# Rules and Regulations

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## ELECTION ASSISTANCE COMMISSION

### 2 CFR Part 5801

### Adoption of Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards

**AGENCY:** Election Assistance Commission.

**ACTION:** Final rule.

**SUMMARY:** The U.S. Election Assistance Commission (EAC) is publishing this final rule to formally adopt the Office of Management & Budget's Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards regulations for EAC grants management, which is already included in the EAC's agreements with its grant recipients.

**DATES:** This final rule is effective December 20, 2024.

**FOR FURTHER INFORMATION CONTACT:** Camden Kelliher, EAC General Counsel. Phone: 202–360–3160, email: *ckelliher@eac.gov*.

**SUPPLEMENTARY INFORMATION:** Through its terms and conditions of its grant awards, the EAC requires grant award recipients and sub-recipients to abide by all federal financial assistance requirements, including 2 CFR part 200. The EAC already has regulations adopting 2 CFR part 180, which can be found at 2 CFR part 5800.

On April 4, 2024, the Office of Management & Budget (OMB) issued memorandum M–24–11, Reducing Burden in the Administration of Federal Financial Assistance in effort to provide government-wide direction to federal agencies on improving the management of federal financial assistance and to ensure the consistent management of such assistance. On April 22, 2024, OMB issued a final rule officially revising its regulations pertaining to federal financial assistance management in title 2 of the CFR and requiring agencies to implement the newly revised regulations as quickly as possible by taking appropriate steps to ensure the regulations apply to all federal financial awards issued on or after October 1, 2024.

The Help America Vote Act of 2002 limits the EAC's rulemaking authority to only to the extent permitted under Section 9(a) of the National Voter Registration Act. However, the EAC in this instance is ''adopting'' 2 CFR part 200—the EAC is not ''making'' rules. Furthermore, 2 CFR 200.106 states agencies awarding federal funds must implement the OMB guidance in 2 CFR in codified regulations.

#### Waiver of Proposed Rulemaking

The rule issued by the EAC concerns matters relating to ''grants, benefits, or contracts,'' 5 U.S.C. 553(a)(2), and is therefore exempt from the requirement of prior notice and comment.

#### Waiver of Delayed Effective Date

Under 5 U.S.C. 553(d), agencies may waive the delayed effective date requirement if they find good cause and explain the basis for the waiver in the final rulemaking document or if the regulations grant or recognize an exemption or relieve a restriction.

OMB informed the public on April 4, 2024, that agencies would be required to adopt the Uniform Guidance and make it effective by October 1, 2024. The public has had significant time to prepare for the promulgation of these final regulations. As such, the EAC has determined there is good cause to waive the delayed effective date.

#### List of Subjects in 2 CFR Part 5081

Accounting, administrative practice and procedure, federal financial assistance, grant programs, grants administration, state and local governments, state-federal relations.

■ For the reasons stated, Part 5801 is established in Chapter LVIII of Title 2 of the Code of Federal Regulations to read as follows:

## PART 5801—UNIFORM ADMINISTRATIVE REQUIREMENTS, COST PRINCIPLES, AND AUDIT REQUIREMENTS FOR FEDERAL AWARDS

Sec.



**Authority:** 2 CFR part 200.

#### § 5801.10 Adoption of 2 CFR Part 200.

The U.S. Election Assistance Commission adopts the Office of Management and Budget (OMB) Guidance in 2 CFR part 200. Thus, this part gives regulatory effect to the OMB guidance.

#### §§ 5801.20 through 5801.99 [Reserved].

**Camden Kelliher,**

*General Counsel, U.S. Election Assistance Commission.*

[FR Doc. 2024–29685 Filed 12–16–24; 8:45 am]

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## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

### 7 CFR Part 331

### 9 CFR Part 121

**[Docket No. APHIS–2019–0018]**

**RIN 0579–AE52**

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

**AGENCY:** Animal and Plant Health Inspection Service, Department of Agriculture (USDA).

**ACTION:** Final rule.

**SUMMARY:** In accordance with Title II, Subtitle B of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (which is cited as the ''Agricultural Bioterrorism Protection Act of 2002'' and referred to as the Act), we are amending and republishing 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 (the list) and the revision of the list as necessary. This action implements the findings from the biennial review of the list. The biennial review was initiated within 2 years of the completion of the previous biennial review. This final rule will focus solely on removing from the select agent list the following pathogens: *Peronosclerospora philippinensis (Peronosclerospora sacchari)* (Plant

Protection and Quarantine select agent), African horse sickness virus (Veterinary Services select agent), and *Brucella abortus, Brucella suis,* and *Brucella melitensis* (overlap select agents).

**DATES:** Effective January 16, 2025.

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

**SUPPLEMENTARY INFORMATION:**

## Background

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

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

In determining whether to include an agent or toxin in the list, the Secretary shall consider the following criteria stated in the Act (7 U.S.C. 8401(a)(1)(B)):

- ''[T]he effect of exposure to the agent or toxin on animal or plant health, and on the production and marketability of animal or plant products;''
- ''[T]he pathogenicity of the agent or the toxicity of the toxin and the methods by which the agent or toxin is transferred to animals or plants;''
- ''[T]he availability and effectiveness of pharmacotherapies and prophylaxis to treat and prevent any illness caused by the agent or toxin;''
- ''[W]hether such inclusion would have a substantial negative impact on the research and development of solutions for the animal or plant disease caused by the agent or toxin; and whether the negative impact [on research and development] would substantially outweigh the risk posed by the agent or toxin to animal or plant health if it is not included on the list'' (added by the 2018 Farm Bill); and
- ''[A]ny other criteria that the Secretary considers appropriate to protect animal or plant health, or animal or plant products.''

Paragraph (a)(2) of section 212 of the Act (7 U.S.C. 8401(a)(2)) requires the Secretary to review and republish the list of select agents and toxins every 2 years and to otherwise revise the list as necessary. To fulfill this statutory mandate, APHIS convenes separate interagency working groups in order to review the lists of PPQ and VS select agents and toxins, as well as any overlap select agents and toxins, and develop recommendations regarding possible changes to the list using the five criteria for listing, stated above, found in the Act. APHIS and CDC coordinate on the biennial review for overlap select agents and toxins that have been determined to pose a severe threat to human and animal health or animal products.

On March 17, 2020, we published in the **Federal Register** (85 FR 15078–01, Docket No. APHIS–2019–0018) an advance notice of proposed rulemaking (ANPR) [1] and request for comments in which we solicited public comment on the possible delisting of one PPQ select agent, *Peronosclerospora philippinensis (P. sacchari),* one VS select agent, African horse sickness virus, and five overlap select agents, *Bacillus anthracis* (Pasteur strain), *Brucella abortus, B. suis,* and *B. melitensis,* and Venezuelan equine encephalitis virus. We discussed the comments received on the ANPR in the proposed rule that followed. On January 30, 2024, we published in the **Federal Register** (89 FR 5795–5819, Docket No. APHIS–2019–0018) a proposal [2] 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. We proposed to delist P. philippinensis (*sacchari),* African horse sickness virus, *B. abortus, B. suis,* and *B. melitensis.*

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

Other changes were intended as clarifications of existing provisions of the regulations. These included proposed definitions of loss, release, and theft, clarifying reporting requirements for ''discovered'' select agents or toxins, a clarification regarding what constitutes an acceptable ''validated inactivation procedure,'' clarifications related to the existing reporting requirements, clarifying that certificates must accompany transfers of a select agent or toxin, including intra-entity transfers, clarifying that the documentation in the IT system for the FSAP program serves as official records required by the regulations, clarifying the documentation that may be needed for the issuance of a certificate of registration, clarifying that a responsible official cannot be approved as the responsible official at more than one registered entity and cannot be the sole alternate responsible official at another registered entity, clarifying requirements related to restricted experiments, clarifying the notification requirements for changes to the application for registration, and clarifying the scope of pre-access suitability assessments.

[1] To view the ANPR and the comments we received, go to *www.regulations.gov.* Enter APHIS–2019–0018 in the Search field.

[2] To view the proposed rule and the comments we received, go to *www.regulations.gov.* Enter APHIS–2019–0018 in the Search field.

Finally, certain proposed provisions would have been new, including provisions regarding effluent decontamination system, biosafety provisions for facility verification requirements for registered biosafety level 3 and animal biosafety level 3 laboratories, and a new requirement related to restricted experiments.

We solicited comments concerning our proposal for 60 days, ending April 1, 2024. We received 69 comments by that date. The comments were from private citizens, research institutions, organizations representing research institutions, organizations representing the domestic cattle, bison, and equine industries, representatives from State fish and wildlife departments, and representatives from State departments of agriculture.

While commenters largely supported our proposed amendments to the list of select agents and toxins, commenters raised legal, operational, and policy concerns about many of our proposed codifications, clarifications, and additions to the regulations.

We proposed to delist *P. philippinensis,* African horse sickness virus, *B. abortus, B. suis,* and *B. melitensis* as select agents, and the comments we received regarding these select agents are discussed below.

*P. philippinensis*

We received one comment specifically addressing *P. philippinensis.* The commenter supported delisting *P. philippinensis,* citing cultivation characteristics that would make propagation difficult and unlikely to produce a dangerous agent. We did not receive any comments stating an opposition to delisting. Accordingly, we are delisting *P. philippinensis* as proposed.

*African Horse Sickness (AHS) Virus*

We received two comments specifically addressing AHS virus.

One commenter agreed with delisting, citing limited communicability and the existence of countermeasures. Another commenter opposed delisting, citing the widespread presence of the disease's vectors in the United States, the high mortality rate for animals associated with the disease, and the absence of available vaccines for AHS virus within the United States. The commenter did acknowledge that vaccines were available internationally but stated that there were no guidelines for their use within the United States, nor did they think APHIS would authorize their use in the event of an outbreak. The commenter further stated that, even if APHIS were to authorize their use in the event of a domestic outbreak of AHS virus, the specific serotype would need to be identified, and a monovalent vaccine procured from a foreign source, which could take months.

We agree that AHS virus causes a life-threatening, hemorrhagic, noncontagious, nonzoonotic, arthropod-borne viral disease of equines. However, the Act's aim is not solely to determine whether a pathogen causes deadly disease, but whether it is likely to be used as a bioterrorism agent, and if used, what the potential impacts would be. In that regard, in deciding whether an agent or toxin should be included on the select agent and toxin list, the Act requires us to take into consideration not only the pathogenicity of the agent, but also the methods by which it is disseminated, and the availability and effectiveness of prophylaxis as well as treatments, such as vaccines and pharmaceuticals.

AHS virus must use arthropod vectors in order to be transmitted. While the commenter is correct that arthropod vectors for the disease do exist within the United States, both the AHS virus and its vector must be present in an environment for transmission to equines to occur, making the virus difficult to effectively disseminate in equine populations. Therefore, we concluded that the AHS virus will unlikely be used as a bioterrorism agent. Additionally, while the commenter is correct that currently there are no vaccines available in the United States for AHS, and, accordingly, no guidelines yet established for use of AHS vaccines within the United States, vaccines are available internationally and in the event of foreign animal disease outbreak, USDA can implement emergency response plans. USDA's manual for response to an introduction of a foreign animal diseases, such as AHS, is found at *https://www.aphis.usda.gov/sites/default/files/fadprep_manual_1.pdf.*

The difficulty in disseminating and transmitting AHS virus and the availability of vaccines played a significant role in the Agricultural Interagency Select Agents and Toxins Technical Advisory Committee, or Ag-ISATTAC's, recommendation to delist AHS virus as a select agent.

Based on the foregoing considerations, we are delisting AHS virus as a select agent, as proposed.

*Brucella Species*

We received 44 comments supporting delisting of all three species of *Brucella* (*B. abortus, B. suis,* and *B. melitensis*). These commenters supported delisting for one or more of the following reasons:

- State animal health officials, researchers, and industry stakeholder groups stated that these species are unlikely to be intentionally used as an agent of bioterrorism. They commented that *Brucella* has a limited to negligible rate as a bioterrorism weapon and the benefits (*e.g.,* research, testing, etc.) outweigh the risks. Also, they stated that these organisms are effectively contained within appropriate biosafety and biosecurity facilities, limiting access to unauthorized individuals.
- Private citizens and animal health groups stated that existing regulatory burden prevents ongoing research into vaccine development specifically in the areas of vaccine efficacy and vaccine delivery in wildlife. We agree regarding the burden to the research community, and that more robust studies can help limit the spread of disease.
- Private citizens commented that brucellosis in humans is rarely fatal and easily treatable in the early stages.
- Stakeholders and private citizens, also, said intervention strategies to reduce the disease in animal populations exist: There are already nationally recognized biosafety measures used by U.S. researchers in handling these agents. For instance, there are effective and well-established antibiotic treatment regimens for brucellosis due to infections with *B. abortus, B. melitensis,* or *B. suis.*

We received an additional 11 comments that only addressed *B. abortus* and supported delisting it. In addition to the above considerations, these commenters supported delisting *B. abortus* to facilitate research and development of more effective vaccines for wildlife reservoirs of the agent.

We received two comments opposing delisting of one or more of the *Brucella* spp. One commenter opposed delisting *Brucella* spp. pending vaccine development, citing an incident where the commenter claimed more than 300 veterinary medical professionals in a foreign country were exposed to *B. abortus* while vaccinating cattle, with multiple mortalities.

While human health considerations generally fall outside of APHIS' administration of the Act, and are instead under the purview of CDC, because the commenter raised concerns related to transmissibility due to human interaction with livestock, we wish to provide context for the incident cited by the commenter and respond to the stated concerns.

The above-cited incident did not occur in the United States. While misuse of vaccines, and improper vaccination protocols have, on rare occasion, resulted in transmission of the

vaccine strain of *B. abortus* to humans domestically, antibiotics are widely available within the United States to treat incidents of brucellosis in humans, and mortality is rare. The Act also directs us to consider not only the availability of prophylaxis, such as vaccines, but also pharmacotherapies, such as antibiotics. For these reasons, we disagree with the commenter that *B. abortus* should not be delisted pending vaccine development. The commenter also did not contest our reasons in the proposed rule for delisting *B. abortus:* The agent is unlikely to be used as an agent of bioterrorism for a large-scale population introduction due to the high concentration of the agent necessary to produce disease as well as modern cattle production processes that limit animal-to-animal transmission routes; there is an efficacious vaccine; there is moderate immunity status within vulnerable populations; there is limited farm-to-farm transmission risk; and there are effective quarantine procedures. In this regard, we note that several of the commenters who supported delisting *B. abortus* provided scientific research or articles that buttressed these considerations.

Another commenter claimed, without evidence, that *B. abortus* was not a real disease, and being used as a pretext to kill bison.

The commenter is incorrect. *B. abortus* is a documented disease of cattle and bison.

Multiple commenters supportive of delisting *Brucella* spp. stated that *B. abortus* is a serious human health risk, and supported delisting insofar as it would, among other things, facilitate vaccine development in cattle and bison that could reduce rancher exposure to the disease.

As we noted above, human health considerations generally fall outside of APHIS' administration of the Act. However, we disagree with the commenters' characterization of the human health risk presented by brucellosis. While it can be fatal, the case fatality rate and person-to-person transmission for *B. abortus* continues to be very low. In addition, the human illnesses caused by *B. abortus* are readily recognized and can be treated with widely available antibiotics.

One commenter requested clarification that the diseases would still be reportable, even if delisted as select agents, and that the domestic brucellosis eradication program would still remain.

Brucellosis is a livestock disease that is reportable to State and Federal animal health authorities in the United States when an outbreak occurs. Our domestic brucellosis eradication program is administered by APHIS and State animal health authorities under a different statute, the Animal Health Protection Act (7 U.S.C. 8301–8317), and will remain in effect.[3]

One commenter stated that it was the commenter's understanding that CDC biosafety level 3 (BSL 3) requirements will still be in effect for *Brucella* spp. even if all three agents are delisted.

Delisting of an agent neither reduces nor affects the recommended biosafety level for laboratory work. BSL 3 laboratory safety and containment is currently recommended for laboratory work with *Brucella* spp. The current BSL 3 laboratory safety and containment recommendations for *Brucella* spp. are outlined in the Biosafety in Microbiological and Biomedical Laboratories (BMBL), available at: *https://www.cdc.gov/labs/bmbl/index.html.*

Finally, several commenters stated that research facilities registered with FSAP and currently conducting ongoing research on *Brucella* spp. will need guidance regarding the impacts of delisting on their work. FSAP will provide such guidance.

Accordingly, we are delisting *B. abortus, B. melitensis,* and *B. suis* as select agents, as proposed.

*CDC Agents*

Finally, we received a few comments on CDC's list of select agents and toxins. These comments are outside of the scope of this rulemaking, and APHIS has routed them to CDC for consideration.

*Nipah Virus*

In its January 30, 2024, proposed rule (89 FR 5823–1), CDC proposed designating Nipah virus, an overlap select agent, as a Tier 1 select agent because of its human transmissibility, high case fatality rate, high severity of illness, and severe long-term effects. However, due to an inadvertent oversight in our proposed rule, APHIS did not propose parallel changes. In its final rule published elsewhere in this issue of the **Federal Register**, CDC is designating Nipah virus as a Tier 1 select agent as proposed based on consideration of the comments received. As a result of CDC's decision, because Nipah virus is an overlap select agent, in this final rule, we are amending 9 CFR 121.3(b) to add an asterisk before ''Nipah virus,'' thus indicating its designation as a Tier 1 select agent. We are doing this to ensure harmonization between our regulations and CDC's regulations regarding this designation.

Therefore, for the reasons given, we are adopting the proposed revisions to the lists of select agents and toxin set forth in 7 CFR 331.3(b) and 9 CFR 121.3(b) and (b) that arose out of the biennial review of the list as final, with the change discussed immediately above. Executive Orders 12866 and 13563 and Regulatory Flexibility Act

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

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

Summary

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107–188), as amended (referred to below as the Bioterrorism Response Act), provides for the regulation of certain biological agents and toxins that have the potential to pose a severe threat to human, animal, or plant health, or to animal or plant products. APHIS, Emergency & Regulatory Compliance Services (ERCS), and the Division of Agricultural Select Agents and Toxins (DASAT) have the primary responsibility for implementing the provisions of the Bioterrorism Response Act with the USDA. Within APHIS, VS select agents and toxins, listed in 9 CFR 121.3, are those that have been determined to have the potential to pose a severe threat to animal health or animal products, and PPQ select agents and toxins, listed in 7 CFR 331.3, are those that have been determined to have the potential to pose a severe threat to plant health or plant products. Overlap select agents and toxins, listed in 9 CFR 121.4, are those

[3] 9 CFR part 78 (Brucellosis; Domestic Brucellosis Regulations).

that have been determined to pose a severe threat to public health and safety, to animal health, or to animal products. Overlap select agents and toxins are subject to regulation by both APHIS, ERCS, DASAT, and the CDC's Division of Regulatory Science and Compliance (DRSC), which has the primary responsibility for implementing the provisions of the Bioterrorism Response Act for the U.S. Department of Health and Human Services (HHS). Together, APHIS, ERCS, DASAT, and CDC's DRSC comprise the Federal Select Agent Program (FSAP).

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

APHIS is delisting three overlap select agents: *Brucella abortus, Brucella suis,* and *Brucella melitensis.* CDC has made parallel regulatory changes with respect to these *Brucella* spp. APHIS is also delisting one PPQ select agent, *Peronosclerospora philippinensis* (*Peronosclerospora sacchari*), and one VS select agent, African horse sickness (AHS) virus. These delisting changes will economically benefit producers, research and reference laboratories, and State and Federal oversight agencies, while also maintaining adequate program oversight of delisted select agents and toxins through HHS CDC and National Institutes of Health guidelines along with USDA–APHIS permits for movement.

Previous regulatory restrictions had effectively prohibited vaccine trials using natural transmission models, limited the opportunity for large animal studies, inhibited available surveillance, and prohibited studies that would evaluate vaccine or diagnostic product efficacy through comingling vaccinated and naturally infected animals. Delisting these five agents could decrease disease management costs for State and Federal governments as well as livestock producers. Additionally, delisting will remove restrictions that limited courier availability for these five agents, a factor that previously resulted in prohibitive shipment costs for many laboratories. Previous shipment costs had inhibited isolate sharing between reference and research laboratories, thus leading to decreased advancements from researchers and laboratories involved in diagnostic improvements and disease eradication efforts. Delisting the three *Brucella* agents (*B. abortus, B. suis,* and *B. melitensis*) as overlap select agents and one VS agent, AHS virus, along with one plant agent, *Peronosclerospora philippinensis,* from the list of select agents and toxins will economically benefit producers, research and reference laboratories, and State and Federal oversight agencies.

*B. abortus* presents little economic or animal health risk as a bioterrorism agent as it is unlikely to result in large-scale population introduction due to the high concentration of the agent necessary to produce disease as well as modern cattle production processes that limit animal-to-animal transmission routes. There is an efficacious vaccine, moderate immunity status within vulnerable populations, limited farm-to-farm transmission risk, and effective quarantine procedures. (Center for Food Security and Public Health, 2009; Moreno, E., 2014; Olsen, S.C., 2011.) *B. melitensis* primarily affects goats and sheep and is of lesser concern because the low farm-to-farm transmission risk due to modern production practices limits the chance of introduction on a scale large enough to impact domestic production. (The Center for Food Security and Public Health, 2009; Moreno, E., 2014; Olsen, S.C., 2011.) *B. suis* also presents a low to moderate animal health risk due to limited farm-to-farm transmission risk because of modern production practices, which reduce the risk of a large-scale introduction. (The Center for Food Security and Public Health, 2009; Stoffregen, W.C., 2006; World Organizsation for Animal Health (OIE), 2017; Zhu, L., et al., 2016.) For these reasons and due to the overwhelming public support, APHIS, in conjunction with CDC, is delisting these three *Brucella* species.

*Peronosclerospora philippinensis* (*Peronosclerospora sacchari*) is only able to survive and reproduce in the host plant and requires specific environmental conditions to become infectious, for which mitigations exist. The production characteristics for large volume production and subsequent dissemination require extensive specialization and reflect high degree of difficulty for dissemination of the agent. Thus, the economic impact of possible misuse of this agent was deemed a low impact. We are delisting the agent based upon affirmative responses to proposed delisting.

AHS virus causes a life-threatening, hemorrhagic, noncontagious, nonzoonotic, arthropod-borne viral disease of equines. However, the Act's aim is not solely to determine whether a pathogen causes deadly disease, but whether it is likely to be used as a bioterrorism agent, and if used, what the potential impacts would be. In that regard, in deciding whether an agent or toxin should be included on the select agent and toxin list, the Act requires us to take into consideration not only the pathogenicity of the agent, but also the methods by which it is disseminated, and the availability and effectiveness of prophylaxis as well as treatments, such as vaccines and pharmaceuticals. AHS is an arthropod-borne illness that must be vectored to be transmitted. Because both the disease and its vector must be present in an environment for transmission to equines to occur, we considered AHS unlikely to be used as an agent of bioterrorism. Vaccines are also available internationally and in the event of foreign animal disease outbreak, we can implement emergency response plans. Based on the foregoing considerations, we are delisting AHS virus as a select agent.

Currently, there are 236 entities registered with APHIS and CDC. Of these entities, 13 are private entities, 30 are Federal entities, 42 are commercial entities, 84 are academic entities, and 67 are State entities. Less than 32 percent of all firms operating within these North American Industry Classification (NAICS) categories are considered to be small entities.

This document provides a cost-benefit analysis, as required by Executive Orders 12866, 13563, and 14094 which direct Federal agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and equity). Executive Order 13563 emphasizes the importance of

quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This document also examines the potential economic effects of this rulemaking on small entities, as required by the Regulatory Flexibility Act.

Description of Final Rule

Pursuant to the Agricultural Bioterrorism Protection Act of 2002, as amended (7 U.S.C. 8401(a)(2)) (Act), APHIS has completed its required biennial review of the current list of select agents and toxins in 7 CFR 331.3 (PPQ select agents) and 9 CFR 121.3 (VS select agents) and 121.4 (overlap select agents overseen jointly with CDC). This final rule implements the recommendations of the interagency working groups with respect to the list of select agents and toxins. APHIS, in conjunction with CDC, is removing the following overlap select agents from the list of select agents and toxins: *Brucella abortus, Brucella suis,* and *Brucella melitensis.* Public response showed overwhelming support for delisting all three *Brucella* species. Therefore, we consider it appropriate to delist these three *Brucella* spp.

We are also delisting *Peronosclerospora philippinensis* (*Peronosclerospora sacchari*). We received only supportive comments for this proposed delisting.

Finally, we are delisting AHS virus. While we received a comment opposed to this delisting, it did not call into question our considerations in proposing delisting.

Overview of the Action and Affected Entities

As previously discussed, there are 236 entities registered with APHIS and CDC. Of these entities,13 are private entities, 30 are Federal entities, 42 are commercial entities, 84 are academic entities, and 67 are State entities. Of these, less than 32 percent of all entities within these NAICS categories are considered to be small entities. The delisting of *B. abortus, B. suis,* and *B. melitensis* is anticipated to economically benefit producers, research and reference laboratories, and State and Federal oversight agencies, while also maintaining adequate program oversight of delisted select agents and toxins through HHS CDC and National Institutes of Health guidelines along with USDA–APHIS permits for movement. Below we provide a cost-benefit analysis, as required by Executive Orders 12866, 13563, and 14094 to examine the potential economic effects of delisting *B. abortus, B. suis, B. melitensis, Peronosclerospora philippinensis* (*Peronosclerospora sacchari*), and AHS virus on small entities.

Expected Costs and Benefits of the Final Rule

There are currently costs associated with registration of the select agents that we are delisting. There are no direct costs for regulated entities associated with the delisting of *Brucella species,* only benefits to facilities to participate in *Brucella* research. If *Brucella* species are delisted, APHIS regulations requiring permits for their movement pursuant to 9 CFR part 122 will be operative, however; new permits cost $150 and permitting information is found here: *https://www.aphis.usda.gov/animal-product-import/organisms-vectors.* Many entities have been requesting the delisting of the *Brucella* spp. for years. State Veterinarians have expressed concern regarding the limitation on brucellosis research because of the designation of *Brucella* as a select agent.[4]

Livestock producer organizations and the United States Animal Health Association have voiced their support and the need for the development of a *B. suis* vaccine, as well as improved diagnostics for *Brucella* spp.[5] Similarly, *Peronosclerospora philippinensis* (*Peronosclerospora sacchari*) has received public support for delisting as the agent is only able to survive and reproduce in the host plant, and AHS, while a life-threatening viral disease of equines, is unlikely to be used as a bioterrorism agent. Previous regulatory restrictions had effectively prohibited vaccine trials using natural transmission models, limited the opportunity for large animal studies, inhibited available surveillance, and prohibited studies that would evaluate vaccine or diagnostic product efficacy through comingling vaccinated and naturally infected animals. These limitations increase disease management costs for State and Federal governments as well as livestock producers.

One previous example of the public requesting delisting of a select agent for research purposes was Valley Fever or *Coccidiodes spp.* Until October 2012, Valley Fever or *Coccidiodes* spp. had been listed as a select agent by both APHIS and CDC. Since delisting, additional research has taken place, resulting in enhanced outreach to inform potential infected citizens. Doctors and medical personnel also are more familiar with it and understand that climate change is contributing to this disease in California. Like Valley Fever, the high cost to work with *Brucella* spp. has prevented appropriate research and field studies to take place, thus hampering new information and research to limit or stop the spread of the disease or at least inform the public of its method of infection. Very few laboratories currently have the resources or ability to do *Brucella* spp. research due to the facility needs required by its current listing as a select agent under the regulations.

Due to the stringent transfer requirements in 9 CFR 121.16 for select agents, currently, there is limited courier availability for *Brucella* spp., *Peronosclerospora philippinensis* (*Peronosclerospora sacchari*), and AHS virus shipments. The lack of available couriers has resulted in prohibitive shipment costs for many laboratories. The increased shipment costs have inhibited isolate sharing between reference and research laboratories, thus leading to decreased advancements from researchers and laboratories involved in diagnostic improvements and disease eradication efforts. Removing the three *Brucella species* (*B. abortus, B. suis,* and *B. melitensis*) as overlap select agents and one VS agent, AHS virus, along with one plant agent, *Peronosclerospora philippinensis,* from the list of select agents and toxins will thus economically benefit producers, research and reference laboratories, and, for *Brucella abortus* delisting, State and Federal oversight agencies.

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

Small-Entity Prevalence

Entities that possess, use, or transfer *B. abortus, B. suis,* and *B. melitensis* along with *Peronosclerospora philippinensis* (*Peronosclerospora sacchari*) and AHS virus would either benefit or be unaffected by this final rule. Potentially affected entities include laboratories, other research institutions, and related entities in possession of the *Brucella* spp. Affected entities (other than Federal and State governmental entities) are likely found within the following NAICS categories:

- 541714, Research and Development in Biotechnology;

[4] State Veterinarian Notes, March 2020: Limitations on brucellosis research due to being listed as a select agent. (*https://liv.mt.gov/_docs/Animal-Health/Newsletters/1st%20%20Quarter%20Newsletter%20Vol%2013%20Iss%201%20C%20Final.pdf*).

[5] United States Animal Health Association (USAHA) Committee on Cattle and Bison, 2020, page 8: AgSAS Delisting Update: *https://www.usaha.org/upload/Committee/2020Reports/Cattle_Bison_Report_2020.pdf.*

• 541715, Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology);
• 325412, Pharmaceutical Preparation Manufacturing;
• 325413, In-Vitro Diagnostic Substance Manufacturing;
• 325414, Biological Product (except Diagnostic) Manufacturing;
• 541940, Veterinary Services;
• 611310, Colleges, Universities and Professional Schools;
• 621511, Medical Laboratories;
• 622110, General Medical and Surgical Hospitals.

The Small Business Administration (SBA) has established small-entity size standards based on the NAICS categories. An entity classified within NAICS 541714 and NAICS 541715 is considered small with 1,000 or fewer employees, and one within NAICS, 325413, and 325414 is considered small with 1,250 or fewer employees and one with NAICS 325124 is considered small with 1,300 or fewer employees. An entity within NAICS 541940 is considered small with annual receipts of $10 million or less, and an entity within NAICS 611310 is considered small with annual receipts of not more than $34.5 million. Entities classified within NAICS 621511 are considered to be small if they have annual receipts of not more than $41.5 million. An entity classified within NAICS 622110 is considered to be small with annual receipts of not more than $47 million.

Potential Impact on Small Entities

As described above, entities that possess, use, or transfer the delisted agents are not expected to be significantly affected by this final rule and will benefit from the enhanced ability to further perform research on the relevant agent.

Currently, there are 236 entities registered with APHIS and CDC. Of these entities, 13 are private entities, 30 are Federal entities, 42 are commercial entities, 84 are academic entities, and 67 are State entities. Approximately 32 percent of all entities within these NAICS categories of laboratories are considered to be small entities and 68 percent are considered large entities.

Of these 236 registered entities, potentially affected entities include laboratories, other research institutions, and related entities in possession of select agents. Potentially affected entities (other than Federal and State governmental entities) are likely found within the following NAICS categories:
• 541714, Research and Development in Biotechnology;
• 541715, Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology);
• 325412, Pharmaceutical Preparation Manufacturing;
• 325413, In-Vitro Diagnostic Substance Manufacturing;
• 325414, Biological Product (except Diagnostic) Manufacturing;
• 541940, Veterinary Services;
• 611310, Colleges, Universities and Professional Schools;
• 621511, Medical Laboratories; or
• 622110, General Medical and Surgical Hospitals.

The SBA has established small-entity size standards based on the NAICS categories. An entity classified within NAICS 541714 and NAICS 541715 is considered small with 1,000 or less employees, and an entity classified within NAICS 325412 is considered small with 1,300 or less employees, 325413, and 325414 is considered small with 1,250 or less employees. An entity in NAICS 541940 is considered small with annual receipts of $10 million or less, and an entity in NAICS 611310 is considered small with annual receipts of not more than $34.5 million. Entities classified within NAICS 621511 are considered to be small if they have annual receipts of not more than $41.5 million. An entity classified within NAICS 622110 is considered to be small with annual receipts of not more than $47 million.

While the breakdown of the size of the entities, as reported by the 2017 Economic Census (updated subset of 2021 County Business Patterns released on July 3, 2024), does not precisely fit the SBA guidelines, the data indicates that the majority (68 percent) of the entities in industries potentially affected by this final rule, other than post-secondary institutions, can be considered large entities. In other words, over 68 percent of all entities included in the above mentioned NAICS codes are large entities meaning only approximately 32 percent of these entities are small entities [6] (see table 1 below). According to the 2017 Economic Census and 2021 subset, the most recent census data available for all entities, 98 percent of entities in NAICS 541714 and 96 percent 541715, 93 percent of entities in NAICS 325412, 86 percent of entities in NAICS 325413, 86 percent of entities in NAICS 325414, 0 percent of entities in NAICS 541940, 13 percent of entities in NAICS 621511, 7 percent of entities in NAICS 611310, and 3 percent of entities in NAICS 622110 can be classified as small entities.[7]

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

| NAICS code | Number of firms in each SBA size class | | Percentage of small firms |
|---|---|---|---|
| SBA Small-entity Standard based on Employment | <1,000 Employees small entities. | 1,000 + Employees large entities. | |
| 541714 Research and Development (R&D) in Biotechnology (commercial and non-profit) 4,714 firms. | 4,638 | 76 | 98 |
| 541715 R&D in the Life Sciences (commercial and non-profit) 9,824 firms | 9,399 | 425 | 96 |
| | <1,250 Employees small entities. | 1,250 + Employees large entities. | |
| 325413 In-vitro Diagnostic Substance 194 firms | 167 | 27 | 86 |
| 325414 Biological Product (except Diagnostic) 288 firms | 247 | 41 | 86 |
| | <1,300 Employees | 1,300 + Employees large entities. | |
| 325412 Pharmaceutical Preparation 1,172 firms | 1,092 | 80 | 93 |
| SBA Small-entity Standard based on Annual Receipts | <$10 million in Receipts small firms. | $10 million + in Receipts large firms. | |

[6] NAICS codes included for all firms totaled 50,281. Of that total, 16,149 were considered small and 34,132 were considered large. Overall percent was 32 percent small firms and 68 percent large firms.

[7] Based on the small business size standards matched to industries described in NAICS, as modified by the Office of Management and Budget in 2017, and reported in the SBA's Small Business Size regulations contained in 13 CFR part 121 (*https://www.ecfr.gov/current/title-13/chapter-I/part-121*) and data by enterprise receipt size (*https://www.census.gov/data/tables/2021/econ/susb/2021-susb-annual.html*) and also when not available in sub 2021 (*https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html*).

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

| NAICS code | Number of firms in each SBA size class | | Percentage of small firms |
|---|---|---|---|
| 541940 Veterinary Services 42 b receipts 28,291 firms | 0 | 28,291 | 0 |
| SBA Small-entity Standard based on Annual Receipts | <$34.5 million in Receipts small firms. | $34.5 million + in Receipts large firms. | |
| 611310 Colleges, Universities, and Professional Schools 2,433 firms | 168 | 2,265 | 7 |
| SBA Small-entity Standard based on Annual Receipts | <$41.5 million in Receipts small firms. | $41.5 million + in Receipts large firms. | |
| 621511 Medical Laboratories 3,365 firms | 438 | 2,927 | 13 |
| SBA Small-entity Standard based on Annual Receipts | <$47 million in Receipts small firms. | $47 million + in Receipts large firms. | |
| 622110 General Medical and Surgical Hospitals 2,560 | 65 | 2,495 | 3 |

The analysis above shows the potential costs of the final rule to be slight as permits would be required for movement. While an interstate transport permit of organisms and vectors will be required, delisted agents will incur less cost than prior to delisting. Prior to delisting, entities had to pay a few thousand dollars in shipping costs alone to move select agent's interstate, due to heightened security measures to move select agent's interstate. The organism and vector permit will cost $150 to move these delisted agents interstate, which is significantly less than the thousands of dollars required to ship select agents interstate. The benefits of the final rule will accrue to all firms conducting research with *Brucella* spp., *Peronosclerospora philippinensis* (*Peronosclerospora sacchari*), and AHS as most of which (68 percent) included in the above mentioned NAICS codes are large entities, meaning only approximately 32 percent of these firms are small entities. Following delisting, they will have the option to purchase a permit for movement only if they decide the benefits of the permit outweigh the cost of $150 per permit. Receipts are in the millions to billions of dollars for these entities; the cost of the permit will be insignificant based upon receipts shown in the Census of Agriculture data. In addition, this is a significant reduction in the cost of shipping select agents interstate which is in the magnitude of a few thousand dollars to move a single select agent interstate. Finally, these entities as mentioned above have already been incurring these shipping costs for interstate movement of delisted and select agents.

Alternatives to the Final Rule

APHIS convenes separate interagency working groups in order to review the list of PPQ and VS select agents and toxins, as well as any overlap select agents and toxins, and develop recommendations regarding possible changes to the list using the five criteria for listing found in the Act. APHIS and CDC coordinate on the biennial review for overlap select agents and toxins that have been determined to pose a severe threat to human and animal health or animal products. The delisting of the three *Brucella* spp., AHS virus, and *P. philippinensis* (*P. sacchari*) is based on the recommendations of the interagency working groups.

The most significant impact of this final rule is the delisting of *Brucella* spp., AHS virus, and *P. philippinensis* (*P. sacchari*), and APHIS and HHS/CDC has carefully considered the alternative of delisting the agents, which would be retaining the agents on the list and continuing regulating these agents.

Retaining the *Brucella* species on the list has several economic, agricultural, and economic effects with little biosecurity benefit. Most notably, retaining *Brucella* species on the list prevents researchers from progressing advancement of science with regards to study of the agents and development of countermeasures for this agent by subjecting these laboratories to Federal Select Agent regulatory authority.

Continuing regulation of *Brucella melitensis, suis,* and *abortus* has a one-time cost of approximately $29,000 to an entity that wishes to register with FSAP for work with these agents. This cost to the regulated community represents a regulatory burden to entities that wish to advance understanding of the agent and research medical countermeasures.

An alternative to the final rule is to not delist these select agents. Retaining *Brucella* spp., AHS virus, and *P. philippinensis* (*P. sacchari*) would maintain the current status quo; it does not consider that these agents no longer pose a severe threat to public health and safety, does not promote better research and vaccine development, and does not align with USDA's decision to delist these agents. In addition, this option is not consistent with the public comment received to support amending the select agent list.

Maintaining the status quo would mean foregoing continued research on an improved *B. abortus* vaccine and development of a *B. suis* vaccine, as well as improved diagnostics for both agents. Similarly, *Peronosclerospora philippinensis* (*Peronosclerospora sacchari*) has received public support for delisting as the agent is only able to survive and reproduce in the host plant, and AHS, while a life-threatening viral disease of equines, is unlikely to be used as a bioterrorism agent. Previous regulatory restrictions had effectively prohibited vaccine trials using natural transmission models, limited the opportunity for large animal studies, inhibited available surveillance, and prohibited studies that would evaluate vaccine or diagnostic product efficacy through comingling vaccinated and naturally infected animals. These limitations also increase disease management costs for State and Federal governments as well as livestock producers.

After carefully considering the technical input of subject matter experts, both within the Federal Government and from public comments, and recommendations from Federal advisory groups, APHIS and HHS/CDC is finalizing the changes to delist agents.

Reasons Action Is Being Considered

APHIS and CDC are delisting *B. abortus, B. suis,* and *B. melitensis* from the select agents and toxins list to reduce costs and enhance opportunities for research on *B. abortus* vaccine and development of a *B. suis* vaccine, as well as improved diagnostics for both agents. The delisting of *Brucella* spp., AHS virus, and *P. philippinensis* (*P. sacchari*) is also based on the recommendations of interagency working groups. *P. philippinensis* (*P. sacchari*) is only able to survive and reproduce in the host plant and requires specific environmental conditions to become infectious, for which mitigations exist. Thus, the economic impact of possible misuse of this agent was deemed a low impact. We are delisting this agent based upon affirmative responses to proposed delisting. With regard to AHS, because both the disease and its vector must be present in an environment for transmission to equines to occur, we considered AHS unlikely to be used as an agent of bioterrorism. Vaccines are available internationally and in the event of foreign animal disease outbreak, we can implement emergency response plans. Based on the foregoing considerations, we are delisting AHS virus as a select agent.

Objectives of and Legal Basis for the Final Rule

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

Projected Reporting, Recordkeeping, and Other Compliance Requirements

Delisting *Brucella* spp., AHS virus, and *P. philippinensis* (*P. sacchari*) will not result in additional reporting, recordkeeping, or other compliance requirements.

Duplication, Overlap, or Conflict With Existing Rules and Regulations

APHIS has not identified any duplication, overlap, or conflict of the final rule with other Federal rules or regulations.

Executive Order 13175

This final rule has been reviewed in accordance with the requirements of Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments.'' Executive Order 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments or legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. What follows is a summary of such coordination to date. APHIS has assessed the impact of this rulemaking on Indian Tribes by soliciting Tribal feedback on its provisions. On April 8, 2022, APHIS sent Tribal nations a letter outlining the provisions of the proposed rule and soliciting their feedback. On May 5, 2022, the Sac and Fox Tribe of the Mississippi in Iowa submitted a response expressing concerns regarding whether possible *Brucella abortus* delisting would materially adversely impact APHIS' domestic quarantine program for the control and eradication of brucellosis in cattle and bison. In response, APHIS clarified that the two issues were distinct, and no adverse operational impacts were anticipated. On June 6, 2022, the Tribe indicated that they have no further comments or concerns. To date, no other Tribes have expressed concerns regarding this rulemaking, nor did Tribes submit comments on the proposed rule during its comment period. Therefore, the Agency has determined that this final rule does not, to our knowledge, have Tribal implications that require formal Tribal consultation under Executive Order 13175.

If a Tribe requests consultation, the Animal and Plant Health Inspection Service will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions, and modifications identified herein are not expressly mandated by Congress.

Executive Order 12988

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

Paperwork Reduction Act

This final rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

**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 are amending 7 CFR part 331 and 9 CFR part 121 as follows:

**Title 7—Agriculture**

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

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

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

■ 2. Amend § 331.3 by revising paragraph (b) to read as follows:

**§ 331.3 PPQ select agents and toxins.**

* * * * *

(b) PPQ select agents and toxins are:

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

(2) *Ralstonia solanacearum;*

(3) *Rathayibacter toxicus;*

(4) *Sclerophthora rayssiae;*

(5) *Synchytrium endobioticum;* and

(6) *Xanthomonas oryzae.*

* * * * *

**Title 9—Animals and Animal Products**

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

■ 3. 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.

■ 4. Amend § 121.3 by revising paragraph (b) to read as follows:

**§ 121.3 VS select agents and toxins.**

* * * * *

(b) VS select agents and toxins are:

(1) African swine fever virus;

(2) Avian influenza virus;

(3) Classical swine fever virus;

(4) * Foot-and-mouth disease virus;

(5) Goat pox virus;

(6) Lumpy skin disease virus;

(7) *Mycoplasma capricolum;*

(8) *Mycoplasma mycoides;*

(9) Newcastle disease virus; [1]

(10) Peste des petits ruminants virus;

(11) * Rinderpest virus;

(12) Sheep pox virus; and

(13) Swine vesicular disease virus.

* * * * *

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

■ 5. Amend § 121.4 by revising paragraph (b) to read as follows:

**§ 121.4 Overlap select agents and toxins.**

* * * * *

(b) Overlap select agents and toxins are:

(1) ** Bacillus anthracis;*

(2) *Bacillus anthracis* (Pasteur strain);

(3) ** Burkholderia mallei;*

(4) ** Burkholderia pseudomallei;*

(5) Hendra virus;

(6) * Nipah virus;

(7) Rift Valley fever virus; and

(8) Venezuelan equine encephalitis virus.

* * * * *

Done in Washington, DC.

**Jennifer Moffitt,**

*Undersecretary, Marketing and Regulatory Programs, USDA.*

[FR Doc. 2024–29567 Filed 12–16–24; 8:45 am]

**BILLING CODE 3410–34–P**

## DEPARTMENT OF ENERGY

### 10 CFR Part 1008

**[DOE–HQ–2024–0085]**

**RIN 1903–AA18**

## Privacy Act of 1974: Implementation of Exemptions

**AGENCY:** U.S. Department of Energy.

**ACTION:** Final rule.

**SUMMARY:** The Department of Energy (DOE or Department) is revising its regulations to exempt certain records maintained under a newly established system of records—DOE–85, Research, Technology, and Economic Security Due Diligence Review Records—from the notification and access provisions of the Privacy Act of 1974. The Department is exempting portions of this system of records from these subsections of the Privacy Act because of requirements related to classified information.

**DATES:** This final rule is effective on January 16, 2025.

**FOR FURTHER INFORMATION CONTACT:** Kyle David, U.S. Department of Energy, 1000 Independence Avenue SW, Office 8H–085, Washington, DC, 20585; facsimile: (202) 586–8151; email: *kyle.david@hq.doe.gov,* telephone: (240) 686–9485.

**SUPPLEMENTARY INFORMATION:**

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## I. Authority and Background

### *A. Authority*

DOE has broad authority to manage the agency's collection, use, processing, maintenance, storage, and disclosure of Personally Identifiable Information (PII) pursuant to the following authorities: 42 United States Code (U.S.C.) 7101 *et seq.,* 50 U.S.C. 2401 *et seq.,* 5 U.S.C. 1104, 5 U.S.C. 552, 5 U.S.C. 552a, 42 U.S.C. 7254, 5 U.S.C. 301, and 42 U.S.C. 405 note.

### *B. Background*

The Privacy Act of 1974 (the Act) (5 U.S.C. 552a) embodies fair information practice principles in a statutory framework governing the means by which the U.S. Government collects, maintains, uses, and disseminates personally identifiable information. The Privacy Act applies to information that is maintained in a ''system of records.'' A ''system of records'' is a group of any records under the control of an agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined to encompass U.S. citizens and lawful permanent residents.

The Privacy Act includes two sets of provisions that allow agencies to claim exemptions from certain requirements in the statute. These provisions allow agencies in certain circumstances to promulgate rules to exempt a system of records from certain provisions of the Privacy Act. For this system of records, pursuant to 5 U.S.C. 552a(k)(1), the Department exempts this system of records from subsections (c)(3); (d); (e)(1), (e)(4)(G), (4)(H), and (4)(I); and (f) of the Privacy Act. This exemption is needed to protect information relating to DOE activities from disclosure to subjects or others related to these activities. Specifically, the exemption is required to safeguard classified information. Pursuant to the Privacy Act and Office of Management and Budget (OMB) Circular A–108, *Federal Agency Responsibilities for Review, Reporting, and Publication under the Privacy Act,* DOE is issuing this Rule to make clear to the public the reasons why this particular exemption is being applied.

## II. Discussion

The Department is exempting portions of a newly established system of records—DOE–85, Research, Technology, and Economic Security Due Diligence Review Records—from subsections (c)(3); (d); (e)(1), (e)(4)(G), (4)(H), and (4)(I); and (f) of the Privacy Act of 1974. To claim this exemption, DOE is amending 10 CFR 1008.12 by adding a new paragraph, (b)(1)(ii)(N). The Department exempts portions of this system of records from these subsections of the Privacy Act because of requirements related to classified information.

The purpose of this system is to enhance DOE's capabilities to aggregate, link, analyze, and maintain information used by the Department to assess research, technology, and economic security (RTES) risk. RTES risks may include risk of foreign government interference and exploitation, intellectual property (IP) loss, national