CENTERS FOR VETERINARY BIOLOGICS DRAFT NOTICE NO. 22-02

TO: Biologics Licensees, Permittees, and Applicants
    Directors, Center for Veterinary Biologics
    Veterinary Services Leadership Team

FROM: Byron Rippke
    Director

SUBJECT: Availability of Avian Influenza Isolate and Sequence Information

I. PURPOSE

The purpose of this notice is to direct interested parties to the genetic sequences from the recent Eurasian clade 2.3.4.4b H5N1 highly pathogenic avian influenza (HPAI) virus isolated from commercial turkeys from Indiana in February 2022. The notice is also to inform interested parties that the HPAI isolate will be available for purchase from the National Veterinary Services Laboratories (NVSL) by March 2022.

II. BACKGROUND

In late December 2021, H5N1 clade 2.3.4.4b was identified as the cause of die-offs in domestic birds in Newfoundland. The virus was found to be highly similar to viruses causing ongoing outbreaks in Europe. In January 2022, the United States reported similar viruses from wild bird surveillance along the Atlantic flyway. On February 9, 2022, the USDA announced the first detection in commercial poultry in Indiana. This is the first detection of Eurasian H5 clade 2.3.4.4 in poultry in the United States since 2015, and the first report of HPAI in poultry since 2020.

Further information on the poultry finding is available at USDA APHIS | USDA Confirms Highly Pathogenic Avian Influenza in a Commercial Turkey Flock in Dubois County, Indiana

Further information on wild bird findings is available at USDA APHIS | 2022 Highly Pathogenic Avian Influenza

III. ACTION (or POLICY)

Veterinary Services is making the HPAI genomic sequence, as well as the HPAI virus, courtesy of the Indiana Board of Animal Health and the Indiana Animal Disease Diagnostic Laboratory, available to facilities to encourage disease research and development to benefit the U.S. poultry industry. The complete genomic
sequence has been submitted to GISAID as Isolate ID EPI_ISL_9909371 for A/turkey/Indiana/22-003707-003/2022.

Available isolate:

Biologics firms that wish to obtain samples of these isolates for research purposes should:

A. Contact the NVSL Diagnostic Virology Laboratory at (515) 337-7551 for guidance regarding the appropriate forms and payments to submit.

B. Submit the completed forms and the payment associated with the order by one of the following methods:

1. Mail: NVSL User Fees, Box 844, Ames, Iowa 50010
2. Email: NVSL_concerns@usda.gov. NVSL will inform customers when the virus is ready to ship.

C. **Note that the HPAI isolate must be transferred in compliance with the Select Agent Regulations. No Material Transfer Agreement will be required. This isolate is not a Master Seed; it is being made available for research and development. The availability of this isolate does not infer any impending change in vaccination policy.**

IV. IMPLEMENTATION/ APPLICABILITY

The HPAI sequence referenced in this announcement and the referenced reagent will be available from NVSL no later than March 1, 2022.