United States Animal Health Association
2019 Resolution
123rd Annual Meeting
Oct. 24-30, 2019
Providence, RI

RESOLUTION NUMBER: 4, 9, 15, and 16 COMBINED APPROVED AS AMENDED

SUBJECT MATTER: African Swine Fever (ASF)/Classical Swine Fever Surveillance Program and Tissues for Official ASF Testing in National Animal Health Laboratory Network Laboratories

BACKGROUND INFORMATION:

African and Classical swine fever (ASF and CSF) viruses are infectious diseases of pigs and spread readily in pig populations. Neither ASF or CSF are zoonotic diseases and do not affect people. The different ASF and CSF virus genotypes vary in virulence from highly pathogenic strains that cause near 100% mortality, to low virulence strains believed to cause carrier states that can be difficult to diagnose. Clinical signs of ASF and CSF viruses in infected swine are often indistinguishable from any number of other systemic diseases endemic to United States (US) swine.

The recent emergence and ongoing spread of ASF among wild, non-commercial, and commercial pig populations in a growing number of countries presents a substantial risk to swine health and pork production globally. CSF continues to infect pigs in the Caribbean and Japan, as well as several other countries. In the event of an introduction of ASF or CSF into the US, early detection would be paramount to an effective response and recovery effort. Effective and real-time surveillance strategies that utilize state of the art diagnostic technologies are critical components of Foreign Animal Disease (FAD) preparedness.

In recognition of the above, on June 1, 2019, the United States Department of Agriculture (USDA) implemented an active ASF Surveillance Program at USDA, National Animal Health Laboratory Network (NAHLN) laboratories that supplemented an already existing CSF surveillance program. This program tests case-compatible diagnostic lab submissions for the presence/absence of ASF and CSF via a real-time polymerase chain reaction (PCR). This is a tremendous step forward in enhancing ASF and CSF surveillance efforts in US swine. Long-term sustainability and efficiency of this ASF/CSF Surveillance Program and the continuous improvement of all FAD diagnostic capabilities and surveillance efforts at the USDA, NAHLN laboratories is of utmost importance to US pork industry stakeholders.

Pooling tissue samples for real-time PCR testing is a common practice used in group, premises, or herd level diagnostic investigations of swine. Pooling of tissues samples (spleen, lymph node, or tonsil) enhances the cost effectiveness and sustainability of surveillance programs and increases the number of case-compatible submissions that can be tested with the finite amount of funding available.

Some swine facilities do not have a Premises Identification Number (PIN) (e.g., non-commercial or infrequent submitters to veterinary diagnostic laboratories). While the goal

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remains for all producers to have a PIN, removing the requirement for a PIN on laboratory accessions would expand the breadth and reach of this surveillance program to be more inclusive of case-compatible veterinary diagnostic laboratory submissions from all swine operations.

RESOLUTION:

The United States Animal Health Association (USAHA) urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) to validate and approve the items listed below. Collectively, these efforts aim to enhance the cost-effectiveness, sustainability, and breadth of coverage provided by the African Swine Fever (ASF)/Classical Swine Fever (CSF) Surveillance Program.

The USDA-APHIS ASF/CSF Surveillance Program at USDA, National Animal Health Laboratory Network (NAHLN) laboratories shall:

- Validate methods and implement a provision for using pooled samples for ASF/CSF polymerase chain reaction testing from case-compatible diagnostic case submissions, and

- Revise the premises identification number requirement so as not to exclude cases from the ASF/CSF Surveillance Program, provided traceability of the sample is assured.

Foreign animal disease (FAD) diagnostic capabilities and capacities at USDA-APHIS NAHLN laboratories shall:

- Continue to expand the number of ante-mortem sample types (e.g., oral fluids, processing fluids, swabs, serum) approved for FAD diagnostic testing that are well suited for herd level detection and high-throughput test methods at veterinary diagnostic laboratories, and

- Expand the number of assays, testing methodologies (nucleic acid and antibody detection, and sequencing analysis) and reagent supplier options approved for FAD diagnostic testing conducted at USDA-APHIS NAHLN laboratories.

INTERIM RESPONSE:

USDA, APHIS, Veterinary Services (VS) recognizes the concerns of USAHA and appreciates the opportunity to respond. Internal APHIS VS discussions are ongoing to determine policy for pooling tissue samples for ASF/CSF testing.

APHIS initiated a pilot temporarily lifting the requirement to evaluate the effect of not requiring a PIN on submissions and associated data quality. The pilot ended on January 31, 2020. Although the number of cases tested without a PIN rose to 7.7%, no extreme effects were noted regarding the number of samples submitted nor in terms of data quality. However, APHIS thinks that the PIN should stay intact, because it improves and reinforces the importance of traceability. APHIS and industry held multiple discussions, and in light of these discussions, APHIS reinstated the requirement that cases must have a PIN to be eligible for ASF/CSF surveillance testing.

Currently, the swine industry's highest priorities is the validation of diagnostic assays for the detection of ASF and foot-and-mouth disease (FMD) in swine oral fluids. Large scale experimental work at Plum Island Animal Disease Center and the Canadian Food Inspection Agency (CFIA) is underway to answer two pivotal questions to evaluate oral fluids as a sample type:

1) How well does OF reflect overall infection status of the pen?
2) Can we detect ASF in OF before onset of clinical signs?

This work follows smaller scale comparison studies using experimental samples that APHIS VS and CFIA conducted in 2019. As part of this evaluation, APHIS is partnering with industry and CFIA to evaluate the utility of oral fluid samples in endemic countries, including Vietnam. The oral fluids study was extended to the end of February 2020 with results expected by late March 2020.

APHIS National Veterinary Services Laboratories (NVSL) is developing a protocol for antibody testing that could be available for deployment to NAHLN labs in the future. NVSL completed an initial methods comparison to evaluate five commercially available ASF PCR kits; final steps in the methods comparison will require field isolates.

FINAL RESPONSE:

USDA, APHIS, Veterinary Services (VS) recognizes the concerns of USAHA and appreciates the opportunity to respond. Internal APHIS VS discussions are ongoing to determine policy for pooling tissue samples for ASF/CSF testing.
APHIS initiated a pilot temporarily lifting the requirement to evaluate the effect of not requiring a PIN on submissions and associated data quality. The pilot ended on January 31, 2020. Although the number of cases tested without a PIN rose to 7.7%, no extreme effects were noted regarding the number of samples submitted, nor in terms of data quality. However, APHIS believes the PIN should stay intact, as it improves and reinforces the importance of traceability. APHIS and industry held multiple discussions, and in light of these discussions, APHIS reinstated the requirement that cases must have a PIN to be eligible for ASF/CSF surveillance testing.
Currently, the swine industry's highest priority is the validation of diagnostic assays for the detection of ASF in swine oral fluids. Following the completion of a negative cohort to evaluate the use of oral fluids as an aggregate sample for the National Veterinary Services Laboratories (NVSL) NAHLN real-time PCR protocol and determining 100% diagnostic specificity, APHIS continued efforts to evaluate diagnostic sensitivity when using oral fluids as a sample type. Working in collaboration with the Canadian Food Inspection Agency (CFIA), APHIS [(Foreign Animal Disease Diagnostic Laboratory (FADDL) and NAHLN)] is performing experimental work at both the Plum Island Animal Disease Center (PIADC) and the CFIA National Centre for Foreign Animal Diseases in Winnipeg to evaluate oral fluids. With support from the Swine Health Information Center, CFIA and APHIS plan to complete field work in Vietnam, when travel resumes.
In the meantime, APHIS (FADDL, NAHLN, and the Center for Epidemiology and Animal Health) is developing a phased approach for oral fluids to allow for more rapid approvals for use in the case of a U.S. outbreak. APHIS has developed an initial protocol for a NAHLN laboratory pilot study to evaluate the feasibility of testing oral fluid samples, in addition to approved individual samples, in support of ongoing oral fluid evaluation efforts. Based on initial results from the pilot and by February 1, 2021, APHIS will provide an initial protocol to align the pilot study with the established hemorrhagic fevers surveillance plan.

APHIS will develop a tiered strategy for approval of oral fluids for specific use cases in the case of a U.S. outbreak. The completed strategy will be available as soon as possible (date to be determined) with interim drafts shared and discussed during working group meetings and industry discussions as appropriate.

• Pool samples to reduce reagent and personnel resources and decreasing result turnaround time: NAHLN laboratories are approved to pool five blood or tissue samples for surveillance and in case of an outbreak. NAHLN laboratories were provided the updated sample chart, including pooling guidance on July 24, 2020, and APHIS held a call with surveillance laboratories on July 28, 2020, to review pooling protocol. The new protocol will increase NAHLN capacity from testing 40,000 pigs a day to testing up to 200,000 pigs a day.

• Utilize novel sample types to reduce collection time in the field and processing time in the laboratory: APHIS is preparing a recommendation to permit spleen swabs as an approved sample type for ASF/CSF testing. Swabs may be pooled to enhanced throughput.

APHIS is evaluating the utility of blood samples and a final recommendation is anticipated no later than November 1, 2020. Additionally, APHIS is developing a protocol for antibody testing that could be available for deployment to NAHLN laboratories in the future. APHIS has completed an initial methods comparison to evaluate five commercially available ASF PCR kits; final steps in the methods comparison will require field isolates.