USDA
United States Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

1400 Independence Ave, SW

Washington, DC 20250

VETERINARY SERVICES MEMORANDUM NO. 800.103

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

FROM: for Jack A. Shere
Deputy Administrator

BURKE HEALEY Digitally signed by BURKE HEALEY Date: 2018.07.18 15:48:24 -04'00'

SUBJECT: Reissuance of Product Licenses for Autogenous Products and Guidance Concerning Restrictions on the Production and Use of Veterinary Biologics

I. PURPOSE

This memorandum gives guidance to licensees, permittees, and applicants concerning Animal and Plant Health Inspection Service (APHIS) restrictions on the production, importation, distribution, and use of autogenous biologics. Restrictions may be determined by the Administrator for the protection of domestic animals in accordance with title 9, *Code of Federal Regulations* (9 CFR), part 102.5(d).

II. CANCELLATION

This memorandum cancels Veterinary Services (VS) Memorandum No. 800.103, dated May 28, 2002.

III. BACKGROUND

APHIS restricts the importation and distribution of veterinary biologics from countries known to have exotic diseases, including, but not limited to, foot-and-mouth disease, rinderpest, highly pathogenic avian influenza, swine vesicular disease, Newcastle disease, African swine fever, and bovine spongiform encephalopathy if, in the opinion of APHIS, such products may endanger domestic animals, livestock, or poultry.

In addition, APHIS restricts the production and distribution of veterinary biologics, including, but not limited to, Brucella Abortus Vaccine, Vesicular Stomatitis Vaccine, and certain diagnostic products used in cooperative State/Federal/industry animal disease control and eradication programs, if it determines such products may interfere with disease surveillance and/or control and eradication efforts.

In May of 2002, APHIS reissued autogenous product licenses to add the following restriction:

> This license does not authorize production, distribution, or shipment of autogenous vaccine/bacterin for foot-and-mouth disease, rinderpest, any H5 or H7 subtype of

> avian influenza, any subtype of avian influenza in chickens, swine vesicular disease, Newcastle disease, African swine fever, classical swine fever, Brucella abortus, vesicular stomatitis, and rabbit hemorrhagic disease or any other disease that the Administrator determines may pose a risk to animal or public health.

IV. POLICY

The restriction described in section III applies to all autogenous product licenses.

APHIS is providing the following definitions to clarify the use of "Newcastle disease" in that restriction, and to aid firms in determining when the restriction does not apply.

The World Organization for Animal Health (OIE) defines "Newcastle disease" as:

> An infection caused by virulent avian paramyxoviruses, serotype 1 (APMV-1) virus isolates that have either an intracerebral pathogenicity index (ICPI) of at least 0.7 in day-old chicks, and/or amino acid sequences in the viral fusion (F) protein that resemble those seen in previously isolated, highly virulent viruses.

The list of Select Agents in 9 CFR 121.3(b) defines "Newcastle disease virus" as:

> A virulent Newcastle disease virus (avian paramyxovirus serotype 1) has an intracerebral pathogenicity index in day-old chicks (*Gallus gallus*) of 0.7 or greater or has an amino acid sequence at the fusion (F) protein cleavage site that is consistent with virulent strains of Newcastle disease virus. A failure to detect a cleavage site that is consistent with virulent strains does not confirm the absence of a virulent virus.

Additionally, the Select Agent exclusion criteria for pigeon paramyxovirus serotype 1 in footnote 5 of 9 CFR 121.3(d)(9) defines it as:

> Pigeon paramyxovirus (PPMV-1) is a species-adapted APMV-1 virus which is endemic in pigeons and doves in the United States and can be identified through monoclonal antibody testing and demonstration of the characteristic amino acid signature at the fusion gene cleavage site. The exclusion is applicable only to viruses recovered from columbid species.

Thus, all APMV field isolates intended for use in preparing autogenous products, must be serotyped and the virulence of all APMV-1 serotypes must be further characterized as to their ICPI and amino acid sequence at the F protein cleavage site. Testing must be conducted at an APHIS-approved laboratory, such as the National Veterinary Services Laboratories (NVSL), or the Agricultural Research Services Southeast Poultry Research Laboratory. The website for diagnostic testing at NVSL is https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/sa_diagnostic_tests/ct_diagnostic_tests, which includes catalogs and the VS 10-4 Submission form.

Isolates not meeting either the OIE or Select Agent definitions of Newcastle disease, or Newcastle disease virus previously mentioned, may be used in autogenous products. Pigeon paramyxovirus meeting the Select Agent exclusion criteria may be used in autogenous products.

V. IMPLEMENTATION

This memorandum is effective immediately.

VI. ADDITIONAL INFORMATION

Contact the Center for Veterinary Biologics-Inspection and Compliance concerning whether a particular isolate (microorganism) may be used to produce an autogenous product. Submit questions by one of the following means:

- U.S. mail:
  Director, Center for Veterinary Biologics - Inspection and Compliance
  1920 Dayton Avenue
  Ames, IA 50010

- NCAH Portal