DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 331

9 CFR Part 121

CFR part 331 and 9 CFR part 121. First, we are changing the title of both parts from ''Possession of Biological Agents and Toxins'' to ''Possession, Use, and Transfer of Biological Agents and Toxins'' to indicate the expanded scope of the regulations. Second, we are adding and removing definitions in §§ 331.1 and 121.1, as detailed below. Third, we are moving the lists of biological agents and toxins out of §§ 331.2 and 121.2 and adding in their place a new section that sets out the purpose and scope of each part. Fourth, we are removing the notification requirements in §§ 331.3 and 121.3, which are no longer applicable, and placing the lists of biological agents and toxins in those sections. We are amending both lists, as discussed below, and moving the exemption provisions found in the original § 121.2 to a new section, § 121.4. Finally, we are adding new sections that set out the effective dates, exemptions, registration requirements, responsibilities of the responsible official, safety and security requirements, transfer requirements, and appeals process. These new sections are discussed in detail below.

Effective and Applicability Dates

Both 7 CFR part 331 and 9 CFR part 121 begin with sections that discuss the effective dates of the regulations, §§ 331.0 and 121.0, respectively. Pursuant to section 213(c) of the Act, the Secretary must, not later than 180 days after the Act's enactment, promulgate an interim final rule establishing the standards and procedures governing the possession, use, and transfer of listed biological agents and toxins that shall take effect 60 days after the date on which the rule is promulgated. However, the Act also requires that the interim final rule include timeframes for the applicability of the rule that minimize disruption of research or educational projects that involve biological agents or toxins listed pursuant to section 212(a)(1) and that were underway as of the effective date of such rule.

Accordingly, in 7 CFR 331.0 and 9 CFR 121.0 we provide that the regulations in both parts are effective on February 11, 2003. On and after that date, any individual or entity possessing, using, or transferring any listed agent or toxin must be in compliance with the provisions of each part.

However, to minimize the disruption of research or educational projects (*e.g.*, teaching demonstrations) involving listed agents or toxins that were underway as of the effective date of these regulations, we provide that any individual or entity possessing such agents or toxins as of the effective date

Definitions

In 7 CFR 331.1 and 9 CFR 121.1, we define the terms used in the regulations. In our August 2002 interim rule establishing the regulations, we defined the terms *bi l gical age , facili , e , e ible facili fficial,* and *i* in both parts, while the term *, e la age i* was defined only in 9 CFR 121.1 (this term is not applicable to the plant-related regulations in 7 CFR part 331).

In this interim rule, we are removing the definition of *e* in both parts because the term is no longer used in 7

single mailing address). If an entity has more than one general physical location, then the entity must register each location and must designate an individual to be the responsible official for each location.

Although not contemplated by the Act, we recognize that there may be times when the responsible official is unavailable. Since some functions may only be performed by the responsible official (*i.e.,* transfers), this may disrupt research or other approved activities. Therefore, in 7 CFR 331.5(c) and 9 CFR 121.6(c), we provide that an entity may designate one or more individuals to be an alternate responsible official, who may act for the responsible official when that individual is unavailable. These individuals must have the authority and control to ensure compliance with the regulations when acting as the responsible official. These individuals will also be subject to a security risk assessment by the Attorney General as part of registration.

To apply for a certificate of registration, 7 CFR 331.8(a) and 9 CFR

section 102 of the Controlled Substances Act (21 U.S.C. 802));

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

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

(G) 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

(H) Has been discharged from the

take; for example, the rule could require that, whenever laboratory manipulation of a microorganism increases its risk profile significantly, whether intentionally or inadvertently, the responsible official report such to the Administrator and discontinue work with the modified organism until the Administrator has made recommendations regarding appropriate safety practices.

Restricting Access to Biological Agents and Toxins

Section 212(e)(1) of the Act provides that the Secretary shall establish appropriate safeguard and security requirements for persons possessing, using, or transferring biological agents or toxins commensurate with the risk such agent poses to animal and plant health, and animal and plant products (including the risk of use in domestic or international terrorism). Section 212(e)(2)(A) goes on to state that the regulations must include provisions to ensure that the registered person provides access to listed agents and toxins to only those individuals whom the registered person has determined have a legitimate need to handle or use such agents or toxins. In addition, section 212(b)(1)(A) requires that the Secretary establish and enforce safety procedures for agents and toxins, including measures to ensure proper training and appropriate skills to handle such agents and toxins.

Accordingly, 7 CFR 331.10(a) and 9

notify the Secretary whether the individual is within any of the categories discussed previously. Then the Secretary will notify the responsible official if an individual is granted or denied access to listed agents or toxins (section 212(e)(4)).

Accordingly, both 7 CFR 331.10(g) and 9 CFR 121.11(g) provide that we will notify the responsible official if an individual is granted full or limited access, or denied access, to biological agents or toxins, and we will notify the individual if he/she is denied access or granted only limited access to such agents or toxins. Paragraph (g) of 9 CFR 121.11 further provides that, for overlap agents or toxins, APHIS or CDC will provide the necessary notification.

Pursuant to section 212(e)(5) of the Act, 7 CFR 331.10(f) and 9 CFR 121.11(f) indicate that we may expedite the access approval process for individuals upon request by the responsible official and a showing of good cause, such as public health or agricultural emergencies, national security, impending expiration of a research grant, or a short-term visit by a prominent researcher. We note, however, that the Act specifically provides that expedited review is not available for individuals or entities seeking to register (section 212(e)(6)).

Both 7 CFR 331.10(j) and 9 CFR 121.11(k) provide that access approval for individuals is valid for 5 years and, thereafter, the responsible official shall request access approval every 5 years for as long as the individual needs access to such agents or toxins. This is consistent with the requirements of the Act.

In 7 CFR 331.10(k) and 9 CFR 121.11(l), we further provide that the responsible official must immediately notify APHIS or, for overlap agents or toxins, APHIS or CDC, when an individual's access to listed agents or toxins is terminated by the entity and the reasons therefore. We believe this information will be relevant to any subsequent determinations to allow that individual access to listed agents or toxins.

Section 212(e)(7)(A)(i) of the Act requires that the regulations provide for an opportunity for review by the Secretary, when requested by the individual involved, of a determination to deny that individual access to listed agents or toxins. Thus, 7 CFR 331.10(i) and 9 CFR 121.11(j) provide that an individual may appeal the Administrator's decision to deny or limit access to biological agents or toxins, in accordance with §§ 331.16 and 121.17, respectively.

Biocontainment and Security Plan/ Biosafety and Security Plan

Sections 212(b) and (c) of the Act require that the Secretary establish and enforce safety procedures for listed agents and toxins, including measures to ensure proper training and appropriate skills to handle agents and toxins, and proper laboratory facilities to contain and dispose of agents and toxins. In addition, sections 212(b) and (c) of the Act require that the Secretary establish and enforce safeguard and security measures to prevent access to listed agents and toxins for use in domestic or international terrorism or for any other criminal purpose. Pursuant to section 212(e)(1), the safeguard and security requirements must be commensurate with the risk posed by the agent or toxin.

Because different agents and toxins pose differing degrees of risk, depending on factors such as their escape potential and availability of a suitable habitat (for plant-related agents) and transmission and effect of exposure to the agent or toxin (for overlap and animal agents or toxins), we believe that it would be counterproductive to attempt to prepare a detailed list of prescriptive requirements for entities (*i.e.*, a ''one size fits all'' design standard). Rather, we have prepared a brief set of performance standards that we will consider to the degree to which they are appropriate to the risks presented by a particular agent or toxin, given its intended use and the location of the entity.

Accordingly, 7 CFR 331.11 requires that, as a condition of registration, an individual or entity must develop and implement a Biocontainment and Security Plan. Similarly, 9 CFR 121.12 requires that, as a condition of registration, an individual or entity must develop and implement a Biosafety and Security Plan. The titles and provisions of the plans are different because the agents listed under 7 CFR 331.3 do not pose a severe threat to human health and, therefore, it is unnecessary to require that the plant-related plan address personnel safety and health.

In 7 CFR 331.11, we provide that the plan must contain sufficient information and documentation to describe the containment procedures and the security systems and procedures. The plan's containment and security provisions must be commensurate with the risk posed by the agent or toxin, given its intended use.

Similarly, in 9 CFR 121.12 we provide that the plan must contain sufficient information and documentation to describe the biosafety and containment procedures, and the security systems and procedures. The plan's biosafety, containment, and security provisions must be commensurate with the risk posed by the agent or toxin, given its intended use.

Pursuant to section 212(e)(9) of the Act, we will provide technical assistance and guidance upon request to help individuals and entities develop their plans.

In 7 CFR 331.11(a)(1), we provide that the plan's containment procedures must be sufficient to contain the agent or toxin (*e.g.*, physical structure and features of the entity, and operational and procedural safeguards) while in 9 CFR 121.12(a)(1) we provide that the plan's biosafety and containment procedures must be sufficient to contain the agent or toxin (*e.g.*, physical structure and features of the entity, and operational and procedural safeguards). As previously noted, these provisions are different because the agents listed under 7 CFR 331.3 do not pose a severe threat to human health and, therefore, it is unnecessary to require that the plant-related plan address personnel safety and health.

We expect that a number of the individuals or entities seeking to register under these regulations will have previously been issued permits under 7 CFR part 330 or 9 CFR part 122, or will have been registered under CDC's select agent regulations in 42 CFR part 72 and thus will have appropriate biosafety and/or containment procedures already in place. It is likely that these biosafety and/or containment procedures will meet the requirements of the regulations or could be easily modified to meet the requirements of the regulations. Therefore, we encourage individuals or entities seeking to register to make use of existing biosafety and/or containment procedures, and to modify such procedures as necessary.

In 7 CFR 331.11(a)(2) and 9 CFR 121.12(a)(2), we further provide that the security systems and procedures must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the threat posed by the agent or toxin. This site-specific risk assessment should involve a threat assessment and risk analysis in which threats are defined, vulnerabilities examined, and risks associated with those vulnerabilities are identified.

The security systems and procedures must be tailored to address site-specific characteristics and requirements, ongoing programs, and operational needs and must mitigate the risks identified in the risk assessment. The

or entity may appeal a denial or revocation of registration. An individual who has been denied access to listed agents or toxins or who has been granted only limited access to listed agents or toxins may appeal that decision. We note that an entity may not appeal the denial or limitation of an individual's access to listed agents or toxins.

Both 7 CFR 331.17 and 9 CFR 121.18 provide that the appeal must be in writing and submitted to the Administrator within 30 days of the decision. The appeal must state all of the facts and reasons upon which the individual or entity disagrees with the decision. Where the denial or revocation of registration or the denial or limitation of an individual's access approval is based solely upon an identification by the Attorney General, APHIS will forward the request for review to the Attorney General to review.

In accordance with section 212(e)(7)(A)(iii), the decision of the Administrator constitutes final agency action for purposes of 5 U.S.C. 702.

Section 212(e)(7)(A)(ii) of the Act provides that the Secretary, during a review of a determination, may consider information relevant to the review ex parte to the extent that disclosure of the information could compromise national security or an investigation by any law enforcement agency.

Civil and Criminal Penalties

While not reflected in the regulations, we note that the Act provides for civil and criminal penalties for violations of the regulations. Under section 212(i) of the Act, any person who violates any provision of these regulations will be subject to a civil money penalty, in addition to any other penalties that may apply under law. The civil money penalty shall not exceed $250,000 for an individual and $500,000 for any other person.

Section 231 of the Act sets out the criminal penalties for violations of the regulations. Section 231(b)(2) of the Act provides that whoever transfers a biological agent or toxin to a person who the transferor knows or has reasonable cause to believe is not registered shall be fined or imprisoned for no more than 5 years, or both. Similarly, section 231(c)(2) provides that whoever knowingly possesses a biological agent or toxin without registering under the regulations shall be fined or imprisoned no more than 5 years, or both.

Immediate Action

Immediate action is necessary in order for USDA to comply with the requirements of Title II, subtitle B, of Pub. L. 107–188, which requires the publication of this interim rule not later than December 9, 2002. Under these circumstances, the Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest.

We will consider comments we receive during the comment period for this interim rule (see **DATES** above). After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments we receive and any amendments we are making to the rule.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The 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.

For this rule, we have prepared an economic analysis. The economic analysis provides a cost-benefit analysis as required by Executive Order 12866, as well as an analysis of the potential economic effects of this proposed rule on small entities, as required under 5 U.S.C. 603. The economic analysis is summarized below. Copies of the full analysis are available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107–188), the Secretary of Agriculture is required to provide by regulation for the establishment and enforcement of standards and procedures governing the possession and use of the listed biological agents and toxins; the establishment and enforcement of safety requirements for the transfer of listed agents and toxins; the establishment and enforcement of safeguard and security measures to prevent access to listed agents and toxins for use in domestic or international terrorism or other criminal purpose; and the establishment of procedures to protect animal and plant health, and animal and plant products, in the event of a transfer in violation of the established safety and security measures. For the Health and Human Services Department (HHS), CDC is taking similar measures related to biological agents and toxins that have the potential to adversely affect human health or human and animal health.

Small Entities

The Regulatory Flexibility Act requires that agencies specifically consider the economic effects of their rules on small entities. The entities most likely to be affected by this rule are those laboratories and other institutions conducting research and related activities that involve the use of listed biological agents and toxins. Most affected entities (other than Federal or State governmental entities) would be considered part of North American Industrial Classification System (NAICS) code 541710, ''Research and Development in the Physical, Engineering, and Life Sciences.'' Some affected entities would be considered part of NAICS 541940, ''Veterinary Services;'' NAICS 611310, ''Colleges, Universities and Professional Schools;'' NAICS 325412, ''Pharmaceutical Preparation Manufacturing;'' NAICS 325413, ''In-Vitro Diagnostic Substance Manufacturing;'' and NAICS 325414, ''Biological Product (except Diagnostic) Manufacturing.''

The Small Business Administration (SBA) has established guidelines for determining when establishments are to be considered ''small'' under the Regulatory Flexibility Act. An entity in NAICS 541710, 325413, or 325414 is considered to be a small entity if it has 500 or fewer employees; for NAICS 325412, that threshold is 750 or fewer employees. An entity in NAICS 611310 is considered small with annual receipts/revenues of $6 million or less.

According to the 1997 Economic Census, no less [1] than 95 percent of life sciences research and development establishments subject to Federal income tax, and no less than 92 percent of those establishments not subject to Federal income taxes, can be considered small. More than 99 percent of ''biological (except diagnostic) manufacturing'' establishments, more than 98 percent of ''diagnostic manufacturing'' establishments, and at least 94 percent of ''pharmaceutical manufacturing'' establishments are considered small. The economic census does not contain information on the establishment size of veterinary service entities. According to data from the U.S. Department of Education, about 31 percent of reporting postsecondary institutions had revenue of less than $6 million in fiscal year 1995–96.

Benefits of the Rule

Benefits associated with this rule are the avoided losses to animals or plants that could be attacked by these organisms, and their products and markets. Losses include reduction in

[1] The establishment size breakdown in the economic census does not precisely fit the SBA guidelines.

yield and productivity of affected hosts, public and private control costs, and loss in export revenue due to trade embargoes. The listed agents and toxins include viruses, bacteria, and fungi that potentially pose a severe threat to plant health or plant products. The listed pathogens could threaten a number of important crops including citrus, corn, potatoes, rice, stone fruit, and soybeans. In 2001, soybean production alone was valued at more than $12 billion. The rule also covers biological agents and toxins that have been determined to have the potential to pose a sever threat to both human and animal health, to animal health, or to animal products. Paragraph (b) of 9 CFR 121.2 lists 21 overlap agents and toxins. This list was drawn from CDC's list of select agents, the overlap being those select agents that pose a risk to both human and animal health. The 23 agents and toxins listed in 9 CFR 121.2(d) include the causative agents of 14 of the 15 diseases classified by the Office International des Epizooties (OIE) as ''List A'' diseases. (The causative agent of the fifteenth List A disease, Rift Valley fever, is an overlap agent listed in the above part.) List A diseases are, according to OIE, those transmissible diseases that have the potential for very serious and rapid spread, irrespective of national borders, that are of serious socioeconomic or public health consequence and that are of major importance in the international trade of animals and animal products. Five of the remaining nine agents and toxins are OIE List B diseases, *i.e.*, transmissible diseases that are considered to be of socioeconomic and/or public health importance within countries and that are significant in the international trade of animals and animal products. The three remaining diseases/disease agents—two restricted foreign animal pathogens and one emerging paramyxovirus—were included on the list based on the determination that they potentially pose a severe threat to animal health or animal products.

The costs associated with outbreaks can be very high as is demonstrated by natural outbreaks that have occurred. For example, it has been estimated that the losses to agriculture and the food chain from the recent FMD outbreak in the United Kingdom, including the costs compensated by the government amount to about £3.1 billion ($4.7 billion). In 1999, Ekboir estimated the potential impacts of an FMD outbreak in California alone at between $8.5 and $13.5 billion.[2] Also, a BSE crisis occurred in the UK (which has a cattle industry about 1/10 the size of that in the United States) in 1996. It has been estimated [3] that the total resource costs to the UK economy as a result of BSE in the first 12 months after the onset of the 1996 crisis were in the range of £740 million to £980 million ($1.2 billion to $1.5 billion), or just over 0.1 percent of the gross domestic product of the United Kingdom. In addition to these losses, the UK lost its entire export market for beef following the crisis.

The above cited consequences relate to natural or accidental introduction. Deliberate introduction greatly increases the probability of an agent or toxin becoming established and causing wide-ranging and devastating impacts on the economy, disruption to society, diminished confidence in public and private institutions, and possible loss of life. The perpetrators would have the advantage of controlling the time of introduction of the agent, introducing agents into remote or highly susceptible areas, multiple introductions of the same agent, or simultaneous release of different agents. Intentional introductions permit an increased probability of survival of a pathogen, the use of highly virulent strains and high concentrations of inoculum, and precise timing of release to coincide with maximal colonization potential.[4]

Costs of the Rule

Facilities that possess listed agents and toxins will be affected by this rule. Those facilities are primarily research and diagnostic facilities. They include Federal, State, and university laboratories, and commercial enterprises.

Because affected entities vary widely and the information needed to determine an individual facility's biosafety, containment and physical security situation will not be available until the registration process occurs, information on specific necessary changes at any individual facility and thus those costs are not available. However, some general observations regarding the potential costs can be made.

Affected Entities

There are approximately 33 academic, commercial, and State and Federal government facilities that have indicated their possession of listed plant pathogens and thus affected by this rule. This information was obtained from the notifications received by Plant Protection and Quarantine, APHIS–USDA.

In addition, there are approximately 619 commercial diagnostic facilities, university research and diagnostic facilities, State and Federal diagnostic and research facilities, and others in possession of animal and/or overlap agents or toxins that are expected to be affected by this rule.[5]

The facilities that deal with listed plant agents and toxins are academic institutions, commercial diagnostic and research facilities, and State and Federal Government facilities. Almost 60 percent of the affected facilities are academic and almost 30 percent government. The affected facilities tend to be small.

The facilities that deal with animal and overlap agents are academic, commercial, government, non-profit, and other. Twenty-nine percent of the facilities with listed agents and toxins are identified academic institutions, 45 percent as private commercial or non-profit entities, and 15 percent as government. The remaining 11 percent are not identified, but include veterinary practices. Animal and overlap agents are used primarily in diagnostic work and research.

The level of security at the facilities dealing with listed agents and toxins is currently very diverse, ranging from a locked freezer to a lock on the door to razor wire perimeter fencing, a guard post, locks or coded entry, and visitor escorts.

Exemptions From the Rule

Clinical and diagnostic laboratories are specifically exempted from the provisions of the regulations for possessing, using, or transferring animal

[2] Ekboir, J.M., ''Potential impact of foot-and-mouth disease in California: The role and contribution of animal health surveillance and monitoring services.'' Davis, CA: Agricultural Issues Center, Division of Agriculture and Natural Resources, University of California, Davis, 1999.

[3] DTZ Pieda Consulting, ''Economic Impact of BSE on the UK economy.'' A Report commissioned by the UK Agricultural Departments and HM Treasury.

[4] National Research Council.

[5] As of October 18, 2002, 1,653 entities had submitted notifications that they possess biological agents or toxins affecting animals and/or humans listed by either USDA or HHS. In this analysis, we use 1,653 entities. In coordination with CDC, we assumed that those facilities with animal agents and those with animal and overlap agents will be affected by the APHIS rule. Those facilities with human agents and those human and overlap agents were assumed to be affected by the CDC rule. About one-half of those facilities with only overlap agents were assumed to be affected by the APHIS rule (50 percent of facilities with only overlaps, except all medical practices which were attributed to the CDC rule and all veterinary practices which were attributed to the APHIS rule). Facilities with both animal and human agents were considered in both analyses. This may cause some double counting if entities with both animal and human agents do not also have separate laboratories for that work. Numbers provided by Ed Gaunt, ASI—contractor collecting and compiling notification information.

or overlap agents or toxins that are contained in specimens presented for diagnosis or verification, and for agents that are contained in specimens presented for proficiency testing; provided that the facilities follow the requirements on disposal, transfer and notification. Facilities that handle fixed tissues that are, bear, or contain listed animal agents or toxins will be exempt from the registration requirements, provided that a permit has been issued to the facility under 9 CFR part 122. In addition, the Secretary may grant exemptions from the applicability of the regulations as they apply to animal only and plant agents and toxins if the Secretary determines that such exemptions are consistent with protecting animal and plant health, and animal and plant products. Registered diagnostic laboratories will also be required to report identifications of listed agents and toxins when presented for diagnosis. APHIS expects to receive 1,000 required notifications of identification and 250 exemption applications in a given year. It is estimated that complying with the exemption requirements will cost $72 per notification and $84 per exemption application.[6]

Registration

Under this rule, unless exempted a person or facility shall not possess, use, or transfer any listed agent or toxin without a certificate of registration issued by APHIS or CDC. The registration process is designed to obtain critical information concerning persons or facilities in possession of certain agents or toxins, as well as the specific characteristics of the agents and toxins. Information to determine that persons seeking to register have a lawful purpose to possess, use, or transfer agents or toxins will also be required as part of the registration process. This will involve security risk assessments by the U.S. Department of Justice, and collecting and providing the required information. Also as a condition of registration, a Biocontainment and Security Plan or Biosafety and Security Plan must be developed. It is estimated that it will cost between $414 and $778 per facility to collect and provide the required information. Registration amendments are expected to cost $86 each. In addition, it is estimated that re-applying for registration will cost $299 to $459 for those facilities to re-apply, as the registration is valid for up to 3 years.[7] It is estimated that the development of the biosafety/biocontainment plan will cost $2,777 at those facilities needing one. The security plan should be covered in the facility security assessment below. Complying with inactivation requirements is estimated to cost $43 per notification.

Transfer

Under this rule, listed biological agents and toxins may only be transferred to persons registered to possess, use, or transfer that particular agent or toxin. However, the sender may be an individual or facility exempt from the requirements of this rule, or an individual or facility located outside the United States. Transfer must occur only with prior authorization, notification of receipt by the recipient, and notification of overdue or damaged shipments. It is estimated that complying with these requirements will cost $124 for each of an expected 6,520 transfers in a year.

Biosafety and Containment Procedures

Biosafety and containment requirements ensure that the combination of work practices and physical containment are proportional to the risk associated with the agent or toxin. USDA permits dealing with the listed agents and toxins already required the biosafety and containment level commensurate with the risk associated with the pathogen covered in the permit or registration. Therefore, to the extent that affected entities are already permittees, the biosafety and containment requirements of this rule will have already been required at those facilities. There are almost 400 individual permittees with listed agents and toxins representing an unknown number of facilities.[8] In addition, some portion of the potentially affected entities will be exempt from the requirements of this rule, and therefore not affected by the biosafety requirements.

Physical Security Procedures

This rule will require that any facility where listed agents and toxins are held adequately provide for the physical security of the premises. This rule does not specify how security needs are to be met, only that they are adequate. Because the current level of security is very diverse, physical security components may have to be added in various quantities (including none) to meet the specific security needs of a given facility.

An example of security spending at USDA laboratories shows security upgrades at NVSL in Ames, IA, completed in 2002 cost $550,077 ($6.63/ft^2, 83,000 ft^2 total area). Installations of electronic security components can include closed-circuit television (CCTV) (*e.g.,* cameras, VCR, and control equipment), intrusion detection system (access-control card readers, card-keys, operating computer and software), all cabling associated with the security system, and integrating the system with the off-site monitoring. Other security related expenses that could be needed at a given facility included a facility security assessment (to prepare the security plan required in the rule) and entry control equipment (x-ray, metal detectors). Other features would entail yearly recurring costs (*i.e.,* off-site monitoring, an equipment maintenance agreement, and guard service).

The average cost per square foot of electronic portion of security for budget purposes ranges from $6.25/$ft^2$ for facilities under 80,000 ft^2 to $8.33/$ft^2$ for facilities in excess of 150,000 ft^2. This is based on average actual security system installations for APHIS facilities, and includes CCTV, intrusion detection systems, integration, perimeter protection, design, construction, and construction management, but not biometric technology, and assumes single-story facilities and has been adjusted for laboratory-type facilities.

This rule will require that all information resources related to listed biological agents and toxins have an appropriate level of protection in the system that is used to acquire, store, manipulate, manage, move, control, display, switch, interchange, receive or transmit that information. Most affected entities have a variety of compelling reasons, including regulatory requirements, for already protecting information.

Other Costs

Other costs associated with this rule include the costs of any additional training that may occur, record keeping, complying with the requirements for theft/loss/release notification, and appealing rulings. It is estimated that yearly recordkeeping will cost from $450 to $1,499 per registered facility. It is estimated that theft, loss, and release reporting will cost $72 for each occurrence. It is estimated that appeal requirements will cost $311 for each

[6] Based on Bureau of Labor Statistics data. Labor rates used are the same as used by CDC in their analysis of listed agents and toxins. See Supporting Statement for Information Collection Request ''Part 73—Select Biological Agents and Toxins'' for CDC rule covering 42 CFR part 73.

[7] Registrations will be valid for up to 3 years. It is estimated that approximately two-thirds of all facilities will be required to reapply within the first 3 years.

[8] Because of the data on notification of possession of listed agents and toxins, we cannot directly link permittees to facilities.

[9] 1997 Economic Census. Department of Commerce, Census Bureau.

[10] AAVLD provided information on 10 diagnostic

in total $1.5 million if one-half of the 652 affected facilities need to develop new plans. The security portion would be developed as part of the facility security assessment above. It is estimated that notifications of inactivation would cost $1,376 per year. Other costs of the rule also include record keeping costs, estimated at $425,265 per year. The estimated total cost associated with notifications of theft, loss and release of listed agents or toxins is $144 per year. The estimated total cost associated with appeals under this rule is estimated to be $311 per year. The estimated total cost associated with expedited reviews under this rule is estimated to be $14,018 per year.

The costs to APHIS include processing facility registrations, notifications of identification of agents and toxins, exemption applications, transfer applications, theft/loss notifications, appeals, performing facility inspections, and providing technical assistance for compliance. It is estimated that this will cost as much as $1.5 million in the first year. Paperwork processing is estimated to cost APHIS $744,705 per year.[13] In addition, APHIS may incur costs associated with providing technical assistance on compliance with this rule. Facility inspections will occur every 3 years and are estimated to cost between $240 and $997 each, or between $156,480 and $650,044 for all registered facilities.[14] Additional inspector training could cost $35,480 annually and security clearances $45,000 for all inspectors.

TABLE 1.—SUMMARY OF

[13] Costs to Government for information Collections for Select Agent Registrations.

[14] These costs are based on current APHIS user fees for facility inspections: Biosecurity Level (BSL) 3, a flat $997, and BSL2 $60 to $80/hr for about 4 hours. Under this rule, users will not be charged for the inspections and thus the Government will absorb the cost of those inspections.

Authority: Secs. 211–213, Title II, Pub. L. 107–188, 116 Stat. 647 (7 U.S.C. 8401).

§ 331.0 Effective and applicability dates.

The regulations in this part are effective on February 11, 2003.On and after that date, any person possessing, using, or transferring any agent or toxin listed in § 331.3 must be in compliance with the provisions of this part. However, so as not to disrupt research or educational projects involving listed agents or toxins that were underway as of the effective date of this part, any person possessing such agents or toxins as of the effective date (current possessors) will be afforded additional time to reach full compliance with this part. Any provision not specifically cited in paragraphs (a) through (f) of this section will be applicable as of February 11, 2003. In addition, any individual or entity who does not possess listed agents or toxins by the effective date of this part, but who wishes to initiate a research or educational project prior to November 12, 2003, must be in compliance with the provisions of this part that are applicable for current possessors at the time of application, as provided in paragraphs (a) through (e) of this section.

(a) During the period from February 11, 2003, to November 12, 2003, biological agents or toxins listed in § 331.3 may only be transferred to an individual or entity that is not registered under this part if the individual or entity has been issued a permit by the Administrator under part 330 of this chapter to import or move interstate that specific agent or toxin. If an individual or entity has not been issued a permit under part 330 of this chapter, the individual or entity may apply for a permit. To receive an agent or toxin, an individual or entity will also be required to submit APHIS Form 2041, in accordance with § 331.13(c). Because USDA permits do not cover intrastate movement, an individual or entity may not receive a listed agent or toxin that is being moved intrastate until that individual or entity is registered in accordance with this part.

(b) By March 12, 2003, the responsible official must submit the registration application package as required in § 331.8. In addition, the responsible official must submit to the Attorney General the names and identifying information for the responsible official; alternate responsible official, where applicable; entity; and, where applicable, the individual who owns or controls the entity.

(c) By April 11, 2003, the responsible official must submit to the Attorney General the names and identifying information for all individuals whom the responsible official has identified as having a legitimate need to handle or use listed agents or toxins, and who have the appropriate training and skills to handle such agents or toxins, as required in § 331.10.

(d) By June 12, 2003, the responsible official must submit to APHIS the security section of the Biocontainment and Security Plan required in § 331.11.

(e) By September 12, 2003, the responsible official must implement the security section of the Biocontainment and Security Plan, as required in § 331.11, and provide security training in accordance with 7 CFR 331.12.

(f) By November 12, 2003, the registration application process must be complete and the entity in full compliance with the regulations in this part.

§ 331.1 Definitions.

Ad i i a . The Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator.

A i al a d Pla Heal h I ec i Se ice (APHIS). The Animal and Plant Health Inspection Service of the United States Department of Agriculture.

A e Ge e al. The Attorney General of the United States or any person authorized to act for the Attorney General.

Bi l gical age . Any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing:

(1) Death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism;

(2) Deterioration of food, water, equipment, supplies, or material of any kind; or

(3) Deleterious alteration of the environment.

Ce e f Di ea e C l a d P e i (CDC). The Centers for Disease Control and Prevention of the United States Department of Health and Human Services.

Diag ic lab a . A laboratory facility that receives specimens for the purpose of determining the identities of pests, pathogens, contaminants, or causes of disease.

E i . Any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.

I . To move into, or the act of movement into, the territorial limits of the United States.

I e a e. From one State into or through any other State, or within the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

Pe i . A written authorization by the Administrator to import or move interstate biological agents or toxins, under conditions prescribed by the Administrator.

PPQ. The Plant Protection and Quarantine Programs of the Animal and Plant Health Inspection Service

Re ible fficial. The individual designated by an entity to act on its behalf. This individual must hdsr:Mbhe entity in fu compli
United States Depart

(2) Any poisonous isomer or biological product, homolog, or derivative of such a substance.

U i ed S a e . All of the States.

USDA. The United States Department of Agriculture.

§ 331.2 Purpose and scope.

(a) This part sets forth the requirements for possession, use, and transfer of biological agents or toxins that have been determined to have the potential to pose a severe threat to plant health or to plant products. The purpose of this part is to ensure the safe handling of such agents or toxins, and to protect against the use of such agents or toxins in domestic or international terrorism or for any other criminal purpose.

(b) Accordingly, this part provides that any individual or entity that possesses, uses, or transfers any agent or toxin listed in § 331.3 must register in accordance with § 331.6. To register, each entity must designate an individual who has the authority and control to ensure compliance with the regulations to be the responsible official. The responsible official must complete and submit the registration application package to APHIS. As part of registration, the responsible official, the entity, and, where applicable, the individual who owns or controls such entity will be subject to a security risk assessment by the Attorney General.

(c) The responsible official is responsible for ensuring compliance with the safety procedures in this part, including implementing the Biocontainment and Security Plan in accordance with § 331.11, providing the proper training to individuals who handle or use agents or toxins listed in § 331.3, and providing proper laboratory facilities to contain and dispose of such agents or toxins. In addition, the responsible official is responsible for ensuring compliance with the safeguard and security measures in this part, including restricting access to only those individuals who have a legitimate need to handle or use agents or toxins and who have been approved in accordance with § 331.10, and transferring such agents or toxins only to registered individuals or entities in accordance with § 331.13.

§ 331.3 List of biological agents and toxins.

(a) The biological agents and toxins listed in this section have been determined to have the potential to pose a severe threat to plant health or to plant products.

Libe bac e af ica , Libe bac e a ia ic Pe cle a hili i e i

Phak a ach hi i
Plum pox potyvirus
Ral ia la acea , race 3, biovar 2
Scle h h a a iae var. *eae*
S ch i e d bi ic
Xa h a ae pv. *ic la*
X lella fa idi a (citrus variegated chlorosis strain)

(b) The Administrator has determined that it would be impractical to regulate a biological agent or toxin that is in its naturally occurring environment. Therefore, any biological agent or toxin listed in this section that is in its naturally occurring environment will not be subject to the requirements of this part, provided that the biological agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

(c) The Administrator has determined that biological agents or toxins that meet any of the following criteria do not have the potential to pose a severe threat to plant health or to plant products. Therefore, an individual or entity that only possesses, uses, or transfers an agent or toxin that meets any of the following criteria will not be subject to the requirements of this part:

(1) Nonviable agents that are, bear, or contain listed agents or toxins;

(2) Genetic elements or subunits of listed agents or toxins, if the genetic elements or subunits are not capable of causing disease.

§ 331.4 Exemptions.

(a) Diagnostic laboratories [1] and other entities possessing, using, or transferring agents or toxins that are contained in specimens presented for diagnosis or verification will be exempt from the requirements of this part, provided that:

(1) The identification of such agents or toxins is immediately reported to the Administrator and to other appropriate authorities when required by Federal, State, or local law; and

(2) Within 7 days after identification, the agents or toxins are transferred or inactivated, and APHIS Form 2040 is submitted to the Administrator.[2] During agricultural emergencies or outbreaks, or in endemic areas, the Administrator may require less frequent reporting. A copy of the completed form must be maintained for 3 years.

(b) In addition to the exemption provided in paragraph (a) of this section, the Administrator may grant a specific exemption upon a showing of good cause and upon his or her determination that such exemption is consistent with protecting animal or plant health, and animal or plant products. An individual or entity that possesses, uses, or transfers agents or toxins may request in writing an exemption from the requirements of this part. If granted, such exemptions are valid for a maximum of 3 years; thereafter, an individual or entity must request a new exemption. If a request for exemption is denied, an individual or entity may request reconsideration in writing to the Administrator. The request for reconsideration must state all of the facts and reasons upon which the individual or entity relies to show that the exemption was wrongfully denied. The Administrator will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision. If there is a conflict as to any material fact, the individual or entity may request a hearing to resolve the conflict.[3]

§ 331.5 Registration; who must register.

(a) Unless exempted under § 331.4, any individual or entity that possesses, uses, or transfers any agent or toxin listed in § 331.3 must register with APHIS.

(b) Each entity must designate an individual to be its responsible official. The responsible official must have the authority and control to ensure compliance with the regulations. The responsible official must complete and sign the registration application package, and will be the individual contacted by APHIS if any questions arise concerning the application or subsequent compliance with the regulations in this part. As part of registration, the responsible official and the entity will be subject to a security risk assessment by the Attorney General. While most registrants are likely to be entities, in the event that an individual applies for and is granted a certificate of registration, APHIS will consider the individual to be the responsible official.

(c) An entity may designate an individual to be an alternate responsible official, who may act for the responsible

[1] However, diagnostic laboratories and other persons will still be required to obtain a permit under part 330 of this chapter in order to import or move interstate any listed agent or toxin.

[2] A diagnostic laboratory or other person must immediately notify APHIS by calling (301) 734–5519. APHIS Form 2040 may be obtained by calling (301) 734–5519 or faxing a request to (301) 734–8700. The form is also available on the Internet at *h :// .a hi . da.g / / e i* . The completed form may be mailed to Biological and Technical Services, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1236; or faxed to (301) 734–8700.

[3] A request for exemption may be mailed to biological and Technical Services, PPQ, APHIS, 4700 River road Unit 133, Riverdale, MD 20737–1236; or faxed to (301) 734–8700.

official when he/she is unavailable. This individual must have the authority and control to ensure compliance with the regulations when acting for the responsible official. This individual will also be subject to a security risk assessment by the Attorney General as part of registration.

§ 331.6 Registration; general provisions.

(a) Unless exempted under this part, an individual or entity shall not possess, use, or transfer any agent or toxin listed in § 331.3 without a certificate of registration issued by APHIS.

(b) A certificate of registration may be issued upon:

(1) Approval of the responsible official; the alternate responsible official, where applicable; the entity; and, where applicable, the individual who controls the entity following a security risk assessment by the Attorney General;[4] and

(2) Approval of the containment and security of the entity. The entity's containment and security procedures must be commensurate with the risk of the agent or toxin, given its intended use. APHIS will review the Biocontainment and Security Plan, and may inspect and evaluate the premises and records to determine compliance with the regulations and the containment and security requirements; and

(3) A determination by the Administrator that the individual or entity seeking to register has a lawful purpose to possess, use, or transfer such agents or toxins.

(c) A certificate of registration will be valid for only the specific agents or toxins listed on the certificate and specific activities and locations. A certificate of registration may cover more than one listed agent or toxin, and it may be amended to cover additional listed agents or toxins.

(d) A certificate of registration may be amended to reflect changed circumstances (*e.g.*, replacement of the responsible official, changes in ownership or control of the entity,[5] changes in the activities involving the agent or toxin). The responsible official must immediately notify APHIS of such changes in circumstances that occur after submission of the application for registration or after receipt of a certificate of registration.

(e) If a responsible official wishes to discontinue possessing, using, or transferring a particular agent or toxin, the responsible official may inactivate the agent or toxin or he/she may transfer the agent or toxin to a registered individuals or entities in accordance with § 331.12. The responsible official must notify APHIS 5 business days prior to the planned inactivation so that we may have the opportunity to observe the inactivation of the agents or toxins. We will notify the responsible official if we wish to observe the inactivation of the agents or toxins.

(f) A certificate of registration will be valid for a maximum of 3 years.

§ 331.7 Denial, revocation, or suspension of registration.

(a) APHIS may deny an application for registration or revoke registration if:

(1) The Attorney General identifies the responsible official, entity, or the individual who owns or controls the entity as within any of the categories described in 18 U.S.C. 175b; or

(2) The Attorney General identifies the responsible official, entity, or the individual who owns or controls the entity as reasonably suspected by any Federal law enforcement or intelligence agency of:

(i) Committing a crime set forth in 18 U.S.C. 2332b(g)(5); or

(ii) Knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence; or

(iii) Being an agent of a foreign power as defined in 50 U.S.C. 1801; or

(3) The responsible official does not have a lawful purpose to possess, use, or transfer agents or toxins listed in § 331.3; or

(4) The responsible official is an individual who handles or uses listed agents or toxins and he/she does not have the necessary training or skills to handle such agents or toxins; or

(5) The entity does not meet the containment and security requirements prescribed by the Administrator;[6] or

(6) There are egregious or repeated violations of the containment or security requirements; or

(7) The Administrator determines that such action is necessary to protect animal or plant health, and animal or plant products.

(b) APHIS may summarily revoke or suspend registration for any of the reasons set forth in paragraph (a) of this section.

(c) APHIS will notify the responsible official in writing if an application for registration is denied or a certificate of registration is revoked or suspended.

(d) Denial of an application for registration, revocation of registration, and suspension of registration may be appealed under § 331.16.

s
riforcmtion mnecssaar dt hgivra cTjT*(dcompleed)nccou

[4] The security risk assessment of the entity and the individual who owns or controls such entity may be waived for Federal, State, or local governmental agencies.

[5] Any change in ownership or control of an entity will require a security risk assessment for the new individual(s) who owns or controls the entity.

[6] If registration is denied for this reason, we may provide technical assistance and guidance.

(b) In addition to the requirements in paragraph (a) of this section, the responsible official for a diagnostic laboratory or other entity possessing, using, or transferring agents or toxins listed in § 331.3 that are contained in specimens presented for diagnosis must immediately report the identification of such agents or toxins to the Administrator and to other appropriate authorities when required by Federal, State, or local law.[7] During agricultural emergencies or outbreaks, or in endemic areas, the Administrator may require less frequent reporting.

§ 331.10 Restricting access to biological agents and toxins.

[7] A diagnostic laboratory or other person must immediately notify APHIS by calling (301) 734–5519.

[8] Technical assistance and guidance may be obtained by calling (301) 734–5519.

[9] For guidance, see the USDA Departmental Manual No. 9610–001, ''USDA Security Policies and Procedures for Biosafety Level-3 Facilities'' (August 30, 2002). The manual may be obtained by calling (301) 734–5519. The manual is also available on the Internet at *h :// . da.g ˛ / ci /di ec ¡ e /DM/DM9610 001.h* . *See* also Appendix F, ''Biosafety in Microbiological and Biomedical Laboratories,'' in Morbidity and Mortality Weekly Report (2002). This document may be obtained by writing to Select Agent Program, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mail Stop E 79, Atlanta, GA 30333. It is also available on the Internet at *h :// .cdc.g ˛ / .*

11

[10] The requirements in this paragraph do not supercede or preempt the enforcement of emergency response requirements imposed by other statutes or regulations.

agencies immediately upon discovery of the theft or loss of agents or toxins listed in § 331.3. The oral notification must be

[12] An entity may not appeal the denial or limitation of an individual's access to listed agents or toxins.

or infectious substance, capable of causing:

(1) Death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism;

(2) Deterioration of food, water, equipment, supplies, or material of any kind; or

(3) Deleterious alteration of the environment.

Ce e f Di ea e C l a d P ę e i (CDC). The Centers for Disease Control and Prevention of the United States Department of Health and Human Services.

Cli ical lab a . A laboratory facility that receives patients and collects specimens for processing or shipping to another laboratory.

Diag ic lab a . A laboratory facility that receives specimens for the purpose of determining the identities of pests, pathogens, contaminants, or causes of disease.

E i . Any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.

I . To move into, or the act of movement into, the territorial limits of the United States.

I e a e. From one State into or through any other State, or within the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

Q e la age i . Any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa) or toxin that poses a risk to both human and animal health and that is listed in § 121.3(b).

Pe i . A written authorization by the Administrator to import or move interstate biological agents or toxins, under conditions prescribed by the Administrator.

P ficie c e i g. A sponsored, time-limited analytical trial whereby one or more analytes, previously confirmed by the sponsor, are submitted to the testing laboratory for analysis and where final results are graded, scores are recorded and provided to participants, and scores for participants are evaluated for acceptance.

Re ible ffficial. The individual designated by an entity to act on its behalf. This individual must have the authority and control to ensure compliance with the regulations in this part.

S eci e . A sample of material collected for use in testing, such as tissues, gastrointestinal contents, feces, bodily fluids (blood, serum, etc.), soil, water, feed or feed ingredients, swabs, cultures, and suspensions.

S a e. Any of the several States of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

T i . The toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes:

(1) Any poisonous substance or biological product that may be engineered as a result of biotechnology produced by a living organism; or

(2) Any poisonous isomer or biological product, homolog, or derivative of such a substance.

U ied S a e . All of the States.

USDA. The United States Department of Agriculture.

§ 121.2 Purpose and scope.

(a) This part sets forth the requirements for possession, use, and transfer of biological agents or toxins that have been determined to have the potential to pose a severe threat to both human and animal health, to animal health, or to animal products. The purpose of this part is to ensure the safe handling of such agents or toxins, and to protect against the use of such agents or toxins in domestic or international terrorism or for any other criminal purpose.

(b) Accordingly, this part provides that any individual or entity that possesses, uses, or transfers any agent or toxin listed in § 121.3 must register in accordance with § 121.7. To register, each entity must ster in

tissi045 27jT*whthe se of wiTjT*F4 -1.1111 TD(each entity m0si045 27jT*whno1w(0111 TD(a

(3) Viruses, bacteria, fungi, and toxins listed in paragraph (b) of this section that have been genetically modified.

(d) *A i al age a d i .*

African horse sickness virus
African swine fever virus
Akabane virus
Avian influenza virus (highly pathogenic)
Bluetongue virus (exotic)
Bovine spongiform encephalopathy agent
Camel pox virus
Classical swine fever virus
C d ia i a i (Heartwater)
Foot-and-mouth disease virus
Goat pox virus
Japanese encephalitis virus
Lumpy skin disease virus
Malignant catarrhal fever virus (exotic)
Menangle virus
M c la a ca ic l /M. F38/*M.*
c ide ca i (contagious caprine pleuropneumonia)
M c la a c ide c ide Mybine speuropneumonia)

[1] However, the importation and interstate movement of these genetic elements or subunits of listed agents or toxins are still subject to the permit requirements under part 122 of this subchapter.

[2] See footnote 1.

[3] A request to review an attenuated strain may be mailed to National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737–1231; or faxed to (301) 734–3652. For overlap agents, a request for review may be mailed to the above address or to Select Agent Program, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mail Stop E 79, Atlanta, GA 30333; or faxed to (404) 498–2265.

[4] A clinical or diagnostic laboratory, or other entity, may immediately notify APHIS by faxing (301) 734–3652. APHIS Form 2040 may be obtained by calling APHIS at (301) 734–3277 or by calling CDC at (404) 498–2265. The form is also available on the Internet at *h ://.a hi . da.g / / cie.b a.h l* or *h ://.cdc.g / d/ h / l a .h* . The completed form may be mailed or faxed to APHIS or CDC, as provided in footnote 3.

overlap agents or toxins may be exempt from the requirements of this part if such product is being used in an investigation authorized by any Federal law and the Administrator determines that additional regulation under this part is not necessary to protect animal or plant health, and animal or plant products.

(1) An individual or entity possessing, using, or transferring such investigational products may apply for an exemption from the requirements of this part by submitting APHIS Form 2042 to APHIS or CDC.

(2) For investigational products authorized under any of the Federal laws specified in paragraph (c) of this section, the Administrator shall make a determination regarding an exemption within 14 days after receipt of the application and notification that the investigation has been authorized under a Federal law.

(e) The Administrator may exempt an individual or entity from the requirements of this part, in whole or in part, for 30 days if it is necessary to respond to a domestic or foreign agricultural emergency involving an overlap agent or toxin. The Administrator may extend the exemption once for an additional 30 days.

(f) Upon request of the Secretary of Health and Human Services, the Administrator may exempt an individual or entity from the requirements of this part, in whole or in part, for 30 days if the Secretary of Health and Human Services has granted an exemption for a public health emergency involving an overlap agent or toxin. The Administrator may extend the exemption once for an additional 30 days.

§ 121.5 Exemptions for animal agents and toxins.

(a) Diagnostic laboratories and other entities possessing, using, or transferring agents or toxins that are contained in specimens presented for diagnosis or verification will be exempt from the requirements of this part, provided that:

(1) The identification of such agents or toxins is immediately reported to the Administrator and to other appropriate authorities when required by Federal, State, or local law; and

(2) Within 7 days after identification, the agents or toxins are transferred or inactivated, and APHIS Form 2040 is submitted to the Administrator.[5] During agricultural emergencies or outbreaks, or in endemic areas, the Administrator may require less frequent reporting. A copy of the completed form must be maintained for 3 years.

(b) Diagnostic laboratories and other entities possessing, using, or transferring agents or toxins that are contained in specimens presented for proficiency testing will be exempt from the requirements of this part, provided that:

(1) The identification of such agents or toxins, and their derivatives, is immediately reported to the Administrator, and to other appropriate authorities when required by Federal, State, or local law; and

(2) Within 90 days of receipt, the agent or toxins are transferred or inactivated, and APHIS Form 2040 is submitted to the Administrator. A copy of the completed form must be maintained for 3 years.

(c) An individual or entity receiving diagnostic reagents and vaccines that are, bear, or contain listed agents or toxins, also known as high consequence livestock pathogens or toxins, that are produced at USDA diagnostic facilities will be exempt from the requirements of this part.

(d) Unless the Administrator by order determines that additional regulation is necessary to protect animal health or animal products, an individual or entity possessing, using, or transferring products that are, bear, or contain listed agents or toxins will be exempt from the requirements of this part if the products have been cleared, approved, licensed, or registered pursuant to:

(1) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *e e*.);

(2) Section 351 of Public Health Service Act (42 U.S.C. 262);

(3) The Virus-Serum-Toxin Act (21 U.S.C. 151–159); or

(4) The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 131 *e e*.).

(e) An individual or entity possessing, using, or transferring experimental products that are, bear, or contain listed agents or toxins may be exempt from the requirements of this part if such product is being used in an investigation authorized by any Federal law and the Administrator determines that additional regulation under this part is not necessary to protect animal or plant health, and animal or plant products. An individual or entity possessing, using, or transferring such experimental products may apply for an exemption from the requirements of this part by submitting APHIS Form 2042 to APHIS.

(f) In addition to the exemptions provided in paragraphs (a) through (e) of this section, the Administrator may grant a specific exemption upon a showing of good cause and upon his or her determination that such exemption is consistent with protecting animal health and animal products. An individual or entity that possesses, uses, or transfers agents or toxins may request in writing an exemption from the requirements of this part. If granted, such exemptions are valid for a maximum of 3 years; thereafter, an individual or entity must request a new exemption. If a request for exemption is denied, an individual or entity may request reconsideration in writing to the Administrator. The request for reconsideration must state all of the facts and reasons upon which the individual or entity relies to show that the exemption was wrongfully denied. The Administrator will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision. If there is a conflict as to any material fact, the individual or entity may request a hearing to resolve the conflict.[6]

§ 121.6 Registration; who must register.

(a) Unless exempted under §§ 121.4 or 121.5, any individual or entity that possesses, uses, or transfers any agent or toxin listed in § 121.3 must register with APHIS or, for overlap agents or toxins, APHIS or CDC.

(b) Each entity must designate an individual to be its responsible official. The responsible official must have the authority and control to ensure compliance with the regulations. The responsible official must complete and sign the registration application package, and will be the individual contacted by APHIS or CDC if any questions arise concerning the application or subsequent compliance with the regulations in this part. As part of registration, the responsible official and the entity will be subject to a security risk assessment by the Attorney General. While most registrants are likely to be entities, in the event that an individual applies for and is granted a certificate of registration, APHIS will consider the individual to be the responsible official.

[5] A diagnostic laboratory or other entity must immediately notify APHIS by faxing (301) 734–3652. APHIS Form 2040 may be obtained by calling (301) 734–3277. The form is also available on the Internet at *h :// .a hi . da.g / / cie.b a.h l.* The completed form may be mailed to National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737–1231; or faxed to (301) 734–3652.

[6] A request for exemption may be mailed to National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737–1231; or faxed to (301) 734–3652.

(c) An entity may designate one or more individuals to be an alternate responsible official, who may act for the responsible official when he/she is unavailable. These individuals must have the authority and control to ensure compliance with the regulations when acting as the responsible official. These individuals will also be subject to a security risk assessment by the Attorney General as part of registration.

§ 121.7 Registration; general provisions.

(a) Unless exempted under §§ 121.4 or 121.5, an individual or entity shall not possess, use, or transfer any agent or toxin listed in § 121.3 without a certificate of registration issued by APHIS or CDC.

(b) A certificate of registration may be issued upon:

(1) Approval of the responsible official; the alternate responsible official, where applicable; the entity; and, where applicable, the individual who owns or controls the entity following a security risk assessment by the Attorney General;[7] and

(2) Approval of the biosafety, containment, and security of the entity. The entity's biosafety, containment, and security procedures must be commensurate with the risk of the agent or toxin, given its intended use. APHIS or CDC will review the Biosafety and Security Plan, and may inspect and evaluate the premises and records to determine compliance with the regulations and the biosafety, containment, and security requirements; and

(3) A determination by the Administrator that the individual or entity seeking to register has a lawful purpose to possess, use, or transfer such agents or toxins.

(c) For overlap agents, APHIS and CDC will review applications for registration and amendments to a certificate of registration, and a certificate of registration or amendment to a certificate of registration will only be issued if APHIS and CDC concur.

(d) A certificate of registration will be valid for only the specific agents or toxins listed in the certificate and specific activities and locations. A certificate of registration may cover more than one listed agent or toxin, and it may be amended to cover additional listed agents or toxins.

(e) A certificate of registration may be amended to reflect changed circumstances (*e.g.*, replacement of the responsible official, changes in ownership or control of the entity,[8] changes in the activities involving the agent or toxin). The responsible official must immediately notify the agency that issued the certificate of registration, either APHIS or CDC, of such changes in circumstances that occur after submission of the application for registration or after receipt of a certificate of registration.

(f) If a responsible official wishes to discontinue possessing, using, or transferring a particular agent or toxin, the responsible official may inactivate the agent or toxin or he/she may transfer the agent or toxin to a registered individual or entity in accordance with § 121.13. The responsible official must notify APHIS or, for overlap agents or toxins, APHIS or CDC, 5 business days prior to the planned inactivation so that we may have the opportunity to observe the inactivation of the agents or toxins. APHIS or CDC will notify the responsible official if we wish to observe the inactivation of the agents or toxins.

(g) A certificate of registration will be valid for a maximum of 3 years.

§ 121.8 Denial, revocation, or suspension of registration.

(a) APHIS may deny an application for registration or revoke registration if:

(1) The Attorney General identifies the responsible official, entity, or individual who owns or controls the entity as within any of the categories described in 18 U.S.C. 175b; or

(2) The Attorney General identifies the responsible official, entity, or individual who owns or controls the entity as reasonably suspected by any Federal law enforcement or intelligence agency of:

(i) Committing a crime set forth in 18 U.S.C. 2332b(g)(5); or

(ii) Knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence; or

(iii) Being an agent of a foreign power as defined in 50 U.S.C. 1801; or

(3) The responsible official does not have a lawful purpose to possess, use, or transfer agents or toxins listed in § 121.3; or

(4) The responsible official is an individual who handles or uses agents or toxins listed in § 121.3 and he/she does not have the necessary training or skills to handle such agents or toxins; or

(5) The entity does not meet the biosafety, containment, and security requirements prescribed by the Administrator;[9] or

(6) There are egregious or repeated violations of the biosafety, containment, or security requirements; or

(7) The Administrator determines that such action is necessary to protect animal or plant health, and animal or plant products.

(b) For overlap agents or toxins, APHIS or CDC shall deny an application for registration or revoke registration if the Attorney General identifies the responsible official, entity, or individual who owns or controls the entity as within any of the categories described in 18 U.S.C. 175b. APHIS or CDC may also deny registration or revoke registration for the reasons set forth in paragraphs (a)(2) through (a)(7) of this section.

(c) APHIS may summarily revoke or suspend registration for any of the reasons set forth in paragraphs (a) and (b) of this section.

(d) APHIS will notify the responsible official in writing if an application for registration is denied or a certificate of registration is revoked or suspended. For overlap agents or toxins, APHIS or CDC will notify the responsible official in writing if an application for registration is denied or a certificate of registration is revoked or suspended.

(e) Denial of an application for registration, revocation of registration, and suspension of registration may be appealed under § 121.17.

§ 121.9 Registration; how to register.

(a) To apply for a certificate of registration, the responsible official must submit all of the information and documentation required in the registration application package to APHIS, including the name, source, and characterization data for each agent or toxin to be registered. For overlap agents or toxins, the responsible official must submit all of the information and documentation required in the registration package to either APHIS or CDC. The responsible official must submit the registration application package to APHIS in cases where he/she is seeking registration for both animal and overlap agents and toxins.

(b) For animal agents and toxins, the registration application package may be obtained by calling (301) 734–3277 or faxing a request to (301) 734–3652. It is also available on the Internet at *h :// .a hi . da.g _ / / cie.b a.h l.* The completed registration application package must be mailed to National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40,

[7] The security risk assessment of the entity and the individual who owns or controls such entity may be waived for Federal, State, or local governmental agencies.

[8] Any change in ownership or control of an entity will require a security risk assessment for the new individual(s) who owns or controls the entity.

[9] If registration is denied for this reason, we may provide technical assistance and guidance.

Riverdale, MD 20737–1231. Assistance in completing the registration application may be requested by calling (301) 734–3277.

(c) For overlap agents and toxins, the registration application package may be obtained by contacting APHIS, as set forth in paragraph (b) of this section, or by calling CDC at (404) 498–2255; faxing a request to (404) 498–2265; or writing to Select Agent Program, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mail Stop E 79, Atlanta, GA 30333. It is also available on the Internet at *h :// .cdc.g , / d/ h /l a .h* . The completed registration application package may be mailed to APHIS at the address provided in paragraph (b) of this section or to CDC's Select Agent Program at the address provided in this paragraph. Assistance in completing the registration application may be requested by calling APHIS or CDC at the telephone numbers provided in this section.

§ 121.10 Responsibilities of the responsible official.

(a) The responsible official is responsible for ensuring compliance with the regulations, including:

(1) Developing and implementing a Biosafety and Security Plan in accordance with § 121.12;

(2) Allowing only approved individuals within the entity to have access to any agents or toxins listed in § 121.3 in accordance with § 121.11;

(3) Providing appropriate training in biosafety, containment, and security procedures for all personnel in accordance with § 121.13;

(4) Transferring agents or toxins only to registered individuals or entities in accordance with § 121.14;

(5) Ensuring that all visitors are informed of and follow the entity's security requirements and procedures;

(6) Notifying APHIS or, for overlap agents or toxins, APHIS or CDC, of changes in circumstances in accordance with § 121.7;

(7) Providing timely notice of any theft, loss, or release of a biological agent or toxin in accordance with § 121.17;

(8) Maintaining detailed records of information necessary to give a complete accounting of all of the activities related to agents or toxins listed in § 121.3 in accordance with § 121.15.

(b) In addition to the requirements in paragraph (a) of this section, the responsible official for a diagnostic laboratory or other entities possessing, using, or transferring agents or toxins listed in § 121.3 that are contained in specimens presented for diagnosis must immediately report the identification of such agents or toxins to the Administrator and to other appropriate authorities when required by Federal, State, or local law.[10] During agricultural emergencies or outbreaks, or in endemic areas, the Administrator may require less frequent reporting.

(c) In addition to the requirements in paragraph (a) of this section, the responsible official must ensure that the following experiments are not conducted unless approved by the Administrator, after consultation with experts:

(1) Experiments utilizing recombinant DNA that involve the deliberate transfer of a pathogenic trait or drug resistance trait to biological agents that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.

(2) Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of toxins lethal for vertebrates at an LD_{50}<100 ng/kg body weight.

§ 121.11 Restricting access to biological agents and toxins.

(a) An individual may not have access to biological agents or toxins listed in § 121.3 unless approved by APHIS or CDC. APHIS will grant, limit, or deny access of individuals to listed agents or toxins. APHIS or CDC will grant, limit, or deny access of individuals to overlap agents or toxins.

(b) The responsible official is responsible for ensuring that only approved individuals within the entity have access to any agents or toxins listed in § 121.3. The responsible official must request such access for only those individuals who have a legitimate need to handle or use agents or toxins, and who have the appropriate training and skills to handle such agents or toxins.

(c) The responsible official must provide appropriate training in biosafety, containment, and security procedures to all individuals with access to agents and toxins listed in § 121.3.

(d) For each individual identified by the responsible official as having a legitimate need to handle or use agents or toxins, the responsible official must submit that individual's name and identifying information to APHIS and the Attorney General. For overlap agents or toxins, the responsible official must submit this information to either APHIS or CDC and the Attorney General.

(e) In addition, the responsible official must submit information about the individual's training and skills to APHIS or, for overlap agents or toxins, APHIS or CDC (*e.g.*, curriculum vitae for principal investigators and researchers, and a description of training completed by support personnel).

(f) APHIS may expedite the access approval process for individuals upon request by the responsible official and a showing of good cause (*e.g.*, public health or agricultural emergencies, national security, impending expiration of a research grant, a short-term visit by a prominent researcher).

(g) APHIS will notify the responsible official if an individual is granted full or limited access, or denied access to listed agents or toxins. APHIS will also notify the individual if he/she is denied access or granted only limited access. For overlap agents or toxins, APHIS or CDC will provide the necessary notification.

(h) APHIS may deny or limit access of an individual to listed agents or toxins if:

(1) The Attorney General identifies the individual as within any of the categories described in 18 U.S.C. 175b;

(2) The Attorney General identifies the individual as reasonably suspected by any Federal law enforcement or intelligence agency of committing a crime set forth in 18 U.S.C. 2332b(g)(5); knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence; or being an agent of a foreign power as defined in 50 U.S.C. 1801;

(3) The individual does not have a legitimate need to handle listed agents or toxins;

(4) The individual does not have the necessary training or skills to handle listed agents or toxins;

(5) The Administrator determines that such action is necessary to protect animal health or animal products.

(i) For overlap agents or toxins, APHIS or CDC will deny an individual access to such agents or toxins if the

[10] A diagnostic laboratory or other entity must immediately notify APHIS by faxing (301) 734–3652.

[11] Technical assistance and guidance may be obtained by calling (301) 734–3277.

[12] For guidance on biosafety and containment

[15] APHIS Form 2041 may be obtained by calling APHIS at (301) 734–3277 or by calling CDC at (404) 498–2265. The form is also available on the Internet at