

# Rules and Regulations

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## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

#### 9 CFR Part 93

[Docket No. APHIS–2008–0112]

RIN 0579–AD31

#### Importation of Horses From Contagious Equine Metritis-Affected Countries

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Interim rule and request for comments.

**SUMMARY:** We are amending the regulations regarding the importation of horses from countries affected with contagious equine metritis (CEM) by incorporating an additional certification requirement for imported horses 731 days of age or less and adding new testing protocols for test mares and imported stallions and mares more than 731 days of age. We are taking these actions in response to incidents that prompted an investigation by an expert review panel, which identified specific weaknesses in the current regulations. This action will provide additional safeguards against the introduction of CEM through the importation of affected horses.

**DATES:** This interim rule is effective March 25, 2011. We will consider all comments that we receive on or before May 24, 2011.

**ADDRESSES:** You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2008-0112> to submit or view comments and to view supporting and related materials available electronically.

- *Postal Mail/Commercial Delivery:* Please send one copy of your comment to Docket No. APHIS–2008–0112, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS–2008–0112.

*Reading Room:* You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

*Other Information:* Additional information about APHIS and its programs is available on the Internet at <http://www.aphis.usda.gov>.

**FOR FURTHER INFORMATION CONTACT:** Dr. Ellen Buck, Senior Staff Veterinarian, Equine Imports, National Center for Import and Export, VS, APHIS, 4700 River Road, Unit 36, Riverdale, MD 20737–1231; (301) 734–8364.

#### SUPPLEMENTARY INFORMATION:

##### Background

The regulations in 9 CFR part 93 (referred to below as the regulations) prohibit or restrict the importation of certain animals into the United States to prevent the introduction of communicable diseases of livestock. Subpart C—Horses, §§ 93.300 through 93.326, pertains to the importation of horses into the United States. Sections 93.301 and 93.304 of the regulations contain specific provisions for the importation of horses from regions affected with contagious equine metritis (CEM), which is a highly contagious venereal disease of horses and other equines caused by an infection with the bacterium *Taylorella equigenitalis*.

The regulations provide that some types of horses may be imported from CEM-affected regions without restriction. For instance, weanlings and yearlings are exempt under § 93.301(c)(2)(iii). Other horses are allowed to be imported from CEM-affected regions provided they meet certain requirements that include quarantine, testing, and treatment as provided under § 93.301(d), (e), and (f).

Horses that fall under this category include Spanish Pure Breed horses from Spain; racing thoroughbreds from Germany, France, Ireland, and the United Kingdom; stallions and mares over 731 days of age; and horses that are imported under special provisions for temporary importation for competition or entertainment purposes.

Approximately 2,500 horses imported from CEM-affected regions undergo CEM quarantine in the United States each year. Over the past 10 years, despite current requirements for pre-import CEM testing in the country of origin, more than 28 CEM-positive horses have been identified during quarantine in the United States.

In 2006, a private veterinarian in the United States detected a *T. equigenitalis* infection during a routine breeding soundness exam of an imported stallion that had been released from CEM quarantine in 2004 after testing negative for CEM. The epidemiological investigation that followed detected two other infected stallions on the same premises. This incident jeopardized the CEM-free status of the United States and had a significant impact on U.S. horse exports. In 2007, in response to this incident, APHIS' Veterinary Services program initiated a review and assessment by Federal, State, and industry officials of U.S. equine import activities to identify any improvements to testing procedures that may be necessary to better mitigate the risk of a CEM-positive horse being released into the U.S. equine population.

A second incident indicating a need to strengthen the CEM regulations occurred in April 2008 when an imported mare undergoing CEM quarantine demonstrated positive results for CEM on a complement-fixation (CF) test, which has not been required for imported mares under the regulations; the required sampling of the clitoral sinuses and clitoral fossa of the mare had shown negative results for *T. equigenitalis*. The attending veterinarian administered the CF test because she knew about the recommendations that followed from the review and assessment of the 2006 incident.

In December 2008, a U.S. origin stallion with no history of residence in a CEM-affected region was undergoing routine testing for semen export, and cultured positive for CEM. APHIS initiated an epidemiologic investigation

to identify other potentially infected horses. Ultimately 23 stallions and 5 mares were identified as infected. An additional 250 stallions and 718 mares were identified as exposed to positive horses. All infected or exposed horses required culturing and treatment at their owners' expense. The suspected source of the outbreak was a stallion imported from Denmark in late 2000 whose CEM infection was not detected on import testing. Because of the outbreak, some countries no longer recognized the United States as CEM-free and consequently placed restrictions on U.S. equine exports. The 2006 and 2008 incidents indicate that the regulations that have been in place are inadequate to identify all imported horses infected with *T. equigenitalis*.

Given the incidents noted above, we have determined that the following regulatory changes are necessary and need to be implemented immediately in order to prevent the potential introduction and spread of CEM in the United States.

#### *Exemption for Weanlings and Yearlings*

The regulations in § 93.301(c)(2)(iii) have exempted weanlings or yearlings (defined as not more than 731 days of age) from CEM quarantine requirements when their age is certified on the import health certificate required under § 93.314(a). The regulations have provided for this exemption because horses less than 2 years old have generally been considered too young to breed and therefore pose only a minimal risk of entering the United States with a venereal disease such as CEM. However, this assumption is now in question because APHIS has identified imported mares 731 days or less of age that were pregnant and therefore at risk of CEM infection.

While retaining the current certification-of-age requirement, we are limiting the exemption from CEM-related restrictions to weanlings and yearlings that have never been bred, and we are requiring that their breeding status be certified on the import health certificate required under § 93.314(a). This change to the regulations provides an additional safeguard against the spread of CEM to the U.S. horse population.

#### *Imported Stallions*

Because stallions do not show clinical signs of CEM after becoming exposed to the bacterium *T. equigenitalis*, diagnosis of CEM cannot be based on clinical signs alone. Furthermore, culture tests do not always detect *T. equigenitalis*. The stallion can look normal and test negative for *T. equigenitalis*, but still

infect the mare to which it is bred naturally or by artificial insemination. Therefore, the regulations under § 93.301(e) provide that stallions over 731 days of age from CEM-affected regions are to be bred to two test mares.

Specifically, the regulations in paragraph (e)(3)(i) have stated that upon arrival at a CEM facility in an approved State, a set of specimens must be taken from a stallion's prepuce, urethral sinus, and fossa glandis, and that after negative culture results have been obtained, the stallion must be test bred to two test mares. After being test bred, a stallion that cultured negative prior to being test bred has not been required to undergo another culture to test for *T.*

*equigenitalis* unless a test mare tested positive for CEM, in which case the stallion would be treated for CEM and the testing process begun again.

We are amending paragraph (e)(3)(i) of § 93.301 to require a fourth specimen to be taken from the stallion's distal urethra and to increase the number of required sets of specimens (a set consists of one culture swab from each location) from imported stallions from one set to three sets at each of the four sites, all taken within a 12-day period with a minimum of 72 hours between each set. At least two of the three sets of specimens must be collected from the stallion, with negative results, before the stallion is bred to two test mares. If the test mares test negative for CEM after breeding, and if all of the stallion's culture specimens test negative for CEM, then the stallion will be released from quarantine.

These changes to the regulations will increase the likelihood of detecting *T. equigenitalis* in imported stallions, thereby reducing the risk that imported stallions will be released from quarantine with undiagnosed CEM infections.

#### *Test Mares*

Test mares are mares used to test stallions for CEM. To qualify to become a test mare, each mare must test negative for CEM as provided under § 93.301(e)(4). The regulations in § 93.301(e)(3)(i)(B) have required that the mucosal surfaces of the clitoral sinuses and clitoral fossa of a test mare must be cultured for *T. equigenitalis* on the third, sixth, and ninth days after breeding with an imported stallion in CEM quarantine. To increase the likelihood of detecting CEM in test mares, we are amending the regulations to require that either the distal cervix or endometrium be cultured for CEM in addition to the clitoral sinuses and clitoral fossa. We are also extending the allowable timeframe in (e)(4)(ii) to

complete all three culture sets from the current 7-day period to a 12-day period, with specimens collected anytime between the third and the fourteenth day after breeding, with a minimum of 72 hours between each set. The additional time allowed to collect all culture samplings was added at the request of the veterinarians, because the 7-day timeframe did not allow any flexibility in scheduling, since samples generally could not be shipped or processed on weekends. Extending the timeframe from 7 days to 12 days to account for the laboratory's hours of operations will help decrease testing delays caused by unusable samples.

Furthermore, the regulations in paragraph (e)(3)(i)(B) have required the blood sample for the required CF test to be drawn from the test mare on the fifteenth day after breeding. We are amending the paragraph to require that a test mare's blood be drawn for a CF test on the twenty-first day after breeding. This amendment aligns our requirements with the World Organization for Animal Health's (OIE) Manual of Diagnostic Tests,<sup>1</sup> which recommends screening mares between 21 and 45 days after breeding.

#### *Imported Mares*

Once an imported mare has arrived at a CEM quarantine facility in an approved State, the regulations in § 93.301(e)(5)(i) have required specimens to be collected from the mucosal surfaces of the clitoral sinuses and clitoral fossa on days 1, 4, and 7 during a 7-day period with all culture sets received by an approved laboratory within 48 hours of collection. To increase the likelihood of detecting CEM in these imported mares, we are adding a requirement, as we are doing for test mares, to collect specimens from either the distal cervix or the endometrium in nonpregnant mares in addition to the specimens taken from the mucosal surfaces of the clitoral sinuses and clitoral fossa. To help avoid test delays and unusable samples due to facility and laboratory hours of operations, we are extending the timeframe to complete sampling from the current 7-day period to a 12-day period with no less than 72 hours between each set.

In addition, we are now requiring that an imported mare be given a CF test upon arrival at a State's CEM quarantine facility. CF testing will allow identification of antibodies from any recent exposure to CEM and provide

<sup>1</sup>To view the OIE *Terrestrial Animal Health Code*, go to [http://www.oie.int/eng/normes/mcode/en\\_sommaire.htm](http://www.oie.int/eng/normes/mcode/en_sommaire.htm).

supplementary information concerning the mare's CEM status.

*Spanish Pure Breed Horses and Thoroughbred Horses; Horses Temporarily Imported for Competition or Entertainment Purposes*

To reflect the changes discussed above, we are amending paragraph (d)(1)(ii)(D) in § 93.301 to require that Spanish Pure Breed horses from Spain and thoroughbred horses over 731 days of age from France, Germany, Ireland, and the United Kingdom, test negative for CEM based on the culturing of three sets of specimens. For female horses, the specimens must be collected from the mucosal surfaces of the clitoral fossa, distal cervix or endometrium, and the clitoral sinuses; for any male horses, the specimens must be collected from the surfaces of the prepuce, the urethral sinus, the distal urethra, and the fossa glandis, including the diverticulum of the fossa glandis. For both female and male horses, the sets of specimens must be collected on three separate occasions within a 12-day period with no less than 72 hours between each set, and the last of these sets of specimens must be collected within 30 days prior to the exportation of the horses to the United States. All specimens must be collected by a licensed veterinarian who either is, or is acting in the presence of, the veterinarian signing the required health certificate.

We are making similar changes to paragraph (f)(3) in § 93.301, which contains special provisions for temporary importation of horses for competition or entertainment purposes. Specifically, we will require that such horses be accompanied by a health certificate that certifies that cultures negative for CEM were obtained from three sets of specimens. For female horses, the specimens must be collected from the mucosal surfaces of the clitoral fossa and clitoral sinuses, with one set of specimens including a specimen from the surfaces of the distal cervix or endometrium; for male horses, the specimens must be collected from the surfaces of the prepuce, the urethral sinus, the distal urethra, and the fossa glandis, including the diverticulum of the fossa glandis. For both female and male horses, the sets of specimens must be collected on three separate occasions within a 12-day period with no less than 72 hours between each set, and the last of these sets of specimens must be collected within 30 days prior to the exportation of horses to the United States. All specimens must be collected by a licensed veterinarian who either is, or is acting in the presence of, the veterinarian signing the certificate.

These changes, which represent an increase in the number of specimens that must be collected, are consistent with the changes we are making for other mares and stallions being imported from CEM-affected regions to the United States and will provide additional safeguards against the spread of CEM to the U.S. horse population.

#### Emergency Action

This rulemaking is necessary on an emergency basis to prevent the introduction and spread of CEM into the equine population of the United States. Under these circumstances, the Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest and that there is good cause under 5 U.S.C. 553 for making this rule effective less than 30 days after publication in the **Federal Register**.

We will consider comments we receive during the comment period for this interim rule (*see DATES* above). After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments we receive and any amendments we are making to the rule.

#### Executive Order 12866 and Regulatory Flexibility Act

This interim rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

We have prepared an initial regulatory flexibility analysis for this action. The analysis identifies U.S. importers of mares and stallions from CEM countries as the small entities most likely to be affected by this action and considers the costs associated with complying with new requirements. Based on the information presented in the analysis, we expect that U.S. importers will experience a slight increase in quarantine and treatment costs as a result of this action. The overall impact of the additional costs for the horse industry is not expected to be significant, given the relatively small number of horses imported from CEM countries.

We invite comment on our initial regulatory flexibility analysis, which is posted with this interim rule on the Regulations.gov Web site (*see ADDRESSES* above for instructions for accessing Regulations.gov) and may be obtained from the person listed under **FOR FURTHER INFORMATION CONTACT**.

#### Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are in conflict with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

#### Paperwork Reduction Act

This interim rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

#### List of Subjects in 9 CFR Part 93

Animal diseases, Imports, Livestock, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements.

Accordingly, we are amending 9 CFR part 93 as follows:

#### **PART 93—IMPORTATION OF CERTAIN ANIMALS, BIRDS, FISH, AND POULTRY, AND CERTAIN ANIMAL, BIRD, AND POULTRY PRODUCTS; REQUIREMENTS FOR MEANS OF CONVEYANCE AND SHIPPING CONTAINERS**

■ 1. The authority citation for part 93 continues to read as follows:

**Authority:** 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 2. Section 93.301 is amended as follows:

- a. By revising paragraph (c)(2)(iii);
- b. By revising paragraph (d)(1)(ii)(D);
- c. In paragraph (e)(1)(iii), by adding the words “distal urethra,” after the words “urethral sinus,” in the second sentence;
- d. By revising paragraphs (e)(3)(i) introductory text, (e)(3)(i)(B), (e)(4)(ii), and (e)(5)(i); and
- e. By revising paragraphs (f)(3).

The revisions read as follows:

#### **§ 93.301 General prohibitions; exceptions.**

\* \* \* \* \*

(c) \* \* \*

(2) \* \* \*

(iii) Weanlings or yearlings that have never been used for breeding, and whose age and breeding status are certified on the import health certificate required under § 93.314(a);

\* \* \* \* \*

(d) \* \* \*

(1) \* \* \*

(ii) \* \* \*

(D) For Spanish Pure Breed horses and thoroughbred horses over 731 days

of age, cultures negative for CEM were obtained from three sets of specimens collected within a 12-day period from the mucosal surfaces of the clitoral fossa, distal cervix or endometrium, and the clitoral sinuses of any female horses and from the surfaces of the prepuce, the urethral sinus, the distal urethra, and the fossa glandis, including the diverticulum of the fossa glandis, of any male horses. For both male and female horses, the sets of specimens must be taken within a 12-day period with no less than 72 hours between each set, and the last of these sets of specimens must be collected within 30 days prior to exportation. All specimens required by this paragraph must be collected by a licensed veterinarian who either is, or is acting in the presence of, the veterinarian signing the certificate; and

\* \* \* \* \*

(e) \* \* \*

(3) \* \* \*

(i) Once the stallion is in the approved State, three sets of specimens consisting of one culture swab from each location shall be taken from the prepuce, the urethral sinus, the distal urethra, and the fossa glandis, including the diverticulum of the fossa glandis, of the stallion and be cultured for CEM. The sets of specimens must be collected on three separate occasions within a 12-day period with no less than 72 hours between each set. No sooner than after the second set of specimens is collected and cultured for CEM with negative results, the stallion must be test bred to two test mares that meet the requirements of paragraph (e)(4) of this section. Upon completion of the test breeding:

\* \* \* \* \*

(B) Each mare to which the stallion has been test bred shall be cultured for CEM from three sets of specimens from the mucosal surfaces of the clitoral fossa, clitoral sinuses, and from either the distal cervix or endometrium between the third and fourteenth day after breeding, with negative results. The sets of specimens must be collected on three separate occasions within a 12-day period with no less than 72 hours between each set. A complement fixation test for CEM must be done with negative results on the twenty-first day after the breeding.

\* \* \* \* \*

(4) \* \* \*

(ii) The test mares must be qualified prior to breeding as apparently free from CEM and may not be used for breeding from the time specimens are taken to qualify the mares as free from CEM. To qualify, each mare shall be tested with negative results by a complement

fixation test for CEM, and specimens taken from each mare shall be cultured negative for CEM. For each culture, sets of specimens shall be collected on three separate occasions from the mucosal surfaces of the clitoral fossa, clitoral sinuses, and from either the distal cervix or endometrium within a 12-day period with no less than 72 hours between each set.

\* \* \* \* \*

(5) \* \* \*

(i) Once the mare is in the approved State, a complement fixation test for CEM must be done, and three sets of specimens shall be collected from the mucosal surfaces of the clitoral fossa and clitoral sinuses, with one set of specimens including a specimen from the surfaces of the distal cervix or endometrium in nonpregnant mares. The sets of specimens must be collected on three separate occasions within a 12-day period with no less than 72 hours between each set. An accredited veterinarian shall collect specimens and shall submit each set of specimens to the National Veterinary Services Laboratories in Ames, IA, or to a laboratory approved by the Administrator in accordance with paragraph (i) of this section to conduct CEM cultures and tests.

\* \* \* \* \*

(f) \* \* \*

(3) At the time of importation, each horse must be accompanied by an import permit in accordance with § 93.304 and a health certificate issued in accordance with § 93.314. For horses imported in accordance with paragraph (f)(2) of this section, the health certificate must also certify that cultures negative for CEM were obtained from three sets of specimens collected from the mucosal surfaces of the clitoral fossa and clitoral sinuses, with one set of specimens including a specimen from the surfaces of the distal cervix or endometrium, of any female horses and from the surfaces of the prepuce, the urethral sinus, the distal urethra, and the fossa glandis, including the diverticulum of the fossa glandis, of any male horses. For both female and male horses, the sets of specimens must be collected on three separate occasions within a 12-day period with no less than 72 hours between each set, and the last of these sets of specimens must be collected within 30 days prior to exportation. All specimens required by this paragraph must be collected by a licensed veterinarian who either is, or is acting in the presence of, the veterinarian signing the certificate.

\* \* \* \* \*

Done in Washington, DC, this 21st day of March 2011.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2011-7098 Filed 3-24-11; 8:45 am]

BILLING CODE 3410-34-P

**DEPARTMENT OF TRANSPORTATION**

**Federal Aviation Administration**

**14 CFR Part 97**

[Docket No. 30773; Amdt. No. 3417]

**Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule.

**SUMMARY:** This rule establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

**DATES:** This rule is effective March 25, 2011. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of March 25, 2011.

**ADDRESSES:** Availability of matter incorporated by reference in the amendment is as follows:

*For Examination—*

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591;

2. The FAA Regional Office of the region in which the affected airport is located;

3. The National Flight Procedures Office, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or