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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 73

[Docket No. CDC-2015-0050]

RIN 0920-AA58

**Possession, Use, and Transfer of Select Agents and Toxins;
Addition of Certain Influenza Virus Strains to the List of
Select Agents and Toxins**

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS)

ACTION: Notice of Proposed Rulemaking; Withdrawal.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS) announces the withdrawal of its 2015 notice of proposed rulemaking (NPRM). The 2015 NPRM proposed to add certain influenza virus strains to the list of HHS select agents and toxins.

DATES: The proposed rule published on July 16, 2015 (80 FR 42079), is withdrawn as of [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Samuel S. Edwin, Director, Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-A46, Atlanta, GA 30329. Telephone: (404) 718-2000.

SUPPLEMENTARY INFORMATION: On July 16, 2015, HHS/CDC published a proposed rule (80 FR 42079) to add certain influenza virus strains to the list of HHS select agents and toxins. Specifically, HHS/CDC proposed to add the influenza viruses that contain the hemagglutinin (HA) from the Goose Guangdong/1/96 lineage (the influenza viruses that contain the hemagglutinin (HA) from the A/Gs/Gd/1/96 lineage), including wild-type viruses as a non-Tier 1 select agent. HHS/CDC also proposed to add any influenza viruses that contain the HA from the A/Gs/Gd/1/96 lineage that were made transmissible among mammals by respiratory droplets in a laboratory as a Tier 1 select agent.

In response to the NPRM, HHS/CDC received 24 comments from industry, academic institutions, professional organizations, and the public. Commenters expressed concern about balancing the risk of impeding research against the risk of an accidental laboratory incident or act of terrorism. Other commenters were concerned that regulation might further limit the ability of veterinarians, researchers, and farmers to identify and respond to influenza outbreaks. Finally, some commenters pointed out that highly pathogenic avian influenza viruses are already regulated as a Department of Agriculture/Animal

and Plant Health Inspection Service (USDA/APHIS) select agent. HHS/CDC agreed with the commenters. Since the publication of the NPRM, the U.S. Government has put in place additional controls regarding the funding and approval of dual use research. In addition, HHS/CDC has worked with USDA/APHIS to ensure that biosafety and biosecurity protocols/measures are in place for regulated entities working with highly pathogenic avian influenza viruses to mitigate the risk to public health and safety. Thus, HHS/CDC believes the public interest is best served by the withdrawal of the NPRM identified in this document. The withdrawal of the proposed rule identified in this document does not preclude HHS/CDC from initiating future rulemaking concerning the influenza viruses that contain the hemagglutinin (HA) from the Goose Guangdong/1/96 lineage (the influenza viruses that contain the hemagglutinin (HA) from the A/Gs/Gd/1/96 lineage), including wild-type viruses or influenza viruses that contain the HA from the A/Gs/Gd/1/96 lineage that were made transmissible among mammals by respiratory droplets.

The NPRM published on July 16, 2015 (82 FR 42079), is hereby withdrawn.

Dated: November 13, 2017.

Eric D. Hargan

Acting Secretary

Department of Health and Human Services

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