What is Contagious Equine Metritis?

Contagious Equine Metritis (CEM) is a sexually-transmitted disease of horses caused by the bacteria, *Taylorella equigenitalis*. Clinical signs in mares may include a mucopurulent vaginal discharge in up to 40% of affected mares, abortion and infertility. Stallions typically show no clinical signs. Both mares and stallions can become chronic CEM carriers and sources of infection for future outbreaks. The transmission rate is high with live cover breeding, but contaminated instruments and equipment may be an indirect means of infecting mares and stallions. The bacteria can also be spread in semen collected for artificial insemination. The United States is considered free of CEM; it is classified as a foreign animal disease in the U.S.

What tests are available to diagnose CEM?

There are two official validated diagnostic tests for CEM; bacterial culture and the serologic complement fixation (CF) test. Bacterial culture is the gold standard test to detect the organism from swabs collected from the genitalia of stallions and mares. Determination of a culture sample as positive or negative takes seven (7) days. The serologic CF test is used to assist in CEM diagnosis, but value is limited to mares that have produced detectable antibodies to *T. equigenitalis*.

Why is there a concern about CEM?

CEM is a highly-contagious reproductive disease. Depending on the severity and location of the infection(s), infected mares can experience temporary infertility for one or more breeding cycles. Since breeding of mares is limited to certain seasons, CEM can have a devastating effect on equine reproductive efficiency. The United States (U.S.) horse industry would suffer great economic losses, if CEM were to become established in this country.

What is done to prevent the entry of CEM into the U.S.?

CEM is endemic in the horse populations in some countries that export horses to the U.S. The U.S. Department of Agriculture (USDA) has import requirements for CEM testing and treatment of mares and stallions over 731 days of age from those countries. Typically, stallions and mares will undergo post-entry CEM testing and treatment at specially approved U.S. quarantine facilities before release for entry into the U.S.

Is there a risk of introduction of CEM into the U.S.?

Yes, there is a risk of introduction of CEM into the U.S. from horses originating in CEM-affected countries. The USDA CEM testing protocols have successfully detected the CEM carrier state in a significant number of imported stallions and mares. All of these animals had been certified CEM-free based on negative pre-export cultures on a single set of culture swabs before export to the U.S.

What are the post-arrival import testing requirements for a mare from a CEM-affected country?

Any mare over 731 days of age from a CEM-affected country must complete the USDA post-arrival CEM protocols. Once the mare has arrived in the approved state CEM quarantine facility, a CEM complement fixation test must be done and three (3) sets of culture specimens, at intervals, must be collected from the mucosal surfaces of the clitoral fossa and clitoral sinuses. In non-pregnant mares, one set of specimens must include a swab from the surface of the distal cervix or endometrium. With receipt of all negative culture results, the mare must be treated for five (5) consecutive days with an ointment effective against the CEM organism. A mare may be released from state quarantine if the mare is CEM CF negative and all cultures performed on specimens taken from the mare are negative.
Are there exemptions to the CEM post-arrival import testing requirements for horses from a CEM-affected country?

Special provisions allow for the exemption of the following equids from post-arrival import CEM testing and treatment protocols:
- Wild zoo animals that are unlikely to have come in contact with domestic horses used for breeding.
- Spanish Pure-Bred Horses imported for permanent entry from Spain.
- Thoroughbreds imported for permanent entry from France, Germany, Ireland or UK.
- Horses over 731 days imported for no more than 90 days of competition.
- Horses over 731 days of age imported for non-competitive public exhibitions and entertainment purposes.

What are the post-arrival import testing requirements for a stallion from a CEM-affected country?

Any stallion over 731 days of age from a CEM-affected country must complete the USDA post-arrival CEM protocols. Once the stallion has arrived at the approved state CEM quarantine facility, one culture specimen shall be taken from each of the following sites on the stallion: the prepuce, the urethral sinus, the distal urethra, and the fossa glandis, including the diverticulum of the fossa glandis. With receipt of negative culture results, the stallion must be test bred to two (2) certified CEM-negative test mares. Following the test breeding, the stallion must be treated for five (5) consecutive days with an ointment effective against the CEM organism. There are post-test breeding testing protocols for the test-bred mares. If all cultures and CF tests from the test-bred mares are negative for CEM, the stallion has met the U.S. entry requirements and may be released from quarantine.

Why is PCR testing not available for use in CEM import testing protocols?

Although published PCR assays for CEM compare very favourably with bacterial cultures, the studies reported to date have involved a very low number of naturally-acquired CEM cases. Additional studies are warranted to validate the PCR test for use in international trade testing protocols.

Can the organism be missed with import testing?

Yes. Concerns in the scientific community suggest the possibility that previous antibiotic treatment of the stallion may suppress the bacterial load to the point it is not detected by a single set of cultures from the stallion taken at arrival in the U.S.

Why is multiple sampling necessary for CEM quarantine testing?

The identification of the CEM carrier animal, specifically stallions, has necessitated a multiple sampling protocol to address the challenges of CEM diagnosis. This is especially true for horses which have previously undergone treatment for the T. equigenitalis. Such animals can remain as a carrier and be difficult to detect on culture or PCR. Due to the need for multiple culture samplings, the confirmation of an animal’s freedom from the carrier state can be very time-consuming and costly.

How does test breeding assist in the diagnosis of CEM?

To maximize the chance of detecting CEM infection, stallions are required to be tested by both bacterial culture and test breeding. Test breeding will sometimes detect a T. equigenitalis infection that bacterial culturing of the stallion did not detect. Test breeding involves breeding a stallion to two (2) certified CEM-negative mares. Following test breeding, the test mares are serially tested for CEM by bacterial culture and a serology test to determine if they are infected. It takes a minimum of thirty-five (35) days after the test breeding to declare the stallion negative.
Why is test breeding a requirement of import testing?

Based on science, USDA concluded that the inherent risks of importing CEM into the U.S. can be mitigated by requiring stallions to be test-bred to two mares as part of the post-arrival quarantine and testing process. The decision was prompted by the difficulties experienced isolating the organism from heavily contaminated sampling sites, especially when dealing with streptomycin-sensitive strains of *T. equigenitalis*.

Has live cover/test breeding been proven to be an effective diagnostic tool?

Yes. Of the twenty-three (23) positive stallions detected during the 2009 United States CEM Outbreak investigation, three (3) stallions were confirmed by test breeding protocols. Difficulties in isolating the CEM organism from heavily contaminated sampling sites led to false negative cultures and the three (3) stallions were only confirmed positive after the live-cover test breeding.

What is the regulatory authority for CEM import protocols?

The USDA, Animal Plant Health Inspection Services (APHIS), Veterinary Services (VS) is responsible for the facilitation of trade of animal and animal products and sets import regulations to protect the health of the U.S. equine population. The Code of Federal Regulations, Title 9, Section 93.301 details the testing protocols for horses imported from CEM-affected countries. As a condition of import, designated horses from CEM-affected countries must complete the required CEM import testing protocols in an approved state quarantine facility.

Why is there only one approved CEM Import Quarantine in California?

Current California regulations designate the UC Davis Center for Equine Health as the approved CEM Import Quarantine for the State of California.

What is the state authority related to CEM Import Quarantine?

The state is required to enter into a written agreement with USDA/APHIS/VS to enforce laws and regulations to control CEM and abide by the conditions of approval established by federal regulations. The state laws require imported stallions to complete the testing and treatment protocols at a designated, approved state CEM import quarantine facility. The State authority can be more restrictive than federal authority, but not less restrictive. In California, this authority is in the California Code of Regulations, Title 3, Section 810.1.

What is the role of California Department of Food and Agriculture (CDFA) in CEM Import Quarantine?

The Center for Equine Health at the University of California at Davis is the approved CEM Quarantine Facility in California. CDFA Animal Health Branch is responsible for regulatory oversight of the CEM import testing program, which includes conducting an annual facility inspection of the approved CEM quarantine facility, performing random onsite observational audits of the testing and treatment procedures, reviewing all laboratory test data, compiling import quarantine summary data, and preparing quarterly summary reports. The daily oversight regulatory authority is delegated to Dr. Claudia Sonder, Director of the UC Davis Center for Equine Health.

How can the regulations be changed to include additional CEM Import Quarantine facilities in California?

The California regulatory change process takes a minimum of one (1) year and requires industry consensus and support for the passage of the regulatory change. To add CEM Import Quarantine facilities in California would require the drafting of a regulation change proposal and support of the proposal by the California equine industry and approval by the California Office of Administrative Law. If industry consensus is not obtained, the current regulation will remain in effect and the UC Davis Center for Equine Health will remain the only approved facility.
How can a private CEM quarantine be approved?

California laws currently prohibit the approval of a private CEM quarantine in the state. A regulation change proposal would need to be approved and this process can take up to two (2) years before acceptance of applications for CEM private quarantine. If the equine industry and regulatory authorities are unable to come to a consensus on the proposed regulations, the regulation change proposal will not be submitted and the current regulations would remain in effect.

Would CDFA support approval of a CEM quarantine facility?

Due to past CEM outbreaks that traced to private import quarantines in other states, there is risk associated with approval of such private quarantine facilities. CDFA would have to carefully assess the risks of a private quarantine facility to ensure the protection of the equine population in California. If a private CEM quarantine were to be approved, it would require significant regulatory oversight at the expense of the industry. For example, Florida permits private CEM quarantine facilities, and to cover the costs associated with regulatory oversight by state personnel, the state charges $1250 per horse quarantined in a Florida approved CEM quarantine facility. This fee is in addition to the CEM quarantine facility charges. Currently, CEM regulatory oversight is delegated by state authority to the University of California Davis, Center for Equine Health and the State of California does not charge for this oversight.

What specific changes can be made to the California CEM Import Program through the regulatory change process?

Only current California CEM regulations can be modified through the regulatory change process, specifically those regulations pertaining to the approval of California CEM Import Quarantine Facilities and the State requirements for those facilities. Changes to the USDA testing and treatment protocols would require change through the federal regulatory change process.

What are the steps for a regulation change for the California CEM Import Program?

The regulation change for the California CEM Import Program would require the following steps:

1. Solicitation of feedback from the California equine industry on potential changes to the current California CEM Import Program.
2. Scientific risk assessment and analysis of each proposed option to determine the most appropriate, science-based, option.
3. Drafting of proposed regulations to incorporate the potential changes.
4. Solicitation of industry feedback on proposed draft regulations.
5. Final submission of proposed regulation change to the California Office of Administrative Law for review and approval.
6. If approved, enactment of the new regulations.

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