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The Committee met on October 3, 2011 at the Adam's Mark Hotel in Buffalo, New York, from 1:00 – 6:00pm. There were 34 members and 49 guests present. The meeting was Chaired by Dr. Kent Fowler. Discussion included the desire and need for a National Monthly Equine Conference Call such as was previously conducted by Dr. Tim Cordes. Dr. Fowler will initiate and organize the first call in November 2011. The possibility was raised to rotate the leadership of this call through volunteers.

Time-Specific Paper:

Dr. Peter Timoney, Gluck Equine Research Center, University of Kentucky, presented a time-specific paper on "Resurgence of Glanders: A Cause for Increasing International Concern". The paper, in its entirety, is included at the end of this report.

Hendra and West Nile Viruses in Australia – What is Happening/What is New?

Peter Kirkland, B.V.Sc., PhD, Veterinary Virology Lab, Elizabeth Macarthur Agricultural Institute (EMAI), Camden, Australia

This powerpoint presentation is available online.

Equine Piroplasmiasis - Texas Situation Update

Andy Schwartz, DVM, Texas Animal Health Commission

The investigation of south Texas index case of Equine Piroplasmiasis (EP), initiated in October 2009, was completed over one year ago. No additional related cases have been disclosed since, helping to confirm that the investigation and tracing of exposed horses was thorough and effective. Affected horses not euthanized are being held under quarantine. Use of these animals is allowed on the quarantine premises only. Treatment studies are ongoing, using the ARS recommended protocol. Results of the treatment are very promising.

From October 2009 through June 2011, over 30,000 Texas horses were tested for EP. Most of these tests were for movement interstate or to events. The test positive prevalence in these horses is approximately .25%, excluding testing associated with the index ranch investigation. The national test prevalence during this same time period was approximately .13%, based on information provided in the National EP Situation Report.

In Texas, EP affected horses fall into three categories: Index case associated, international imports on the CF test, and Quarter Horse racehorses. Almost all cases disclosed in Texas over the past year were in the QH racehorse population. Disease spread among this population is thought to be iatrogenic.

To address the QH racehorse situation, the Texas Animal Health Commission (TAHC) passed rules earlier this year requiring a 12 month EP test to enter racetracks, and requiring all EP tests be done on a TAHC test record.

A resolution was passed at the USAHA 2010 Annual Meeting requesting information on horses imported into the US during 1995 – 2005, on the CF test. Records show approximately 9000 horses entered Texas during this time. Efforts are underway to contact owners of these horses imported in 2005, offering a test at no cost. Results of this effort will be used to gauge additional tracing and contacts.

Efficacy of Imidocarb Dipropionate Against *Theileria equi* in Experimentally Infected Horses

Dr. Juanita Grause, USDA-APHIS-NVSL, Serology Section of Diagnostic Bacteriology Lab

Theileria equi, one of the causative agents of equine piroplasmiasis, is endemic in many regions of the world but is considered a foreign animal disease in the United States. In an effort to exclude *T. equi*, the U.S. practices stringent serological screening of horses prior to entry. The discovery of *T. equi* infection in U.S. horses was an impetus for this study. Current sanctioned options available in cases of infected domestic horses include euthanasia and permanent quarantine. Chemotherapeutics that eliminate infection and subsequently transmission risk are a critical need for management of infected horses. In this study, we sought to determine whether imidocarb dipropionate treatment of experimentally infected horses would eliminate *T. equi* infection. Previous studies testing the efficacy of imidocarb dipropionate yielded conflicting results. Here, nine horses were experimentally inoculated with *T. equi*, and six of these were treated with imidocarb dipropionate after the resolution of acute disease. Parasite elimination was demonstrated in all but one horse by the following tests: nested polymerase chain reaction, intravenous blood transfusion from treated to naïve horses, and reversion to seronegative status by CFT, IFA and cELISA. These data show imidocarb dipropionate was capable of eliminating infection in 83% of the horses experimentally infected with an isolate of *T. equi* derived from an infected horse previously imported from Peru.

Update on Detection of Persistent Infection of *T. equi* and *B. caballi*

Dr. Don Knowles, Animal Disease Research Unit, ARS-USDA-PWA & Department of Veterinary Microbiology and Pathology, Washington State University

The re-emergence of *Theileria* causing infection and disease in U.S. horses has led to research testing for methods to eliminate persistent infection. Imidocarb dipropionate is proving effective in eliminating persistent *T. equi* infection in a high percentage of U.S. horses. Also, nested PCR and serologic testing is showing utility in demonstrating *T. equi* elimination from persistently infected horses. Concurrent with the re-emergence of *T. equi*, increased surveillance for infection of U.S. horses with *Babesia caballi* has revealed a small number of U.S. horses with serologic evidence of infection. These horses, those with serological evidence of infection with *B. caballi*, are being studied by additional methods of detection to determine their true serologic and infection status.

Equine Herpesvirus Myeloencephalopathy (EHM) Outbreak Associated with an Equine Event in Ogden, Utah 2011

Angela M. Pelzel, DVM, USDA, APHIS, Veterinary Services

On May 13, 2011, cases of equine herpesvirus myeloencephalopathy (EHM) caused by equine herpesvirus-1 (EHV-1) began to be identified in horses that had recently attended a regional cutting horse event in Ogden, Utah from April 29-May 8, 2011. A total of 421 horses were considered to have been exposed to the virus at the event and subsequently traveled to 19 different states potentially exposing more than 1,685 additional horses. Due to misinformation being widely circulated through social media channels, equine industry groups and state animal health officials requested USDA-APHIS-Veterinary Services' (VS) assistance in gathering and distributing accurate national case information during the incident. APHIS-VS additionally provided standardized guidance to the state animal health officials on recommended management of infected and exposed horses. The incident was considered closed on June 23, 2011 after no more new cases were being identified. Despite quick intervention by the equine industry, individual horse owners and trainers, and state animal health officials, a total of 90 confirmed EHV-1 or EHM cases were identified in association with the outbreak. Of the 90 confirmed cases, 54 cases were in horses that attended the Ogden, Utah event. A total of 13 horses died or were euthanized during the outbreak. APHIS-VS is currently conducting a retrospective EHV-1 study to more fully characterize the cases, assess the economic impact and identify potential risk factors involved in the outbreak.

Equine Infectious Anemia Proposed Rule

Troy T. Bigelow, DVM, Staff Veterinarian, USDA-APHIS-VS-NCAHP-ASEP

The U.S. equine industry and stakeholders are important to the USDA. The USDA has been listening to your concerns, assisting with disease outbreaks such as EHV, and working on animal health rules to protect the equine industry.

2010 EIA testing data identified 47 horses on 30 separate premises as positive. This is consistent with previous years.

USDA Veterinary Services recognizes previous USAHA resolutions asking USDA to place the EIA UMR in to the CFR. Veterinary Services has started the rule making process where a proposed EIA rule is being drafted for publication in the Federal Register. The EIA proposed rule is comprehensive and covers all aspects of EIA including movement requirements, handling of exposed and reactor animals, and laboratory testing requirements. The proposed rule is designed to be comprehensive yet flexible to allow for future change. This rule will assist States by creating consistent standards for EIA.

USDA Veterinary Services has also been developing rules for contagious equine merits (CEM). The interim CEM rule published in the Federal Register March 25, 2011 was seeking comments on testing requirements for stallions, testing imported mares and requirements for stallions. Enforcement of the CEM interim rule is currently on indefinite delay while comments are being reviewed. That said, per the recommendation from a recent reviews VS is developing a CEM database. The database developed in APHIS SharePoint will receive data via an Excel spreadsheet designed to facilitate entry into the SharePoint database. Summary information can be provided to states about the State's activities.

Importation of Horses from CEM-Affected Countries

USDA –APHIS-VS March 2011 CEM Rule – Process Summary: Kentucky State's Perspective

Mr. Rusty Ford, Equine Programs Manager, Kentucky Department Agriculture, Office State Veterinarian

This paper is presented in its entirety at the end of this report.

Committee Business

Following conclusion of the scientific program, the Committee went into Business Session. Two resolutions on Equine Piroplasmiasis (EP) were considered, approved and forwarded to the Committee on Nominations and Resolutions for approval by the general membership. One of these resolutions requests that USDA-APHIS-VS develop and publish guidelines for the release from State quarantine of test negative Equine Piroplasmiasis (*T. equi*) equids that meet given qualifications. The other EP resolution urges USDA-APHIS-VS-NCIE to require both a negative Complement Fixation (CFT) and negative cELISA test for importation of equids into the U.S. A resolution to support NAHLN annual funding was also considered, approved and forwarded to the Committee on Nominations and Resolutions for approval by general membership. The meeting was adjourned at 6:00pm.

Report of the Subcommittee on Equine Piroplasmosis (EP)

Dr. Mike Short, Chair

Florida Department of Agriculture and Consumer Services

Since the USAHA meeting in November of 2010 there has been significant national EP surveillance and research accomplished. EP testing of horses has been driven through industry as well as regulatory authorities. Industry testing has occurred thorough multiple routes including, sanctioned race tracks and breed sponsored events and sales. Regulatory testing has been done primarily through disease investigations, and required international export and interstate testing.

Since November 2009 there have been more than 130,000 horses tested in the US, with 176 horses determined to be positive for EP (excludes the horses detected as positive during the investigation of the 2009 Texas ranch outbreak). All of the positive EP horses, except one with ongoing investigation, have been in one of two high risk categories; those horses imported prior to August 2005 using the CF test and those Quarter Horses involved in racing.

There has been a large amount of EP research done in the past year, with several significant discoveries. Most of this research has occurred at USDA, VS, ARS in Pullman Washington and has included; confirmation that *Amblyomma cajennense* is a competent vector for the transmission of *Babesia equi*; Imidocarb diproprinate can be a successful treatment to clear EP infected horses of the organism *Babesia equi*; and the development of a diagnostic test that will detect the clearance of organism from a treated EP infected horse.

During the past year the EP Subcommittee held two meetings which took place via conference calls. The primary efforts of the subcommittee were focused on discussing the Long-Term Recommendations of the EP Working Group, the issue with false positive *Babesia caballi* results on the commercial cELISA test kit, the most recent EP research findings.

The EP Subcommittee drafted two resolutions for presentation at the Infectious Diseases of Horses Committee.

Significant points of information and discussion were:

- Update on status of the EPWG long-term recommendations
 - o Comments were reviewed by the USDA, APHIS, VS management team and staff and specific responses have been drafted for each recommendation. The VS Management Team is currently reviewing the draft responses. The final responses to each recommendation should be sent to the National EP Working Group soon.
- *B. caballi* suspect case follow-up protocol
 - o There have been a small number of *B. caballi*, cELISA positive results on horses that have had no epidemiological link to high risk disciplines or management and have been of low risk signalment and/or of low risk breed. These same cases have been yielding discrepant results on additional testing. In those cases, additional testing using new diagnostics at NVSL and USDA, ARS in Pullman are being utilized to assist in the true determination of the horse's status. In many of those cases, while the cELISA is at the 40% inhibition level or higher it is believed that the result is a false positive and the test is reacting to a protein not originating from the *B. caballi* organism.
 - o In some cases, transfusion from one of these cELISA positive horses to an uninfected, splenectomized horse has been done. In those cases, the transfusion data has supported the additional testing conclusion of the horse being negative for the *B. caballi* organism.
 - o The final determination of the horse's status in such cases is made jointly by USDA, VS staff and the Chief State Animal Health Official.
- Current Research at ARS Pullman
 - o ARS in Pullman, WA has facilitated treatment of horses in several states, including 150 horses from the Texas index ranch for *B. equi*. Of the 150 Texas horses treated, 147 of those horses were treated successfully (cleared of organism).
 - o ARS, Pullman is continuing to work on validating a clearance test for use after treatment of infected horses. The hope is to have a test that will be accurate in

detection of actual infection and will be accepted by US trading partners and regulatory authorities in the US.

- o Glen Scoles of ARS, Pullman, WA is the lead author on a paper documenting transmission of *B. equi* by adult *Ambloomma cajennense* ticks in Texas.
- Other Discussion
 - o The issue of EP testing of horses being shipped from Puerto Rico to the US mainland is occurring using the cELISA test for both *B. caballi* and *B. equi*. Currently these horses are being tested as a matter of policy due to the USDA tick quarantine.
 - o National Veterinary Services Laboratories runs the cELISA and complement fixation test (CFT) for horses being imported into the US. A small number of these horses are negative on the cELISA and positive on the CFT. There is discussion to make the cELISA and CFT required for import and classify horses that test positive for either test as a positive for EP (reactor), which is consistent with domestic protocol as stated in VS Memorandum 555.20.

RESURGENCE OF GLANDERS: A CAUSE FOR INCREASING INTERNATIONAL CONCERN

Peter J. Timoney, MVB, MS, PhD, FRCVS
Gluck Equine Research Center, University of Kentucky

Introduction:

Glanders is a highly contagious bacterial disease of equids that has been known to afflict equine populations for well over 2000 years since recorded by Aristotle in 350 BC. Some in the major horse breeding and performance countries would regard glanders purely of historical interest, whose geographic distribution is restricted to certain countries/regions of the world where it has been endemic for many centuries. As such, it is not perceived of importance as a potential threat to equine health. This would have been a reasonable assumption prior to the advent of horse transportation by jet aircraft some 50 to 60 years ago. Circumstances have changed dramatically over the intervening years, however, and it is now possible to ship horses by air to almost anywhere around the globe. Continued expansion in the volume of international movements of horses unfortunately, is not without attendant concerns. Although economically beneficial for the equine industries in many countries, the increase in trade is linked to a greater risk of spread of a wide range of equine infectious diseases (Timoney, 2007). In certain instances, diseases have been introduced into naïve equine populations in countries previously free of such infections, or from which they may have been eradicated at some point in the past. This has resulted not only in economic hardship for the industry concerned, but also in a paradigm shift in the global distribution of particular equine diseases including glanders.

General Features and Significance

The etiological agent of glanders is *Burkholderia mallei*, a bacterium that was first discovered by Loeffler and Schuetz in 1862 (Loeffler, 1886). Aside from its significance as a disease of equids, glanders is also widely considered one of the most important zoonotic diseases, a fact that was suspected as far back as 1830. In view of how readily it can be transmitted to humans and the serious consequences of infection, *B. mallei* was one of the first infectious agents to be used for biological warfare purposes (Lehavi *et al.*, 2002; Wittig *et al.*, 2006). Together with dourine, glanders was included amongst the nine most significantly regarded diseases of livestock at the time that led to the establishment of the Office International des Epizooties (O.I.E.) in 1924. It is an O.I.E. listed equine disease and because of the importance of *B. mallei* both as an equine and a human pathogen, outbreaks involving equids must be notified immediately to the O.I.E., now the World Organisation for Animal Health (Anon, 2010).

Host Range

Although glanders is a disease primarily of equids, it can also affect humans and sometimes, Felidae, camels, bears and walruses (Hunting, 1887; Fernandez and White, 2010; Wernery *et al.*, 2011). Amongst the family *Equidae*, donkeys are most susceptible, mules less so and horses still less again, especially cases of chronic infection in endemic areas (Wittig *et al.*, 2006). Whereas cattle and swine are resistant to infection, small ruminants can become infected if maintained in close contact with affected horses. Glanders can also occur in carnivores that have had access to infected meat.

Known Geographic Distribution

Glanders is endemic in various regions of the world including but not exclusive of Asia, the Middle East and South America (Wittig *et al.*, 2006; Wernery, 2011). The disease status of Africa and parts of the former Soviet Union is presently unknown. The following countries have reported or are believed to have had outbreaks of glanders since 1998: Afghanistan, Bahrain, Brazil, India, Iran, Iraq, Kuwait, Lebanon, Mongolia, Pakistan, P.R. China, Syria, Turkey and the United Arab Emirates. Disease events over the past 5 to 10 years, however, would indicate that glanders is no longer as geographically restricted in terms of its global distribution as previously believed. More recent outbreaks in countries from which it was previously eradicated e.g. Bahrain, Lebanon and the United Arab Emirates, heighten the risk of further spread through international horse movements. Furthermore, there have been reports from certain countries in which glanders continues to be endemic e.g. India, of a resurgence in the frequency and extensiveness of outbreaks of the disease in certain states (Malik *et al.*, 2010; Pawaiya and Chauhan, 2008). Accordingly, it behooves veterinary practitioners and animal health officials alike to

be more aware of the disease and more conscious of the risks inherent in the importation of horses from certain countries/regions of the world of unknown or questionable glanders status.

The importance of the risk assessment when considering such shipments cannot be over emphasized. This can best be illustrated by the case of an eight-year-old Crioula mare that was imported into Germany from the state of São Paulo, Brazil, in 2006 (Elschner *et al.*, 2009). Reportedly, glanders had not occurred in the area of the state where the horse had been located within six months immediately prior to export. Furthermore, the mare was certified as negative for complement-fixing (CF) antibodies to *B. mallei* at a serum dilution of 1:10. Within two weeks following her arrival in Germany, she developed an elevated temperature, signs of respiratory illness followed by evidence of an exudative lymphangitis involving metacarpal and metatarsal regions of some of her limbs. Initially, the attending veterinarian believed the mare had a routine respiratory tract infection and treated her accordingly. It was only after the respiratory signs were unresponsive to repeated treatments that glanders was considered a remotely possible cause of the mare's illness. All appropriate laboratory examinations were carried out to establish whether this indeed could be the case. These confirmed a diagnosis of glanders. Very fortunately, the disease was confined to the index case and there was no spread of infection off the affected premises.

A more recent glanders scare involved a horse that was imported from Lebanon into Switzerland via Germany in January 2011 (International Collating Centre Report, 2011). The following month, an outbreak of glanders occurred in Lebanon, affecting at least 25 horses. Once official notification of the disease was received by Switzerland sometime later, the imported animal was located, quarantined and serologically tested. The initial result on the horse, which had remained clinically normal, was positive for glanders. However, a retest was conducted by the O.I.E. Reference Laboratory for glanders in Germany and this failed to confirm the earlier finding. After due consideration, the horse was determined to be uninfected with *B. mallei*. Although the outcome was favorable, this incident reemphasizes the risks associated with the shipment of horses from countries of questionable glanders-free status, and also, how easily this disease could have been introduced on the occasion of this particular importation.

Modes of Transmission

Glanders can be transmitted by direct or indirect means. Most commonly, it is spread through direct physical contact with horses affected with nasal or pulmonary forms of the disease (Hunting, 1887; Fernandez and White, 2010). Indirectly, glanders can be transmitted through the ingestion of food or drinking water contaminated with discharges from the respiratory tract or ulcerated skin lesions of affected horses. It can also be contracted through horses sharing feed troughs/containers, water bowls/buckets, or items of harness contaminated with infective material. The risk of spread of the disease is enhanced under conditions of stress or overcrowding. The importance of the subclinically infected carrier animal cannot be over emphasized as the reservoir and means of persistence and dissemination of *B. mallei* in equine populations in which glanders is endemic.

Clinical Forms of the Disease

Glanders can present in several forms, nasal pulmonary and cutaneous, depending on location of the primary lesion (Hunting, 1887; Fernandez and White, 2010; Wittig *et al.*, 2006). Individual horses may be affected with more than one form of the disease. The incubation period can range from a few days up to six months, based on various agent, host and environmental factors. Horses can be acutely/chronically infected with *B. mallei*. If untreated, cases of glanders are usually fatal. Acutely affected horses die within a few days to several weeks.

-- Nasal form: Horses affected with this form of the disease developed a high fever, anorexia, coughing and become dyspneic. They present with a viscous, yellowish-green, mucoid or sanguinopurulent nasal discharge. This may be accompanied by a purulent ocular discharge. Nodules become evident in the nasal mucosa which subsequently ulcerate and later form stellate scars.

-- Pulmonary form: This acute form of glanders is associated with a prolonged incubation period that can extend up to six months. Affected animals develop fever, dyspnea and a persistent cough. Diarrhea and polyuria may supervene in some infected horses, leading to progressive loss of bodily condition.

-- Cutaneous form (farcy): Ulcerative lymphangitis or farcy usually develops over an extended period of time. Initial signs of farcy include fever, dyspnea, coughing, lymphadenomegaly and lymphangitis. Periods of exacerbation of clinical signs follow, resulting in increasing weight loss and debilitation. The cutaneous form of the disease is characterized by the development of subcutaneous nodules along the course of the lymphatics of the face, legs, costal region or ventral abdomen. Nodules frequently rupture

and ulcerate, giving rise to a multifocal ulcerative dermatitis. Affected lymphatics, which are swollen and frequently considerably thickened, are popularly referred to as “farcy pipes”.

Differential Diagnoses for Glanders: There are a significant number of other infectious diseases, bacterial, fungal or viral, that, based on their clinical features, need to be considered in the context of a differential diagnosis for glanders (Fernandez and White, 2010). These include: melioidosis (*B. pseudomallei*), strangles (*Streptococcus equi*), ulcerative lymphangitis (*Corynebacterium pseudotuberculosis*), epizootic lymphangitis (*Histoplasma capsulatum* var. *farcinimosum*), tuberculosis (*Mycobacterium avium* ssp *avium*, *M. bovis*), sporotrichosis (*Sporotrichum schenckii*), botryomycosis (*Staphylococcus aureus* and certain other bacteria), horsepox.

Diagnosis

It is important to emphasize that the clinical signs associated with the early stage or carrier stage of glanders are not confirmatory *per se*. Establishment of a diagnosis of the disease is based on the outcome of various *in vivo* and *in vitro* laboratory tests (Allen, 1929). The mallein test [intradermo-palpebral (most sensitive and reliable), the ophthalmic or subcutaneous route of administration] is a very useful test that can be performed on a suspect case of glanders. Isolation of *B. mallei* can be attempted from discharge/tissue specimens either by bacteriological culture or by intraperitoneal inoculation of a guinea pig (Strauss reaction) (Frothingham, 1901). Alternatively, or preferably additionally, bacterial nucleic acid can be detected by the polymerase chain reaction (PCR) assay (Ulrich *et al.*, 2006) pulse field gel electrophoresis (PFGE), PCR-restriction fragment length polymorphism (RFLP) (Tanpiboonsak *et al.*, 2004) or microarray (Schmoock *et al.*, 2009). Most frequently, a suspect case of glanders is screened serologically for antibodies to *B. mallei* by CFT, competitive enzyme-linked immunosorbent assay (cELISA) (Thepthai, 2005) or less frequently, Western blot (Neubauer *et al.*, 2005). A positive result in the CFT may not always be specific for the glanders bacillus; it may represent a cross-reaction with *B. pseudomallei*, the causal agent of melioidosis and a closely related organism. Furthermore, the test is not as sensitive as the mallein test for the diagnosis of glanders.

Prevention and Control

Critical to effective prevention and control of glanders is prompt identification, euthanasia and appropriate disposal of all positive cases of the disease (Hunting, 1887; Wittig *et al.*, 2006). Affected premises shall be quarantined and movement controls strictly enforced. Potentially contaminated areas must be disinfected, thoroughly cleaned and re-disinfected. All feed/bedding must be destroyed. Complete eradication can only be achieved through a comprehensive, long-term testing program of all at-risk equids and a rigorously enforced culling program of any additional cases of the disease that might be turned up. While antibiotic treatment of affected animals is resorted to in some areas of the world where glanders is endemic, it is not the preferred option for most countries when dealing with an outbreak of the disease.

Summary

There is evidence of resurgence of glanders in some of the countries in which the disease is endemic as reflected in an increased frequency of outbreaks (Paar, 2009). In recent years, glanders has been re-introduced into countries in which it was previously eradicated. Proof of the dissemination of glanders through the international movement of horses has been documented. Disease events during the past five years underscore the need for enhanced vigilance over the potential risk of spread and wider geographic distribution of glanders resulting from continued growth in the volume of international trade in horses.

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**Importation of Horses from CEM-Affected Countries
USDA –APHIS-VS March 2011 CEM Rule – Process Summary
Kentucky State’s Perspective**

Rusty Ford

Equine Programs Manager, Kentucky Department Agriculture

Two independent Contagious Equine Metritis (CEM) Importation Program reviews were conducted in 2003 and 2007 at the request of USDA APHIS. The panel of reviewers included state and federal animal health officials, laboratory personnel, researchers and private veterinary practitioners. Each review resulted in the identification of need to improve the program's efficacy. The reviewers provided specific recommendations to Veterinary Services Management Team which they concluded were needed to reach the program's intended goal of insuring the U.S. remained CEM Free. The most recent recommendations were provided to the management team in May of 2007. These changes included enhanced regulatory oversight, better data management and establishing a minimal set of standards. The reviewers recommended minimal change to the prescribed testing after concluding the procedures, when properly implemented, would provide the needed opportunity to detect equine animals infected with the CEMO.

On March 15, 2011, USDA APHIS published an interim rule governing the importation and subsequent quarantine and testing of mares and stallions imported from CEM Affected countries. The rule was published as an interim rule citing a recent outbreak and recommendations made by a panel of experts. In contrast to the procedures followed in making a 'final rule', Federal Regulations required this interim rule to become effective immediately and disallowed USDA APHIS the opportunity to provide affected entities advanced notice of the included changes. State Animal Health Officials, and other stakeholders, expressed concern to USDA over the rule being published as effective immediately and without consideration of the negative impact these changes would have on stakeholders. Specific concern was caused by the Interim Rule's inclusion of testing procedures and protocol changes that had not been identified as beneficial by reviewers and when implemented would result in considerable expense. Another concern was omission of procedural aspects the reviewers had identified as needed. In response to the concerns, USDA announced implementation and enforcement of the interim rule would be delayed until July 25 in order to provide industry stakeholders the opportunity to offer public comment. Following the commenting period, and after reviewing the comments received, USDA APHIS announced the scheduled implementation of the interim rule was again being delayed until further notice. The delay is/was to allow time for USDA to give consideration to amending the language regarding the number of required pre-breeding stallion cultures as well as the anatomical sites collected from imported mares and test mares.

BACKGROUND:

Contagious Equine Metritis (CEM) was first diagnosed in Europe in 1977. In 1978, CEM was diagnosed affecting the thoroughbred population in Central Kentucky with the source of infection traced to a stallion imported from Europe. A year later CEM was detected in Missouri.

These outbreaks resulted in USDA implementing by regulation pre-import testing requirements as well as post importation quarantine and testing for adult equidae imported into the United States from countries identified as CEM Affected. Throughout the 1980s and through 1993, the quarantine and testing procedures remained 'relatively' unchanged. Both mares and stallions were treated prior to testing by culture. Imported stallions were treated and then bred to two mares with those mares subjected to a series of swabs collected post breeding.

Following an extensive review of the program in 1993, protocols for both mares and stallions were amended. The changes included both mares and stallions be sampled prior to any treatment. The anatomical areas cultured from the mare were also revised to eliminate uterine swabs. Before these changes, imported pregnant mares remained under quarantine throughout their gestation. Today, imported mares can qualify for release from quarantine in as little as 14 days post arrival.

With the changes to the post importation quarantine protocols reducing the length of quarantine and the associated costs, the number and types of importing horses increased significantly. This growing number of imports is demonstrated by data showing that in 1993, 58 thoroughbred and 18 warm blood mares cleared CEM Quarantine in Kentucky. Comparatively, during calendar year 2000, 248 thoroughbred and 196 warm blood mares cleared CEM Quarantine in KY. A similar increase was seen in the number of stallions importing. The accompanying charts (figures 1 and 2) demonstrate the number of mares and stallions importing through Kentucky CEM facilities from 1989 through 2010. The demand for required quarantine space resulted in requests from a number of states seeking USDA's approval to conduct CEM Quarantines.

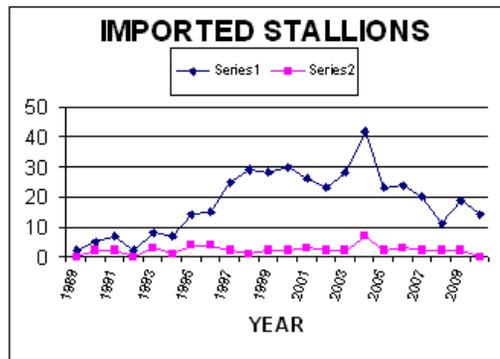
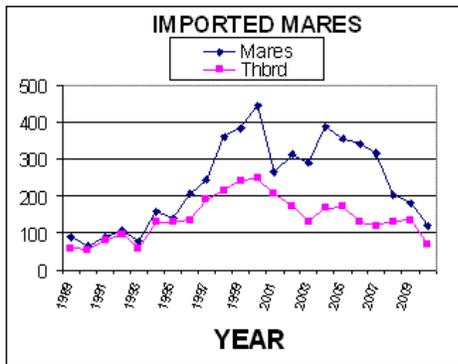


Fig 1

Fig 2

In both the 2003 and 2007, program reviewers concluded that the science used in developing the testing and treatment protocols was sound and when properly implemented does provide a reliable means of identifying infected horses during the quarantine period. A number of reviewers did express concern over the opportunity for insufficient regulatory oversight and improper implementation of the testing procedures resulting from the increase in states and facilities being approved to conduct CEM import quarantines. Recommendations and suggestions on establishing specific minimal standards of oversight, training, and facility requirements were included in the 2007 formal recommendations made to Veterinary Services' management team. These procedural changes were not included in the interim rule published in March 2011 and do not appear to be included in the planned final rule at this time. It is hoped and anticipated that USDA APHIS plans to incorporate these recommendations via VS Memorandum and/or Policy Directives.

FINAL RULE (Based on Preliminary Information Received)

As of September 2011, the Final CEM Rule has not been published. Changes to the testing protocol anticipated to be included in the Final Rule includes imported mares being subjected to a Complement-Fixation (CEM-CF) test and a single cervical or endometrial swab being included with the third set of cultures. Testing changes for clearing imported stallions are expected to include an additional site to be sampled on stallions prior to breeding, a single cervical or endometrial swab be collected from each test mare both pre- and post breeding, and collection of the post breeding serum sample for complement fixation testing be extended from day 15 to day 21 post breeding.

CONCERNS – Lacking Guidance on Minimal Standards, and Regulatory Oversight

Both the 2003 and 2007 CEM Program reviews resulted in the respective panel of experts concluding the testing procedures and protocols were sufficient and would successfully identify infected animals when properly implemented. The reviewers did suggest, and it is believed that USDA is including the changes to the testing procedure described above in the proposed final rule. The reviewers felt the additional testing of imported mares by CF could help identify recently exposed mares prior to investing in three sets of cultures, and including cervical or endometrial swabs might enhance the opportunity to detect infected mares that may have been treated prior to exporting their country of origin.

The reviewers concluded that the ability to identify infected equidae would be grossly compromised if the prescribed testing procedures (to include sample collection, handling, submission, and laboratory testing) were not consistent with or in full compliance with the established protocols. This conclusion

appears valid based on our understanding that outbreaks of CEM in this country in 2006 and 2008 were traced to imported horses being incorrectly tested and subsequently released from quarantine without having met the prescribed protocol. The source of infection for a domestic stallion discovered in 2011 remains unknown today. The program review recommendations included required training of individuals (regulatory, veterinary practitioners and laboratory personnel) with responsibility in determining imported horses successfully complete quarantine as prescribed, implementation of a more efficient and effective means of communicating program changes, establishing minimal sets of standards for all aspects of the process, and development of a national data management system to track equidae imported into and completing CEM testing in the United States.

Training: USDA has offered laboratory training as well as applicable training to regulatory officials and private veterinary practitioners. The interim rule (and to our knowledge the final rule), does not 'require' mandatory training for approval to conduct CEM Import Quarantines.

Minimal Standards: for facilities and all personnel working in the quarantine facility were detailed in the 2007 recommendations but were not included in the interim or proposed final rule.

Regulatory Oversight: VS's Area Office and State Animal Health Officials should work together to ensure the level of regulatory oversight of CEM Quarantine Facilities is sufficient and to ensure the procedures and processes are being properly implemented and complied with.

Data Management: This past August USDA APHIS, VS distributed to CEM Coordinators an Excel spreadsheet with instructions to provide detailed information to the VS Regional offices monthly for submission to NCIE. Much of the requested information is USDA generated and not available to state CEM coordinators. Some states have established system of collecting, managing and reporting data associated CEM imported horses. To avoid duplication of data entry, and to assure responsible use of resources, it is hoped USDA will require states to only report the available and pertinent data and allow individual states to report the data via means compatible with their individual systems. The Kentucky Department of Agriculture has made this request to USDA and at the time of this writing is awaiting a reply.