BURKE HEALEY Digitally signed by BURKE HEALEY Date: 2020.07.13 10:25:33 -06'00'

# VS Memorandum 800.85

## Avian Influenza Vaccine

### 1. Purpose and Background

This memorandum informs all interested parties of the conditions under which the Center for Veterinary Biologics (CVB) considers license applications for avian influenza vaccines. This information supplements the applicable Standard Requirements found in title 9, *Code of Federal Regulations* (9 CFR), parts 113.200 and 113.300.

USDA, APHIS, VS considers avian influenza (AI) in chickens an exotic disease and regulates the production and use of vaccine according to guidelines specified in VS Guidance 8605.1. Permits issued pursuant to 9 CFR 122.2 regulate the importation and/or interstate shipment of AI viruses.

This memorandum represents the Agency's position on this topic. It does not create or confer any rights for or on any person and does not bind the U.S. Department of Agriculture (USDA) or the public. The information it contains may be made available to the public. While this document provides guidance for external users, VS employees may not deviate from the directions provided herein without appropriate justification and supervisory concurrence.

Pursuant to the Congressional Review Act (5 U.S.C. § 801 et seq.), the Office of Information and Regulatory Affairs designated this rule as a non-major rule, as defined by 5 U.S.C. § 804(2).

### 2. Document Status

A. Issue date: 08/07/2020

B. This document replaces Veterinary Services Memorandum 800.85 dated May 18, 2006, which is cancelled.

### 3. Authorities and References

#### A. Authorities (*Code of Federal Regulations* (CFR)):

- 7 CFR 371.4
- 9 CFR part 102
- 9 CFR part 113
- 9 CFR part 122

### B. References

- VS Guidance 8605.1, Animal and Plant Health Inspection Service Policy on H5 and H7 Avian Influenza

## 4. Audience

VS employees and members of industry

## 5. Guidance

### A. Product Master Seed Viruses (MSVs)

1. Licensees and applicants (firms) must meet all applicable Standard Requirements for MSVs, prescribed in 9 CFR 113.200 and 113.300, with the following additional considerations:

   a. Interstate Movement – VS regulates all importations or interstate movements of AI viruses by permit, under 9 CFR 122.2, with the exception of Master Seeds approved by CVB, which require CVB approval for movement.

   b. Conventional Killed Vaccines – VS does consider licensing conventional killed AI vaccines provided that firms obtain and use the MSVs under the following conditions:

      i. *Acceptable MSVs* – Firms must only use AI viruses of low pathogenicity obtained from the Diagnostic Virology Laboratory of the National Veterinary Services Laboratories (NVSL), to produce MSVs for conventional killed vaccines. Firms may obtain any hemagglutinin (H) type from this source.

      ii. *VS Organisms and Vectors (OV) Permit Required* – Firms must apply for an OV permit to obtain AI isolates; typically, a biosecurity inspection is required before issuing such permit. OV will issue permits for AI isolates with the restriction that use of the isolate is limited to *in vitro* studies. AI isolates may be used to produce and test vaccines only when APHIS so authorizes.

   c. Recombinant Derived Vaccines – APHIS does consider licensing live or inactivated recombinant vaccines, subunit vaccines, or other biotechnology-derived AI vaccines produced from recombinant-derived MSVs. Firms must

obtain an OV permit to acquire the AI viruses necessary to construct such MSVs.

d. Conventional Modified Live Vaccines – Due to the high rate of mutation documented for AI viruses, APHIS does not consider license applications for conventional modified live AI vaccines.

## B. Product Development

1. Firms must meet all applicable Standard Requirements for licensure including, but not limited to, 9 CFR 113.200 and 113.300, with the following additional considerations:

   a. Product Claims – Firms may develop products with a claim for use in either chickens or turkeys for any H type. Firms must support all claims for each species, each H type, each age, and route of administration with appropriate data.

   b. Challenge Studies Involving Licensed Product – Firms must support applications for regularly licensed products with appropriate vaccination-challenge efficacy data. Conduct challenge studies using highly pathogenic avian influenza virus in support of an application for licensure under biosafety level 3 containment conditions. Regardless of the challenge strain used, firms must obtain CVB approval of the laboratory, study protocol, and challenge virus before initiating the study.

   c. Conditional Licensing – APHIS only considers applications for conditionally licensed products that meet the conditions found in 9 CFR 102.6. Furthermore, all applicants or licensees seeking or holding conditional licenses for AI vaccines must work toward eventual regular licensure of these products.

## C. Product License Restrictions

1. A. General License Restrictions – APHIS adds the following restrictions to all licenses issued for AI vaccines:

   a. *Distribution in Each State* – "Distribution in each State shall be limited to authorized recipients designated by proper State officials – under such additional conditions as these authorities may require."

b. *Distribution for Export* – "Export distribution shall be limited to authorized recipients designated by proper animal health regulatory officials – under such additional conditions as these authorities may require."

2. Additional License Restrictions – APHIS also adds the following additional restrictions to licenses issued for all AI vaccines for use in chickens, as well as for all H5 and H7 AI vaccines for use in turkeys: "Domestic distribution and use shall be under the supervision or control of USDA, APHIS, VS, as part of an official USDA animal disease control program."

## D. Product Labeling

1. Limited Species Recommendations – Because of the license restrictions on distribution and use, individual product labels may recommend use of the product in chickens or turkeys, but not both.

2. Distribution Statement – For licenses carrying the restriction listed in C.1 above, the domestic product labels must carry the following statement: "This product may only be distributed and used as part of an official USDA animal disease control program."

3. Indication of Types – Product labels must indicate the H and N type of the AI virus used to produce the product.

## E. Implementation/Applicability

Updated policy in this memorandum is effective immediately.