



UNITED STATES ANIMAL HEALTH ASSOCIATION

2014 RESOLUTION

118TH ANNUAL MEETING

OCTOBER 16-22, 2014 ~ KANSAS CITY, MO

RESOLUTION NUMBER: 1 APPROVED

SOURCE: USAHA/AAVLD COMMITTEE ON ANIMAL EMERGENCY MANAGEMENT

SUBJECT MATTER: Radiological Incident Response and Resources

BACKGROUND INFORMATION:

With more than 100 fixed nuclear facilities nationwide, states must be prepared to assist citizens in the event of a site emergency. Public health and other partners will look to animal/agricultural responders for resources needed for pets and service animals. State animal/agriculture emergency planners have identified a severe lack of these resources and therefore a serious gap in our national animal response capability.

Since October, 2006, the Pet Evacuation and Transportation Standards (PETS) Act has required local and state emergency plans to include citizens with pets and service animals before, during, and after disasters of all types. Citizens evacuated during a radiation emergency event arriving at reception centers with their pets and service animals will require triage, radiation monitoring, external decontamination, and post-decontamination services and support. Trained personnel, standardized protocols and equipment (including personal protective equipment) must be in place to provide these services. Because only a very limited number of persons have received animal decontamination training at both state and federal levels, resources would be immediately overwhelmed in a disaster.

The Department of Health and Human Services and National Disaster Management System (HHS/NDMS) have proven experience at the development and maintenance of personnel resources such as the National Veterinary Response Team (NVRT) to assist states. We believe HHS/NDMS/NVRT provides the ideal solution to fill this critical response gap by development of the following resources: caches of equipment to include mobile animal decontamination portals, personnel teams with current training in animal decontamination techniques, and delivery of guidance and standardized training that can build local response capability to assist animal/agricultural and public health emergency responders and citizens at local, state and federal levels.

RESOLUTION:

The United States Animal Health Association urges the Department of Health and Human Services to develop and maintain personnel, equipment, and training resources, especially those needed for pet and service animal decontamination, to supplement state animal response in radiation emergencies and all-hazards events.



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RESOLUTION NUMBER: 2 APPROVED

SOURCE: USAHA/AAVLD COMMITTEE ON ANIMAL EMERGENCY MANAGEMENT

SUBJECT MATTER: Veterinary License Reciprocity In Emergencies

BACKGROUND INFORMATION:

Large-scale animal emergency disasters can occur during events such as hurricanes, floods, fires, and disease outbreaks. These events have often exhausted in-state resources requiring states to reach out to other states and national organizations to assist in animal emergency response and recovery efforts. The veterinary community has organized itself sufficiently in recent years to respond to such requests for assistance. A limiting factor in fulfilling requests for assistance is the lack of a standardized means of addressing reciprocal licensure during emergencies. Inconsistencies in states' licensing board processes as well as refusal of some boards to recognize out-of-state licenses during emergencies has led to delays in providing assistance when critically needed.

Nationally, there are two professional and legal means for addressing this issue. First, the Emergency Management Assistance Compact (EMAC) is a congressionally ratified mutual aid compact that legally establishes a national system to facilitate the deployment of resources across state lines during an emergency or disaster. To date, all fifty states, the District of Columbia, Puerto Rico, Guam, and the United States Virgin Islands are EMAC members. EMAC is state law; therefore, in most cases, a licensing board does not supersede state law. The state emergency management agencies (EMAs) within the EMAC Member States are responsible for the implementation of EMAC. Second, request of licensed veterinary professionals via non-EMAC processes such as Memoranda of Agreement (MOA) between state emergency management and recognized entities or organizations allows for specific requirements for deployment to be outlined in advance which streamlines the license reciprocity processes.

These means are both effective and protective due to the national veterinary licensure examination and continuing education requirements in place to ensure continuity and standardization of the practice of veterinary medicine in the United States.

RESOLUTION:

The United States Animal Health Association urges the American Association of Veterinary State Boards to develop and distribute to Veterinary State Boards a position statement in support of reciprocal veterinary medical licensure as outlined under state emergency management laws, regulations, and guidelines.



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RESOLUTION NUMBER: 3 APPROVED

SOURCE: USAHA/AAVLD Committee on Environment and Toxicology

SUBJECT MATTER: Reportable Toxicoses

BACKGROUND INFORMATION:

Following the observation that animal disease diagnostic laboratory Toxicology sections provide analytical services that often cross state lines, this Committee found that a vast majority of states (42 of 50) have no requirement for reporting toxicoses or toxicants that could be of a food safety or animal population concern. Laboratories certified by accrediting bodies generally have "Client Confidentiality" policies that prevent the release of testing data to third parties unless authorized by the owner/submitting party or required by law. This Committee has reports of cases where the reporting of toxicoses or toxicants could have been important from an animal health or food safety standpoint but a lack of requirement for reporting has resulted in non-reporting. This Committee also recognizes that the required reporting of all toxicants identified by a Toxicology laboratory would be overwhelming, because all compounds can be potentially toxic.

RESOLUTION:

The United States Animal Health Association requests all members of the National Assembly of State Animal Health Officials include toxicoses/toxicants as part of their required reportable diseases. This required reporting should be inclusive of cases of toxicoses, identification of adulterated products, and cases in which toxicants could contaminate the feed or food supply. The Committee recommends that the wording for these reportable conditions be written such that it would not require the reporting of all measured chemicals found by the laboratory (e.g. the reporting of every measured nitrate test whether of clinical concern or not).

The Committee recommends that the following could serve as a template for inclusion in a state's reportable disease list:

Cases of toxicoses, large mortalities of unknown cause, or identification of adulterants/toxicants that have the potential to be a public health, animal health or food safety threat must be reported.

The Committee believes that such timely reporting will serve to increase the protection of animal and public health.



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RESOLUTION NUMBER: 4, 12, AND 24 COMBINED APPROVED AS AMMENDED

SOURCE: COMMITTEE ON IMPORT- EXPORT
COMMITTEE ON TRANSMISSIBLE DISEASES OF SWINE
COMMITTEE ON FOREIGN AND EMERGING DISEASES

SUBJECT MATTER: Need for United States Department of Agriculture, Animal and Plant Health Inspection Services Risk Assessment and Rulemaking prior to Allowing Imports from Countries with African Swine Fever

BACKGROUND INFORMATION:

For the last few years, African Swine Fever (ASF) has spread from Russia to Eastern European countries. This is a deadly disease of swine for which there is no vaccine available and little hope of a vaccine being developed in the near future. Other than killing the infected animals and applying sanitary measures, there are no tools to control the disease. Many of the cases have been in feral swine, but ASF has also been found in commercial herds in countries with significant commercial production, such as Poland and Lithuania.

Recent media reports indicate the United States is preparing to accept importation of meat from Lithuania. The media reports focused on the United States Department of Agriculture (USDA), Food Safety Inspection Service's audit of Lithuania's food safety system to determine equivalence with the United States system. The U.S. industry supports equivalence audits as a means of assuring the food safety of meat and meat products in international trade. Equivalent food safety systems, however, do not address the risk of transmitting a foreign animal disease such as ASF via trade in meat and meat products. That requires a risk assessment by the USDA, Animal and Plant Health Inspection Service which to our knowledge has not been done.

The introduction of ASF into the U.S. swine herd would be economically devastating to the U.S. pork industry and other commodities including corn and soybeans. It would cost USDA and the public millions, if not billions, of dollars in disease control expenditures and indemnity payments for infected animals, with little hope of eradication. Export markets would likely be lost immediately, sending prices into an unprecedented downward spiral.

RESOLUTION:

The United States Animal Health Association requests that United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) conduct a risk assessment of any country that has African Swine Fever (ASF) - in domestic, wild, or feral swine - which currently exports or seeks to export swine, porcine genetic material, pork or pork products into the United States. USDA-APHIS shall apply this risk assessment as the basis for independent rulemaking as opposed to amendment of current regulations that pertain to other Foreign Animal Diseases. Such rulemaking would include a proposed rule and a comment period. Only after such rulemaking and consideration of comments should imports be considered. If, during rulemaking, USDA-APHIS recommends development of an ASF Free Compartment within such a country, it is requested that producers in the Compartment be required to follow and document the same biosecurity practices as would US producers in the case of an ASF outbreak. These biosecurity practices are outlined in the Secure Pork Supply Plan (<http://www.securepork.org/plan-components.php>).

INTERIM RESPONSE:

The U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services (VS) shares the concerns of the U.S. Animal Health Association and appreciates the opportunity to respond.

APHIS mitigates the risk of introduction of African swine fever (ASF) into the United States by restricting the importation of pork and pork products from ASF-affected regions. Foreign regions that are subject to these restrictions are specified on an APHIS web-based list of ASF-affected regions. These import restrictions apply irrespective of any findings by the USDA Food Safety and Inspection Service, or any other Federal agency, regarding whether the foreign regions meet other separate requirements for eligibility to export to the United States. The APHIS restrictions are effective until the region is removed from its ASF-affected list, which APHIS does only after performing a risk analysis to determine the ASF status of the region.

Most foreign regions in which ASF is present are included on APHIS' ASF-affected list. The exceptions are regions of the European Union (EU), to which ASF has recently spread. In response to the recent spread of ASF in Europe, APHIS is drafting a trade restrictive action for ASF-affected regions of the EU and will add those regions to its ASF-affected list. Adding these geographic regions to the list would subject pork and pork products from these regions to APHIS import restrictions designed to mitigate the risk of ASF introduction into the United States. This action would be similar to the APHIS approach of mitigating the risk of disease incursions into the United States from the EU of other serious diseases of livestock and poultry, namely classical swine fever, highly pathogenic avian influenza, and Newcastle disease. APHIS will continue to monitor available epidemiological information for ASF outbreaks and update its list of ASF-affected regions accordingly.



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RESOLUTION NUMBER: 6 AND 11 COMBINED APPROVED

SOURCE: COMMITTEE ON IMPORT-EXPORT
COMMITTEE ON BLUETONGUE AND RELATED ORBIVIRUSES

SUBJECT MATTER: Bluetongue, National Strategy for Animal Exports

BACKGROUND INFORMATION:

The importance of bluetongue and related orbivirus infections to the United States livestock industry was the focus of a recent United States Department of Agriculture Gap Analysis workshop available at: <http://www.ars.usda.gov/SP2UserFiles/Program/103/OrbivirusGapAnalysisWorkshopFinalFeb2014.pdf>. The global range of bluetongue virus has expanded recently, notably:

- The discovery since 1998 of at least ten new serotypes of bluetongue virus in the Southeast indicates that previously exotic viruses now are entering the United States, likely from the Caribbean Basin. Some of these viruses have now spread beyond the southeastern United States.
- The emergence of numerous serotypes of bluetongue virus into Europe since 1998 has been associated with extensive clinical disease in both sheep and cattle. Climate change is widely accepted to have played a role in the spread of bluetongue viruses into Europe through its impact on the insect vector, particularly in the Mediterranean Basin.

Endemic bluetongue virus infection has resulted in the imposition of non-tariff trade barriers to the international export of ruminant livestock from the United States. At present, there is no coordinated surveillance for bluetongue virus in the United States to detect potential introductions of new virus serotypes or document their spread. Without comprehensive surveillance it will be difficult or impossible for the United States to develop an internationally accepted regionalization strategy to facilitate livestock exports.

RESOLUTION:

Given the historic and ongoing negative impact of endemic bluetongue virus infection to the export of ruminant livestock from the United States, the United States Animal Health Association requests that the United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, develop, educate and facilitate a national strategy for animal exports, possibly through regionalization supported by a national surveillance program as prescribed by the World Organization for Animal Health's (OIE) Terrestrial Animal Health Code chapter 8.3.

INTERIM RESPONSE:

The U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services (VS) shares the concerns of the U.S. Animal Health Association and appreciates the opportunity to respond.

Currently, VS is in the early stages of determining and evaluating possible strategies for national bluetongue surveillance in ruminants to support export of ruminant livestock from the United States.



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RESOLUTION NUMBER: 7 **APPROVED AS AMENDED**

SOURCE: USAHA/AAVLD COMMITTEE ON AQUACULTURE

SUBJECT MATTER: Use of the Lacey Act to Regulate Animal Pathogens

BACKGROUND INFORMATION:

In the 2014 United States Congress, two bills (S.1153 & H.R.996) were introduced that will, if passed into law, undoubtedly create numerous problems not only for the movement of aquacultured animals within the United States (US) but also for the movement of all species of domesticated livestock.

Currently the United States Fish and Wildlife Service's (USFWS) authority is limited to the control over a few aquatic animal diseases under Title 50 regulations. Under the National Aquatic Animal Health Plan (NAAHP) many believe that this authority should be rescinded by Congress and given to United States Department of Agriculture (USDA), which has authority over all other animal diseases and is the internationally recognized competent authority by the International Office of Epizootics (OIE – World Organization of Animal Health). S.1153 and H.R. 996 seek to dramatically expand USFWS' disease authority over all animal diseases, including aquatic animal diseases, by giving USFWS the ability to arbitrarily list any nonnative pathogen or parasite as an injurious species, hence creating two competing competent authorities. Furthermore, these acts eliminate various safeguards that Congress put into the Injurious Species Act, such as complying with the Administrative Procedures Act, thereby allowing the USFWS to more quickly list a species as injurious, without adequate review by the United States Animal Health Association (USAHA), industry, and others. An example of what would occur with the passage of S.1153 and H.R. 996 is illustrated by USFWS' recently publishing in the Federal Register the agency's intent to list all amphibians infected with the Chytrid fungus as injurious species (see USAHA Resolution #8, 2010).

The seriousness of the problems that enactment of these bills will create for animal agriculture cannot be overstated. For instance, with the authority thus granted, USFWS could list Chytrid fungus as an injurious species, even though the USDA, Animal and Plant Health Inspection Service has refused to restrict the movement of animals infected with this organism because Chytrid fungus has been in the US for over 80 years and is already widely distributed. If this organism was to be listed by the USFWS as an injurious species, however, then any interstate shipment of aquatic animals, such as a semi-truck shipment of live fish with an inadvertent hitchhiker such as a single infected tadpole, would expose the shipper to felony prosecution under the Lacey Act, where the minimum fine would be \$100,000. The USFWS could also list a nonnative cattle or swine disease organism as injurious, if the disease organism could also infect deer or elk and hence was considered a "nonnative wildlife taxa." Such a listing would subject any interstate shipper of infected cattle or swine to the same felony Lacey Act prosecution as stated above. Such authority would also cover infected dead product being shipped interstate.

The extended authority that would be granted to the USFWS by passage of these bills would, unfortunately, open America's farmers to unnecessary regulations and litigation and severely limit our farmers' ability to conduct business.

The USDA is the competent federal agency with regulatory oversight over domestic animal diseases. The previous memorandum of understanding between the three agencies i.e. National Oceanographic and Atmospheric Administration [NOAA], USFWS, and USDA provides guidance and cooperation among the different agencies and gives stakeholders the knowledge and assurance of each agency's sphere of influence. This understanding has also been restated in the National Aquatic Animal Health Plan (2008). This cooperation is critical and has been strongly supported by the USAHA.

RESOLUTION:

The United States Animal Health Association (USAHA) strongly opposes the passage of S.1153 and H.R. 996 and any similarly worded bills that seek to allow the United States Fish and Wildlife Service to use the injurious species provisions of the Lacey Act to regulate animal pathogens. Further, the USAHA strongly encourages the United States Department of Agriculture, Animal and Plant Health Inspection Service, United States Fish and Wildlife Service, National Oceanic and Atmospheric Administration, and the Association of Fish and Wildlife Agencies to clearly determine the appropriate agency or agencies for regulatory oversight of wildlife diseases and the appropriate agency for domestic animal diseases, without regulatory duplication.



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RESOLUTION NUMBER: **8** **APPROVED**

SOURCE: **COMMITTEE ON JOHNE'S DISEASE**

SUBJECT MATTER: **Assess Johne's Disease Fecal Check Test Performance**

BACKGROUND INFORMATION:

The United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, National Veterinary Services Laboratory's Johne's Disease fecal check test is a valuable resource to cattle producers, veterinarians, diagnostic laboratories, and animal health agencies. Most samples included in the Johne's Disease fecal check test are characterized as high fecal shedders and non-infected cattle, but most fecal shedders in infected herds shed low numbers of organisms. Variation in precision of results from the Johne's Disease fecal check test from laboratories passing fecal check tests has been observed, in addition to variation in sensitivity of fecal tests used. This has led to concerns about interpretation of results from Johne's Disease fecal testing among laboratories passing the Johne's Disease fecal check test.

The Mycobacterial Diseases of Animals - Multistate Initiative brings together leading scientists, industry representatives, and regulatory officials with a shared vision of improving food security through a reduction in losses from two of the most important diseases of livestock-bovine tuberculosis and Johne's Disease. This group would provide the appropriate expertise for leading a review of the current evaluation and reporting processes.

RESOLUTION:

The United States Animal Health Association requests that the United States Department of Agriculture, Animal and Plant Health Inspection Service sponsor the Mycobacterial Diseases of Animals Multi-State Initiative to create a working group to evaluate the current Johne's Disease fecal check test and propose a plan by the 2015 USAHA Committee on Johne's Disease meeting to improve and report assessment of laboratory performance.

INTERIM RESPONSE:

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

VS will reach out to the Mycobacterial Diseases of Animals - Multistate Initiative to create the working group by March 31, 2015. Support for conference calls and webinars to initiate the working group will be provided and, once initiated, consideration will be given on how and where to host a meeting based on the agenda and objectives outlined.



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RESOLUTION NUMBER: 9 APPROVED

SOURCE: COMMITTEE ON INFECTIOUS DISEASES OF CATTLE, BISON, AND CAMELIDS

SUBJECT MATTER: Importation of Fetal Bovine Serum

BACKGROUND INFORMATION:

Concerns about the current and expected future shortage of North American origin fetal bovine serum is leading to strong concern over importation of contaminating viruses including pestivirus in fetal bovine serum. Current testing is based on decades-old technology which does not adequately detect new and emerging viruses.

RESOLUTION:

The United States Animal Health Association strongly encourages the United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services to revise Title 9 Code of Federal Regulations Section 113.53 standards as they apply to fetal bovine serum testing to make changes requiring the use of appropriately sensitive technology and addressing country of origin labeling.

INTERIM RESPONSE:

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

VS' Center for Veterinary Biologics (CVB) has developed a group to work on determining which tests should be conducted and how the current rule should be amended. As per the request at the USAHA meeting, once industry subject matter experts have been identified, they will be invited to provide their perspective also. Additionally, the CVB is in the process of developing a working group with the biologics industry to gather information as to how they test Fetal Bovine Serum, and to gain a better understanding of testing the industry may be doing that is additional and/or outside of the current regulatory requirements.



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RESOLUTION NUMBER: 10 APPROVED AS AMENDED

SOURCE: COMMITTEE ON INFECTIOUS DISEASES OF CATTLE, BISON, AND CAMELIDS

SUBJECT MATTER: General Standards for Trichomoniasis Interstate Movement Requirements of Bulls

BACKGROUND INFORMATION:

As of August 2014, trichomoniasis regulations for interstate movement of bulls have been adopted by 28 states. Because rules have been created in collaboration with state animal health officials, private veterinarians, producers, and industry groups much variability exists in requirements between states.

This variability creates confusion and additional expense when bulls are transported interstate. However, a collaborative movement towards consensus on key components has been built on the following: a) the age of virgin bull that can be exempted from testing, b) the length of time that a bull can travel on a negative test, and c) the number of tests and type of test.

RESOLUTION:

The United States Animal Health Association urges state animal health officials that bulls not known to originate from trichomoniasis positive herds be accepted by importing states under the following conditions:

1. Virgin bulls up to 18 months of age be exempted from trichomoniasis testing requirements.
2. A negative trichomoniasis test is valid for 60 days after collection if the bull is held separate from females.
3. A single, negative DNA amplification-based test of samples collected by a United States Department of Agriculture Category II Accredited Veterinarian certified by the state of origin to collect trichomoniasis samples for interstate movement.



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RESOLUTION NUMBER: 13 **APPROVED**

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

SUBJECT MATTER: **Equine Veterinary Accreditation Modules**

BACKGROUND INFORMATION:

Recent equine disease events in the United States (US) highlighted the limited working knowledge of equine practitioners regarding equine regulatory diseases; specifically the scientific laboratory advances and changes in the understanding of disease epidemiology related to equine herpes virus myeloencephalopathy, equine infectious anemia, equine piroplasmiasis, equine viral arteritis, and contagious equine metritis. Knowledge of diagnostic technologies and appropriate testing is critical to the protection of the US equid population. Continued education and outreach to private practitioners on equine regulatory diseases is imperative.

The mission of the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS), National Veterinary Accreditation Program (NVAP) is to ensure the health of the nation's livestock and animal populations through educating private practitioners across the US. Accredited private practitioners are essential protectors of equine health. Recent changes in the USDA-APHIS-VS-NVAP require supplemental training for maintenance of accreditation. Private practitioners must complete USDA-APHIS-VS-NVAP approved supplemental training. Currently equine specific modules are limited to "International Movement of Horses and Slaughter Horse Transport." The addition of equine regulatory disease modules for private practitioners enables equine veterinarians to remain current and ensures continued protection of the US equid population.

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 develop National Veterinary Accreditation Program (NVAP) Equine Disease Modules to address the current science and epidemiology of equine regulatory diseases of interest, including but not limited to, equine herpes virus myeloencephalopathy, equine infectious anemia, equine piroplasmiasis, equine viral arteritis, and contagious equine metritis. Additionally, the USAHA encourages USDA-APHIS-VS-NVAP to collaborate with the USDA-APHIS equine specialists and state animal health officials in equine disease module development.

INTERIM RESPONSE

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

APHIS agrees that adding a National Veterinary Accreditation Program (NVAP) equine diseases module would be useful for accredited veterinarians. APHIS will determine the resources and funding needed to produce this module, with the goal of commencing work in fiscal year 2016. Content for the module will be developed with input from APHIS and State animal health officials, as well as industry experts. Completion of NVAP educational modules typically takes from 12 to 18 months.



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RESOLUTION NUMBER: 14 **APPROVED**

SOURCE: COMMITTEE ON INFECTIOUS DISEASE OF HORSES

SUBJECT MATTER: Enhancements to States' Contagious Equine Metritis Post-Entry Quarantine and Testing Programs

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. Included in the Program Review Team's report to USDA were comments describing deficiencies in regulatory oversight and accountability of programs in states approved by USDA allowing importation, quarantine and testing of equids originating from countries categorized by USDA as CEM affected. Furthermore, the reviewer's did include specific and detailed recommendations that would correct identified deficiencies with regulatory program oversight and other areas.

The 2009 CEM incident in the United States involving 48 States and 991 exposed equids initiated "The First Conference of Experts on CEM" at the United States Animal Health Association (USAHA) meeting in San Diego in 2009. The conference experts concluded that inadequate regulatory oversight of a CEM facility was likely a factor contributing to the outbreak. During this same USAHA conference the Committee on Infectious Diseases of Horses adopted language in a resolution urging that the recommendations included in the program review be implemented. The February 2013 VS Guidance Document 13406.1 with the incorporated Code of Federal Regulations provides standards which each state approved to import horses for CEM Quarantine must adhere as well as setting the minimal facility quarantine, testing, and treatment requirements.

To date, the method USDA utilizes to assess the infrastructure and applicability of each approved state's individual programs when importing horses from CEM affected countries remains unclear. The review team's report recommended the USDA Program Coordinator devise a system of auditing states approved to conduct CEM quarantines. To date, no auditing system to insure State programs are operating in accordance with and fully meeting the defined standard has been implemented. To avoid additional failures in the program that put our domestic populations at increased risk of disease, a credible and measurable means of auditing approved States to insure all facilities within that State meet the established quarantine and program testing standards of each CEM Quarantine Facility is necessary and should be evaluated annually. A component included in the evaluation should be defining the routine regulatory oversight instituted and practiced in each approved State.

The success or failure of this CEM import program is solely dependent on proper implementation of the prescribed quarantine, animal management and testing procedures. Proper implementation is achievable only if knowledgeable, technically trained and qualified individuals provide day-to-day regulatory program oversight.

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:

1. Define specific benchmarks for annual evaluation of each approved state's Contagious Equine Metritis (CEM) Import Quarantine Program. USAHA requests USDA-APHIS-VS develop a standard Annual CEM Import Quarantine State Report Form and Annual Facility Inspection Report Form. The Annual State Report includes an assessment of the state's infrastructure for CEM oversight and the standard operating procedures utilized by CEM import quarantine facilities. The individual facility inspection report should, at a minimum, include evaluation of housing, horse handling, equine care practices, movement within the facility, record keeping, biosecurity practices of facility employees and

veterinarians, and knowledge and training related to reproductive anatomy, sample collection, or handling protocols.

2. Develop protocols for suspending or revoking state approval or individual facility approval when there is a failure to meet the established program standards.
3. Require approved states to have trained qualified personnel, who have completed the USDA's CEM training course to manage the state's CEM Program.
4. Work with CEM state coordinators to review and modify the CEM quarantine facilities' data reporting protocols and to develop a searchable data repository which can produce industry requested summary reports.
5. Provide an annual report of the CEM Import Program to the state animal health officials and equine stakeholders.

INTERIM RESPONSE:

In order from the resolution:

1. The contagious equine metritis (CEM) import testing program is a joint State-Federal program. APHIS develops regulations and program standards. Facility standards are described in VS Guidance 13406.1, "CEM Testing for Imported Horses at Approved Quarantine Facilities." The primary responsibility for oversight and facility inspection lies with participating State animal health officials. State officials are responsible for approval of individual CEM import quarantine facilities and have the ability to revoke approval of non-conforming facilities.

Criteria for approval of a State to conduct CEM import testing are found in 9 CFR 93.301 (h), and give wide latitude for States to operate as they see fit. Requiring an annual facility inspection report is an individual state decision. More specific Federal oversight criteria would require changing the existing CEM regulation. APHIS will obtain input from stakeholders to determine if rulemaking is needed to require more stringent federal oversight over CEM import quarantine facilities through industry meetings, regularly scheduled industry conference calls, and national assembly calls.

2. Requirements for State approval are described in 9 CFR 93.301 (h). APHIS does not approve individual facilities. Facilities are approved by the participating State. Guidelines for facility approval are described in VS Guidance 13406.1, CEM Testing for Imported Horses at Approved Facilities. Responsibility for ensuring compliance lies with the State.

Approval of a State can be revoked if a State does not comply with Federal regulations as described in 9 CFR 93.301 (h) (5), which allows the Administrator to revoke approval of a State upon determinations that any requirements of the CEM regulations are not being met.

3. At this time, there is a regulatory requirement for training of laboratory personnel only. Because this is a joint State-Federal program, at this time it is the responsibility of the State to ensure that personnel working in or overseeing state facilities have appropriate training. While APHIS cannot require training of personnel working in or overseeing test facilities, such training has been provided in the past. In addition, a training course is planned for July 2015.
4. APHIS will work with State CEM coordinators to achieve this.
5. APHIS will provide a summary report at the United States Animal Health Association Infectious Diseases of Horses Committee meeting.



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RESOLUTION NUMBER: 15 **APPROVED**

SOURCE: COMMITTEE ON INFECTIOUS DISEASES OF HORSES

SUBJECT MATTER: Development of Equine Infectious Anemia Working Group

BACKGROUND INFORMATION:

Equine infectious anemia (EIA) has historically been controlled in the United States by the individual states with support of their equine industries. States have instituted regulations to require testing for entry, movement and/or co-mingling, and quarantine of test-positive equids. Annually, approximately 2 million equid samples are tested for EIA, and over the last three years 0.01 percent of the samples were reported as positive. The true prevalence of the infection is not known as there is a significant untested population and in general the only tested animals are those moving interstate or otherwise in accordance with state laws. In recent years, many of the reported cases have been from states with historically low numbers of cases, and a substantial proportion of those positives were in equids not previously tested for EIA; specifically a higher risk population of unsanctioned racing Quarter Horses.

Changes to the federal Equine Infectious Anemia Control program are needed, as the traditional methods have reached a plateau for disease detection. Additionally, recently identified deficiencies in the federal EIA program include, but are not limited to, lack of laboratory oversight, lack of standardization for private practitioners requesting official tests, lack of uniformity in state procedures for managing EIA positive horses, and lack of uniformity in surveillance testing for EIA. Addressing the identified issues is important to the protection of equine health in the United States. Stakeholder and animal health official input is necessary to explore regulatory and non-regulatory options for EIA disease control.

RESOLUTION:

The United States Animal Health Association (USAHA) urges the United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services to convene a working group to discuss and develop recommendations for advancing Equine Infectious Anemia (EIA) disease control and the publication of a proposed EIA rule. The USAHA recommends the EIA working group include state animal health officials, academia (EIA subject matter experts), national and private laboratory representatives, American Association of Veterinary Laboratory Diagnosticians representatives, and industry stakeholders.

INTERIM RESPONSE:

The United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services (VS) recognizes the concerns of the United States Animal Health Association and appreciates the opportunity to collaborate with stakeholders in the establishment of an Equine Infectious Anemia (EIA) discussion group.

The development of a successful strategy for EIA will require support and consensus among a wide group of internal and external stakeholders. Thus, VS plans to convene a discussion group to examine current strategies and regulations for the nationwide control of EIA. The discussion group will be composed of State/Tribal, Federal, and industry representatives, including the American Horse Council, American Association of Equine Practitioners, other equine industry representatives, and the National Assembly of State Animal Health Officials. The discussion group will convene in early 2015 and meet biweekly by conference call. A summary document is expected in summer 2015.



UNITED STATES ANIMAL HEALTH ASSOCIATION

2014 RESOLUTION

118TH ANNUAL MEETING

OCTOBER 16-22, 2014 ~ KANSAS CITY, MO

RESOLUTION NUMBER: 16 AND 23 COMBINED APPROVED

SOURCE: COMMITTEE ON INFECTIOUS DISEASES OF HORSES
COMMITTEE ON LIVESTOCK IDENTIFICATION

SUBJECT MATTER: Record and Electronically Capture Radio Frequency Identification on Imported Horses

BACKGROUND INFORMATION:

With increased global livestock movement there is an increase in disease risk to the United States' horse population. Horse diseases considered high risk include, but are not exclusive to, equine piroplasmiasis, contagious equine metritis, dourine, glanders, equine infectious anemia, African horse sickness, equine viral arteritis and Venezuelan equine encephalomyelitis.

A lack of a reliable and traceable permanent identification system for horses imported into the United States makes it difficult to conduct trace back of animals that are potentially positive or exposed to an infectious disease. There is an immediate need to establish a standard method of permanent identification and traceability for all horses imported into the United States. A 2014 United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, Investigative and Enforcement Services investigation in California led to the detection of an Equine Piroplasmiasis positive Spanish Purebred Horse with a microchip originating in Spain. The lack of microchip recording and electronic capture on import records at the time of importation delayed the investigation of potentially exposed horses as the microchip had to be traced through manufacturers to verify the origin of the horse. Recent equine disease events involving horses imported to the U.S. demonstrate the risk of importation of various diseases. Therefore, traceability of these animals is a critical element in the protection of the U.S. horse population.

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 revise the Code of Federal Regulations to require all equids imported into, or returning to, the United States be identified with an implanted radio frequency identification (RFID) microchip that complies with the International Organization for Standardization 11784 and 18

85 standards (134.2 kHz), unless already implanted with a readable 125 kHz microchip. Universal RFID readers should be present at all import centers and border stations to read both 125 and 134.2 kHz microchips. Additionally, the USAHA urges USDA-APHIS-VS to, at the time of equid importation into the United States, record microchips of imported horses and electronically capture microchip data in a searchable database accessible to animal health officials during a disease investigation.

INTERIM 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 anticipate changing import regulations to require microchips on all imported and exported horses at this time. Identification requirements for imported or returning horses follow requirement for domestic movement. Acceptable forms of individual identification include microchips, tattoos, and descriptions including markings. Because microchips are not required for domestic interstate movement of horses, microchips are not required for import. Some imported horses do have radio frequency identification when they arrive. When a

microchip is present, APHIS plans to use the Veterinary Services Process Streamlining (VSPS) import module to capture microchip numbers, when available, on imported horses. Microchip information in VSPS is accessible to VS personnel and will be provided to State Animal Health Officials on request in the event of an outbreak.



UNITED STATES ANIMAL HEALTH ASSOCIATION

2014 RESOLUTION

118TH ANNUAL MEETING

OCTOBER 16-22, 2014 ~ KANSAS CITY, MO

RESOLUTION NUMBER: 17 **APPROVED**

SOURCE: **COMMITTEE ON SCRAPIE**

SUBJECT MATTER: **Proposed Scrapie Rule**

BACKGROUND INFORMATION:

While the Scrapie Eradication Program has been extremely successful in decreasing the prevalence of scrapie in the United States, eradication has not yet been achieved in sheep or goats. Improved traceability and surveillance are needed to detect the last remaining cases of scrapie, proving to our trading partners that the United States is scrapie-free thus adding approximately \$50 million in export value. Mandatory identification of sheep has allowed slaughter surveillance to be the key in reducing the prevalence of scrapie in sheep by 85 percent. Slaughter surveillance of goats has been problematic because currently only 50% of mature goats are officially identified at slaughter, making it challenging to conduct effective surveillance.

A draft proposed rule to amend 9 Code of Federal Regulations Parts 54 and 79 has been in clearance for six years. This proposed rule would address standards for official identification and traceability for goats as well as other gaps in the regulation. To succeed in the eradication of scrapie, it is imperative that this rule be promptly published for comment and finalized.

RESOLUTION:

The United States Animal Health Association urges the Secretary of Agriculture to give publication of the scrapie proposed rule the priority necessary for it to be published and finalized in federal fiscal year 2015. This proposed rule, which provides for improved traceability for goats and addresses other gaps in the current regulation, is a critically important element needed to achieve scrapie eradication in the United States.



UNITED STATES ANIMAL HEALTH ASSOCIATION

2014 RESOLUTION

118TH ANNUAL MEETING

OCTOBER 16-22, 2014 ~ KANSAS CITY, MO

RESOLUTION NUMBER: 18 **APPROVED**

SOURCE: COMMITTEE ON BRUCELLOSIS

SUBJECT MATTER: Brucellosis Eradication Program Goals, Objectives, and Priorities

BACKGROUND INFORMATION:

Even though the Brucellosis Eradication Program has succeeded in eradicating brucellosis from the United States (US) domestic cattle and bison herds, eradication has not been achieved in all species and continued surveillance and response is needed to detect any resurgence or reintroduction of the disease and to prove to our trading partners that the US is free.

In 2009, the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) issued a concept paper outlining a new direction for the Bovine Brucellosis Program. Associated new regulations have not yet been delivered. In addition to rulemaking, the concept paper stated that federal animal health officials would be responsible for developing program standards, surveillance plans, and other policy documents to meet the performance standards stated in the regulations. Many of these federal activities, including rulemaking, have not been accomplished because in part there have been no goals established for completion of these objectives.

The USDA-APHIS-VS implemented its reorganization in early November 2013. Under this new USDA-APHIS-VS organization it is unclear as to what the USDA-APHIS-VS brucellosis program objectives and priorities are for 2015 and beyond and how USDA-APHIS-VS will accomplish its activities as outlined in the 2009 brucellosis plan. The United States Animal Health Association supports the cattle commodity concept because it provides the flexibility to work on multiple issues more easily than before. Existing animal disease eradication programs, including brucellosis eradication, must have clearly stated annual goals that provide cooperators with the methods to complete the eradication efforts and enter into a surveillance mode as has been done with the other 16 animal diseases that are now foreign to the United States.

RESOLUTION:

The United States Animal Health Association urges the Secretary of Agriculture of the United States to publish the proposed Brucellosis rule to provide stakeholders with annual program goals, objectives, and priorities for the brucellosis eradication program so the original program goal of eradication can be achieved and the eradication program completed.



UNITED STATES ANIMAL HEALTH ASSOCIATION

2014 RESOLUTION

118TH ANNUAL MEETING

OCTOBER 16-22, 2014 ~ KANSAS CITY, MO

RESOLUTION NUMBER: 19 **APPROVED**

SOURCE: COMMITTEE ON BRUCE4LLOSIS

SUBJECT MATTER: Brucellosis in the Greater Yellowstone Area

BACKGROUND INFORMATION:

The State and Federal governments and the livestock industries have spent billions of dollars since 1935 to eradicate *Brucella abortus* infection from livestock in the United States. The presence of *B. abortus* in the United States has a significant economic impact on the livestock industry and may have an impact on international trade.

The only known remaining focus of brucellosis caused by *B. abortus* in the United States is in the bison and elk in the Greater Yellowstone Area (GYA) and all signatory parties to the original Greater Yellowstone Interagency Brucellosis Committee (GYIBC) Memorandum of Understanding (MOU) (Secretaries of the United States Department of Agriculture (USDA) and United States Department of the Interior, and the Governors of the states of Montana, Idaho, and Wyoming), which created the GYIBC, agreed to a shared objective to eliminate *B. abortus* from the GYA. With the expansion of this disease in elk populations remote from feedgrounds and the resulting transmission to livestock, a plan to eliminate *B. abortus* from bison and elk in Yellowstone National Park, Grand Teton National Park, and the National Elk Refuge, and other areas of the GYA, consistent with the objectives of the original GYIBC MOU, is urgently needed.

After more than a decade of work on an environmental impact statement concerning remote vaccination of bison in Yellowstone National Park using biobullets, the Park chose a "no action" alternative, in part due to potential inadequacies of the use of biobullets to deliver RB51 vaccine to bison in the Park setting.

Recent *Brucella* research conducted by USDA, Agricultural Research Service scientists has demonstrated statistically reduced abortions and colonization in bison following a single annual RB51 booster vaccination. Additionally, USDA, Animal and Plant Health Inspection Service personnel are testing prototypes of a new darting system designed specifically for delivering lyophilized RB51 vaccine to bison in a free range setting.

Results of vaccine efficacy studies conducted on captive bison in containment are not necessarily indicative of results that would be achieved in a field study.

RESOLUTION:

The United States Animal Health Association strongly urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service; USDA, Agricultural Research Service; United States Department of the Interior, National Park Service; and the State of Montana, to initiate a multi-year field trial to evaluate delivery methods and efficacy of RB51 vaccination on Yellowstone bison. Even preliminary results of such a field trial will indicate the efficacy of remotely delivered, boosted, RB51 vaccination in free-ranging Yellowstone bison and determine its utility as a tool to eliminate *Brucella abortus* from the bison population.

INTERIM RESPONSE:

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

VS recognizes the need for further study and evaluation of RB51 regarding its efficacy and field delivery methods for vaccination of Yellowstone bison. APHIS will continue to collaborate with USDA Agricultural Research Service, Department of the Interior, National Park Service, and the State of Montana in development of methods to deliver brucellosis vaccines to bison and develop projects to assess the efficacy of vaccination in Yellowstone bison.



UNITED STATES ANIMAL HEALTH ASSOCIATION

2014 RESOLUTION

118TH ANNUAL MEETING

OCTOBER 16-22, 2014 ~ KANSAS CITY, MO

RESOLUTION NUMBER: 21 **APPROVED**

SOURCE: **COMMITTEE ON BRUCELLOSIS**

SUBJECT MATTER: **Validation of the Brucella Ring Test for Large Dairies**

BACKGROUND INFORMATION:

With the increase in average herd size of United States dairies and the loss of the indirect Enzyme Linked Immunosorbent Assay for brucellosis milk surveillance, states that deem it necessary to continue brucellosis milk surveillance testing are faced with logistical and financial challenges to ensure the validity of their surveillance protocol. At present, the Brucella Ring Test (BRT) is the only test available for detection of antibodies to *Brucella sp.* in bulk milk tank samples. It is, however, only validated for samples up to 1500 head.

RESOLUTION:

The United States Animal Health Association (USAHA) urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) to direct the National Veterinary Services Laboratories (NVSL) to pursue validation of the Brucella RingTest (BRT) for *Brucella abortus* and *Brucella suis* for a sample size up to 5000 head in order to accommodate the increasing average herd size of United States dairies. The USAHA further urges USDA-APHIS, Veterinary Services, NVSL to investigate other tests should such validation of the BRT not be possible.

INTERIM RESPONSE:

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

VS' National Veterinary Services Laboratories (NVSL) will propose a study design for validation of the Brucella RingTest (BRT) for *Brucella abortus* and *Brucella suis* for bulk milk tank volumes containing collections of up to 5,000 head and give the Brucellosis scientific subcommittee an opportunity to comment prior to initiating. In addition, the NVSL will evaluate current antigen preparations, commercial ELISA's, as well as possible new antigen preparations at the NVSL in an ELISA-based format to potentially improve sensitivity and specificity.



UNITED STATES ANIMAL HEALTH ASSOCIATION

2014 RESOLUTION

118TH ANNUAL MEETING

OCTOBER 16-22, 2014 ~ KANSAS CITY, MO

RESOLUTION NUMBER: 22 **APPROVED**

SOURCE: COMMITTEE ON BRUCELLOSIS

SUBJECT MATTER: Brucellosis Testing in Farmed Cervidae

BACKGROUND INFORMATION:

Over the last 50 years during the eradication of bovine brucellosis in cattle in the United States, only the elk and bison in the Greater Yellowstone Area (GYA) have been an impediment to the eradication. Whitetail deer, mule deer, and elk in the other 47 brucellosis free states have never been identified as being either a reservoir for the disease or a public health risk in regard to being infected with *Brucella abortus* or transmitting the agent. The elk in the GYA are not privately owned or controlled, and it is presently illegal to trap, possess, or transport these free-ranging elk privately. Therefore they cannot legally enter animal commerce channels and are not an issue in regard to interstate shipment of brucellosis-infected elk.

Currently, when shipping interstate, a negative *Brucella abortus* blood test must be performed which will then allow thirty days to transport the animal. Should a delay occur beyond the 30 days, the animal must be retested.

RESOLUTION:

The United States Animal Health Association (USAHA) urges state regulatory officials to extend the number of days to accept a negative brucellosis test of farmed cervidae from 30 days to 45 days when the herd of origin is located outside of a State's Brucellosis Designated Surveillance Areas. Furthermore, USAHA urges the United States Department of Agriculture, Animal and Plant Health Inspection Service to incorporate this recommendation into rule as the agency develops the upcoming federal program for cervids.

INTERIM RESPONSE:

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

The requirement to test for brucellosis within 30 days of movement is a State requirement. Currently, there is no Federal requirement for brucellosis testing for the interstate movement of cervids. APHIS has developed a tuberculosis and brucellosis proposed rule and program standards to address ongoing disease risks, including current scientific perspectives on disease transmission and control. The proposed rule and program standards are in departmental clearance at this time. Once the clearance process is completed, the proposed rule and standards will be published in the Federal Register for public comment. We encourage stakeholders to submit their comments at that time.



UNITED STATES ANIMAL HEALTH ASSOCIATION

2014 RESOLUTION

118TH ANNUAL MEETING

OCTOBER 16-22, 2014 ~ KANSAS CITY, MO

RESOLUTION NUMBER: 25 APPROVED

SOURCE: COMMITTEE ON PUBLIC HEALTH AND RABIES

SUBJECT MATTER: Increased Fiscal Year 2016 Funding for the United States Department of Agriculture, Animal and Plant Health Inspection Service, Wildlife Services Oral Rabies Vaccination Program

BACKGROUND INFORMATION:

Rabies programs in the United States that have integrated oral rabies vaccine (ORV) with traditional public and animal health measures have successfully eliminated the transmission of the canine variant of rabies in south Texas coyote populations, halted the westward expansion of raccoon rabies variant at the Appalachian Mountains, and in 2011 eliminated raccoon rabies on Long Island, New York. Successful contingency programs have moved toward Texas gray fox rabies elimination. Today, federal, state and local sponsored and funded ORV programs continue to monitor areas where rabies variants have been eliminated while addressing new challenges. The funding level requested would allow the United States Department of Agriculture (USDA) to maintain ongoing logistical support and wildlife rabies case surveillance necessary for the program, while maintaining existing operational programs to control rabies in target wildlife populations and continue investigation into the control of skunk rabies. Additional funding is needed to address outbreaks and provide emergency response. The USDA, Animal and Plant Health Inspection Service, Wildlife Services, ORV program continues to reduce transmission of rabies to wildlife, livestock, domestic pets and humans. The United States Animal Health Association agrees with the World Organization for Animal Health (OIE) that the best place to address rabies control is at the animal source. Regular distribution of ORV to immunize target wildlife species increases the percentage of rabies immune animals in ORV baiting zones. Creating a reservoir population of immune animals results in a decrease in rabies cases and prevents the spread of rabies to new areas. The United Nations Food and Agriculture Organization believes that terrestrial rabies and foot-and-mouth disease should be the next global disease targets for eradication.

RESOLUTION:

The United States Animal Health Association requests the Congress to appropriate \$28 million for program management and contingency actions at the state level in the Fiscal Year 2016 budget line item for the United States Department of Agriculture, Animal and Plant Health Inspection Service, Wildlife Services, Oral Rabies Vaccine Program.



UNITED STATES ANIMAL HEALTH ASSOCIATION

2014 RESOLUTION

118TH ANNUAL MEETING

OCTOBER 16-22, 2014 ~ KANSAS CITY, MO

RESOLUTION NUMBER: 26 **APPROVED**

SOURCE: **COMMITTEE ON BIOLOGICS AND BIOTECHNOLOGY**

SUBJECT MATTER: **Manufacturing of Veterinary Biologicals without Licensure**

BACKGROUND INFORMATION:

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS), Center for Veterinary Biologics (CVB), has the licensing and enforcement responsibilities for the Virus-Serum-Toxin Act (VST Act) to assure that veterinary biological products distributed in the United States are pure, safe, potent, and effective.

The VST Act requires USDA to provide by regulation an exemption from licensure requirements for biological products made by a veterinarian for use within that veterinarian's practice. USDA-APHIS has promulgated such a regulation at 9 Code of Federal Regulations (CFR) § 107.1(a). Veterinary biologics that fall under this provision are not manufactured in a USDA-APHIS-VS-CVB licensed establishment and have not been reviewed by USDA-APHIS-VS-CVB for safety or efficacy. Some commercial enterprises have undertaken to contract with veterinarians to manufacture and supply unlicensed vaccine products as their "agents." Millions of doses of unlicensed and unregulated vaccines have been administered to food animals under this arrangement, thus exponentially increasing the risk and potential impact from a manufacturing error by the unlicensed manufacturer.

In order to correct this practice, USDA-APHIS published a proposed rule to amend the 9CFR 107.1 regulation in July 2012 [77 Federal Register 42195, July 18, 2012]. The effect of the proposed rule would be to guide such outsourced biologics into the USDA-APHIS-VS-CVB approval process where safety and efficacy are evaluated and manufacturing is overseen, while preserving the intent of the exemption. The proposed rule has not been finalized. With this action, USDA-APHIS has signaled to those who wish to responsibly interact with the agency that this market activity is inappropriate and being eliminated. In individual interactions, USDA-APHIS-VS-CVB has advised biologics manufacturers not to approach the market in this manner, as it is being eliminated. However, there are companies that continue to operate in this manner.

RESOLUTION:

The United States Animal Health Association urges the United States Department of Agriculture, Animal and Plant Health Inspection Service to finalize proposed rule 77 Federal Register 42195, July 18, 2012 regarding the exemption to licensure of veterinary biologics.

INTERIM RESPONSE:

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

In late fiscal year 2014, VS' Center for Veterinary Biologics (CVB) posted a revision to VS Memo 800.211 on the website for public comment. This memo addresses many of the concerns that were raised by various individuals and groups when the proposed rule to revise 9 CFR 107.1 was originally published in late 2012. The revised memo expands the ability of biologics manufacturers to utilize platform technologies/biotechnology to bring innovative products to the market more quickly, reducing the need to produce unlicensed product under a veterinary exemption using a 3rd party manufacturer. The comment period closed January 16, 2015. CVB is currently assessing the comments received. Once the outstanding concerns are addressed, VS Memo 800.211 can be finalized. CVB will also proceed with the publication of the final rule to revise 9 CFR 107.1.



UNITED STATES ANIMAL HEALTH ASSOCIATION

2014 RESOLUTION

118TH ANNUAL MEETING

OCTOBER 16-22, 2014 ~ KANSAS CITY, MO

RESOLUTION NUMBER: 28 **APPROVED**

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

SUBJECT MATTER: **Epidemiology of Chronic Wasting Disease in Farmed Cervids**

BACKGROUND INFORMATION:

Chronic wasting disease (CWD) has been recognized in wild cervids since the 1980s and in farmed cervid herds in the United States since 1997. Since 2012, CWD has been detected in herds monitored longer than the five years required by the United States Department of Agriculture's National Herd Certification Program.

Availability of complete epidemiological information is critical for evaluating the effectiveness of science-based disease control programs; however, very little information is available on CWD epidemiology in the 65 affected farmed cervid herds. Analysis of data from herds with CWD will improve risk assessment; and potentially identify factors contributing to the detection of CWD in herds monitored longer than five years, enhance mitigation strategies to reduce the likelihood of CWD in farmed cervids, and facilitate its earliest detection when it is present.

RESOLUTION:

The United States Animal Health Association (USAHA) requests the United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services to work cooperatively with the states to assemble, analyze, summarize, and make available to the Committee on Captive Wildlife and Alternative Livestock at the USAHA meeting in 2015, all pertinent information from epidemiological investigations of Chronic Wasting Disease (CWD) in farmed and free-ranging cervid herds. Specific information requested includes but is not limited to: prevalence of CWD in positive herds; demography of positive and negative animals in infected herds; results from all tissues that were tested; proximity of affected herd to wild and/or farmed cervid herds with CWD; duration of monitoring prior to detection of the first case, including numbers of animals in the herd, numbers tested and numbers not tested; results of trace-forward and trace-back investigations; and all other pertinent data that will enhance risk assessment of CWD in farmed cervids and identification of effective mitigation measures.



UNITED STATES ANIMAL HEALTH ASSOCIATION

2014 RESOLUTION

118TH ANNUAL MEETING

OCTOBER 16-22, 2014 ~ KANSAS CITY, MO

RESOLUTION NUMBER: 29 **APPROVED**

SOURCE: COMMITTEE ON TUBERCULOSIS

SUBJECT MATTER: Approval of Lelystad Tuberculins for Use in the Bovigam® Assay

BACKGROUND INFORMATION:

The Bovigam® assay is currently approved by the United States Department of Agriculture, Animal and Plant Health Inspection Service for the diagnosis of *Mycobacterium bovis* in cattle. The Bovigam assay is used as a confirmatory test for caudal fold test tuberculin responders. The assay currently uses CSL tuberculin.

The Tuberculosis Scientific Advisory Sub-Committee (TB SAS) recently reviewed documentation on field trial comparisons of CSL tuberculin and Lelystad tuberculin in the Bovigam® assay. The comparisons showed that the assay sensitivity in confirmed *M. bovis* infected cattle was 73.8% and 45.2% for Lelystad and CSL tuberculins, respectively. This difference was statistically significant. Assay specificity in presumed *M. bovis* negative cattle was 96.9% and 95.1%, respectively for Lelystad and CSL tuberculins. This difference was not statistically significant.

In 2012, the TB SAS also reviewed similar data that demonstrated increased sensitivity of the Bovigam® when Lelystad tuberculin was used compared to CSL tuberculin.

Conclusions of the 2014 report from the TB SAS indicated that it would be appropriate to use Lelystad tuberculins in the stimulation phase of the Bovigam® assay.

RESOLUTION:

The United States Animal Health Association requests the United States Department of Agriculture, Animal and Plant Health Inspection Service to license the Bovigam® assay so that Lelystad tuberculins may be used in the stimulation phase of the assay as part of official tuberculosis program procedures.

INTERIM RESPONSE:

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

In order to proceed, the manufacturer must submit an application to the Center for Veterinary Biologics (CVB) for licensure. Once the application has been received, CVB will work with the manufacturer to expedite evaluation of the Lelystad tuberculins for use in the Bovigam assay. Concurrently, VS will review information about the performance of the Lelystad tuberculins in the Bovigam assay according to VS Memorandum 552.40, Evaluation of Tests Proposed for Official Use In the Bovine Tuberculosis Eradication Program. We can then issue a decision regarding official program use after the CVB evaluation for licensure is completed.



UNITED STATES ANIMAL HEALTH ASSOCIATION

2014 RESOLUTION

118TH ANNUAL MEETING

OCTOBER 16-22, 2014 ~ KANSAS CITY, MO

RESOLUTION NUMBER: 30 **APPROVED**

SOURCE: COMMITTEE ON SHEEP AND GOATS

SUBJECT MATTER: State or Regional Brucellosis and Tuberculosis Classification for Sheep and Goats

BACKGROUND INFORMATION:

The United States Department of Agriculture (USDA) has established disease classification systems for Program Diseases that help determine the risk of those diseases within states or regions. Brucellosis classifications cover cattle, bison, and swine. Tuberculosis classification covers cattle, bison, and captive cervids. Goats and sheep are susceptible to both brucellosis and tuberculosis but the current disease classification system does not address these species. These diseases rarely occur in sheep or goats in the United States (US). Attempts to determine the prevalence of brucellosis and tuberculosis in US goats and sheep found two reports. In 1999 a South Texas herd of goats and one sheep were diagnosed with *Brucella melitensis*. USDA currently lists the status of the US as "Free" of *B. melitensis* for diseases reportable to the World Health Organization (OIE). Tuberculosis was diagnosed 1991 and 1992 in two pygmy goats housed in zoos.

Despite the lack of any evidence of brucellosis or tuberculosis in dairy sheep or goats, the Pasteurized Milk Ordinance (PMO) was modified in 1997 to require annual whole herd brucellosis and tuberculosis testing. A resolution from the United States Animal Health Association (USAHA) in 1998 requested a delay in the 1999 implementation of these requirements. A policy letter from the American Association of Small Ruminant Practitioners the same year supported no test requirements for sheep and goats. The end result of these concerns was the addition of the "random statistical herd sampling" option to the PMO in 2001 which sets a minimum sample size based on herd or flock size.

Animal health rules from the 2011 PMO exempt cattle and bison from any testing requirements if they are from an area which has a Certified Brucellosis-Free status and a Modified Accredited Advanced Tuberculosis or greater status. Since these classifications do not include sheep and goats the PMO testing requirements for these species remain in effect.

Establishing a brucellosis and tuberculosis classification for sheep and goats would allow State Veterinarians and USDA Assistant District Directors to develop appropriate brucellosis and tuberculosis surveillance and testing requirements for sheep and goats while still protecting public health.

USDA, Animal and Plant Health Inspection Service, Veterinary Services responded with information concerning data of sheep and goats tested for brucellosis and tuberculosis from 2009 through 2013 from 30 States. None of the 30 states reporting detected a case of brucellosis or tuberculosis in a sheep or goat during this time period. On average, 4,850 animals were tested for brucellosis and 2,295 animals were tested for tuberculosis each year. Brucellosis and tuberculosis are both federally reportable diseases, and neither has been reported by any of the 50 states or territories in sheep and goats in the last 15 years at least.

Testing for brucellosis and tuberculosis in sheep and goats is a significant impediment to interstate commerce without establishing a proven health risk.

RESOLUTION:

The United States Animal Health Association urges the United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services to officially declare domestic sheep and goats in the

United States to be free of brucellosis and tuberculosis and further asks states that require testing of brucellosis and tuberculosis in sheep and goats to rescind these requirements.

INTERIM RESPONSE:

The United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services (VS) recognizes the concerns of the United States Animal Health Association regarding the brucellosis and tuberculosis status of U.S. sheep and goats and appreciates the opportunity to respond.

In fiscal year 2014, VS collected brucellosis and tuberculosis test data for the last five years from the States. Thirty States provided test data; on average, 6,311 animals (665 sheep; 5,646 goats) were tested for brucellosis and 4,409 animals (76 sheep; 4,333 goats) were tested for tuberculosis in these States each year. These numbers of samples are insufficient to make a status determination based solely on this testing. VS completed a report using this data, which will be made available to the Committee on Sheep and Goats. VS is looking at other options for accurately establishing the brucellosis and tuberculosis status of U.S. sheep and goats.



UNITED STATES ANIMAL HEALTH ASSOCIATION

2014 RESOLUTION

118TH ANNUAL MEETING

OCTOBER 16-22, 2014 ~ KANSAS CITY, MO

RESOLUTION NUMBER: 31 **APPROVED**

SOURCE: COMMITTEE ON SHEEP AND GOATS

SUBJECT MATTER: *Brucella ovis* Testing of Rams

BACKGROUND INFORMATION:

Many States require a negative *Brucella ovis* Enzyme Linked Immunosorbent Assay (ELISA) test for rams being imported from other states and countries. Likewise, many grazing associations and ram sales require a negative test. In spite of attempts to standardize the ELISA test reagents, antigens, dilutions, low positive controls, and protocols, many laboratories continue to get *B. ovis* ELISA test results that are called "indeterminate" or may be interpreted as "positive" at one laboratory and "negative" on the same animal's sample at another laboratory. There is, at times lack of consistency or agreement between laboratories on the *B. ovis* ELISA test. The United States Department of Agriculture, Animal and Plant Health Inspection Service, National Veterinary Services Laboratory had earlier suggested standardized test protocols, but there is still lack of consistency between laboratories on applied test protocols.

These discrepancies create inconvenience and added expense for producers, lack of producer and veterinary practitioner confidence and trust in the laboratories, and leave regulatory personnel with many questions about proper disposition of test positive and "indeterminate" rams.

RESOLUTION:

The United States Animal Health Association (USAHA) urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service, National Veterinary Services Laboratory and the USDA, Agricultural Research Service (ARS) to review the protocols for enzyme linked immunosorbent assay (ELISA) *Brucella ovis* testing (test reagents, antigens, dilutions, low positive control) among laboratories conducting the ELISA test and develop an explanation for the "indeterminate" and discrepant results between labs.

USAHA also urges USDA-ARS and USDA-APHIS-NVSL to develop strict, standard testing protocols for all laboratories for the *B. ovis* ELISA test. We further urge American Association of Veterinary Laboratory Diagnosticians and state diagnostic laboratories to adhere to these standard testing protocols.

USAHA further urges USDA-ARS to develop an accurate and consistent *Brucella ovis* confirmatory test for samples with "indeterminate" results to help facilitate prudent regulatory and sheep management decisions.

INTERIM RESPONSE:

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

VS' National Veterinary Services Laboratories (NVSL) will continue to provide annual proficiency tests for the *Brucella ovis* ELISA, and will survey the testing laboratories to follow up on protocol adherence. NVSL will work with USDA-ARS to develop an explanation for the indeterminate and discrepant results between laboratories, and to investigate the possibility of a more accurate test for use in the future.



UNITED STATES ANIMAL HEALTH ASSOCIATION

2014 RESOLUTION

118TH ANNUAL MEETING

OCTOBER 16-22, 2014 ~ KANSAS CITY, MO

RESOLUTION NUMBER: 32 **APPROVED**

SOURCE: COMMITTEE ON SHEEP AND GOATS

SUBJECT MATTER: Q-Fever (*Coxiella burnetti*) for Sheep and Goats and for Humans in the United States

BACKGROUND INFORMATION:

Q-Fever is a zoonotic disease caused by the bacterium *Coxiella burnetti*. *Coxiella* infection is found in many species in many countries of the world, including the United States. 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 recent Q-fever epidemic (human and goat) in the Netherlands.

Currently there is no vaccine available in the United States to prevent *Coxiella burnetti* 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 burnetti* in the United States 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 burnetti*.

2013 Action: Q-Fever (*Coxiella burnetti*) vaccine for sheep and goats and for humans in the United States remains of strong interest to the Committee. Committee recommends that this resolution is still important and be carried forward. Interim response provided some promise of progress; final response with updates would be appreciated.

2014 Action: USAHA Committee on Sheep and Goats urges USDA One Health Office to collaborate with the Center for Disease Control to gather the data on the impact of *Coxiella Burnetti* on human health and the relationship of that to the incidence of disease in animals. This information would be invaluable to support the advancement of the licensure of human and animal vaccines in the United States.

RESOLUTION:

In priority order:

First, 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) to facilitate the licensure of a safe and effective Q-Fever (*Coxiella burnetti*) vaccine for sheep and goats.

Second, the USAHA encourages the Food and Drug Administration to facilitate the licensure of a safe and effective Q-Fever (*Coxiella burnetti*) vaccine for humans.

Third, the USAHA encourages USDA-APHIS-VS, Center for Veterinary Biologics to facilitate the importation, for investigation and research, of available animal Q-fever (*Coxiella burnetti*) vaccines from Canada, the European Union, and Australia.