The movement of aquatic animals is mired with varied and complex regulations. In the United States (US) the majority of states use the inspection and diagnostic guidance established in American Fisheries Society Fish Health Section’s “Suggested Procedures for the detection and identification of certain finfish and shellfish pathogens” (known as the Blue Book) to regulate domestic movement. For international movement, the majority of countries either follow the guidance provided by the World Organization for Animal Health (OIE) or develop their own import health requirements. This has resulted in American aquaculture producers and exporters having to meet multiple standards and requirements to move their animals as well as having to pay for duplicative and meaningless testing. Currently, both guidance documents, the Blue Book and the OIE Manual of Diagnostic Tests for Aquatic Animals, reference outdated or otherwise inadequate sampling and diagnostic procedures.

The US commercial aquaculture industry needs better diagnostic assays and the ability to reduce testing through options like farm-level testing and the ability to pool specimens. Further, laboratories conducting aquatic animal health testing need a core subject matter expert group, which may make recommendations, as well as coordinate positive control material and share information.

The United States Animal Health Association (USAHA) requests that the United States Department of Agriculture (USDA) form an aquatic animal health diagnostic working group with domestic subject matter experts in the field of fish, mollusks, and crustaceans. This working group will recommend standards and procedures for new assays to be developed and address issues with existing assays. Further, this group will identify gaps in knowledge and find ways to address these gaps, such as the impact of specimen pooling on assay sensitivity and specificity. This group should work closely with the American Fisheries Society Fish Health Section “Suggested Procedures for the detection and identification of certain finfish and shellfish pathogens” (known as the Blue Book) committees, USDA staff, and other federal and state partners to reduce duplicative, meaningless, and over-burdensome testing regulations for aquatic animal movement both domestically and internationally.
USDA, Animal and Plant Health Inspection Service, Veterinary Services (VS) recognizes the concerns of USAHA and appreciates the opportunity to respond. VS has formed an Aquatic Animal Health Diagnostic Working Group. Members of the group initially met in February 2020 during Aquaculture America. The working group planned to meet again in August 2020 in Ames, Iowa, but was unable to do so because of COVID-19. The group has begun regular meetings to discuss fit for purpose testing as well as the need to develop a reference manual of updated protocols using both the OIE Aquatic Manual and the American Fisheries Society Fish Health Section Blue Book as models.

VS has also proposed a specific ad hoc working group to study harmonization of shellfish pathogen testing for specific pathogen surveillance and database development.
RESOLUTION NUMBER:  2       APPROVED

SUBJECT MATTER:    Commercial Aquaculture Health Program Standards

BACKGROUND INFORMATION:

The Commercial Aquaculture Health Program Standards (CAHPS) were initiated by the National Aquaculture Association and developed with the United States Department of Agriculture (USDA) in 2014. The standards set forth a model framework for the health of commercially farm raised aquatic animals. CAHPS recognized and built upon current activities and existing guidelines for health of aquatic animals by establishing uniform standards for United States farmed aquatic animal health and movement.

The United States Animal Health Association applauds the efforts of the USDA, Animal and Plant Health Inspection Service for working with the National Aquaculture Association to develop the CAHPS. We believe that the program must further evolve to benefit all domestic commercial aquaculture, especially with regards to national and international trade. The effectiveness and success of the program requires the cooperation of not only industry but also state and federal entities.

RESOLUTION:

The United States Animal Health Association (USAHA) strongly encourages the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) to engage with states to identify how the Commercial Aquaculture Health Program Standards (CAHPS) may be utilized in conjunction with existing health inspections for animal movement. USAHA recommends that USDA-APHIS-VS engage with states having well established aquatic animal health policies, which could become a national model for the acceptance and integration of CAHPS to meet state regulatory requirements for aquatic animal health.

FINAL RESPONSE:

USDA, APHIS, VS recognizes the concerns of USAHA and appreciates the opportunity to respond. APHIS drafted a five-year VS Aquaculture Business Plan in May 2020, which is built around the concept of CAHPS and focuses on farm-raised aquatic animal health. This plan allows for the “ramp up” of CAHPS and supports a uniform national framework based on science, risk, and feasibility for the aquaculture program to meet the needs of the domestic aquaculture industry.
RESOLUTION NUMBER 3  APPROVED

SUBJECT MATTER:  Import Health Requirements for Live Aquatic Animals

BACKGROUND INFORMATION:

At present, there are only United States (US) federal import health requirements for the importation of live salmonid species and their gametes [United States Fish and Wildlife Service], as well as eight cyprinid species considered susceptible to Spring Viremia of Carp Virus [United States Department of Agriculture (USDA)]. All other live aquatic animals are entering the US with no US federal requirements with regard to animal health. In 2019, USDA responded to the first detection of Tilapia Lake Virus (TiLV), which was linked to infected fingerlings imported from Thailand. These fingerlings entered the US and the destination state legally with no mandatory health requirements, even though the country of origin was known to be positive for TiLV. Further, over the last several years, detections of World Organisation for Animal Health-listed pathogens and other emerging pathogens, such as Red Sea Bream Iridovirus, Infectious Hypodermal and Hematopoietic Necrosis Virus, and Ostr eid Herpesvirus, have been linked to imports. The impact of these detections are felt by domestic industry because of animal loss, facility quarantines, export bans, and the need for enhanced surveillance. Import controls would not be intended to ban trade but to ensure that aquatic animals entering the US are healthy and do not pose risks to domestic aquaculture production or natural resources.

RESOLUTION:

The United States Animal Health Association (USAHA) requests that the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) immediately initiate a comprehensive pathways risk analysis for the introduction of World Organisation for Animal Health-listed pathogens from imported live fish, mollusks and crustaceans. Regarding prioritized pathogens, and with support of the domestic industry, USDA-APHIS-VS should implement appropriate import health requirements necessary to mitigate the risk of introduction.

FINAL RESPONSE:

USDA, APHIS, VS appreciates the recommendation from USAHA and the opportunity to respond. APHIS recognizes the risk of the introduction of OIE-listed and emerging pathogens from imported live fish, mollusks, and crustaceans. As of August 25, 2020, APHIS is conducting six risk evaluations for the following pathogens: infectious
hypodermal and haematopoietic necrosis virus, red sea bream iridovirus, TiLV, decapod iridescent virus, virulent Aeromonas hydrophila, and ostreid herpesvirus-1; the conclusions of which will be used to evaluate appropriate ways to mitigate these concerns, including potential import controls.
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 remains for all
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.

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.
RESOLUTION NUMBER: 5, 17, and 31 Combined APPROVED AS AMENDED

SUBJECT MATTER: Adequate Funding for National Animal Vaccine and Veterinary Countermeasures Bank

BACKGROUND INFORMATION:

The 2018 Farm Bill under section 12101 Animal Disease Prevention and Management:

1. Established the National Animal Disease Preparedness and Response Program (NADPRP), which allows the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service to enter into cooperative agreements with states, universities, industry, and other entities on projects and research to advance animal health.

2. Established the National Animal Vaccine and Veterinary Countermeasures Bank (NAVVCB) to maintain sufficient quantities of vaccine and other countermeasures to help to address an outbreak of foot-and-mouth disease (FMD) or other high consequence foreign animal disease.

3. Reauthorized the National Animal Health Laboratory Network (NAHLN) with authorized appropriations of $30 million per year.

Funding for the first four years ($120 million) is provided up front as no-year money. NADPRP (1 above) must receive a minimum of $5 million for the first four years (of the $120 million) and $18 million (of the $30 million) annually, thereafter ($38 million of the total $150 million).

Of the remaining $112 million in 2018 Farm Bill funding not required to be spent on NADPRP, monies may be dedicated to the NAVVCB (2 above) to provide a robust vaccine and countermeasures bank with priority given to FMD response capabilities and to support diagnostic capabilities through the NAHLN.

Response to a Foreign Animal Disease (FAD) often includes mass depopulation of animals, but the USDA FAD PReP plan for FMD is contingent on vaccination for all but the smallest, localized outbreak. The United States (US) currently does not have access to enough FMD vaccine to handle more than a very small, localized disease event. Worldwide vaccine production is limited, and there is no surge capacity to produce the millions of doses needed to address a large-scale outbreak in the US. The cumulative impact of an outbreak on the beef and pork sectors over a 10-year period would be more than $128 billion. The annual jobs impact of such reduction in industry revenue is 58,066 in direct employment and 153,876 in total employment. Corn and soybean farmers would lose $44 billion and nearly $25 billion, respectively, making the impact on these four
industries alone almost $200 billion. A workable FMD vaccine bank can minimize the impact on the US economy and reduce government costs of a catastrophic FMD outbreak in the US.

RESOLUTION:
The United States Animal Health Association (USAHA) urges the United States Department of Agriculture (USDA) and State Animal Health Authorities to support a total of $92 million for the National Animal Vaccine and Veterinary Countermeasures Bank (NAVVCB), with a minimum of $20 million for each of the first four years and $12 million in the fifth year, of the funding established in the 2018 Farm Bill to provide adequate number of doses of foot-and-mouth disease vaccine and surge capacity. This $92 million for NAVVCB is to include a reasonable stockpile of foreign animal disease testing kits/reagents needed for outbreak response.

Additionally, the 2018 Farm Bill prevention funding the National Animal Disease Preparedness and Response Program (NADPRP) should not be used to fund current USDA, Animal and Plant Health Inspection Service (APHIS) activities with the states nor should it inhibit full appropriation of the National Animal Health Laboratory Network laboratory authorization within USDA, National Institute of Food and Agriculture, Food and Agriculture Defense Initiative and APHIS budgets.

FINAL RESPONSE:

USDA, APHIS, Veterinary Services recognizes the concerns of USAHA and appreciates the opportunity to respond.

In the first round of funding for Section 12101 programs in 2019, APHIS awarded $5.2 million through the NADPRP to support 39 projects in 25 States. The projects will advance the capabilities, capacity, and readiness of the nation’s animal agriculture sector responders through training and exercises. APHIS also awarded $5 million through the NAHLN to support 26 projects in NAHLN laboratories. APHIS announced the 2020 NADPRP and NAHLN funding opportunities in July, with proposals being due by September 14, 2020. Up to $10 million will be targeted toward NADPRP projects focused on increasing practical livestock biosecurity measures or advancing rapid depopulation and disposal abilities to be used during high consequence animal disease outbreaks. Up to $5 million will be directed toward NAHLN projects that enhance test development and validation, emergency preparedness, electronic data management and exercises and drills centered on the laboratory.

To ensure the cattle industry’s FMD vaccine concerns are addressed, in July, APHIS announced a $27.1 million purchase of FMD vaccine antigen concentrate for the NAVVCB. In addition, in August, APHIS announced the availability of a sources sought notice to gather information from diagnostics manufacturers on their ability to supply test kits for three major livestock diseases: FMD, African swine fever, and classical swine fever. Based on the information gathered, APHIS will determine if test kits and/or their components are recommended for inclusion in NAVVCB.
RESOLUTION NUMBER: 7 and 36 Combined          APPROVED AS AMENDED

SUBJECT MATTER: Strengthening the United States Animal Disease Traceability and Disease Prevention Infrastructure

BACKGROUND INFORMATION:
State Animal Health Officials (SAHO) and livestock industry members work collaboratively with the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) to protect the health of the nation’s livestock, and a comprehensive animal traceability system is critical to this collective mission. While many domestic components of the United States (US) traceability system are robust and successful, the current regulatory framework and practices applicable to livestock moving through US ports of entry allow animals from foreign countries to move throughout the US without traceability or the knowledge of state and federal animal health authorities. These traceability gaps may negatively impact trade and the health of domestic livestock by hampering state and federal animal health officials’ ability to effectively manage a domestic or foreign animal disease outbreak.

Language in Title 9 Code of Federal Regulations § 93.405, Health Certificate for Ruminants, only requires imported sheep and goats moving through US ports of entry to be accompanied by accurate certificates of veterinary inspection. Other livestock species are exempt from this requirement. Lack of minimum traceability standards for all imported species enables livestock to be diverted once in domestic markets without the knowledge of SAHOs. The lack of enforceable regulatory language has also impeded APHIS' Investigative and Enforcement Services from being able to take action against persons who knowingly import livestock illegally when cases are referred by SAHOs.

Requiring accurate data on movement documents for imported livestock is critical, but appropriate information sharing between federal officials managing livestock movement through US border ports and SAHOs responsible for overseeing the domestic movement of imported livestock is also imperative to ensure comprehensive animal traceability. SAHOs are not always notified in a timely manner of international livestock movement into their states, and federal animal health officials do not consistently share movement paperwork with state offices. This hampers SAHOs’ ability to meet the expectation of federal partners to properly manage the domestic animal disease traceability program and to trace animals in instances of livestock diversion.

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The United States Animal Health Association appreciates the work that USDA APHIS VS does to protect domestic livestock health and promote a robust animal traceability system. We are optimistic that USDA APHIS VS’ willingness to pursue timely and reasonable regulatory and practice changes at US border ports will further protect domestic livestock from the risks of imported diseases while minimizing regulatory burdens on trade.

RESOLUTION:

The United States Animal Health Association (USAHA) requests the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) to 1) amend the language in Title 9 Code of Federal Regulations to require that every imported livestock animal travel with an official certificate of veterinary inspection containing comprehensive traceability information, including complete individual official animal identification and accurate consignor and consignee physical addresses; and 2) transmit a copy of the certificate of veterinary inspection to the state animal health official of the animal’s destination state within twenty-four hours of the import.

FINAL RESPONSE:

On April 29, 2020, APHIS issued an import alert regarding the use of known invalid destination addresses. This alert notified stakeholders that any animal(s) with a known invalid destination address listed on import documentation will be held at the port of entry, or subject to return to Mexico or Canada if entering via a land border port, until the importer of record provides a valid destination address.

In fiscal year (FY) 2021, APHIS will look to amend the language in title 9 Code of Federal Regulations to ensure the exporting country issued health certificates for all live animals contain comprehensive traceability information including complete individual official animal identification and accurate consignor and consignee physical addresses. Please continue to alert APHIS when SAHOs are informed of persons who knowingly import livestock illegally to support enforcement actions.

In the interim, APHIS has tools to ensure traceability of imported animals and availability of such records to SAHOs. The VS Process Streamlining (VSPS) system allows all SAHOs to view immediately an animal that is imported into the country destined to their State. In FY 2021, APHIS will provide a training webinar and discussion for SAHOs on the utilization of VSPS. However, virtual training specifically for SAHOs was recorded and is located in the VSPS Library: VSPS Training for SAHOs.

The Animal Health Services (AHS) application with mobile capabilities will be released the first quarter of FY 2021 and includes the ability for accredited veterinarians to create interstate certificates of veterinary inspection (ICVI) in a mobile platform. This will allow the ability for ICVIs to be created for imported animals at sorting pens after entry into the United States if required by the State of destination. The Enterprise Messaging Service then allows for sharing the data by messaging it from AHS and VSPS to State and Federal systems as requested.
Additionally, the Animal Health Event Repository (AHER) integrates data received into multiple VS databases and offers the ability for SAHOs to query animal identification numbers to simplify the trace investigation process. States and third-party stakeholders are also beginning to provide data to AHER, expanding the pool of available animal identification number records, which enhances tracing efficiency.
RESOLUTION NUMBER: 8       APPROVED

SUBJECT MATTER: Inclusion of Biosafety Level 3 Necropsy Space in the Process for National Animal Health Laboratory Network Laboratory Participation

BACKGROUND INFORMATION:

The National Animal Health Laboratory Network (NAHLN) supports United States animal agriculture by developing and increasing the capabilities and capacities of a national veterinary diagnostic laboratory network for early detection, rapid response, and appropriate recovery from high-consequence animal diseases.

Beginning in 2016, all laboratories in the NAHLN were transitioned to a new structure with the designations of Levels 1, 2, 3, Affiliate, or Specialty laboratories, as described in the “NAHLN Concept Paper” See (https://www.aphis.usda.gov/animal_health/nahln/downloads/NAHLN_structure_concept_paper.pdf)

The NAHLN Concept Paper describes critical needs and capacities for the various laboratory levels. For example, some Level 1 laboratory responsibilities are:

- Maintain capacity to provide surge testing for disease agents of interest;
- Be fully accredited by the American Association of Veterinary Laboratory Diagnosticians, International Organization for Standardization (ISO) 17025, or by another accrediting body with equivalent standards;
- Have staff members trained in testing procedures and proficiency tested in diseases of interest;
- Have the capability to electronically send diagnostic test results to United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) databases;
- As requested by the USDA, help other laboratories develop and implement Information Technology (IT) capabilities to permit them to communicate testing results with NAHLN;
- Provide and maintain biosafety level 3 laboratory (BSL3) space adequate for work performed;
- Accept samples that originate from other States affected by disease outbreaks, especially those from Level 2 laboratories;
- Have an acceptable periodic review conducted under the oversight of USDA.
The ongoing approval for state laboratories to participate in the NAHLN is described in the NAHLN document “General Process for NAHLN Approval” (Document # WI-NAHLN-0034.01). Processes include:

- Completion of a laboratory capability and capacity assessment (current capabilities, resources, commitment by State, and other relevant factors), in a standardized format, The “NAHLN Laboratory Matrix”, which is largely based upon the NAHLN needs described in the NAHLN Concept Paper.
- USDA, APHIS and USDA, National Institute of Food and Agriculture review and verify the information provided in the laboratory Self-Assessments, and other pertinent information.
  - The information from this assessment is used to establish NAHLN laboratory network level designation for the next fiscal year (Level 1, Level 2, Level 3, Affiliate, or Specialty).
  - Level 1, 2 and 3 laboratory categorizations are used to decide NAHLN funding levels for infrastructure support based on the laboratory level designation assigned.

In 2020, NAHLN proposes adding BSL3 necropsy capacity and capability to the NAHLN Laboratory Matrix as a new criterion for annual evaluation of NAHLN laboratory level designation. This new addition does not enhance the mission of the NAHLN for the following reasons:

1. The primary mission of the NAHLN for early detection, rapid response, and appropriate recovery are not enhanced by BSL3 necropsy space in NAHLN laboratories.
   a. Early detection of foreign animal disease (FAD) from field samples of diagnostic unknowns does not require BSL3 necropsy capacity and capability because diagnostic unknowns sent to the laboratory as a potential index case carcass do not yet have laboratory confirmed FAD, therefore, do not require BSL3 necropsy capacity and capability.
   b. Effective and efficient rapid response to FAD does not require BSL3 necropsy capacity and capability, but rather is better accomplished by submitting samples collected in the field then shipped to NAHLN laboratories as samples, not carcasses. This optimizes biosecurity/biosafety of FAD response activities (samples safer to ship or transport to lab than carcasses) and reduces costs of FAD response activities (samples cheaper to ship to lab than carcasses). The practice of shipping samples to NAHLN labs during FAD response has been the normal procedure of the NAHLN since NAHLN inception.
   c. Appropriate recovery from FAD does not require BSL3 necropsy capacity and capability for the reasons state in “b” above and, more practically, because proof of negative testing does not generate carcasses from FAD mortalities.

2. The addition of BSL3 necropsy laboratory capacity and capability to the NAHLN evaluation laboratory matrix may disadvantage Level 2 laboratories from reaching Level 1 status, and may reduce the number of Level 1 laboratories needed for effective implementation of the NAHLN mission.

**RESOLUTION:**

The American Association of Veterinary Laboratory Diagnosticians and United States Animal Health Association (USAHA) urge the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) and National Animal Health Laboratory Network (NAHLN) to remove Biosafety Level 3 necropsy capacity and capability from
the annual NAHLN laboratory evaluation matrix used in the annual process for NAHLN laboratory approval and laboratory level designation.

FINAL RESPONSE:

USDA, APHIS, VS recognizes the concerns of USAHA and appreciates the opportunity to respond. In 2019, the NAHLN Executive Council approved the NAHLN recommendation to include necropsy space capable of accommodating a 250-pound animal for the highest amount of points in the Lab Space category of the Matrix, prior to the AAVLD/USAHA annual meeting. Based on this resolution, the NAHLN Coordinating Council, as well as the NAHLN Executive Committee, initiated further discussions regarding the inclusion of necropsy space in Biosafety level-3 as a requirement for the highest level of points for the category. The final determination is that the recommendation will stand as originally approved based on the inherent benefits of having BSL-3 necropsy space available in the NAHLN. The absence of BSL-3 necropsy space is not intended to keep an otherwise capable laboratory from reaching Level 1 designation and so has been weighted only a seven on a scale of 1-10.
RESOLUTION NUMBER: 10  
APPROVED AS AMENDED

SUBJECT MATTER:  Adequate Funding for the National Animal Health Laboratory Network

BACKGROUND INFORMATION:

The 2018 Farm Bill under section 12101 Animal Disease Prevention and Management:

1. Established the National Animal Disease Preparedness and Response Program (NADPRP), which allows the United States Department of Agriculture, Animal and Plant Health Inspection Service to enter into cooperative agreements with states, universities, industry, and other entities on projects and research to advance animal health.

2. Established the National Animal Vaccine and Veterinary Countermeasures Bank (NAVVCB) to maintain sufficient quantities of vaccine and other countermeasures to help to address an outbreak of foot-and-mouth disease (FMD) or other high consequence foreign animal disease.

3. Reauthorized the National Animal Health Laboratory Network (NAHLN) with appropriations authorization of $30 million per year.

Funding for the first four years ($120 million) is provided up front as no-year money.

NADPRP (1 above) must receive a minimum of $5 million for the first four years (of the $120 million) and $18 million (of the $30 million) annually, thereafter, ($38 million of the total $150 million).

The $112 million in 2018 Farm Bill funding not required to be spent on NADPRP was intended to be used to provide additional support for the NAHLN (3 above) with the remainder dedicated to the NAVVCB (2 above) to provide a robust vaccine and countermeasures bank, with priority given to FMD response capabilities.

The NAHLN is the frontline for detection of a disease event and provides critical support for disease monitoring during the outbreak and certification of a return to disease absence after the outbreak. The NAHLN has never been fully funded ($30 million per year) at the federal level. In addition, availability of adequate test kits/reagents for foreign animal
disease (FAD) outbreak response testing has been identified as a critical concern in every FAD tabletop exercise conducted.

RESOLUTION:

The United States Animal Health Association (USAHA) urges the United States Department of Agriculture (USDA) to provide at least $5 million from the funding in the 2018 Farm Bill each of the 5 years dedicated as additional support of National Animal Health Laboratory Network (NAHLN) infrastructure and improvements in testing capabilities and capacities.

Additionally, USAHA urges the USDA to assure that the 2018 Farm Bill prevention funding not be used to replace current funding for USDA, Animal and Plant Health Inspection Service (APHIS) activities with the states nor should it inhibit full appropriation of the NAHLN laboratory authorization within USDA, National Institute of Food and Agriculture, Food and Agriculture Defense Initiative and USDA-APHIS budgets.

FINAL RESPONSE:

USDA, APHIS, Veterinary Services recognizes the concerns of USAHA and appreciates the opportunity to respond. On February 7, 2020, USDA leadership received the letter sent by the American Association of Veterinary Laboratory Diagnosticians to members of Congress and USDA leadership with similar requests. APHIS announced the open period for 2020 Farm Bill funding opportunities on July 15, 2020; proposals are due on September 14, 2020. APHIS will direct up to $5 million in funding towards NAHLN projects that enhance test development and validation, emergency preparedness, electronic data management and exercises and drills centered on the laboratory. APHIS will award the funding through a competitive process similar to the process followed successfully in 2019. No further determination for distribution of NAHLN Farm Bill funding has been made to date for years 2021 through 2023.
RESOLUTION NUMBER: 11 APPROVED

SUBJECT MATTER: Abnormal Equine Health Events at International Import Quarantine Facilities

BACKGROUND INFORMATION:

The recent closure of the United States Department of Agriculture’s (USDA) Miami Animal Import Center, in conjunction with previous disease outbreaks associated with imported equidae, has raised concerns amongst animal health officials and the industry overall. Notably, between November 2018 and April 2019, the USDA identified over 200 sick horses imported from the European Union. Management of imported equidae displaying signs of ill health at an Animal Import Quarantine facility is critical for protecting the health of the United States equine population.

RESOLUTION:

The United States Animal Health Association (USAHA) urges the USDA, Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) to take the following actions at all International Animal Import Quarantine Facilities:

1) Develop standard operating procedures for import quarantine facility staff and veterinarians to identify, investigate, document, report, and track cases of abnormal equine health events.

2) Develop a standardized electronic system to consistently and uniformly record details of each abnormal health event which should minimally include vital signs, physical exam findings, and date and time of examination.

3) Identify abnormal health events/parameters in equines and conduct further assessment to classify such as contagious, non-contagious, or other.

4) Adopt a system to accurately evaluate each equine displaying clinical signs of disease, to clinically evaluate each case of a potentially infectious disease, to identify the infectious agent, and to determine the possible risk of exposure to other imported equines. Protocols should include diagnostic testing at owner/agent’s expense, based on the syndromic clinical presentation.

5) Notify State Animal Health Officials in both the state of destination and the state in which the equine is currently located of any abnormal equine health events identified and classified as possibly infectious. The notification should include any potentially exposed cohorts with report prior to release from quarantine.
6) Modify VS 17-30 (Report of Animals, Poultry, or Eggs Offered for Importation) such that it documents the potential risk of exposure to infectious disease for any equines associated with the abnormal health event.

7) Develop and implement a compliance agreement between owners/agents and the USDA that includes recommended biosecurity measures for destination premises.

8) Track all abnormal health events for equines being imported into the United States and report such events to equine stakeholders if requested or applicable.

**FINAL RESPONSE:**

USDA, APHIS, VS appreciates the recommendation from USAHA and the opportunity to respond. APHIS recognizes the concern of managing imported horses that arrive ill or become ill while in Federal import quarantine. APHIS has made improvements to the current national standard operating procedures (SOP) by increasing communication with State Animal Health Officials (SAHOs) on these standards and increasing sick horse notifications.

APHIS provided the revised national SOP to the USAHA committee on equine in August 2020. This SOP strengthens the procedures completed by port personnel for sick horses in quarantine and outlines required communication and notification to SAHOs in the State of final destination. The SOP has been received positively by the committee, acknowledging that the national SOP addresses many of the recommendations from the USAHA Committee on Equine working group.

In addition, APHIS encourages States to utilize the VS Process Streamlining (VSPS) system. This system allows all SAHOs to view information immediately when an animal is imported into the country destined for their State. APHIS will provide opportunities in fiscal year 2021 including a webinar to discuss how VSPS can be used for State officials. APHIS prerecorded videos located in the VSPS library are specifically geared towards SAHOs on how to access VSPS. APHIS will continue to modify and improve information collection, tracking, and reporting on cases of sick horses to enable timely notification to officials in exporting countries and press for corrective actions to reduce the number of sick horses exported to the United States.
RESOLUTION NUMBER: 12  APPROVED

SUBJECT MATTER: Contagious Equine Metritis Import Quarantine Program State Reviews

BACKGROUND INFORMATION:

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS), initiated a review of the United States’ Contagious Equine Metritis (CEM) import program in 2007. The resulting report included comments describing program deficiencies regarding regulatory oversight and accountability.

The USDA’s current method of assessing the infrastructure and relevance of approved state CEM programs remains unclear. Thus, the review team’s report recommended that the USDA’s CEM Coordinator devise a more coherent system of review of states approved for the CEM Import Quarantine Program. To date, no reports of reviews conducted by the USDA regarding current state CEM programs have been received. Furthermore, state CEM coordinators agree that in order to accurately identify CEM carrier stallions, it is crucial that all stallion breeding’s be observed by regulatory personnel. Deficits in the CEM program could put domestic equine populations at an increased risk of disease and affect the trade status of the United States equine industry; it is imperative to implement credible and measurable means of periodically ensuring that all facilities within approved states conform to and remain compliant with the established standards.

RESOLUTION:

The United States Animal Health Association (USAHA) urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) to conduct on-site visits and reviews of states approved for Contagious Equine Metritis (CEM) import quarantine. The review should include an assessment of the state’s regulatory procedures and processes, including but not limited to direct state or federal oversight of test-breeding of stallions and the standard operating procedures utilized by CEM import quarantine facilities. Furthermore, the USAHA requests that the USDA-APHIS-VS provide a report of state reviews at the annual USAHA Committee on Equine meeting and have this report available to all equine stakeholders.

FINAL RESPONSE:

USDA, APHIS, VS appreciates the recommendation from USAHA and the opportunity to respond. The APHIS National CEM program incorporates specific import requirements for
horses imported from CEM-affected regions and for CEM quarantine and testing completed in State-approved facilities.

All components of the CEM program are being evaluated. On January 1, 2020, the updated guidance document for CEM testing at approved quarantine facilities became effective. As part of this guidance, all approved States signed a memorandum of understanding (MOU) agreeing to comply with CEM quarantine and testing requirements as outlined in title 9, Code of Federal Regulations (CFR), section 93.301. At this time, all States comply with requirements in the MOU and the CFR. We look forward to conducting State reviews if noncompliance should occur.

Thoroughbred horses imported for permanent entry from France, Germany, the United Kingdom, and Ireland may be imported under a CEM testing exemption if all pre-export requirements have been fulfilled. APHIS is continuing discussions with the above countries to ensure pre-export testing and movement restrictions are upheld for thoroughbred horses to continue under this exemption.

APHIS is committed to the National CEM program and is working to improve this program so that horses from CEM-affected regions do not endanger the U.S. domestic equine population or industry.
RESOLUTION NUMBER: 13  APPROVED

SUBJECT MATTER: Equine Viral Arteritis International Import Requirements

BACKGROUND INFORMATION:

Equine Viral Arteritis (EVA) has significantly impacted international trade in equidae and equine semen. The import control policies of most countries currently deny entry to carrier stallions and Equine Arteritis Virus (EAV) infective semen because of the associated disease risks. Currently, the United States (US) is the only major equine-breeding country without an import control policy for EVA.

In a serosurvey conducted as part of the United States Department of Agriculture (USDA) National Animal Health Monitoring Systems Equine 1998 study there was a low seroprevalence of EAV infection in most United States equidae as they have never been exposed to the virus. Thus, the vast majority of the US equine population could be considered completely susceptible to natural infection. This was illustrated by the occurrence of a major outbreak of EVA in 2006, primarily in Quarter Horses. The virus spread widely based on shipment of infective semen and dispersal of mares and foals after completion of breeding of mares with infective semen.

The absence of any restrictions on the import of carrier stallions or EAV infective semen into the United States has greatly increased both the likelihood of the virus becoming more widely disseminated in the nation’s equine population and the risk of economically damaging outbreaks of EVA. Importations of EAV carrier stallions and infective semen not only augments the number of carrier stallions in the breeding population at large but also increases the potential for disease outbreaks through the introduction of more highly virulent strains of EAV, previously exotic to the country.

RESOLUTION:

The United States Animal Health Association urges the United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services to develop, implement, and enforce Equine Viral Arteritis import testing requirements pertaining to equine semen and stallions in accordance with the World Organisation for Animal Health (OIE) Code Chapter for Equine Arteritis Virus infection.

FINAL RESPONSE:

USDA, APHIS, VS appreciates the recommendation from USAHA and the opportunity to respond. APHIS recognizes the concern for the introduction and further dissemination of
highly virulent strains of EVA through importation of possible infective equine semen and carrier stallions into our equine domestic population. In accordance with the agreement of Sanitary and Phytosanitary Measures (SPS) through the international treaty of the World Trade Organization (WTO), the United States must have an active domestic surveillance program and be able to show control of disease prior to adopting international import restrictions. Therefore, APHIS recommends establishing a working group with USAHA to review the current EVA domestic surveillance and sanitary concerns. Under this working group, APHIS will provide guidance on appropriate WTO SPS measures for achieving domestic control of disease and collaborate with USAHA to update the domestic surveillance program standards.

In addition, APHIS would like to collaborate with USAHA to increase communication efforts with the U.S. equine industry by developing outreach materials that can be posted on USDA and USAHA websites. The materials will focus on notifying stakeholders of disease concern and how to prevent the domestic and international spread of EVA.
RESOLUTION NUMBER: 18  APPROVED

SUBJECT MATTER:  Valid Sampling Methods and Protocols for Feed and Feed Inputs

BACKGROUND INFORMATION:

The incursion of foot and mouth disease virus (FMDV), classical swine fever virus (CSFV), and African swine fever virus (ASFV) into the United States (US) would result in the immediate loss of export markets for live swine, pork, and pork products. A Center for Agricultural and Rural Development (CARD), Food and Agricultural Policy Research Institute (FAPRI) study led by Dr. Dermot Hayes, economist at Iowa State University, estimated that in the first year of an ASF outbreak in the United States revenue loss by commodity would be $8 billion for pork, $4 billion for corn and $1.5 billion for soybeans.

Peer-reviewed research has demonstrated survival of ASFV and other swine diseases in animal feed ingredients1 and ASFV transmission in feed2. To better understand and address the risk of pathogen introduction through feed, the US pork industry has helped convene a feed risk task force that includes industry stakeholders, the United States Department of Agriculture and the Food and Drug Administration. The task force has identified gaps in knowledge and subsequent research needs that include the development of diagnostic testing capability for feed and feed ingredients and the development of a response plan that will support feed ingredient monitoring for foreign animal disease contamination. Research to address these gaps has been funded by the Swine Health Information Center and the National Pork Board. It is expected that the research results will provide information that will help in the development of valid sampling methods and protocols for foreign feed and feed inputs.


RESOLUTION:

The United States Animal Health Association (USAHA) urges the Food and Drug Administration (FDA), Center for Veterinary Medicine and United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) to work with the United States (US) pork industry to develop valid sampling methods and protocols to detect pathogens in foreign feed and feed inputs that can be applied at the point of embarkation to the US or upon arrival at the port of entry.

FINAL RESPONSE:
USDA, APHIS, VS recognizes the concerns of USAHA and appreciates the opportunity to respond. APHIS and FDA continue to work with industry and academic partners on the feed risk task force to identify available data and gaps in information that limit the development of valid sampling methods and protocols to detect pathogens in foreign feed and feed inputs.

The task force and a panel of experts participating in a recently completed structured expert elicitation recognized there is a lack of data describing the likelihood of feed contamination and the feed ingredients likely to be contaminated by specific pathogens of concern. These needed data are foundational to the development of valid sampling methods and protocols designed to detect pathogens in foreign feed and feed inputs.

Following the September 2019 meeting, regular discussions have occurred between APHIS and FDA. APHIS continues to investigate the science and feasibility of regulatory options. Specific options considered include a permit process, and possible regulations. However, there are many scientific and technical questions that need to be addressed as well as logistical challenges that must be considered before APHIS proceeds with any of the possible action items. Limited personnel resources, ongoing scientific developments, regulatory requirements, evaluation of potential costs to the regulated industry, time necessary to implement regulatory actions, and the response to the COVID-19 outbreak have delayed a final determination.
RESOLUTION NUMBER: 19      APPROVED

SUBJECT MATTER: Efficient Diagnostic Sample Validation and Approval for Foreign Animal Diseases of Swine

BACKGROUND INFORMATION:

Swine oral fluids have been used extensively for disease surveillance in swine populations\(^1\) and pen-based oral fluid samples improves detection over single-animal testing\(^2\). Since 2011, the Pork Checkoff has funded 9 research studies related to assay development, diagnostic performance, and validation of swine oral fluids for foreign animal diseases. The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Services, Veterinary Services has completed a series of swine oral fluid validation research projects and is currently working on a study looking at pen sensitivity. The Swine Health Information Center, through a USDA Foreign Agricultural Service grant, will fund research into field validation of swine oral fluids for African swine fever (ASF). Research into other aggregate samples types have been funded by the Pork Checkoff to validate meat juice for the detection of antigen and antibody for ASF. Swine processing fluids are gathering more interest as an aggregate sample collected during tail docking and castration to monitor for endemic diseases, and it is anticipated that research will be funded to evaluate this sample type for foreign animal disease (FAD) detection. It is important as the pork industry evolves and adopts aggregate sampling that these sample types are validated and approved by USDA for FAD surveillance prior to and after an FAD outbreak.


RESOLUTION:

The United States Animal Health Association (USAHA) urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) to work with United States pork industry to validate and approve swine oral fluids, swine processing fluids, and meat juice for detection of antigen and antibody for classical swine fever, African swine fever and foot and mouth disease.
FINAL RESPONSE:

USDA, APHIS, VS recognizes the concerns of USAHA and appreciates the opportunity to respond. VS recognizes that the swine industry’s highest priority is the validation of diagnostic assays for the detection of ASF and foot-and-mouth disease in swine oral fluids. APHIS is in the process of evaluating oral fluids as described in the response to resolution number 4, 9, 15, and 16 combined: *ASF/Classical Swine Fever Surveillance Program and Tissues for Official ASF Testing in National Animal Health Laboratory Network Laboratories*. Evaluation of further sample types such as processing fluids and meat juice are under consideration. Results obtained through evaluation of oral fluids will be used to guide plans for evaluation of these other sample types.
RESOLUTION NUMBER: 21  APPROVED

SUBJECT MATTER: Evaluating and Recognizing Compartments

BACKGROUND INFORMATION:

In April 2018 the United States Department of Agriculture’s (USDA), Animal and Plant Health and Inspection Service (APHIS) notified stakeholders that the agency is proposing criteria that will be used to evaluate and recognize livestock compartments in other countries. In this announcement APHIS proposes that the evaluation criteria for compartmentalization will be similar to what the agency already uses for regionalization requests with a few differences. The information gathered from the evaluation of the proposed criteria, combined with site visits from agency personnel, would allow “APHIS to determine whether the animals within the compartment are managed in a way that keeps them distinct and separate from other animal populations within the country”.

Prior to China’s report of African swine fever (ASF) in August 2018, the United States (US) pork industry had been heavily engaged in the development of the Secure Pork Supply (SPS) Plan, a business continuity plan for pork producers. The plan incorporates principles specific to compartmentalization and could serve as a mechanism for implementing compartmentalization plans for the pork industry in the event of an outbreak of a foreign animal disease. Since August 2018, the US pork industry has stood up multiple groups that are addressing ASF prevention, response and business continuity. Better understanding of compartmentalization has been a common theme among these groups. An open frank dialogue between industry and federal animal health officials regarding compartmentalization, the proposed criteria, and how compartments are evaluated and recognized would be beneficial.

RESOLUTION:

The United States Animal Health Association (USAHA) urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) to host a meeting with the United States pork industry and State Animal Health Officials to discuss the proposed criteria that will be used to evaluate and recognize livestock/livestock products compartments domestically and internationally.
FINAL RESPONSE:

USDA, APHIS, VS thanks the USAHA for seeking to collaboratively address compartmentalization concepts in a proactive manner. Compartments are intended to promote safe trade by mitigating the risk of animal disease transmission while allowing impacted markets to recover from animal disease outbreaks. Thus, APHIS welcomes the opportunity to continue discussions with swine stakeholders regarding development and implementation of compartmentalization in the swine sector in the United States.

APHIS personnel continue to engage in conversations with industry representatives regarding compartmentalization, which is based on an internationally recognized set of audited processes and standards to assure safe trade in live animals and products in the face of trade-restricting disease outbreaks, such as African Swine Fever (ASF). APHIS also continues to engage in additional continuity of business discussions with swine industry representatives.

APHIS will schedule a meeting (in a virtual format due to COVID-19 restrictions and concerns) to discuss with the U.S. swine industry opportunities for compartmentalization prior to an outbreak to facilitate trade in response to a domestic ASF outbreak. The planned outcomes of this meeting will include actionable “next steps” for utilizing compartmentalization as a viable market enhancement for pork industry stakeholders wishing to pursue it.
RESOLUTION NUMBER: 22  APPROVED

SUBJECT MATTER: Stop Movement – Criteria for Implementing and Releasing

BACKGROUND INFORMATION:

In 2018 and 2019, at the request of the United States pork industry, the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) National Training and Exercise Program (NTEP) hosted a series of four exercises to improve preparedness and response to African swine fever (ASF). The pork industry appreciates USDA, APHIS, VS prioritizing these exercises which were viewed by the industry as positive experiences that highlighted gaps to be addressed cooperatively by industry and state and federal animal health officials. One gap identified by these exercises is the need for specific criteria for implementing and releasing a national 72-hour stop movement ban. The United States pork industry is concerned that in the face of an ASF outbreak there is no agreed upon criteria for re-starting swine movements once a 72-hour movement ban is implemented. This lack of criteria will result in the extension of a national movement ban past 72 hours resulting in severe welfare and business ramifications over and above the impacts of the disease itself on production. For the swine industry that moves over a million pigs on any given day to harvest and for production purposes, it is important that industry, state and federal animal health officials undertake a cooperative approach to develop the criteria for releasing movement bans.

RESOLUTION:

The United States Animal Health Association (USAHA) urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) to work with the United States pork industry and state animal health officials to develop criteria for implementing and releasing national movement standstills due to the occurrence of a trade and commerce limiting foreign animal disease of swine.

FINAL RESPONSE:

USDA, APHIS, VS recognizes the concerns of USAHA and appreciates the opportunity to respond. APHIS is committed to continuing to work with the United States pork industry and State Animal Health Officials (SAHOs) to ensure business continuity should there be
a foreign animal disease outbreak in swine and to develop goals and criteria for any movement standstills.

On March 6, 2020, USDA’s Under Secretary for Marketing and Regulatory Programs, Greg Ibach, announced USDA’s action plan if African Swine Fever (ASF) virus is detected in the United States. Upon ASF virus confirmation by the National Veterinary Services Laboratories the Secretary of Agriculture will, among other actions:

- Take immediate steps to declare an Extraordinary Emergency; and
- Issue a National Movement Standstill of at least 72 hours with a detection in domestic swine or feral pigs.

APHIS produced the *ASF Response Plan: The Red Book (April 2020)* reflecting these policies and describing the guidance stakeholders can expect from APHIS in the event of a movement standstill.

Specifications of issuance will at least be defined for:

- A specific geographical area or boundary (e.g., nationwide or other);
- A specific requirement that all live swine in transit at issuance must reach a destination;
- A specific time indicating the duration of a standstill (e.g., 72 hours);
- A specific list of what items are restricted from movement (e.g., live swine and germplasm); and
- A specific list of what items are exempt from movement restrictions (e.g., negligible risk Food Safety and Inspection Service-inspected products).

The Agency has also developed and distributed a concept of operations for the first 72 hours of an ASF outbreak. This document is under review with SAHOs and other stakeholders participating in weekly ASF Working Group meetings. The document, *ASF Response: Chronology and State Checklist*, is posted at [www.aphis.usda.gov/fadprep](http://www.aphis.usda.gov/fadprep).

The *ASF Response: Chronology and State Checklist* specifies:

- Purpose for the National 72-hour Movement Standstill
- Specifications and standards for the Movement Standstill
- Options for “Hour 73 Decisions”
- Summary table of regulatory actions for ASF outbreak
RESOLUTION: 24 APPROVED

SUBJECT MATTER: Chronic Wasting Disease Amplification Assay Approval

BACKGROUND INFORMATION

There are currently two official tests approved by the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) for chronic wasting disease (CWD) diagnostics: immunohistochemistry (IHC) and enzyme-linked immunosorbent assay (ELISA).

Early detection of CWD is critical for wild, farmed, and captive cervid disease management. Tests that can detect prions earlier in the course of infection than those currently available would enhance intervention and could potentially lead to better outcomes. Additionally, tests that are more sensitive and could potentially be used with other tissues and biofluids, such as those from live or hunter-collected carcasses, would be extremely useful.

These tests, known as amplification assays, are used in human diagnostics at present. Several federal and university laboratories have been using real-time quaking induced conversion (RT-QuIC) and protein misfolding cyclic amplification (PMCA) for influential CWD research. These assays have advanced our knowledge of disease pathogenesis and prion shedding.

Despite their documented increased sensitivity, these assays have not been evaluated by the USDA, APHIS, VS, National Veterinary Services Laboratory or Agricultural Research Services for approval to be used by National Animal Health Laboratory Network and state veterinary diagnostic laboratories. A recent survey of diagnostic laboratories with current IHC or ELISA capabilities indicated an overwhelming willingness to use the RT-QuIC platform if it was approved by USDA.

RESOLUTION

The United States Animal Health Association (USAHA) urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) to evaluate the utility of real-time quaking induced conversion (RT-QuIC) as an official test for Chronic Wasting Disease (CWD). If this CWD test demonstrates acceptable
sensitivity and specificity, we urge USDA to approve the assay to be used by the National Veterinary Services Laboratory and National Animal Health Laboratory Network approved veterinary diagnostic labs. We encourage USDA-APHIS to work with the United States Department of the Interior United States Geological Survey (USGS) to determine an appropriate source of recombinant prion protein for use in RT-QuIC assays that will be provided to approved NAHLN labs at a minimum cost.

FINAL RESPONSE:

USDA, APHIS, VS recognizes the concerns of USAHA and appreciates the opportunity to respond. Due to significant interest from stakeholders, VS is evaluating the appropriateness of using the RT-QuIC assay as an official ante and/or postmortem CWD diagnostic test that would be used by VS, or in partnership with NAHLN laboratories.

VS is collaborating with ARS, USGS, and the National Institutes of Health to generate a standardized RT-QuIC protocol and the data necessary to evaluate the sensitivity and specificity of the RT-QuIC assay for detection of CWD in ante mortem rectal and tonsil biopsies, as well as post mortem medial retropharyngeal lymph nodes. Issues that need to be addressed include the following: lack of a commercially available testing substrate suitable for widespread use (currently this assay is limited to research use), lack of a standardized kit, and challenges associated with procuring the correct, clean sample tissues required for the assay under field conditions. We look forward to further discussion, should this CWD test demonstrate its utility as an official CWD diagnostic assay.
BACKGROUND INFORMATION:
While the National Scrapie Eradication Program (NSEP) has been successful in decreasing the prevalence of scrapie in the United States, eradication of scrapie has not yet been achieved. With all disease eradication programs, as prevalence of the disease declines, the ability to identify the remaining cases becomes an ever greater challenge. With the 2019 publication of the NSEP standards, continued discovery of unique features of goat scrapie, improved live animal diagnostics and understanding of nonclassical scrapie are needed to achieve scrapie eradication.

We appreciate that scrapie program leaders have incorporated scientific discovery into pilot projects and the evolution of eradication program standards. Scrapie research continues to be valuable in efforts toward scrapie eradication. Research on the genetics of scrapie susceptibility/resistance in sheep and goats, differences in clinical signs and incubation periods in sheep and goats and live animal diagnostics are of continued importance. Research on the identification, diagnosis and epidemiology of nonclassical scrapie is also vital to achieving eradication of classical scrapie in the United States. Given the long incubation period of the disease, scrapie research requires multi-year commitment to carry out research on the epidemiology and pathogenesis of scrapie infection.

RESOLUTION:
The United States Animal Health Association (USAHA) urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) and the USDA, Agricultural Research Service to work together to continue research into the pathogenesis, clinical signs, diagnosis and genetic resistance to disease of scrapie in sheep and goats, and validate and implement new approaches into the National Scrapie Eradication Program.

FINAL RESPONSE:
USDA, APHIS, VS understands the concerns of the USAHA and appreciates the opportunity to respond. VS is evaluating using genotype to focus diagnostic testing on more susceptible sheep. The National Veterinary Services Laboratories (NVSL) is conducting a pilot project, in collaboration with a National Animal Health Laboratory Network laboratory. The project uses swabs taken from the brain after the obex has been
removed from the samples, then it is ran on high throughput PCR to determine scrapie resistance. Determining the genetic status of the submitted sample will allow the laboratory to focus resources on genetically susceptible animals leading to reduced costs for the slaughter surveillance program.

VS is also developing genotype testing for goats. Currently, there are two ongoing goat projects. The first project, with 3,000 goats, is designed to determine the genetic susceptibility of the U.S. goat herd to classical scrapie. The National Veterinary Services Laboratories (NVSL) is receiving samples from all 50 states, proportional to their required scrapie surveillance numbers. Utilizing this data, NVSL is developing a real-time PCR based assay to enable more cost effective and rapid characterization of susceptible animals. NVSL is working with and modifying the assay developed by Canada. The second project is related to the National Animal Health Monitoring System (NAHMS). NVSL has received and characterized over 4,000 goat samples from NAHMS’ participants. The results will be released to the participants. These projects will achieve two objectives: 1) build a background database of the frequency of susceptible scrapie alleles in the United States and 2) build capacity and experience running the test. The samples collected will provide an enough samples to validate the new real-time PCR assay. Both are critical components of strengthening the goat scrapie eradication program. These projects for goats are ongoing and completion is expected in approximately one year.
Q-Fever is a zoonotic disease caused by the bacterium *Coxiella burnetii*. Coxiella infection is found in many species in many countries of the world, including the United States (US). The disease is a major cause of abortion in sheep and goats, which results in significant economic losses to producers, but also results in significant risk of transmission to human beings. Exposure to the products of abortion or raw milk products either directly or through environmental contamination poses a significant public health risk, as demonstrated by the large-scale 2005-2011 Q-fever epidemic (human and goat) in the Netherlands.

Currently there is no vaccine available in the US to prevent *Coxiella burnetii* infection or abortion in sheep and goats. Such a vaccine is available in Europe. The availability/approval of a safe and effective sheep and goat vaccine for *Coxiella burnetii* in the US would serve to safeguard human health and prevent production losses due to this potentially devastating disease. Humans not in direct contact with aborting animals also face some risk of indirect environmental exposure, so effective vaccination of sheep and goats could play a key role in minimizing human exposure. Additionally, the availability and approval of a safe and effective human vaccine would provide protection for those with occupational risk of exposure to *Coxiella burnetii*.

The United States Animal Health Association approved Resolutions on this matter in 2013 and 2014. Despite willingness of United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, Center for Veterinary Biologics to work with companies to approve vaccines in the US, no companies have come forward requesting approval and challenges remain for approval of import of effective vaccines, especially given the select agent listing of this agent, which requires Biological Safety Level (BSL)-3 facilities for research. Continued work toward import of vaccines as well as development of strategies for domestic production of *Coxiella burnetii* vaccines which would prevent the disease as well as the shedding of the organism are vital to reducing the impact of Coxiella infections in animals and man through a One Health approach. There is a need for development of animal models of placental accumulation and shedding of *C. burnetii* to facilitate rapid screening and testing of vaccine candidates. Specifically, we recognize the need for the construction of a mouse model of placental accumulation utilizing BSL-2-approved Nine Mile phase II clone 4 (RSA 439) *C. burnetii* to facilitate rapid screening of vaccine and treatment candidates in low cost environment. These will support the development of a full virulence (phase I) model of *C. burnetii* placental accumulation and
shedding to test vaccine and treatment candidates in preparation for efficacy testing in ruminant livestock.

RESOLUTION:

The United States Animal Health Association (USAHA) encourages the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS), Center for Veterinary Biologics (CVB) to continue to work to facilitate the licensure or importation of a safe and effective Q-Fever (Coxiella burnetii) vaccine for sheep and goats.

In addition, USAHA urges the USDA, Agricultural Research Service (ARS) to continue development of research models that could lead to the development of vaccines in the United States; the development of tests for accumulation and shedding of Coxiella burnetii; and identification of genetic tools for improved control of Coxiella infections, including reduced shedding. USDA-ARS should pursue vaccine candidates that can be cost-effectively produced in a Biological Safety Level-2 facility.

FINAL RESPONSE:

USDA, APHIS, VS, recognizes the concerns of the USAHA and appreciates the opportunity to respond. VS CVB stands ready to evaluate any requests for either a domestic license, or for a permit to import the vaccine from outside of the United States. To date, CVB has not received any applications for either a license, or a permit to import vaccine.
RESOLUTION NUMBER:  28       APPROVED

SUBJECT MATTER:   Scrapie Eradication Program–Animal Identification

BACKGROUND INFORMATION:

The National Scrapie Eradication Program (NSEP) relies greatly on owner compliance to identify their animals as they leave the farm for exhibition or sales. No-cost official ear tags have greatly encouraged identification (ID) and thus encourage producer premises registration in the scrapie database and program compliance. There have been a multitude of problems noted with the use of official metal program tags such as infection, poor retention, difficulty in accurately recording the numbers, and safety hazards when shearing. With the publication of the interstate movement rule which requires the same ID requirements of goats as currently exist for sheep, the next few years are critical in encouraging goat and sheep producer compliance regarding ID and tagging. The industries feel strongly that, at a minimum, the provision of a limited number of no-cost official plastic tags will incentivize new goat and sheep producer compliance. In addition, the industries do not want to compromise the NSEP that has been built over the past 18 years at an expense of more than $260 million.

RESOLUTION:

The United States Animal Health Association (USAHA) urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) to continue to provide, at a minimum, a limited number of no-cost official plastic tags to producers enrolling in the National Scrapie Eradication Program for the first time. USDA-APHIS would provide the no-cost ear tags, but producers would be responsible for acquiring an applicator. Further, USAHA urges USDA-APHIS to continue to provide no-cost tags to markets and dealers.

FINAL RESPONSE:

USDA, APHIS, Veterinary Services recognizes the concerns of USAHA and appreciates the opportunity to respond. As agreed at the October 2019 stakeholder meeting, APHIS will continue to provide a limited number of plastic tags to new producers and metal tags to markets and dealers through fiscal year (FY) 2021. Contracts are in place to accomplish this goal. Due to an increase in the cost of metal tags, APHIS may further limit the number of tags provided to markets and dealers in FY 2021.
RESOLUTION NUMBER:  30 APPROVED

SUBJECT MATTER: National Poultry Improvement Plan Staffing

BACKGROUND INFORMATION:

The United States Department of Agriculture, Animal and Plant Health Inspection Service, National Poultry Improvement Plan (NPIP) is the federal government’s poultry disease control program administered in cooperation with state animal health officials and poultry producers. Currently, out of a national staff of five, there are three scientific positions in the NPIP and two of these are vacant. The NPIP Senior Coordinator position is filled, but the Compartmentalization Veterinary Medical Officer and the NPIP Authorized Laboratory Coordinator positions remain vacant.

Since its origins in 1935, the NPIP has grown tremendously due to its long history of success. The effectiveness of the program’s unique industry-driven structure has made it the home for controlling diseases far beyond what the program creators envisioned. As we saw following the Highly Pathogenic Avian Influenza outbreak in 2015-17, the multibillion-dollar United States poultry industry relies on the NPIP to monitor and respond to many of the most impactful diseases of poultry that negatively impact the poultry and product movement regionally and internationally. The role of these positions is vital.

Recently, the NPIP has expanded to include: shifting from oversight of hatchery and breeder monitoring to oversight of the entire commercial poultry industry for avian influenza; compartmentalization; expansion of laboratory workshops; and the newly mandated biosecurity audits. These programs along with the 2020 NPIP Biennial Conference magnify the impact of these vacancies. For the continued success of the program there is an urgent need to bring the NPIP office to full capacity.

RESOLUTION:

The United States Animal Health Association (USAHA) requests that the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) expedite the process to hire the best qualified Compartmentalization Veterinary Medical Officer and the National Poultry Improvement Plan (NPIP) Authorized Laboratory Coordinator for the positions located at the NPIP office.
FINAL RESPONSE:

USDA, APHIS, VS is pleased to report a new hire for the NPIP staff. In addition to Dr. Kathryn Burden, who joined the NPIP team on February 3, 2020, NPIP welcomed Dr. Savannah Thomas as the NPIP Compartmentalization Coordinator on August 17, 2020. Dr. Thomas' background in poultry medicine and commercial poultry production brings a wealth of information and perspective to the NPIP team and will aid her in managing all aspects of the compartmentalization program.
RESOLUTION NUMBER: 32  APPROVED

SUBJECT MATTER: Removal of Select Agent Status for Brucella species

BACKGROUND INFORMATION:

In order to protect the nation from terrorist attacks, select agent regulations restrict possession, transfer, and use of select agents and toxins. The restrictions have been highly effective in limiting access to dangerous agents and toxins by unauthorized individuals. Unfortunately, these same restrictions have limited opportunities for important research on Brucella spp., including B. abortus, B. melitensis, and B. suis. B. abortus is a disease endemic in Greater Yellowstone Area (GYA) wildlife, while B. suis is endemic in feral swine populations throughout the United States (US), and B. melitensis is a foreign animal disease that has successfully been kept out of domestic livestock and wildlife populations in the United States.

A recent paper published by Olsen et. al documents that Brucella spp. can be removed from the biological select agent and toxins list based on clinical, biological, and epidemiological properties of the bacteria. In particular, the paper highlights that Brucella spp. are readily available in endemic areas, thus easily attained by individuals or groups with nefarious intentions. Previous reports estimating human morbidity and mortality in the event of a Brucella bioweapons attack did not adequately consider the fact that brucellosis is the most common zoonotic infection reported in humans annually. Humans are considered dead end hosts for Brucella and are typically infected from exposure to animal reservoirs or animal products. Additionally, previous reports have listed the infectious dose for Brucella to be 10 to 100 bacteria, but research in closed environments indicate that aerosol exposure to a much higher concentration of bacteria is required to result in infection; thus, use of Brucella under natural conditions as a bioweapon would likely result in a limited to negligible rate of infection in humans or animals.

Costs associated with the effective eradication of swine and bovine brucellosis in the US between 1934 and 1998 are conservatively estimated to be over 3 billion dollars. The persistence of brucellosis in wildlife reservoirs with an expanding terrain both within the GYA and the greater US has resulted in potential incursions of the disease into the national domestic cattle and swine herds. A limitation on research due to the select agent status of Brucella spp. has reduced the capacity of research institutions to study Brucella under field conditions, a necessary step to develop effective vaccines and diagnostic tools. The continued expansion of wildlife reservoirs of Brucella spp. without
efficient vaccines and sensitive, specific diagnostic tools will result in additional costs to producers, and state and federal governments for disease control programs.

RESOLUTION:

The United States Animal Health Association (USAHA) urges the United States Department of Homeland Security (DHS) to support the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) and the United States Department of Health and Human Services, Centers for Disease Control and Prevention in the removal of *Brucella abortus*, *Brucella suis*, and *Brucella melitensis* from the biological select agent and toxins list, thereby enabling needed *Brucella* spp. research and diagnostics.

FINAL RESPONSE:

USDA, APHIS, Veterinary Services recognizes the concerns of USAHA and appreciates the opportunity to respond. APHIS concurs with USAHA’s recommendation to urge DHS to support the removal of brucella species from the select agent (SA) list to enable research and diagnostic work. In March 2020, APHIS and CDC published an Advanced Notice of Proposed Rule Making notifying the public of the intention to remove brucella species and other pathogens from the SA list. APHIS received over 220 comments supporting removal of brucella from the SA list. APHIS is moving forward with the proposed rule to remove brucella from the SA list and will continue to work with CDC and DHS to explore options to achieve this goal.
BACKGROUND INFORMATION:

On March 11, 2013, the United States Department of Agriculture (USDA) Animal Disease Traceability rule became effective. Unless specifically exempted, livestock moving interstate must be officially identified and accompanied by an interstate certificate of veterinary inspection or other documentation, such as owner-shipper statements or brand certificates. Stocker/feeder cattle less than 18 months of age are exempted from the rule. States are allowed to issue official National Uniform Eartagging System (NUES) tags to producers to identify livestock.

We strongly support the implementation of the radio frequency identification (RFID) tag as the primary method of official identification. For cattle exporters, low frequency RFID tags have long been the international standard for cattle identification. We believe the transition to RFID tags as the primary official identification tag to be long overdue and an important step in protecting the health of our animals and the strength of our industry. The low frequency (LF) RFID tag allows us to better identify one specific animal at a time – an important ability when working in close systems, such as head locks/stanchions and necessary due to the particular nature of our work. We have been using LF RFID tags for years, specifically the 840 combo tag. We are right there, side by side, wand in hand, with our efficient USDA inspectors during export inspections and have been from the start.

We are, however, very concerned with the current plan to eliminate the old metal (NUES/Steel/Brite) tag for official usage, even as a backup identification (ID). Having only one form of official ID leaves us vulnerable to identification error, which can have far reaching disease and economic consequences. Despite the high retention of RFID tags, when dealing with thousands of animals, ID tags are frequently lost. Identifying the exact animal with a lost RFID in a small, closed herd, may not be a problem, however, when dealing with large combined groups assembled from multiple herds, we must rely on the implementation of an additional official ID for correct identification. Cattle exporters commonly use combo RFID tags – when that RFID is lost, so is the animal’s visual ID. If a metal tag is in place as a backup source of official ID, these cattle can still be identified or rectified.

Cattle exports undergo health testing at an approved laboratory associated with the official ID. If an animal loses their RFID while undergoing final export inspection, and if the animal has lost the single RFID official ID, it is then impossible to demonstrate that the animal has undergone the necessary health testing. Because of this one tag loss, the whole shipment would be stopped, as there is now one animal with a different health status than the group.
If that animal was tagged with both a RFID and a metal tag, and both are forms of official ID, the second is checked and the problem is solved, and the shipment continues. A solid unique backup is vital in the fight to protect our animal’s health and industry’s bottom-line. Because uniqueness is a vital requirement of an official ID, RFID tags cannot be manufactured with duplicate numbers. Double-tagging an animal with dual RFIDs is also problematic. Double RFIDs of the same frequency causes ID confusion. Double RFID tagging of a different frequency requires either multiple wands, a significant expense in hardware and software, or manual entry of bulky 15-digit RFID numbers, an obvious user/entry error issue and a significant time delay. In the face of all of these concerns and the presence of already implemented and tested system, we urge USDA/APHIS to keep the metal tag as a backup official ID.

We understand that this scenario was not envisioned with the transition to RFID as the official ID, and while we fully support RFID as official ID, it is also necessary to retain the NUES tags for backup, secondary official ID, to be purchased by the producer, and to only be used when RFID tags are already in place.

RESOLUTION:

The United States Animal Health Association (USAHA) urges the United States Department of Agriculture (USDA) and State Animal Health Officials to work with livestock exporters to ensure a system is in place to allow for a backup identification system for animals being exported to account for loss of official identification.

FINAL RESPONSE:

USDA, Animal and Plant Health Inspection Service (APHIS), Veterinary Services recognizes the concerns of USAHA and appreciates the opportunity to respond. The Animal Disease Traceability rule (title 9, Code of Federal Regulations (9 CFR), part 86) covers identification of livestock for interstate movement. These requirements are also applied to livestock for official identification for other purposes, including export. The current rule allows for some notable exceptions for “use of more than one official identification” (9 C.F.R. part 86.4 (c) (2)). Using this framework, the APHIS continues to work with livestock exporters and will ensure there is a backup identification system in place for animals being exported. Currently either metal tags or a second RFID tag of a different frequency may be used for back-up identification. Dual RFID tags provide significant cost savings by avoiding time and stress on cattle for manual restraining cattle to read visual tags. Current advancements in technology may provide in the future an option for readers to read both frequencies and seamlessly integrate data as cattle move through the alleyways. APHIS is also considering the option of a specific export visual tag; however, no decisions have been reached on this option if metal tags are discontinued.
RESOLUTION NUMBER:  34  APPROVED AS AMENDED
SUBJECT MATTER: Continuation of Proposed Electronic Identification Transition Timeline

BACKGROUND INFORMATION:

In April 2019, the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) announced a timeline to transition to the mandatory use of electronic identification (ID) tags for cattle covered under the 2013 Animal Disease Traceability (ADT) Rule. While not accompanying the announcement, this timeline was the product of over two years of due process during which time nine regional meetings were held nationally from April 2017 through July 2017, state and local meetings were held with feedback provided, and 462 written comments were received. A sixteen member state-federal working group was formed; the working group held fifteen meetings over seven months, and contributed more than 500 hours of work, resulting in a comprehensive document which summarized the issues, needs, and options of the current ADT program and detailed 14 points as recommendations. Further discussion and feedback was generated through three public traceability summits, and Undersecretary Ibach produced a list of agency-specific objectives to enhance traceability. Finally, an additional state-federal working group was formed to specifically address one of the objectives: a plan to transition to electronic ID. This working group again received input from all sectors of industry before generating the proposed timeline which was adopted by the USDA.

While not unanimous, the transition timeline was met with significant positive responses and as outreach efforts continued, industry support grew as State Animal Health Officials, livestock market operators, industry organizations, and practicing veterinarians committed to engage in a successful transition.

The groups previously mentioned have invested considerable resources to ensure a smooth transition as defined by the timeline. Significant time and energy has been devoted to explaining the timeline to stakeholders and activities have already begun to accomplish the first step of the transition - ending free National Uniform Eartagging System (NUES) tag distribution by 12/31/19.

In late October 2019 it was announced that the timeline was being suspended until USDA could evaluate the method in which the timeline was proposed and determine what steps were necessary to ensure a transparent process was utilized to arrive at the timeline and to satisfy any legal challenges.
The withdrawal of the transition timeline creates confusion, doubt, and lack of trust amongst stakeholders and continues to leave unaddressed a major gap in the nation’s resilience to an incursion of a high consequence animal disease.

RESOLUTION:

The United States Animal Health Association (USAHA) urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS), State Animal Health Officials, and livestock industries to move as quickly as possible to continue the momentum toward electronic identification and to work together to institute a modified transition timeline with the same end date of January 1, 2023 and the extension of National Uniform Eartagging System tag distribution being no more than 12 months or no later than December 31, 2020.

FINAL RESPONSE:

USDA, APHIS, VS recognizes the concerns of USAHA and appreciates the opportunity to respond. On July 6, 2020, APHIS posted a notice in the Federal Register requesting public comment on whether to transition to radio frequency identification (RFID) as the only approved official identification device in cattle and bison, as well as a proposed timeline for this transition. The Notice is open for public comment for 90 days with the comment period closing on October 5, 2020. After receipt and review of stakeholder comments, APHIS will implement a decision on the path forward that best meets stakeholder’s needs. Currently, APHIS continues to provide free metal NUES tags and offers the option of free RFID tags in lieu of the NUES tags.
RESOLUTION NUMBER:  35  
APPROVED

SUBJECT MATTER:  Funding for Infrastructure and Radio Frequency Identification (RFID) Tags

BACKGROUND INFORMATION:

In April 2019, the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) announced a timeline to transition to the mandatory use of electronic identification (ID) tags for cattle covered under the 2013 Animal Disease Traceability (ADT) Rule. While not accompanying the announcement, this timeline was the product of over two years of due process, during which time nine regional meetings were held nationally from April 2017 through July 2017, state and local meetings were held with feedback provided, and 462 written comments were received. A sixteen member state-federal working group was formed; the working group held fifteen meetings over seven months, and contributed more than 500 hours of work, resulting in a comprehensive document which summarized the issues, needs, and options of the current ADT program and detailed 14 points as recommendations. Further discussion and feedback was generated through three public traceability summits, and Undersecretary Ibach produced a list of agency-specific objectives to enhance traceability. Finally, an additional state-federal working group was formed to specifically address one of the objectives: a plan to transition to electronic ID. This working group again received input from all sectors of industry before generating the proposed timeline which was adopted by the USDA.

While not unanimous, the transition timeline was met with significant positive responses and as outreach efforts continued, industry support grew as State Animal Health Officials, livestock market operators, industry organizations, and practicing veterinarians committed to engage in a successful transition.

The groups previously mentioned have invested considerable resources to ensure a smooth transition as defined by the timeline. Significant time and energy has been devoted to explaining the timeline to stakeholders and activities have already begun to accomplish the first step of the transition - ending free National Uniform Eartagging System (NUES) tag distribution by 12/31/19.

In late October 2019, it was announced that the timeline was being suspended until USDA could evaluate the method in which the timeline was proposed and determine what steps were necessary to ensure a transparent process was utilized to arrive at the timeline and to satisfy any legal challenges.

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The withdrawal of the transition timeline creates confusion, doubt, and lack of trust amongst stakeholders and continues to leave unaddressed a major gap in the nation’s resilience to an incursion of a high consequence animal disease.

As a further point of confusion, plans to potentially provide “free” official calfhood vaccination (OCV) radio frequency identification (RFID) tags and making a “cost-share” available for non-OCV RFID tags were announced as options in addition to continuing provision of “free” NUES tags. State Animal Health Officials and many industry stakeholders have repeatedly indicated that the industry wishes for infrastructure improvements rather than a short-term, complicated method of cost-share for RFIDs.

RESOLUTION:

The United States Animal Health Association (USAHA) strongly urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) to discontinue the distribution of National Uniform Eartagging System tags within twelve months or no later than December 31, 2020 and utilize available funding for infrastructure development and provide access for producers to obtain radio frequency identification tags. USAHA further urges USDA-APHIS-VS to avoid “voucher” programs which would create additional administrative challenges.

FINAL RESPONSE:

As part of APHIS’ overall effort to continue to encourage the use of RFID, on January 31, 2020, APHIS began to offer at no cost, low frequency RFID ear tags for cattle and bison as an alternative to the free metal NUES tags. The RFID tags can be used for official calfhood vaccination for brucellosis or for those heifers that will likely be replacement cattle in herds and States that do not vaccinate for brucellosis. The RFID tag option is available at no cost through the same ordering and distribution channels as the NUES tags from the VS warehouse in Kansas City, Missouri.

In fiscal year 2019, APHIS provided additional funding to States to invest in infrastructure (RFID readers). In 2020, APHIS provided similar additional funding, specifically targeted at building electronic ID infrastructure using tag reading devices and tag applicators in livestock markets and by accredited veterinarians.

On July 6, 2020, APHIS posted a Notice in the Federal Register requesting public comment on whether to transition to RFID as the only approved official identification device in cattle and bison, as well as a proposed timeline for this transition. The Notice is open for public comment for 90 days (comment period closes on October 5, 2020). After receipt and review of stakeholder comments, APHIS will implement a decision on the path forward and an associated timeline that best meets stakeholder’s needs. However, should it be determined to transition away from metal tags, the transition would need to allow ample time and will not be accomplished by December 31, 2020.
RESOLUTION NUMBER: 38  APPROVED

SUBJECT MATTER: Equine Infectious Anemia and Equine Piroplasmosis Control Strategies

BACKGROUND INFORMATION:

Over the past ten years, multiple states have investigated either Equine Piroplasmosis (EP) and/or Equine Infectious Anemia (EIA) in Quarter Horses involved in non-sanctioned race activities. All indications are that transmission and disease introduction is related to management practices, including the use of blood and/or plasma products of non-domestic origin within the equine population, rather than natural transmission by vectors. Additionally, in recent years, an increasing number of illegally imported horses have been identified as positive for EP and/or EIA. The nature of non-sanctioned race events makes tracking infected and exposed horses difficult and serves as a significant barrier to effective epidemiological investigations.

During investigations and while horses are maintained under quarantine or hold order, state animal health officials have determined that in many cases, horses have continued to participate in race events and move interstate despite the quarantine or hold order. Additionally, horse substitutions and horse disappearances are complicating efforts to control these diseases. Failure to permanently identify all cohorts, multiple names for the same horse, alteration of tattoos, communication barriers, and inability to reliably determine ownership complicate the ability of animal health officials to conduct thorough epidemiological investigations.

Identification of horses involved in these disease investigations would be enhanced through the placement of International Organization for Standardization (ISO)-compliant microchips that are recorded in the United States Department of Agriculture, Animal Identification Management System (AIMS) and Emergency Management Response System (EMRS) databases. This permanent identification would serve both immediate and potentially future diseases investigations.

Given the increasing frequency at which disease investigations are being conducted for EP and/or EIA involving quarter horses in non-sanctioned racing, it is only a matter of time until these diseases impact larger equine populations involved in activities such as barrel racing, polo, and other pleasure events.

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RESOLUTION:

United States Animal Health Association (USAHA) urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) to develop strategies for the control of Equine Piroplasmosis (EP) and Equine Infectious Anemia (EIA). USDA, APHIS, VS should coordinate these strategies with State Animal Health Officials. USAHA further requests that the American Horse Council and other equine stakeholders seek funding to fully support these programs. Further we request USDA-APHIS-VS Animal Disease Traceability funds to maintain an inventory of International Organization for Standardization (ISO)-compliant microchips at the USDA Kansas warehouse to provide to state and federal animal health officials for use in EIA and EP disease investigations.

FINAL RESPONSE:

USDA, APHIS, VS recognizes the concerns of the USAHA and appreciates the opportunity to respond. The VS Equine Health Team will begin drafting an EP Uniform Standards document in the first quarter of fiscal year 2021, which will take up to six (6) months. The document is intended to capture the strategies, surveillance, and response procedures for control of EP in the United States. Additionally, VS plans to redevelop the 2007 EIA Uniform Methods and Rules into a Uniform Standards document to address the new risk factors and response changes needed in light of the current epidemiology of EIA cases in the United States. This Uniform Standards document will be more in line with current naming conventions for these types of documents within VS and there will be no difference between the intent of Uniform Standards versus Uniform Methods and Rules documents, rather it will be an update to the current naming conventions. We will involve the National Assembly of State Animal Health Officials in the drafting and review of these proposed documents.

In August 2020, the VS Equine Health Team purchased 1,250 ISO-compliant 840 equine microchips, which are currently available for use by State and Federal animal health officials in responding to cases of EP and EIA.