Rules and Regulations

Federal Register
Vol. 87, No. 169
Thursday, September 1, 2022

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 121

[Docket No. APHIS–2022–0034]

Possession, Use, and Transfer of Select Agents and Toxins; Regulation of an Attenuated Vaccine Strain of Venezuelan Equine Encephalitis Virus as a Select Agent

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Regulatory determination.

SUMMARY: We are notifying the public that the Animal and Plant Health Inspection Service (APHIS) has determined that the modified Venezuelan equine encephalitis virus (VEEV) strain TC–83(A3G), which is a modification to the attenuated strain VEEV TC–83, has demonstrated increased pathogenicity and lethality and that the strain has the potential to pose a severe threat to animal health or animal products. We are advising the public that VEEV strain TC–83(A3G) is therefore a select agent and subject to APHIS' select agent and toxin regulations.

DATES: Effective September 1, 2022.

FOR FURTHER INFORMATION CONTACT: Dr. Randy Capsel, Science Officer, Division of Agricultural Select Agents and Toxins, Emergency and Regulatory Compliance Services, Animal and Plant Health Inspection Service, 4700 River Road, Riverdale, MD 20737; Telephone: (301) 851–3402; email: *Randy.T.Capsel@usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Agricultural Bioterrorism Protection Act of 2002, as amended (the Act, 7 U.S.C. 8401) 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. The Act also provides authority for APHIS to jointly regulate with the U.S. Department of Health & Human Services' Centers for Disease Control and Prevention (CDC) biological agents and toxins that have the potential to pose a serve threat to both public health and safety and animal health or animal products.

The regulations in 9 CFR part 121 (referred to below as the regulations) implement the provisions of the Act by setting forth the requirements for possession, use, and transfer of Veterinary Services select agents and toxins. In § 121.4 of the regulations, paragraph (e) sets forth a process by which an attenuated strain of a select agent or toxin modified to be less potent or toxic may be excluded from the requirements of the select agent and toxin regulations in part 121 based upon a determination by APHIS' Administrator that the attenuated strain or modified toxin does not pose a severe threat to public health and safety, animal health, or animal products. Under § 121.4(e)(2), if an excluded attenuated strain is subjected to any manipulation that restores or enhances its virulence, resulting in a select agent that poses a severe threat to animal health or animal products, the resulting select agent will be subject to the requirements of the regulations in part 121.

Venezuelan equine encephalitis virus (VEEV) is a member of the genus Alphavirus in the family Togaviridae, and is a small, enveloped virus with a genome consisting of a single strand of positive-sense RNA. VEEV is a mosquito-borne virus that causes encephalitis or encephalomyelitis in all equine species and humans. Because it can affect both animals and humans, VEEV is listed as an overlap select agent in § 121.4(b) of the regulations and therefore is subject to regulation by both APHIS and CDC. On February 7, 2003, VEEV strain TC–83 was excluded from the regulations because mice vaccinated subcutaneously with VEEV strain TC–83 rapidly developed immunity to subcutaneous or airborne challenge with virulent VEEV.[1] Based on these findings, APHIS, in collaboration with CDC, determined that the attenuated strain did not have the potential to pose a severe threat to animal health or animal products.

However, based on a recent review by subject matter experts, APHIS has determined that a modification to the excluded, attenuated VEEV vaccine strain TC–83 has been shown to increase its virulence and pathogenicity. An adenine (A) at position 3 in TC–83 has been shown to contribute to the attenuation of VEEV. In TC–83(A3G), the A has been changed to a guanine (G), which is found in all wild-type isolates of VEEV. The reversion of this nucleotide mutation to the wild-type nucleotide resulted in increased lethality in mice when compared to mice inoculated with the vaccine strain TC–83. Additional data determined that the pathogenic effects of TC–83(A3G) are more pronounced in young mice.

As a result, the modification of the excluded, attenuated VEEV vaccine strain TC–83 to create VEEV strain TC–83(A3G) restores the virus's virulence and has the potential to pose severe threat to animal health or animal products. Therefore, VEEV strain TC–83(A3G) is subject to the regulations in part 121.

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

Done in Washington, DC, this 29th day of August 2022.

Anthony Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2022–18990 Filed 8–30–22; 11:15 am]

BILLING CODE 3410–34–P

[1] See *https://www.selectagents.gov/sat/exclusions/overlap.htm.*