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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, USDA.

ACTION: Advance notice of proposed rulemaking and request for comments.

SUMMARY: In accordance with the Agricultural Bioterrorism Protection Act of 2002, we are soliciting public comment regarding the list of select agents and toxins that have the potential to pose a severe threat to animal or plant health, or to animal or plant products. The Act requires the biennial review and republication of the list of select agents and toxins and the revision of the list as necessary. Accordingly, we are soliciting public comment on the current list of select agents and toxins in our regulations and suggestions regarding any addition or reduction of the animal or plant pathogens currently on the list of select agents.

DATES: We will consider all comments that we receive on or before [Insert date 60 days after date of publication in the Federal Register].

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

- Federal eRulemaking Portal: Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2019-0018>.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2019-0018, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2019-0018> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: Mrs. Sally Rejas, Program Analyst, Agriculture Select Agent Services, Strategy & Policy, VS, APHIS, 4700 River Road, Riverdale, MD 20716; (301) 851-3384.

SUPPLEMENTARY INFORMATION:

Background

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 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 primary responsibility for implementing the provisions of the 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 Department of Health and Human Services.

Title II, Subtitle B of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (which is cited as the “Agricultural Bioterrorism Protection Act of 2002” and referred to below as the Act), section 212(a), provides, in part, that the Secretary of Agriculture (the Secretary) must establish by regulation a list of each biological agent and each toxin that the Secretary determines has the potential to pose a severe threat to animal or plant health, or to animal or plant products.

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

- The effect of exposure to the agent or toxin on animal or plant health, and on the production and marketability of animal or plant products;
- The pathogenicity of the agent or the toxicity of the toxin and the methods by which the agent or toxin is transferred to animals or plants;
- The availability and effectiveness of pharmacotherapies and prophylaxis to treat and prevent any illness caused by the agent or toxin;

- Whether such inclusion would have a substantial negative impact on the research and development of solutions for the animal and plant disease caused by the agent or toxin and whether the negative impact would substantially outweigh the risk posed by the agent or toxin to animal or plant health if it is not included on the list (added by the 2018 Farm Bill); and
- Any other criteria that the Secretary considers appropriate to protect animal or plant health, or animal or plant products.

Paragraph (a)(2) of section 212 of the Act requires the Secretary to review and republish the list of select agents and toxins every 2 years and to revise the list as necessary. To fulfill this statutory mandate, PPQ and VS each convene separate interagency working groups in order to review the lists of PPQ and VS select agents and toxins, as well as any overlap select agents and toxins, and develop recommendations regarding possible changes to the list using the five criteria for listing found in the Act. In this document, we are asking for comments on the current list¹ of select agents and toxins and on any other significant pathogens so as to inform the working groups as they begin the biennial review process.

As detailed below, we are considering removing one PPQ select agent, one VS select agent, and four overlap select agents. CDC is publishing a notice concurrently which also lists the overlap agents under consideration. Proposed select agent removals are as follows:

¹ You may view the lists of select agents and toxins on the internet at <http://www.regulations.gov/#!docketDetail;D=APHIS-2019-0018>.

PPQ Select Agents

- *Peronosclerospora philippinensis* (*Peronosclerospora sacchari*): This agent is only able to survive and reproduce in the host plant and requires specific environmental conditions to become infectious, for which mitigations exist.

VS Select Agents

- African horse sickness virus: This virus is difficult to successfully disseminate and effectively transmit. An effective vaccine exists.

Overlap Select Agents

- *Bacillus anthracis* (Pasteur strain): This agent presents little economic or animal health risk due to low mortality rates, low virulence, and minimal risk of farm-to-farm transmission due to modern production practices (e.g., physical separation of groups of animals on farms and robust quarantine protocols in the face of any infection).
- *Brucella abortus*: This agent presents little economic or animal health risk as it is unlikely to result in large-scale population introduction due to the high concentration of the agent necessary to produce disease as well as modern cattle production processes that limit animal-to-animal transmission routes. There is an efficacious vaccine, moderate immunity status within vulnerable populations, limited farm-to-farm transmission risk, and effective quarantine procedures.
- *Brucella melitensis*: This agent, which primarily affects goats and sheep, is of lesser concern because the low farm-to-farm transmission risk due to modern production practices limits the chance of introduction on a scale large enough to impact domestic production.

- *Brucella suis*: This agent presents a low to moderate animal health risk due to limited farm-to-farm transmission risk as a result of modern production practices which reduce the risk of a large-scale introduction.
- Venezuelan equine encephalitis virus: An effective vaccine exists for this agent, which contributes to a high level of immunity within vulnerable populations. Furthermore, large-scale production and efficient dissemination would be difficult due to the virus' limited ability to persist in the environment outside of an infected animal or mosquito host.

At the conclusion of the comment review process, we will publish another document in the *Federal Register* either republishing the lists of select agents and toxins in 7 CFR 331.3, 9 CFR 121.3, and 9 CFR 121.4 or proposing changes to one or more of the lists.

This action 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.

Authority: 7 U.S.C. 8401; 7 CFR 2.22, 2.80, 371.3, and 371.4.

Done in Washington, DC, this 25th day of February 2020 .

Greg Ibach

Under Secretary for Marketing and Regulatory Programs.

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