

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2024–0010]

Notice of Withdrawal of Select Agent Regulatory Exclusion for African Swine Fever Virus–G–ΔI177L

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of withdrawal of select agent regulatory exclusion.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service (APHIS) has withdrawn the select agent regulatory exclusion for African swine fever virus (ASFV) strain, ASFV–G–ΔI177L. Possession, use, and transfer of this strain must now comply with the select agent and toxin regulations. APHIS withdrew the select agent regulatory exclusion for this strain because it has evaluated new information and determined that this strain, when adapted to cell lines other than that used for virus development, has the potential to pose a severe threat to animal health or animal products.

DATES: As of February 7, 2024, the subject select agent exclusion was withdrawn.

FOR FURTHER INFORMATION CONTACT: Dr. Jacek Taniewski, DVM, Director, Division of Agricultural Select Agents and Toxins, Animal and Plant Health Inspection Service, 4700 River Road, Riverdale, Maryland 20737; telephone: (301) 851–2070; email: jacek.taniewski@usda.gov.

SUPPLEMENTARY INFORMATION:

Background

The Agricultural Bioterrorism Protection Act of 2002, as amended (7 U.S.C. 8401, referred to below as the Act) provides for the regulation of certain biological agents and toxins that

have the potential to pose a severe threat to 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.

In accordance with the Act, APHIS promulgated the select agent and toxin regulations found in 7 CFR part 331 and 9 CFR part 121. Paragraph (e) in § 121.3 of the select agent and toxin regulations states that an attenuated strain of a select agent or a select toxin modified to be less potent or toxic may be excluded from the requirements of the select agent and toxin regulations based upon a determination by the Administrator that the attenuated strain or modified toxin does not pose a severe threat to animal health or animal products.

African swine fever virus (ASFV) is listed as a select agent in § 121.3(b) of the select agent and toxin regulations. APHIS approved the initial regulatory exclusion for ASFV strain ASFV–G–ΔI177L, based on an application submitted in accordance with the select agent and toxin regulations and with review and recommendations from the Agriculture Interagency Select Agents and Toxins Technical Advisory Committee (Ag–ISATTAC) at a meeting on April 2, 2020. The exclusion became effective on April 3, 2020. Pursuant to § 121.3(e)(1) of the select agent and toxin regulations, APHIS listed the exclusion on the National Select Agent Registry website at <https://www.selectagents.gov>.

On February 7, 2024, APHIS withdrew the previously approved select agent regulatory exclusion for the ASFV–G–ΔI177L strain. APHIS will remove this strain from the list on the National Select Agent Registry website concurrent with this notice. APHIS notified all entities that were known to have the previously excluded ASFV strains that possession, use, and transfer of these ASFV strains must now comply with the select agent and toxin regulations in 9 CFR part 121. APHIS based the decision to withdraw the exclusion on newly acquired information obtained in February 2024 regarding safety and genome instability potentially leading to reversion of virulence that was unavailable to Ag–ISATTAC during the April 2020 discussion for regulatory exclusion.

Recent *in-vitro* and *in-vivo* studies conducted for a European Union grant provided general information that under certain conditions, the strain can demonstrate an increase or reversion to virulence. More specifically, the ASFV–G–ΔI177L strain was adapted to growth on a Zuckermann macrophage (ZMAC) cell line, which is a porcine macrophage cell line that supports high levels of ASFV replication. The resulting virus used in back passage swine studies and upon a fifth passage in swine showed clinical signs and/or gross pathology that is consistent with ASFV infection. Due to the development of clinical signs and associated gross pathology that resulted from inoculation with the cell line adapted virus, APHIS determined that the ASFV–G–ΔI177L strain represents an increased risk under certain conditions. For these reasons, APHIS further determined that the ASFV–G–ΔI177L strain does not maintain acceptable attenuation to continue to remain excluded under § 121.3(e).

With the publication of this notice, we are informing the public that we withdrew the previously approved select agent regulatory exclusion for the ASFV–G–ΔI177L strain, effective on February 7, 2024, and that the possession, use, and transfer of this ASFV strain must now comply with the select agent and toxin regulations in 9 CFR part 121. This notice serves as an official record and public notification of this action.

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

Done in Washington, DC, this 10th day of May 2024.

Michael Watson,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2024–10770 Filed 5–15–24; 8:45 am]

BILLING CODE 3410–34–P