation, or revocation of access approval under this part. The appeal must be in writing, state the factual basis for the appeal, and be submitted to the Administrator within 180 calendar days of the decision.

(c) The Administrator's decision constitutes final agency action.

Done in Washington, DC, this 29th day of September 2011.

Gregory L. Parham,
Administrator, Animal and Plant Health Inspection Service.

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