RESOLUTION NUMBER: 6, 13, 29, 34, and 42 Combined APPROVED

SOURCE: **COMMITTEE ON INFECTIOUS DISEASES OF CATTLE, BISON AND CAMELIDS**
COMMITTEE ON INFECTIOUS DISEASES OF HORSES
COMMITTEE ON CAPTIVE WILDLIFE AND ALTERNATIVE LIVESTOCK
COMMITTEE ON TRANSMISSIBLE DISEASES OF POULTRY AND OTHER AVIAN SPECIES
COMMITTEE ON SHEEP AND GOATS

SUBJECT MATTER: **Laboratory Approval for Regulatory Diseases**

BACKGROUND INFORMATION:

Laboratories performing animal surveillance testing are integral to establishing the health status of the national herds and flocks as well as individual animals destined for export. Currently, the United States Department of Agriculture has no authority to restrict laboratories from conducting foreign animal disease diagnostic testing on livestock and poultry samples. For example, one private laboratory in the United States is advertising Polymerase Chain Reaction (PCR) testing for all of the following Foreign Animal diseases: African swine fever, African horse sickness, avian influenza, classical swine fever, foot and mouth disease, Nipah virus, Newcastle disease virus, pestes des petits ruminants virus, rinderpest, rift valley fever, contagious equine metritis, glanders, piroplasmosis, and surra.

Additionally, there is limited state authority or oversight over laboratories conducting diagnostic testing for diseases of regulatory importance on samples obtained from livestock and poultry. The same laboratory conducting the above listed foreign animal disease tests offers PCR tests for equine infectious anemia, brucellosis, infectious bursal disease, influenza, Johne's disease, pseudorabies, Q fever, rabies, West Nile Virus and vesicular stomatitis. Other private laboratories are promoting new diagnostic testing modalities for diseases of regulatory importance such as chronic wasting disease.

There is no requirement that the tests offered by unregulated laboratories are approved and validated to assess infection status accurately, nor are there requirements that tests offered by unregulated laboratories conform to national regulatory testing requirements. Diagnostic tests, especially PCR, are difficult to perform and a small deviation from standards could potentially result in a false positive or false negative test result. The practitioner or producers are likely not aware of these difficulties in performing the test, or the potential regulatory ramifications of a false test result reported to state animal health officials. Ultimately, the inability to prescribe laboratory testing standards necessary for

ensuring the health of livestock and poultry places animal agriculture in the United States at significant risk.

RESOLUTION:

The United States Animal Health Association (USAHA) urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service, Veterinary Services to restrict foreign animal disease diagnostic testing to laboratories approved by the USDA and to take regulatory enforcement action against non-approved laboratories conducting testing for foreign animal diseases. If USDA does not currently have authority for these actions, USAHA urges USDA to take measures to establish those authorities.

Additionally, the USAHA recommends state animal health officials assess state authority or oversight over laboratories conducting diagnostic testing for diseases of regulatory importance on samples obtained from livestock and poultry.

FINAL RESPONSE:

The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service, Veterinary Services (VS) recognizes the concerns of the U.S. Animal Health Association and appreciates the opportunity to respond. VS has explored several regulatory options to restrict foreign animal disease diagnostic testing to laboratories approved by USDA. We are continuing to seek viable solutions and look forward to further ideas and discussions with our stakeholders. Additionally, VS is developing a regulation to clarify and standardize requirements for approval of laboratories performing official testing. The regulation will complement the rule we are drafting to codify the National Animal Health Laboratory Network and the National List of Reportable Animal Diseases. VS has developed a draft guidance document that describes best practices to make the approval process for diagnostic tests more consistent across VS programs.

RESOLUTION NUMBER: 8 **APPROVED**

SOURCE: **AAVLD/USAHA COMMITTEE ON AQUACULTURE**

SUBJECT MATTER: **Quality Assurance Training for Aquatic Animal Laboratories**

BACKGROUND INFORMATION:

Pathogen testing is a legal requirement for transport, export, and management of aquatic animals in many jurisdictions within the United States and beyond. It is critical that the results of this testing be accurate, credible and beyond reproach. Currently, many laboratories performing this testing have little or no quality assurance/quality control programs in place and no training available. Many smaller state, federal or tribal laboratories feel they do not have the resources to accomplish accreditation through World Organization for Animal Health (OIE) or International Organization for Standardization (ISO) 17025.

A grassroots effort has been initiated through the Fish Health Section (FHS) of the American Fisheries Society (AFS) to create and implement a voluntary, multi-tiered approach for quality assurance, based largely on Chapter 3 of the FHS/United States Fish and Wildlife Services Blue Book, as well as key ingredients of other accreditation programs. A standing committee consisting of several state, federal and private partners has created the first Tier (pre-qualification) which was announced in January 2016. The second Tier (recognition) is under development. The committee is exploring ways to partner with other agencies with ongoing programs to help further this effort.

RESOLUTION:

The United States Animal Health Association encourages the United States Department of Agriculture, Animal and Plant Health Inspection Service and the National Animal Health Laboratory Network to provide support and initiate quality management training for the American Fisheries Society (AFS), Fish Health Section (FHS) Quality Assurance Initiative which can be provided at regional meetings of the aquatic diagnostic testing community (e.g., AFS-FHS annual meeting, Eastern Fish Health Workshop, and Western Fish Disease Workshop).

FINAL RESPONSE:

The U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services recognizes the concerns of the U.S. Animal Health Association and appreciates the opportunity to respond. The National Animal Health Laboratory Network (NAHLN)

program staff, in collaboration with meeting organizers, hosted quality management system training at the regional meetings of the aquatic diagnostic testing community (e.g., the American Fishery Society (AFS) – Fish Health Section annual meeting, Eastern Fish Health Workshop, and Western Fish Disease Workshop) in April and June 2017. Following the training, NAHLN has discussed next steps with the standing committee, which consists of several State, Federal, and private partners from AFS. We have tentatively planned a face-to-face meeting for late 2017 to identify future opportunities for collaboration.

RESOLUTION NUMBER: 10 APPROVED

SOURCE: USAHA/AAVLD COMMITTEE ON NATIONAL ANIMAL HEALTH LABORATORY NETWORK

SUBJECT MATTER: Laboratory Requirements for Program Disease Testing

BACKGROUND INFORMATION:

Quality assurance for animal disease laboratory testing and electronic messaging of diagnostic results are of critical importance for maintaining and enhancing the state of preparedness for actively managing diseases of high consequence to the United States animal health. Quality assured test results, and seamless (electronic) connectivity of information between diagnostic laboratories and the appropriate state and federal veterinary medical agencies are needs of 21st century U.S. animal agriculture.

RESOLUTION:

The American Association of Veterinary Laboratory Diagnosticians (AAVLD) and the United States Animal Health Association (USAHA) recommend that a working group inclusive of representation from AAVLD, USAHA, the United States Department of Agriculture, and the United States Food and Drug Administration (FDA) be formed to provide a formal review and subsequent recommendation for implementation of minimum quality and reporting requirements of laboratories responsible for conducting diagnostic testing associated with determination of animal disease status under the various USDA and FDA programs. The resulting review and recommendations for consideration should be provided to each of the contributing organizations prior to the 2017 Annual Meeting of USAHA and AAVLD.

FINAL RESPONSE:

The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service, Veterinary Services (VS) recognizes the concerns of the U.S. Animal Health Association and appreciates the opportunity to respond. VS has an ongoing initiative working towards a proposed rule to streamline the overall approval processes for laboratories that conduct official USDA testing. In addition to consolidating our authority, this effort will provide consistent inspection protocols, proficiency testing methods, definitions, and quality system guidelines. The quality system guidelines will recognize existing international quality standards, such as ISO 17025 and accrediting bodies to this standard. The proposed rule will reference the minimal and critical elements of a recognized quality system. Stakeholders are supportive of this initiative.

VS established several small working groups (WGs) that analyzed current VS animal disease testing guidelines and regulations and provided their recommendations for use in the overall initiative. Additionally, VS formed a WG with representation from the American Association of Veterinary Laboratory Diagnosticians, National Assembly of State Animal Health Officials, and the U.S. Food and Drug Administration to gather input from external stakeholders to discuss the specific minimum requirements. The WG is currently identifying basic quality principles for laboratories conducting tests regulated by USDA. These principles will be used as a basis for their final recommendations.

RESOLUTION NUMBER: 12 and 14 Combined **APPROVED**

SOURCE: **COMMITTEE ON TRANSMISSIBLE DISEASES OF SWINE**
COMMITTEE ON INFECTIOUS DISEASES OF HORSES

SUBJECT MATTER: **State Animal Health Official and Submitting Veterinary Diagnostic Lab Access to Veterinary Diagnostic Laboratory Records Reported from the National Animal Health Laboratory Network Labs and the National Veterinary Services Laboratory to the United States Department of Agriculture's Laboratory Messaging Service**

BACKGROUND INFORMATION:

The United States Department of Agriculture's (USDA) Laboratory Messaging Service (LMS) is a database application that serves as the centralized point of receipt for electronic veterinary diagnostic records being reported from veterinary diagnostic labs (National Animal Health Laboratory Network (NAHLN) labs) to the USDA. LMS also receives test results being reported from cases forwarded from NAHLN labs to the USDA, National Veterinary Services Laboratory (NVSL) for further diagnostic testing. Significant advances have been made in the NAHLN's ability to electronically transfer (message) veterinary diagnostic records from NAHLN labs and NVSL to LMS. These stepwise improvements in connectivity between veterinary diagnostic laboratories (VDLs) and USDA represent great progress towards establishing seamless and scalable systems of reportable disease veterinary diagnostic information transfer between U.S. VDLs and veterinary medical officials. However, USDA does not currently have an effective application for providing State Animal Health Officials electronic access to the VDL records received into LMS that have originated from animals or farm sites in their respective States. Similarly, NAHLN labs do not have electronic access to diagnostic results from case submissions in which they forward onto NVSL for further testing. Permissioned access solutions are needed to bridge this gap in connectivity that exists between the USDA's LMS, State Animal Health Officials, and VDLs.

RESOLUTION:

The American Association of Veterinary Laboratory Diagnosticians (AAVLD) and the United States Animal Health Association (USAHA) encourage the United States Department of Agriculture (USDA) to develop an application that provides State

Animal Health Officials electronic access to veterinary diagnostic laboratory records originating from animals or farm sites in their respective States that have been reported from National Animal Health Laboratory Network Labs or USDA, National Veterinary Services Laboratory (NVSL) to USDA's Laboratory Messaging Service. Similarly, AAVLD and USAHA encourage USDA

to provide veterinary diagnostic laboratories electronic access to diagnostic results from case submissions in which that same veterinary diagnostic laboratory has forwarded onto NVSL for further testing.

FINAL RESPONSE:

The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service, Veterinary Services (VS) recognizes the concerns of the U.S. Animal Health Association and appreciates the opportunity to respond. VS has assessed current capabilities and initial requirements to report collated testing data for official USDA testing conducted at National Animal Health Laboratory Network (NAHLN) laboratories to State animal health officials (SAHOs) from animals or farm sites in their respective States. After assessing our systems, VS intends to pilot test a State-based reporting solution to provide SAHOs with electronic access to veterinary diagnostic laboratory results that have been electronically reported to VS using the VS Lab Messaging System (LMS). We anticipate that we will receive authorization from USDA to use the web-based software application for this reporting in spring 2018. Pending results of the pilot project and successful deployment of the software into a production environment, VS would plan a roll-out of this reporting solution to the States during fiscal year 2018.

RESOLUTION NUMBER: 16, 23, and 40 Combined **APPROVED**

SOURCE: **COMMITTEE ON SCRAPIE**
COMMITTEE ON LIVESTOCK IDENTIFICATION
COMMITTEE ON SHEEP AND GOATS

SUBJECT MATTER: **Continued United States Department of Agriculture Provision of Plastic Scrapie Program Ear Tags for Sheep and Goats Producers**

BACKGROUND INFORMATION:

While the National Scrapie Eradication Program (NSEP) has succeeded in decreasing the prevalence of scrapie in the United States, the NSEP has not eradicated scrapie in sheep or goats. The NSEP must make continued improvements in traceability and surveillance is needed, not just to achieve the eradication of scrapie, but also to advance animal disease traceability (ADT) efforts.

Much of the success of the NSEP is attributable to the U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service's work with producers to find identification (ID) devices with good retention and that lend themselves to improving animal care and management. Currently, USDA provides small metal tags or more visible plastic ear tags to producers, sales yards, fairs, veterinarians, and veterinary clinics. The plastic tags have a larger profile and lend themselves to management systems where tag numbers are read and recorded. The metal tags are too small to be used as visible ID for management purposes, and they are more likely to lead to infections in goats than the plastic tags.

The publication of the NSEP final rule is expected in 2017 and will include new requirements for official identification and traceability for certain classes of goats and sheep previously excluded from mandatory official ID. In addition to the increasing numbers of new sheep and goat producers entering the program on a continuing basis, longtime producers of low-risk goats and sheep, who were previously exempted, will have mandatory ID requirements for the first time. A change in tag-provision policy at this critical time jeopardizes the ability of veterinarians and scrapie program officials to facilitate compliance by these herd owners. Elimination of USDA-provided tags that provide visible ID will compromise accurate recording of ID and compliance with recordkeeping requirements for both traceability and the scrapie program.

USDA should explore alternative sources of funds and cost saving options to support the USDA-provided plastic ear tags. Benefits of the USDA-provided plastic tags outweigh the savings that could be achieved by cutting the funding for this item. The success in ADT attributable to the NSEP and the wide adoption of sheep and goat plastic ear tags demonstrate the value of providing ID options that benefit both producers and traceability.

RESOLUTION:

The U.S. Animal Health Association urges the U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service to continue to provide plastic ear tags for the National Scrapie Eradication Program (NSEP) in the most economical and case appropriate manner. These USDA-provided tags are critical to successful identification and traceability of sheep and goats for NSEP and animal disease traceability.

FINAL RESPONSE:

The U.S. Department of Agriculture, Animal and Plant Health Inspection Service (APHIS), Veterinary Services recognizes the concerns of the U.S. Animal Health Association and appreciates the opportunity to respond. APHIS does not expect to receive an increase in funding in the Equine, Cervid, and Small Ruminant line item in fiscal year (FY) 2018. Further, we have exhausted the no-year funding that was used to provide official eartags to producers in recent years. As a result, APHIS is looking at ways to reduce tag costs to preserve other scrapie program activities under our expected FY 2018 budget. APHIS is considering several options that may be implemented alone or in combination, including providing only metal eartags, providing a limited number of plastic tags to any one entity, not providing tag applicators, and/or changing the way metal tags are distributed. APHIS recognizes that reducing or eliminating the availability of USDA-provided official plastic tags may adversely impact ID compliance and thereby traceability; however, other options for cutting costs, such as reducing scrapie surveillance, would likely have greater negative impacts on the program. APHIS has not made a final decision at this time.

RESOLUTION NUMBER: 17 and 41 Combined **APPROVED**

SOURCE: **COMMITTEE ON SCRAPIE**
COMMITTEE ON SHEEP AND GOATS

SUBJECT MATTER: **Goat Scrapie Genetic Resistance**

BACKGROUND INFORMATION:

Genotype selection for scrapie resistance in sheep has proven to be a great asset in efforts to eradicate scrapie in sheep. The availability of genetic tools for goats should have similar benefits. Based on the information presented by the U.S. Department of Agriculture, Agricultural Research Service researchers, sufficient data exists to support further efforts toward testing for goat scrapie genotype resistance and development of field applications in the National Scrapie Eradication Program.

RESOLUTION:

The U.S. Animal Health Association (USAHA) urges the U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service to pursue efforts to develop pilot projects to explore the use of goat scrapie genotype testing in the National Scrapie Eradication Program. USAHA also requests that USDA-Agricultural Research Service conduct surveys to assess the frequency of resistant genotypes in U.S. goats and identify methods to expand the availability of resistant genotypes to U.S. goat producers.

FINAL RESPONSE:

The U.S. Department of Agriculture, Animal and Plant Health Inspection Service (APHIS), Veterinary Services recognizes the concerns of the U.S. Animal Health Association and appreciates the opportunity to respond. We understand the importance of better characterization of genetic resistance to scrapie in goats to assist producers in breeding for resistance and to reduce the number of animals depopulated in a herd when scrapie is detected. However, genetic resistance to scrapie is more difficult to characterize in goats compared to sheep because of a wider number and variety of genotypes associated with resistance and fewer cases of scrapie in goats in the United States, resulting in less research. APHIS continues to prioritize the importance of this research with our partners at the Agricultural Research Service (ARS) and will develop genetic-based flock plans for scrapie-infected goatherds, as appropriate. In July 2017, APHIS provided ARS with 43 scrapie-exposed goats when an infected herd was depopulated

RESOLUTION NUMBER: 18 **APPROVED**

SOURCE: **COMMITTEE ON SCRAPIE**

SUBJECT MATTER: **Identifying Non-Traditional Sheep and Goat Marketing and Slaughter Channels**

BACKGROUND INFORMATION:

While the National Scrapie Eradication Program (NSEP) has been successful in decreasing the prevalence of scrapie in the United States, the NSEP has not yet achieved eradication of the disease. With all disease eradication programs, as prevalence of the disease declines, the ability to identify the remaining cases becomes an ever greater challenge.

There is evidence that increasing numbers of sheep and goats are marketed and slaughtered outside of the traditional marketing system and may not be available for scrapie surveillance, the impact of which may prolong the time until eradication is achieved. It is also likely that the demand for nontraditionally marketed animals will continue to rise, resulting in negative ramifications for the program.

RESOLUTION:

The U.S. Animal Health Association urges the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services to actively pursue identification of nontraditional sheep and goat marketing and slaughter channels and to create a program to obtain samples from these channels.

FINAL RESPONSE:

The U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services (VS) recognizes the concerns of the U.S. Animal Health Association and appreciates the opportunity to respond. VS agrees with the importance of identifying nontraditional sheep and goat marketing and slaughter channels to improve the coverage of scrapie surveillance across all segments of the sheep and goat populations. VS has provided support to collect and test samples from sheep and goats offered for sale at live-bird markets in Texas and New York. VS will continue to encourage efforts to identify and collect and test samples from nontraditional outlets for selling and slaughtering sheep and goats, as funding is available.

RESOLUTION NUMBER: 19 APPROVED

SOURCE: COMMITTEE ON BRUCELLOSIS

SUBJECT MATTER: Review of State Brucellosis Management Plans

BACKGROUND INFORMATION:

All States are essentially free of bovine brucellosis, and the disease has largely been eliminated from the United States cattle population, despite occasional "spillover" infection from infected wildlife reservoirs. The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) published an Interim Rule in 2010, which effectively removed State status for bovine brucellosis. APHIS has detected eleven infected cattle or domestic bison herds within the Designated Surveillance Area (DSA) as a result of testing required within the DSA since 2010, effectively identifying and mitigating disease risk to the U.S. cattle population.

Under the 2010 Interim Rule, the Greater Yellowstone Area (GYA) States are responsible for defining the boundaries of the DSA, conducting surveillance "sufficient to prevent the spread of brucellosis…," and implementing a Brucellosis Management Plan (BMP), approved by Veterinary Services (VS) in a Memorandum of Understanding. VS last reviewed GYA State BMPs in 2012.

State required testing of DSA cattle, and domestic bison herds appear to be effective in identifying infected herds at low prevalence. GYA States and APHIS are identifying affected herds prior to leaving the DSA, found no infected outside of the DSA, and documented no cases of herd-to-herd transmission since the 2010 rule, and implementation of DSA required testing.

However, surveillance in wildlife outside of the Wyoming DSA has identified seropositive elk annually for the last four years, and the boundaries of the DSA have not been expanded accordingly. The finding of seropositive elk in areas outside of a DSA may indicate current or past infection, the implication of which is that cattle and domestic bison herds in the area may also be at risk of infection. Lack of timely action in expanding DSA boundaries in response to finding exposed wildlife may result in exposed or infected cattle or bison leaving the area undetected.

RESOLUTION:

The United States Animal Health Association (USAHA) urges the U.S. Department of Agriculture, Animal and Plant Health Inspection Service (APHIS) to conduct reviews of Greater

Yellowstone Area (GYA) Brucellosis Management Plans and their implementation, at least once every three years. In addition, USAHA also encourages GYA States and APHIS to continue to conduct wildlife surveillance outside of Designated Surveillance Areas (DSA), and for the States to adjust DSA boundaries accordingly to include geographic areas where there is a potential risk of transmission of brucellosis from wildlife to cattle or domestic bison.

FINAL RESPONSE:

The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services recognizes the concerns of the U.S. Animal Health Association and appreciates the opportunity to respond. APHIS works with States in the Greater Yellowstone Area (GYA) to develop and review their brucellosis management plans. APHIS will ensure each GYA State is reviewed at least once every three years and will conduct its next State-level review by early fall 2017. Thereafter, one State will be reviewed annually at a minimum, on a rolling 3-year schedule. The State of Wyoming's review was recently completed and a report is working its way through clearance.

APHIS will continue to encourage wildlife surveillance as part of a comprehensive approach to brucellosis eradication. However, USDA has no purview to enforce such surveillance, and can only encourage such partnerships between GYA States and their respective wildlife authorities. The extent to which wildlife surveillance occurs within a GYA State will be a factor in the comprehensive review of each State's brucellosis management plan and subsequent boundaries of their respective designated surveillance area.

RESOLUTION NUMBER: 20 APPROVED

SOURCE: COMMITTEE ON BRUCELLOSIS

SUBJECT MATTER: Brucellosis Milk Enzyme-Linked Immunosorbent Assay Validation as an Additional Test for Brucellosis in Bulk Milk

BACKGROUND INFORMATION:

The Brucellosis Ring Test (BRT) is the only approved test for detection of antibodies to Brucella spp. in bulk milk tank samples; however, this test consistently demonstrates false positives. If the brucellosis milk enzyme-linked immunosorbent assay (ELISA) is demonstrated to have improved sensitivity and specificity, the U.S. Animal Health Association supports work by the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services to validate the ELISA, in addition to the BRT, as an approved brucellosis bulk milk surveillance test.

The IDEXX milk ELISA test was available for bulk milk tank sampling from the early 2000s until 2006 or 2007. During that time, the milk ELISA was utilized for bulk milk tank samples due to the superior sensitivity when compared to the BRT. When IDEXX discontinued the production of the milk ELISA test, the BRT was the only approved test for bulk milk tank sampling in the United States.

RESOLUTION:

The U.S. Animal Health Association urges the U.S. Department of Agriculture, Animal and Plant Health Inspection Service to direct the National Veterinary Services Laboratory to pursue validation of the brucellosis milk enzyme-linked immunosorbent assay.

FINAL RESPONSE:

The U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services (VS) recognizes the concerns of the U.S. Animal Health Association (USAHA) and appreciates the opportunity to respond. VS' National Veterinary Services Laboratories evaluated three brucella milk enzyme-linked immunosorbent assays (ELISAs) for sensitivity and forwarded these results to VS' Center for Veterinary Biologics for statistical review. VS will provide results to the USAHA Brucellosis Subcommittee at the 2017 annual meeting, and based on these results; VS will determine the next steps needed to fully evaluate these ELISAs for use in the State-Federal Cooperative Brucellosis Eradication Program.

RESOLUTION NUMBER: 22 and 37 Combined APPROVED

SOURCE: **COMMITTEE ON IMPORT, Export and International Standards**
COMMITTEE ON TUBERCULOSIS

SUBJECT MATTER: **Cervid Import from Manitoba**

BACKGROUND INFORMATION:

On January 1, 2003, the Canadian Food Inspection Agency (CFIA) and the Manitoba Department of Agriculture adopted the creation of a zone around Riding Mountain National Park (RMNP) with a different tuberculosis (TB) status than the rest of Manitoba and Canada. Manitoba was split into two areas and re-classified their TB status according to the following new criteria:

- Riding Mountain TB Eradication Area: Game hunting areas that will be upgraded from their current TB-accredited status to the new TB-accredited-advanced status; and
- Manitoba TB Eradication Area: Remainder of the province (approximately 90 percent of Manitoba cattle herds) and will be upgraded from its current TB-accredited status to TB-free status.

The U.S. Department of Agriculture, Animal and Plant Health Inspection Service's (APHIS) live import protocol for cervids from Canada to the United States has a specific TB requirement for Manitoba animals that add additional isolation time.

Section 2.4 (h) of the protocol states, "For farmed cervids originating from Manitoba (or Manitoba farmed cervids which are added to a herd in another province) prior to the individual cervid TB test required under in Section 3, the animals must be isolated as a group for at least 60 days without addition."

APHIS' live animal import protocol for other species, such as camelids, has no special condition for Manitoba animals. APHIS' import protocol for cattle mentions Manitoba's special TB status but does not require any extra testing or isolation for TB-certified herds.

All farmed cervid herds in Manitoba are enrolled in a mandatory TB surveillance program administered by CFIA.

RESOLUTION:

The U.S. Animal Health Association urges the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services to amend the live cervid import protocol, upon

request from the Canadian Food Inspection Agency, to exclude Manitoba cervids that originate outside the Riding Mountain National Park Tuberculosis Eradication Area from the isolation requirements prior to testing.

FINAL RESPONSE:

The U.S. Department of Agriculture, Animal and Plant Health Inspection Service (APHIS), Veterinary Services recognizes the concerns of the U.S. Animal Health Association and appreciates the opportunity to respond. The Canadian Food Inspection Agency (CFIA) provided APHIS with tuberculosis surveillance data for farmed and wild cervids in Manitoba. APHIS evaluated this data and discussed the issue with the CFIA during the bilateral trade meeting in early spring 2017. After this discussion, APHIS amended the import protocol for farmed cervid imports from Canada and eliminated the 60-day pre-export isolation requirement specifically for the region of Manitoba. The updated import protocol can be found at the following location:
https://www.aphis.usda.gov/regulations/vs/iregs/animals/downloads/farmed_cervids_from_canada_Updated_2017.pdf

RESOLUTION NUMBER: 25 **APPROVED**

SOURCE: **COMMITTEE ON BIOLOGICS & BIOTECHNOLOGY**

SUBJECT MATTER: **International Promotion of the United States Regulatory System for the Regulation of Veterinary Biological Products**

BACKGROUND INFORMATION:

The U.S. Department of Agriculture (USDA) has regulated the veterinary biologics industry for over 100 years, and under the Virus-Serum-Toxin Act of 1913 (amended in 1985), has developed regulatory methods to ensure that the veterinary biologics manufactured in the United States are pure, safe, potent, and effective. This regulatory system is described in the Code of Federal Regulations (CFR) beginning at 9 CFR part 101 (Subchapter E). In 2015, the U.S. domestic veterinary biologics industry manufactured over 100 billion doses of high-quality products for both domestic and global markets. More recently, certain countries (often with local industry support interests) have intimated in the international arena that the U.S. regulatory system is not equivalent, and by implication, inferior to their regulatory systems. Consequently, some countries are no longer accepting inspection certification from USDA. Some countries insist on conducting their own inspections, while others will accept certificates of inspection from a regulatory body that is a member of the Pharmaceutical Inspection Cooperation Scheme (PIC/S). PIC/S is a non-binding cooperative arrangement between regulatory authorities to promote quality inspections and facilitate cooperation and networking among these authorities to promote mutual confidence. Approximately fifty regulatory authorities are currently members of the PIC/S.

The USDA, Animal and Plant Health Inspection Service (APHIS), Center for Veterinary Biologics (CVB) have worked to promote an understanding of their regulatory system through participation in the Veterinary International Conference on Harmonization (VICH), outreach to Latin America through a World Organization of Animal Health (OIE) program called CAMEVET, and participation in the Institute of International Cooperation in Animal Biologics, which is an OIE collaborating center located at Iowa State University that conducts programs often attended by foreign governments. These outreach efforts are appreciated; however, more is needed to help promote and protect export markets for U.S. veterinary biologics. Countries with recent specific issues include Russia, Thailand, and Turkey. The CVB should evaluate leveraging other ongoing APHIS trade outreach programs to promote their regulatory system further and evaluate joining the PIC/S.

RESOLUTION:

The U.S. Animal Health Association urges the U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service programs, including International Services, Veterinary Services' National Import Export Services, and the Center for Veterinary Biologics, to develop a plan to increase USDA efforts to promote the U.S. regulatory system for veterinary biologics as a high-quality regulatory system designed to ensure the production of pure, safe, potent, and efficacious veterinary biological products. The plan should specifically evaluate outreach to problematic areas and joining the Pharmaceutical Inspection Cooperation Scheme.

FINAL RESPONSE:

The U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services (VS) recognizes the concerns of the U.S. Animal Health Association and appreciates the opportunity to respond. VS' Center for Veterinary Biologics (CVB) held several meetings with the biologics industry throughout the year to discuss the broader acceptance of U.S. standards internationally. During these meetings, we discussed options relative to modifications or additions to CVB's regulatory documentation to provide increased visibility of the similarities between the U.S. regulatory system and other international Good Manufacturing Practices-based methods. CVB looked at the Pharmaceutical Inspection Cooperation Scheme (PIC-S) requirements for facilities and presented this information to the biologics industry. Discussions with industry are on-going. VS has not made a final determination relative to joining the PIC-S at this point.

RESOLUTION NUMBER: 30 **APPROVED**

SOURCE: **COMMITTEE ON CAPTIVE WILDLIFE AND ALTERNATIVE LIVESTOCK**

SUBJECT MATTER: **Live Animal Testing for Chronic Wasting Disease**

BACKGROUND INFORMATION:

Detection of chronic wasting disease (CWD) in live animals is an important component of CWD prevention and control programs. With the funding decrease for CWD indemnification, the need for a successful live animal test option, with a high rate of sensitivity and specificity, is critical in both a trace-forward/trace-back scenario, as well as in herd management plans.

There have been numerous studies evaluating the sensitivity and specificity of tonsillar biopsies in cervids. Similar to scrapie, PrP (CWD) in deer accumulates in the retropharyngeal lymph nodes and tonsillar follicles before central nervous system involvement or clinical symptoms (Sigurdson et al., 1999; Spraker et al., 2002b; O'Rourke et al., 2003). Ante-mortem testing of these tissues by immunohistochemistry provides a reliable preclinical diagnosis in deer (Wild et al., 2002; Wolfe et al., 2002).

RESOLUTION:

The U.S. Animal Health Association urges the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services to expedite evaluation and approval of tonsillar biopsies into the Chronic Wasting Disease (CWD) Program Standards, providing for rapid implementation and deployment as a viable, accurate, and reliable means of live animal testing for CWD in cervids.

FINAL RESPONSE:

The U.S. Department of Agriculture, Animal and Plant Health Inspection Service (APHIS), Veterinary Services recognizes the concerns of the U.S. Animal Health Association and appreciates the opportunity to respond. APHIS supports research to develop and validate live animal tests for chronic wasting disease. We are obtaining data and collecting samples through pilot projects and routine herd depopulations to evaluate the sensitivity and specificity of tonsil biopsy as an antemortem diagnostic tool. We are working to accumulate an adequate number of tonsil biopsy samples from CWD-positive animals to complete this evaluation.

Resolution number: **31 and 39 Combined** **APPROVED**

Source: **COMMITTEE ON CAPTIVE WILDLIFE & ALTERNATIVE LIVESTOCK**
COMMITTEE ON TUBERCULOSIS

Subject Matter: **National Cervid Tuberculosis Herd Accreditation Program**

BACKGROUND INFORMATION:

The primary objective of the cervid bovine tuberculosis (TB) herd accreditation program is to eliminate Mycobacterium bovis, the causative agent of bovine TB, in farmed/captive cervids as part of a comprehensive approach to eradicate bovine TB in domestic cattle and bison in the United States. The U.S. Department of Agriculture (USDA) requires that all farmed/captive cervids destined for interstate movement be tested for bovine TB.

The 2005 Code of Federal Regulations (CFR), 9 Part 77 was updated to separate cervids from the cattle and bison program, and a new testing criterion for cervids was implemented. Herds that participate in the USDA, Animal and Plant Health Inspection Service's cervid bovine TB herd accreditation program must test their entire herd of cervids over 12 months of age as negative for bovine TB two times in 9 to 15-month intervals to establish an accredited free herd. The accreditation is valid for 33 to 39 months from the original anniversary date, and the herd must perform a negative whole herd retest in that period of time to maintain the accredited status. Animals from accredited-free herds are allowed to move interstate at any time without further testing.

Details on the bovine TB testing requirements for interstate movement of cervids from monitored herds, qualified herds, and accredited herds from modified accredited States and zones are provided in the Federal regulations (9 CFR Parts 77 and 86) and in the 1999 Uniform Methods and Rules (UM&R) on Bovine Tuberculosis Eradication.

Language from USDA Website referencing 1999 UM&R:

> **Bovine Tuberculosis (bTB) Testing Requirements for Interstate or International Movement**
> Last Modified: Apr 7, 2015
> **According to the 1999 TB UM&R:**
> 1. No captive cervid with a response to any tuberculosis test is eligible for international movement.

2. No captive cervid with a response to any tuberculosis test is eligible for interstate movement unless said animal is subsequently classified “negative for tuberculosis” based upon an official tuberculosis test or is consigned directly to slaughter.
3. Captive cervids that originate from accredited herds may be moved interstate without further tuberculosis testing, provided that they are accompanied by a certificate stating that such captive cervids originated from an accredited herd.
4. Captive cervids not known to be affected with or exposed to tuberculosis that originate from qualified herds may be moved interstate if the animals are accompanied by a certificate stating that they originate from a qualified herd and have been classified negative to an official tuberculosis test that was conducted within 90 days prior to the date of movement. If the qualifying test was administered within 90 days of movement, the animal(s) to be moved do not require an additional test.
5. Captive cervids not known to be affected with or exposed to tuberculosis that originate from monitored herds may be moved interstate if they are accompanied by a certificate stating that such captive cervids originate from a monitored herd and have been classified negative to an official tuberculosis test that was conducted within 90 days prior to the date of movement.
6. Captive cervids not known to be affected with or exposed to tuberculosis that originate from all other herds may be moved interstate, provided that (1) they are accompanied by a certificate stating that such captive cervids have been classified negative in response to two official tuberculosis tests conducted no less than 90 days apart, (2) the second test was conducted within 90 days prior to the date of movement, and (3) the animals were isolated from all other members of the herd during the testing period.
7. Captive cervids less than 12 months of age that originate from and were born in qualified or monitored herds may be moved without further tuberculosis testing, provided that they are accompanied by a certificate stating that such captive cervids originated from such herds and have not been exposed to captive cervids from a lower status herd.
8. Institutions that have been accredited by the American Zoo and Aquarium Association (AZA) are exempt from these requirements when movement is between accredited member facilities. Captive cervids in zoological parks that have been accredited by AZA are exempt from the regulations in this subpart when the captive cervids are moved directly interstate between AZA member facilities. Any captive cervids moved interstate that are not moved directly from an AZA member facility to another AZA member facility must be moved in accordance with the regulations in this subpart.
9. Except for captive cervids moving interstate under permit directly to slaughter or necropsy, each captive cervid or shipment of captive cervids to be moved interstate must be accompanied by a certificate issued within 30 days of the movement by a State or Federal animal health official or an accredited veterinarian. The certificate must state the number of the official eartag or other identification approved by the Administrator for each captive cervid to be moved, the number of captive cervids covered by the certificate, the purpose of the

movement, the origin and destination of the captive cervids, the consignor, and the consignee.

Language from 1999 UM&R:

Part VI—Herd Status Plans for Captive Cervids

A. Accredited herd plan for captive cervids

1. Animals to be tested - Testing of herds for accreditation or reaccreditation shall include all captive cervids and all other hoof stock over 12 months of age and animals under 12 months of age that are not natural additions, except that animals under 12 months of age that are not natural additions originating from an accredited herd need not be tested.

2. Qualifying standards - To meet the requirements for accredited herd status, the herd must pass at least three consecutive official tests for tuberculosis conducted at 9- to 15-month intervals with no evidence of bovine tuberculosis.

   In herds previously infected, the fourth, fifth, and sixth annual whole-herd negative test will requalify the herd for accreditation.

   Herds meeting these standards may be issued a certificate by local State and Federal animal health officials.

3. Additions - Accredited herd additions must originate directly from one of the following and have no exposure to captive cervids from herds of lesser status than the additions' herd of origin:

   a. An accredited herd.

   b. A qualified or monitored herd, provided that the individual animals for addition had negative results on an official tuberculosis test conducted within 90 days prior to entry and were isolated from members of the accredited herd until these animals had a negative result on an official tuberculosis test conducted at least 90 days following entry.

   c. A herd not meeting the requirements of (a) or (b) in this section. Individual animals for addition must be isolated from all other members of the herd of origin and must have negative results on two official tests for tuberculosis conducted at least 90 days apart. The second of these tests must be conducted within 90 days prior to movement to the premises of the accredited herd. The additions must be kept in isolation from members of the accredited herd until the additions have a negative result on an official tuberculosis test conducted at least 90 days following the date of entry. Animals other than natural additions added to an accredited free herd shall not receive the accredited herd status for sale or movement purposes until they have a negative result on a retest 90 days after entry and until they have been included in a recertification herd test.

RESOLUTION:

The U.S. Animal Health Association urges the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services (VS) to issue a VS Guidance Document stating that "animals other than natural additions added to an accredited free herd shall not receive the accredited herd status for sale or movement purposes until they have a negative result on a retest 90 days after entry and until they have been included in a recertification herd test" is no longer applicable in the National Cervid Tuberculosis (TB) Herd Accreditation Program and no additional TB test is required for the accredited individual animal addition(s).

FINAL RESPONSE:

The U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services recognizes the concerns of the U.S. Animal Health Association and appreciates the opportunity to respond. The language from the tuberculosis 1999 Uniform Methods and Rules is the same language included in the draft program standards, published in conjunction with the brucellosis and bovine tuberculosis proposed rule in December 2015. At this time, we are reviewing the comments we received on the draft program standards, and we will consider this resolution as we revise them.

RESOLUTION NUMBER: 32 **APPROVED**

SOURCE: **COMMITTEE ON CAPTIVE WILDLIFE & ALTERNATIVE LIVESTOCK**

SUBJECT MATTER: **Chronic Wasting Disease Testing Protocol for Wild Cervidae**

BACKGROUND INFORMATION:

Over the past 15 years, the U.S. Department of Agriculture, Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) and State regulatory officials have worked to control and prevent the spread of chronic wasting disease (CWD).

Producers raising CWD-susceptible species can only move their animal's interstate if they are in compliance with the CWD program set forth in Title 9 Code of Federal Regulations (CFR) Parts 55 & 81, which state animals must originate from herds with at least five years of CWD monitored status.

State wildlife agencies that plan and execute elk restoration projects from one State to another are moving CWD susceptible species interstate without following minimum interstate movement requirements for farmed cervidae. Instead, Title 9 CFR Part 81.3 states the source population be considered "low-risk" by the receiving State and APHIS.

To date, over two dozen herds of wild elk have been captured and transported to other States across the Nation that follow no CWD protocol set forth in the CWD Program Standards. The movement of CWD susceptible cervid species with unknown CWD status by State wildlife agencies can undermine the success of CWD control programs that have been in place in many States for more than 15 years. CWD has been found in 23 States. Eight of the 23 States have detected CWD in the free-ranging deer populations, but not in the farmed cervid herds.

The U.S. Animal Health Association Committee on Wildlife Diseases approved a resolution at the 2015 annual conference that requested APHIS Veterinary Services (VS) to develop a guidance document for captive deer, elk, or moose captured from a wild population for interstate movement and release.

APHIS released VS Guidance Document 8000.1 "Surveillance and Testing Requirements for Interstate Transport of Wild Caught Cervids" in October 2016, but the requirement of an antemortem test, such as the rectal biopsy, is only optional.

Exact language is as follows:

"Optionally, a whole-herd rectal biopsy or other mutually agreed-on method of antemortem CWD test with concurrent genotyping may be performed on the assembled herd. Laboratory results must be "not detected" on all animals. Animals with untestable or incorrect location samples (i.e., samples that are autolyzed or of the wrong tissue type) may be retested."

RESOLUTION:

The U.S. Animal Health Association urges the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services (VS) to amend the language in VS Guidance Document 8000.1 "Surveillance and Testing Requirements for Interstate Transport of Wild Caught Cervids," the Chronic Wasting Disease Program Standards, and Title 9 Code of Federal Regulations (CFR) Part 81.3, (b) Animals captured for interstate movement and release, to indicate that any wild cervid of a Chronic Wasting Disease (CWD) susceptible species captured and transported interstate for release shall require:

1) A rectal biopsy or other mutually agreed-on method of antemortem CWD test with concurrent genotyping performed on the assembled herd; and
2) Documentation of a sampling scheme sufficient to detect CWD at 1 percent prevalence with 95 percent confidence in wild cervids within the defined source population from which the animals are being moved and conducted within the most recent three-year period. Such sampling scheme shall include both passive (hunter harvest and found dead) and targeted surveillance for CWD.

FINAL RESPONSE:

The U.S. Department of Agriculture, Animal and Plant Health Inspection Service (APHIS), Veterinary Services recognizes the concerns of the U.S. Animal Health Association and appreciates the opportunity to respond. APHIS revised Guidance Document 8000.1 in response to several comments we received, including the proposed language contained in this resolution.

We clarified the requirements about the description of the area's disease history, surveillance, and epidemiology for chronic wasting disease (CWD). Specifically, we added the requirement that, "Cumulative sampling over the most recent three-year period should be sufficient to detect at least a 1 percent prevalence of CWD in the source population with 95 percent confidence." Ante-mortem testing for CWD may help to inform decisions about the risk of CWD in the source population for the wild-caught cervids. However, APHIS does not intend to require the rectal biopsy for routine herd surveillance or as a pre-movement test in farmed cervids. In light of this, we retained the option for State animal health officials to require ante-mortem testing for CWD in the guidance document. We also clarified Appendix 1 of the guidance document. APHIS issued the revised Guidance Document 8000.2 in September 2017. APHIS will not pursue changes to the Code of Federal Regulations (CFR) Part 81.3, at this time.

RESOLUTION NUMBER: 33 **APPROVED**

SOURCE: **COMMITTEE ON TRANSMISSIBLE DISEASES OF POULTRY AND OTHER AVIAN SPECIES**

SUBJECT MATTER: **Approval of Real Time Reverse Transcriptase Polymerase Chain Reaction Matrix Assay for Avian Influenza Surveillance in National Poultry Improvement Plan Authorized Laboratories**

BACKGROUND INFORMATION:

National Poultry Improvement Plan (NPIP)-authorized labs have successfully conducted avian influenza screening of flocks using agar gel immunodiffusion (AGID) and enzyme linked immunosorbent assay (ELISA) tests with approval of their Official State Agency (OSA) and State Animal Health Officials (SAHOs) for 18 years. The real-time reverse transcriptase polymerase chain reaction (RRT-PCR) matrix assay for influenza A provides highly sensitive detection, which is critical to ensure birds are negative prior to translocation to other facilities. Authorized laboratories have successfully utilized molecular diagnostics for Salmonella and Mycoplasma, and these assays have proven invaluable in NPIP program testing and compliance.

An NPIP authorized primary breeder company laboratory not affiliated with the National Animal Health Laboratory Network that uses a U.S. Department of Agriculture approved influenza A matrix assay RRT-PCR, achieves ISO 17025 quality certification, satisfactorily passes an National Veterinary Services Laboratory (NVSL) avian influenza matrix RRT-PCR proficiency test, and has an agreed memorandum of understanding with their SAHOs and OSA should be allowed to use the assay as a screening test within the NPIP's U.S. Avian Influenza Clean program. Any non-negative detection at a NPIP-authorized laboratory would immediately be forwarded to the NVSL for confirmation. Notification of SAHOs and the OSA will occur as outlined in NPIP provisions and State animal health emergency protocols.

The following proposal was approved at the 2016 NPIP Biennial Conference:

§ 145.14 Testing
(d) For avian influenza.
(2) *Agent detection tests.* Agent detection tests may be used to detect influenza A matrix gene or protein but not to determine hemagglutinin or neuraminidase subtypes. Samples for agent detection testing should be collected from naturally

occurring flock mortality or clinically ill birds.
(i) *The real time reverse transcriptase/polymerase chain reaction (RRT-PCR) assay.*
(A) The RRT-PCR tests must be conducted using reagents approved by the Department and the Official State Agency. The RRT-PCR must be conducted using the National Veterinary Services Laboratories (NVSL) official protocol for RRT-PCR or a test kit licensed by the Department and approved by the OSA and the State Animal Health Official, and must be conducted by personnel who have passed an NVSL proficiency test.
(a) For non-National Animal Health Laboratory Network (NAHLN) Authorized Laboratories:
(i) RRT-PCR testing can only be used by primary breeder company Authorized Laboratories,
(ii) RRT-PCR testing can only be performed on their own breeding flocks and only used for routine surveillance,
(iii) The Authorized Laboratory has a quality system that is accredited as ISO/IEC 17025 or equivalent to perform the avian influenza RRT-PCR assay,
(iv) The Authorized Laboratory Memorandum of Understanding (MOU) included approval of use between the Authorized Laboratory, the Official State Agency (OSA), and the State Animal Health Official(s) of both the location of the Authorized Laboratory and the location where the breeder flocks reside,
(v) Split samples for testing must occur between the Authorized Laboratory and a NAHLN laboratory at a frequency designated in the MOU.
(B) Positive results from the RRT-PCR must be further tested by Federal Reference Laboratories using appropriate tests for confirmation. Final judgment may be based upon further sampling and appropriate tests for confirmation.

§ 146.13 Testing
(b) Avian influenza.
(2) *Agent detection tests*. Agent detection tests may be used to detect influenza A matrix gene or protein but not to determine hemagglutinin or neuraminidase subtypes. Samples for this testing should be collected from naturally occurring flock mortality or clinically ill birds.
(i) *The real time reverse transcriptase/polymerase chain reaction (RRT-PCR) assay.*
(A) The RRT-PCR tests must be conducted using reagents approved by the Department and the Official State Agency. The RRT-PCR must be conducted using the National Veterinary Services (NVSL) official protocol for RRT-PCR or a test kit licensed by the Department and approved by the OSA and the State Animal Health Official, and must be conducted by personnel who have passed an NVSL proficiency test.
(a) For non-National Animal Health Laboratory Network (NAHLN) Authorized Laboratories:
(i) RRT-PCR testing can only be used by primary breeder company Authorized Laboratories,
(ii) RRT-PCR testing can only be performed on their own breeding flocks and only used for routine surveillance,
(iii) The Authorized Laboratory has a quality system that is accredited as ISO/IEC 17025 or equivalent to perform the avian influenza RRT-PCR assay,
(iv) The Authorized Laboratory Memorandum of Understanding (MOU) included approval of use between the Authorized Laboratory, the Official State Agency (OSA), and the State

Animal Health Official(s) of both the location of the Authorized Laboratory and the location where the breeder flocks reside,
(v) Split samples for testing must occur between the Authorized Laboratory and a NAHLN laboratory at a frequency designated in the MOU.

(A) Positive results from the RRT-PCR must be further tested by Federal Reference Laboratories using appropriate tests for confirmation. Final judgment may be based upon further sampling and appropriate tests for confirmation.

RESOLUTION:

The U.S. Animal Health Association urges the U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service, Veterinary Services to approve the use of a USDA approved real-time reverse transcriptase polymerase chain reaction (RRT-PCR) matrix assay for influenza A in National Poultry Improvement Plan (NPIP)-authorized primary breeder company laboratories, as outlined in the NPIP proposed and passed change to the 9 Code of Federal Regulations 145.14 and 146.13 (Testing).

FINAL RESPONSE:

The U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services (VS) recognizes the concerns of the U.S. Animal Health Association and appreciates the opportunity to respond. Based on this committee's support, the National Poultry Improvement Plan (NPIP) Biennial Conference, the National Assembly of State Animal Health Officials, and VS will be moving forward with implementing this policy. We will share a draft template memorandum of understanding (MOU) with the impacted States and primary breeder groups for review and comment prior to finalization. Actual implementation of the MOU will be dependent on the primary breeder laboratory receiving their ISO17025 accreditation.

(Note: The reference to 9 CFR Part 146.13 is not applicable here as that deals with the commercial poultry industry, not primary breeders. The background information specifically mentions primary breeders only.)

RESOLUTION NUMBER: 35 **APPROVED**

SOURCE: **COMMITTEE ON TRANSMISSIBLE DISEASES OF POULTRY AND OTHER AVIAN SPECIES**

SUBJECT MATTER: **Upland Gamebird Secure Poultry Supply Plan**

BACKGROUND INFORMATION:

The upland gamebird industry is a $1.9 billion industry that produces pheasants, bobwhite quail, chukar, and Hungarian partridges for the U.S. gamebird hunting industry.

To minimize business interruption during a highly pathogenic avian influenza event, the U.S. Department of Agriculture, Animal and Plant Health Inspection Service continues to develop Secure Poultry Supply (SPS) plans for the table-egg layer, broiler, and turkey industries using new risk assessments and past experience to act as tools to help emergency decision makers provide rapid science-and risk-based decisions on the issuance or denial of movement permits within a Control Area.

The North American Gamebird Association, through its gamebird SPS plan working group, is attempting to develop a SPS plan for upland gamebirds, which will be based upon a specific science- and risk-based plan and will include completed risk assessments.

RESOLUTION:

The U.S. Animal Health Association supports the current funding from U.S Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services for the Upland Gamebird Secure Poultry Supply Plan risk assessments and encourages continued funding for these risk assessments beyond the current cooperative agreement.

FINAL RESPONSE:

The U.S. Department of Agriculture, Animal and Plant Health Inspection Service (APHIS), Veterinary Services recognizes the concerns of the U.S. Animal Health Association and appreciates the opportunity to respond. At this time, APHIS cannot commit additional funding to this activity. We will continue to evaluate internal resources to determine what efforts we can direct towards these risk assessments.

RESOLUTION NUMBER: **38** **APPROVED**

SOURCE: **COMMITTEE ON TUBERCULOSIS**

SUBJECT MATTER: **Optimization and Standardization of Purified Protein Derivative Tuberculin Application for Interferon-gamma Release Assays**

BACKGROUND INFORMATION:

Infection with Mycobacterium bovis (M. bovis) continues to impact the U.S. cattle industry, with a significant number of tuberculosis (TB)-infected herds detected in different States in 2016. The caudal fold tuberculin (CFT) test is the primary screening test used in the bovine TB program. A major disadvantage of this test is that it requires cattle to be handled twice, once for the injection and a second time to interpret the test. Further, the person performing the test must also be adequately trained and sufficiently experienced to interpret the test results accurately. Experience is critical and determining a "response" may be subjective, especially if the response to the injection is weak. Test result accuracy may also depend on the purified protein derivative tuberculin that is applied. Current regulation allows a range of potency as prescribed in the respective regulation of Title 9 Code of Federal Regulations (CFR) 113.409(c).

Currently, used antibody tests demonstrate poor specificity, resulting in too many false negative test results and leading to undetected reactors remaining in the herd. In addition, antibody tests can interfere with the CFT.

BOVIGAMTM is one official auxiliary test used in cattle herds with the approval of the State Animal Health Officials and U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, National Import Export Services Service Centers. This test may be used under direction of the Designated TB Epidemiologist and with concurrence of the Regional TB Epidemiologist. BOVIGAMTM is an IFN-y release assay which is widely used in different national TB eradication programs world-wide. In 2015, the World Organization for Animal Health (OIE) approved BOVIGAMTM for use as a primary test. Resolution 29/2014 recommends the use of BOVIGAMTM utilizing Lelystad PPD due to improved sensitivity, whereby specificity remains equivalent in comparison to PPD from the Commonwealth Serum Laboratories origin. However, test accuracy is dependent upon standardized and harmonized batch production of the applied PPD tuberculin for the stimulation of the whole blood samples.

An optimized and more standardized PPD tuberculin for IFN-y release assay applications should be developed to improve the national TB program, which is urgently needed by the cattle industry.

RESOLUTION:

The U.S. Animal Health Association urges the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Center for Veterinary Biologics (CVB) to work with Veterinary Services' Cattle Health staff to optimize purified protein derivative tuberculin for interferon-gamma release assays. The resulting product(s) should be submitted to the CVB for licensing purposes.

FINAL RESPONSE:

The U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services (VS) recognizes the concerns of the U.S. Animal Health Association and appreciates the opportunity to respond. The National Veterinary Services Laboratories, in association with the Agricultural Research Service's National Animal Disease Center, are evaluating *M. bovis* and *M. avium* purified protein derivatives from four commercial sources. In addition, VS is working to determine if variability exists between commercial sources of the enzyme-linked immunosorbent assay plates using plasma from known positive and negative animals. VS expects to complete this work in fiscal year 2018.

RESOLUTION NUMBER: 44 **APPROVED**

SOURCE: **COMMITTEE ON Parasitic and vector-borne diseases**

SUBJECT MATTER: **Development of Cattle Fever Tick Prevention and Treatment Methods for Both Livestock and Wildlife**

BACKGROUND INFORMATION:

The Texas Cattle Fever Tick Eradication Program (CFTEP), established in 1906, is the oldest livestock pest eradication program in the Nation. CFTEP's mission is to eradicate fever ticks through the management of a permanent quarantine zone, as well as through temporary quarantine areas created to address the presence of fever ticks outside the permanent quarantine zone. The 100 percent treatment of cattle requirement, while primarily responsible for the successful eradication of fever ticks from the United States in 1946, creates a burden for producers by increasing gathering frequency and handling of cattle.

Producers have historically treated cattle fever ticks by applying a variety of acaricides through the use of swim vats. Due to environmental concerns and tick resistance issues, coumaphos is the only remaining, licensed topical acaricide for use in eradication efforts and has a required treatment interval of 7 to 14 days. Doramectin is the only approved systemic acaricide and has a required treatment interval of 25 to 28 days. Systematic treatment of infested cattle must occur at the frequency prescribed by one of the two treatments for the duration of the quarantine period. Quarantine periods for infested cattle can last nine months or longer.

Moving forward, development and implementation of preventative therapies, such as vaccines, will be key to mitigating the risk of fever tick incursions from Mexico and reducing the size of cattle fever tick outbreaks. A recently developed fever tick vaccine is now in use in beef cattle in the permanent quarantine zone and temporary preventive quarantine areas. The vaccine will be a valuable tool in eradication efforts. While it is highly efficacious against the *Rhipcephalus annulatus* tick, it has only moderate efficacy against the *R. microplus* tick, the species of fever tick involved in the current large outbreaks.

Wildlife, such as white-tailed deer, and exotic wildlife, such as red deer, elk, and nilgai antelope, are also very competent fever tick hosts. Expanding populations of these wild and exotic hosts have led to, and are continuing to be major contributors to, fever tick outbreaks outside of the permanent quarantine zone. The most recent of these include the current outbreak in Cameron and Willacy counties in Texas. An approximately 223,000-acre temporary preventive quarantine area was established in October 2014 in Cameron County after the discovery of infested cattle on three premises outside of the permanent quarantine zone. Since October 2014, the number of infested premises in Cameron and Willacy Counties has risen to nearly 40, and the number of quarantined acres has risen to nearly 360,000. Approximately two-thirds of the currently infested

premises are attributed to infested nilgai antelope, demonstrating that the species is an important contributor to the northern movement of the cattle fever tick. Similarly, wildlife hosts contribute to an increase in fever tick infestations in the permanent quarantine zone as land use transitions away from cattle ranching and into wildlife only operations. There is no current treatment method for nilgai antelope or other exotic wildlife hosts, and only one approved treatment for white-tailed deer.

The diminishing number and short treatment interval of approved treatments, the limited number of new treatment and prevention mechanisms for cattle, and the limited to non-existent treatment and prevention methods for wild and exotic hosts are putting fever tick eradication efforts at risk. Additionally, as the current fever tick outbreaks spread, cattle producers are forced to assume the additional costs of increased gathering and treatment of cattle when there is no available effective mechanism to treat infested wild and exotic hosts. The only current mechanism for control of infested exotic wildlife hosts is lethal removal.

RESOLUTION:

The U.S. Animal Health Association (USAHA) urges the U.S. Department of Agriculture, Animal and Plant Health Inspection Service (APHIS) to collaborate with the Agricultural Research Service to prioritize research projects to:

1) develop, and gain approval for the use of new, systemic cattle fever tick treatment products with longer treatment intervals for cattle;
2) develop, and gain approval for the use of new cattle fever tick treatment products for wildlife, especially nilgai antelope; and
3) develop, and gain approval for the use of improved cattle fever tick preventive therapies, such as vaccines, for both cattle and wildlife hosts.

Further, USAHA urges APHIS to prioritize resources for cattle fever tick eradication efforts through increased support of the APHIS, Veterinary Services, Cattle Fever Tick Eradication Program.

FINAL RESPONSE:

The U.S. Department of Agriculture, Animal and Plant Health Inspection Service (APHIS), Veterinary Services recognizes the concerns of the U.S. Animal Health Association and appreciates the opportunity to respond. APHIS has taken several steps to address cattle fever tick treatments, wildlife mitigations, and preventative therapies on both domestic and wild hoof stock. In late 2016, we coordinated a meeting with the Agricultural Research Service (ARS), Mexican government officials, academic institutions in the United States and Mexico, and industry representatives to discuss a variety of tick mitigations. The meeting allowed for comprehensive expert input on a holistic response to both historical and new dynamics in tick spread, resistance factors, vaccines, wildlife treatments, and other related approaches.

APHIS also met with ARS to develop a research request on improved products for equines, resulting in less frequent treatment, exotic wildlife treatment for use in the field, more effective methods of applying current modalities (including CoRal), fever tick vaccine, other protocols under development, longer duration methods for cattle treatment, and development of baits for vaccine treatment of wildlife.