Avian Metapneumovirus Questions and Answers

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There is an immediate need in the field. How will CVB Notice 24-10 speed the process for getting aMPV products in the field?

The notice allows CVB to use a risk-based approach to meet an emergent need in the field. For the first time, CVB is authorizing the use of experimental autogenous vaccine (inactivated) to expedite product availability. The CVB is allowing import of Master Seed (aMPV virus) and Master Cell Stock (cells) for domestic production of live products to speed manufacturing. CVB will perform concurrent testing of Master Seeds and Master Cell Stocks to save time on product availability. May also provide some flexibility on using some existing data to speed up the licensure process.

Can CVB disclose the firms manufacturing experimental autogenous vaccine or importing product? Is there an update of time to market?

Manufacturers are both producing experimental autogenous vaccine and have been granted import permits for killed vaccines. The names of the manufacturers are considered confidential business information (CBI) and CVB cannot reveal the manufacturers. Stakeholders are encouraged to reach out to manufacturers with questions.

Flocks with aMPV have secondary infections causing morbidity and mortality and some flocks are experiencing drops in egg production. Has CVB considered import of live vaccines?

Historically, CVB has not allowed import of live vaccines due to the risk, especially for poultry. CVB performed limited purity and safety testing of the first serial for Avian Metapneumovirus for modified live viral vaccines to determine eligibility for importation as part of the risk assessment. Based on the satisfactory CVB testing and risk assessment, CVB has issued several permits.

May CVB share any progress on licensing and/or validation of commercial ELISA or PCR kits for aMPV?

CVB is facilitating import for aMPV diagnostic test kits.

Where is an APHIS map of aMPV incidence in the U.S.?

Reporting to APHIS is voluntary so APHIS does not have the full U.S. data.

Does CVB limit the number of times an import may be issued for killed vaccines?

A Research and Evaluation (R&E) permit issued under emergency authorization to meet an emergent need in the field is generally valid for one year and may cover multiple imports. R&E permits may be renewed until the product is no longer needed such as if a license is issued for a killed product. CVB has issued import permits for multiple inactivated aMPV vaccines and can reissue permits or grant new permits as the need in the field is assessed and warranted.

If a vaccine is fully licensed, will the conditionally licensed products be allowed to advance to full licensure?

CVB will evaluate the field need and supply situation then determine a time period for conditionally licensed products to remain on the market while they complete the requirements for full licensure. Regulatory flexibility will be extended as needed.

Subtypes A and B may be present on the same farm and flock. Will CVB consider the use of multiple subtypes for autogenous vaccines?

Yes, multiple strains of aMPV may be used in the experimental autogenous product for distribution.

What countries would enact trade restrictions in response to aMPV vaccination?

Countries with reference to aMPV on current live animal export protocols as of July 30, 2024, include the following: Argentina; Australia; Brazil; Chile; Ecuador; Nicaragua; Peru; Uzbekistan; El Salvador; and Guatemala.

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