United States Animal Health Association

**2022 Resolution**

126th Annual Meeting
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Minneapolis, MN

**RESOLUTION NUMBER: 34** **Approved**

**SOURCE:** **COMMITTEE ON FOREIGN AND EMERGING DISEASES**

**SUBJECT MATTER:** **Policy Development Necessary for the Importation and Use of Point of Care Assays**

## BACKGROUND INFORMATION:

The 2021 Joint National Animal Health Laboratory Network (NAHLN) and National Animal Disease Preparedness and Response Program (NADPRP) funding targeted six projects supporting the development and/or evaluation of point-of-care (POC) diagnostic tests to enhance the nation's ability to quickly detect high-consequence foreign animal diseases (FADs) and accelerate response and containment efforts. POC assays for high-consequence FADs support laboratories in disease outbreak response, however, many of these potentially useful FAD POC assays have been developed for use in other countries but have not been tested or validated for use in the United States. There is a well-defined process in the 9 Code of Federal Regulations (CFR) part 104 for obtaining permits for importation of biological products, including POC diagnostic test kits. This process must "reasonably ensure that the product is pure, safe, potent, and efficacious". This process can be lengthy and expensive. It is not conducive to rapid approval for emergency use. However, 9CFR part 106.1 provides provisions for exemption of those requirements:

> "The Administrator may exempt any biological product from one or more of the requirements of this subchapter if he determines that such product will be used by the Department or under the supervision or control of the Department in the prevention, control or eradication of animal diseases in connection with (a) an official USDA program; or (b) an emergency animal disease situation, or (c) a USDA experimental use of the product."

Policies should be developed and implemented to ensure a national framework that quickly allows for importation, evaluation, and use of POC diagnostic assays. Additionally, polices should be in place stating when, where, and by whom POC diagnostics will be used, how results will be reported, and what actions will be taken related to POC diagnostic test results.

## RESOLUTION:

The United States Animal Health Association urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) to develop and implement policies which enable rapid exemption according to 9 Code of Federal Regulations (CFR) Part 106.1 of selected point-of-care (POC) assays from the 9 CFR Part 104 requirements for Permits for Biological Products. Policies should also be developed that address when, where, and by whom POC assays would be used, how those performing assays will be trained, and how POC test results will be reported and used.

**INTERIM RESPONSE:**

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) recognizes the concerns of the United States Animal Health Association (USAHA) and appreciates the opportunity to respond.

Exempting a diagnostic tool for use in a departmental program from licensure, as listed in 9 CFR 106.1, would not lessen the vetting required to ensure the tool is appropriate for the purposes intended.

The current process to allow the importation of diagnostic test kits for research and evaluation, which comprises 9 CFR 104.4, coupled with the movement of these products within the United States under the authorities listed in 9 CFR 103.3, *Shipment of Experimental Product*, has been a successful use of VS' Center for Veterinary Biologics' regulatory flexibility with diagnostic test kits imported for use in emerging diseases. The submission of key information, such as manufacturer and location, as well as production process and sensitivity/specificity data, help to advise VS on acceptable candidates and screening of products prior to actual use.

VS is identifying a cross-unit working group to review recommendations provided by the NAHLN Coordinating Council for consideration when developing policies and procedures for use of point of care testing. The working group will provide draft policies and procedures to the VS Deputy Administrator prior to asking for review and input from state animal health officials.