United States Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 11-01

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

FROM: Richard E. Hill, Jr. */s/ Richard E. Hill, Jr.*
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SUBJECT: The Management and Disposition of Eggs, Chickens, and Biological Products Following a Chicken Anemia Virus (CAV) Outbreak in a Source Flock

I. PURPOSE

This Notice informs interested parties of the requirements for the regulated veterinary biologics industry regarding the management and disposition of eggs, chickens, and biological products following a CAV outbreak in a source flock.

II. BACKGROUND

Veterinary Services Memorandum (VS Memo) 800.65 provides guidance on preparing veterinary biological products that use embryonated chicken eggs or chicken tissue as an ingredient. It is meant to assist licensees, permittees, and applicants in meeting the purity and quality requirements in Title 9, Code of Federal Regulations (9 CFR) Part 113.50. The memorandum defines the infectious agents that should be excluded from eggs and chickens used in the production of veterinary biological products. It also describes procedures for the management and disposition of eggs, chickens, and suspect materials following a disqualifying disease outbreak in a source flock.

In the early 1990s, the Center for Veterinary Biologics (CVB) became aware that specific pathogen free (SPF) source flocks used for ingredients of veterinary biologics were seropositive for CAV. Soon after, it was recognized that establishing and maintaining CAV seronegative source flocks was extremely challenging due to the ubiquitous and environmentally rigorous nature of CAV. Due to this unique challenge, along with the understanding that seroconversion in flocks coincides with the reduction of viremia and ability to vertically transmit CAV to embryonated eggs[1], the CVB decided not to include CAV as an agent of concern in VS Memo 800.65, Section IV.B., which would require

SPF flocks to be serologically monitored for CAV. Yet, many source flocks are monitored for other reasons, such as fulfilling requirements of foreign regulatory authorities even though the CVB does not require source flocks to be serologically monitored for CAV.

The decision not to include CAV as an agent of concern does not mean that action is not required should clinical signs or seroconversion be detected in a source flock. In the event of a CAV outbreak in a source flock, suspected materials are to be managed as described in VS Memo 800.65, Section V., with the clarifying guidance described below.

III. POLICY

Notification of CAV outbreaks will follow procedures described in VS Memo 800.65, Section V.A. The licensee or permittee should require the source flock owner to notify them within 24 hours of a positive test result indicating a CAV outbreak, such as seroconversion in a CAV naïve source flock. When notified of a CAV outbreak in a source flock, the licensee or permittee must notify the CVB-Inspection and Compliance (CVB-IC) within 24 hours. This notification is required under 9 CFR 116.5 and clarified in CVB Notice 05-24.

Determining the period of suspect eggs in a disease outbreak is described in VS Memo 800.65, Section V.B. The suspect period for a CAV outbreak in a source flock begins 3 weeks prior to the day after blood was collected for the last negative CAV serological test result and will end 13 days following the date blood was collected that first tested positive for CAV. Thus, eggs laid after 13 days following seroconversion of the source flock qualify for the preparation of biological products according to VS Memo 800.65. No further CAV testing is required from these recovered source flocks or for biological products prepared using their eggs.

The disposition of materials suspected to contain extraneous CAV is described in VS Memo 800.65, Section V.C. However, if the product is appropriately tested and the presence of extraneous CAV is not demonstrated, suspect materials may continue to be used in the preparation of veterinary biologics. Thus, suspect eggs, tissue culture, or birds can be inoculated with production seed for the purpose of manufacturing product. These materials may also be used for testing of biological products.

In the case of a CAV outbreak, the CVB-IC will supply a protocol to licensees and permittees that must be used for the testing of biological products prepared with ingredients suspected of containing extraneous CAV, along with an accompanying letter notifying them of the seroconversion date and suspect period. The CVB may also choose to perform confirmatory testing and/or validate the manufacturer's testing records prior to authorizing the release of these products to the market. If the presence of extraneous

CAV is detected, the respective product is determined to be unsatisfactory and the CVB will not approve release of final product to the market. Reporting the results of extraneous CAV testing is described in VS Memo 800.65, Section V.E.3.

IV. IMPLEMENTATION

This Notice clarifies the current CVB requirements for the management and disposition of eggs, chickens and biological products following a CAV outbreak in a source flock. It also implements new policy that permits the use of uninoculated materials suspected to contain extraneous CAV to be used in the preparation of veterinary biologics.

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[1] Yuasa N, Taniguchi T, Imada T, Hihara H. Distribution of chicken anaemia agent (CAA) and detection of neutralizing antibody in chicks experimentally inoculated with CAA. Natl Inst Anim Health Q (Tokyo) 1983;23:78-81.