

Rules and Regulations

Federal Register

Vol. 74, No. 1

Friday, January 2, 2009

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 71, 83, and 93

[Docket No. APHIS–2007–0038]

RIN 0579–AC74

Viral Hemorrhagic Septicemia; Interstate Movement and Import Restrictions on Certain Live Fish

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule; delay of effective date.

SUMMARY: On September 9, 2008, we published an interim rule in the **Federal Register** to restrict the interstate movement and importation into the United States of live fish that are susceptible to viral hemorrhagic septicemia, a highly contagious disease of certain freshwater and saltwater fish. That interim rule was scheduled to become effective on November 10, 2008. Subsequently, on October 28, 2008, we published a notice in the **Federal Register** announcing the delay of the effective date of the interim rule until January 9, 2009. We are now delaying the effective date of the interim rule indefinitely to provide APHIS with time to make some adjustments to the interim rule that are necessary for the rule to be successfully implemented.

DATES: The effective date for the interim rule amending 9 CFR parts 71, 83, and 93, published at 73 FR 52173–52189 on September 9, 2008, is delayed indefinitely.

FOR FURTHER INFORMATION CONTACT: Dr. P. Gary Egrie, Senior Staff Veterinary Medical Officer, National Center for Animal Health Programs, VS, APHIS, 4700 River Road Unit 46, Riverdale, MD 20737–1231; (301) 734–0695; or Dr. Peter L. Merrill, Senior Staff

Veterinarian, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737–1231; (301) 734–8364.

SUPPLEMENTARY INFORMATION:

Background

Viral hemorrhagic septicemia (VHS) is a highly contagious disease of certain freshwater and saltwater fish, caused by a rhabdovirus. It is listed as a notifiable disease by the World Organization for Animal Health. The pathogen produces variable clinical signs in fish including lethargy, skin darkening, exophthalmia, pale gills, a distended abdomen, and external and internal hemorrhaging. The development of the disease in infected fish can result in substantial mortality. Other infected fish may not show any clinical signs or die, but may be lifelong carriers and shed the virus.

On September 9, 2008, we published an interim rule in the **Federal Register** (73 FR 52173–52189, Docket No. APHIS–2007–0038) to amend 9 CFR parts 71, 83, and 93 by establishing regulations to restrict the interstate movement and the importation into the United States of certain live fish species that are susceptible to VHS. We announced that the provisions of the interim rule would become effective November 10, 2008, and that we would consider all comments on the interim rule received on or before November 10, 2008, and all comments on the environmental assessment for the interim rule received on or before October 9, 2008.

Delay of Effective Date

After the publication of the interim rule, we received comments that addressed a variety of issues, including the feasibility of implementing certain requirements.

Based on our review of those comments, on October 28, 2008, we published a document in the **Federal Register** (73 FR 63867, Docket No. APHIS–2007–0038) announcing that we were delaying the effective date of the interim rule from November 10, 2008, until January 9, 2009, while retaining November 10, 2008 as the close of the comment period for the interim rule and October 9, 2008 as the close of the comment period for the environmental assessment.

We are now delaying the effective date of the interim rule indefinitely to

provide APHIS with time to make some adjustments to the interim rule that are necessary for the rule to be successfully implemented.

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.

Done in Washington, DC, this 22nd day of December 2008.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E8–31208 Filed 12–31–08; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 93

[Docket No. APHIS–2007–0095]

RIN 0579–AC63

Importation of Cattle From Mexico; Addition of Port at San Luis, AZ

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations regarding the importation of cattle from Mexico by adding San Luis, AZ, as a port through which cattle that have been infested with fever ticks or exposed to fever ticks or tick-borne diseases may be imported into the United States. A new facility for the handling of animals is to be constructed on the Mexican side of the border at the port of San Luis, AZ, that will be equipped with facilities necessary for the proper chute inspection, dipping, and testing that are required for such cattle under the regulations. We are also amending the regulations to remove provisions that limit the admission of cattle that have been infested with fever ticks or exposed to fever ticks or tick-borne diseases to the State of Texas. The statutory requirement that limited the admission of those cattle to the State of Texas has been repealed. These changes will make an additional port of entry available and relieve restrictions on the movement of imported Mexican cattle within the United States.

DATES: *Effective Date:* This rule is effective January 2, 2009 except for the amendment (amendatory instruction 3)

to § 93.427(b)(2) introductory text, for which the effective date is delayed indefinitely. The Animal and Plant Health Inspection Service will publish a document announcing an effective date for that provision in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Dr. Betzaida Lopez, Staff Veterinarian, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737-1231; (301) 734-8364.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 93 prohibit or restrict the importation of certain animals, birds, and poultry into the United States to prevent the introduction of communicable diseases of livestock and poultry. Subpart D of part 93 (§§ 93.400 through 93.436, referred to below as the regulations) governs the importation of ruminants; within subpart D, §§ 93.424 through 93.429 specifically address the importation of various ruminants from Mexico into the United States.

In § 93.426, paragraph (a) states that all ruminants offered for entry into the United States from Mexico must be inspected at the port of entry and found to be free from communicable diseases and fever tick infestation and to not have been exposed to communicable diseases and fever tick infestation. Ruminants found to be affected with or to have been exposed to a communicable disease, or infested with fever ticks, are to be refused entry except as provided in § 93.427(b)(2).

Under § 93.427(b)(2), cattle that have been exposed to splenetic, southern, or tick fever, or that have been infested with or exposed to fever ticks, may be imported from Mexico for admission into the State of Texas, except that portion of the State quarantined because of fever ticks, either at one of the land border ports in Texas listed in § 93.403(c) of the regulations, or at the port of Santa Teresa, NM, provided that certain conditions are met. Those conditions are spelled out in paragraphs (b)(2)(i) through (b)(2)(v) of § 93.427.

On January 9, 2008, we published in the **Federal Register** (73 FR 5132-5135, Docket No. APHIS-2007-0095) a proposal¹ to amend the regulations by adding San Luis, AZ, as a port through which cattle that have been infested with fever ticks or exposed to fever ticks or tick-borne diseases may be imported

into the United States. A new facility for the handling of animals is to be constructed on the Mexican side of the border at the port of San Luis, AZ, that will be equipped with facilities necessary for the chute inspection, dipping, and testing that are required for such cattle under the regulations. We also proposed to amend the regulations to remove provisions that limit the admission of cattle that have been infested with fever ticks or exposed to fever ticks or tick-borne diseases to the State of Texas. The statutory requirement that limited the admission of those cattle to the State of Texas has been repealed. These changes were intended to make an additional port of entry available and relieve restrictions on the movement of imported Mexican cattle within the United States.

We solicited comments concerning our proposal for 60 days ending March 31, 2008. We received 52 comments by that date. They were from private citizens, industry groups, and State agriculture organizations.

Thirty-eight commenters supported the proposed rule. Fourteen commenters expressed concerns regarding the proposed rule. The issues they raised are discussed below.

One commenter objected to allowing cattle infested with fever ticks to be imported into the United States.

The regulations currently allow cattle that have been exposed to splenetic, southern, or tick fever, or that have been infested with or exposed to fever ticks, to be imported into the United States; we proposed to allow their importation through the port of San Luis. However, the animals would have to meet the requirements in the regulations for inspection, dipping, and certification of freedom from ticks before entering the United States.

Many commenters expressed concern that the opening of the new port at San Luis may cause an increase in the number of Mexican cattle imported into the United States annually, particularly because it would reduce the cost to ship for some entities. The commenters also stated that this increase could cause financial harm to cattle ranchers in the United States or damage the international reputation of the U.S. cattle industry. Several commenters expressed concern with the risk assessment, stating that its conclusion that the rule would not increase risk was based on a faulty assumption that the new port would not lead to an increase in the volume of cattle exports from Mexico.

In response to these comments, we have prepared an addendum to the risk

assessment,² which gives additional details regarding the reasons we do not expect this rule to increase the number of Mexican cattle imported into the United States. As the addendum states, increases or decreases in Mexican cattle import volumes are due to a number of factors, most importantly weather, the financial situation of Mexican cattle farmers, and the price of feeder cattle in the southwestern United States. In addition, although imports have increased over time, the total export market for Mexican cattle is not expected to increase in the future because the demand for domestic beef within Mexico continues to increase. Mexican beef calf exports are almost all destined for the United States already. Therefore, it is unlikely that Mexican cattle producers will have a large number of additional cattle available for export to the United States.

In addition, even if the export market were to increase, we would not expect large numbers of cattle to enter the United States through San Luis. Currently, the majority of Mexican cattle (about 80 percent) are destined for New Mexico or Texas ports, with only a small percentage (about 15 percent) going to ports in more westerly States, including Arizona and California. This is because the mountainous terrain and lack of well-developed roads running east to west within Mexico make it difficult for cattle from eastern States of Mexico, where the majority of cattle are produced, to utilize ports in more westerly States within the U.S. If these trends continue, we would expect the bulk of the increase in Mexican cattle imports to continue to enter through New Mexico and Texas ports based on proximity, cost, and convenience of travel. The Mexican States that are closest to the San Luis port and that would, therefore, be most likely to use the San Luis port are: Baja California Norte, Baja California Sur, Nayarit, Sinaloa, and Sonora. Because these five Mexican States account for only about 14 percent of Mexican cattle production, even if they were to increase their cattle exports, it is unlikely that there will be a significant increase in the number of Mexican cattle exported to the United States as a result of our opening the port of San Luis to cattle that have been exposed to splenetic, southern, or tick fever, or that have been infested with or exposed to fever ticks.

One commenter asked what impact the proposed rule would have on the price of cattle and beef.

¹ To view the proposed rule, supporting documents, and the comments we received, go to <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2007-0095>.

² See footnote 1 for the address to view the risk assessment and the addendum to the risk assessment.

Since the amount of cattle entering the United States from Mexico is not expected to increase significantly as a result of this final rule, cattle prices should not be greatly affected. However, some importers who have been importing Mexican cattle into the United States through ports in Texas and New Mexico may save some shipping costs by switching to the port in San Luis. To the extent that these savings on shipping costs are passed on by brokers, consumers could see lower prices.

Several commenters expressed concern that allowing cattle to be imported through the port at San Luis would result in more Mexican cattle moving to areas in the United States conducive to tick establishment.

We expect most of the cattle that will be imported through the port at San Luis will be cattle that otherwise would have been imported through Texas or New Mexico ports, and not cattle that would otherwise not have been imported. Because brokers importing cattle from Mexico usually supply cattle to the same entities they have previously dealt with, we do not expect the U.S. destination of Mexican cattle to change as a result of this rule. As stated in the addendum to the risk assessment, cattle imported through the port at San Luis will most likely be bound for California or other areas of Arizona where non-exposed cattle and cattle not previously infested with fever ticks and found to be eligible for importation have historically gone. Although there are areas within Southern California that may be conducive to fever tick establishment, fever ticks within the United States have been confined to certain quarantined areas in Texas since 1943 despite continual importation of Mexican cattle into the United States.

As stated previously, even if cattle infested with fever ticks are presented for importation, they would have to meet the requirements in the regulations for inspection, dipping, and certification of freedom from ticks of any type before entering the United States. Although dipping cattle with acaricide is not considered 100 percent effective against ticks, these measures are the same requirements for cattle entering at other ports. Therefore, opening the port at San Luis to Mexican cattle that have been infested with fever ticks or exposed to fever or tick-borne diseases does not present an additional risk of introduction and spread of fever ticks or introduction and spread of tick fever.

Several commenters expressed concern that the area around the proposed San Luis port may also be

conducive to tick establishment if cattle remain in the area.

As stated in the risk assessment, the area surrounding the port of San Luis is not suitable for the establishment of fever ticks. This is because precipitation levels in the area around the port are too low to support the establishment of fever ticks. While moisture from the Colorado River and from private wells in the area may create micro-habitats that could increase the chance of survival for fever ticks, cattle imported through the port at San Luis are not likely to remain near the port. Finally, even if tick-infested cattle were imported and did remain near the port at San Luis, they, along with all other cattle imported through the port, would have been inspected, dipped, and certified as free from ticks of any type before entering the United States. As stated previously, although not 100 percent effective against ticks, these are the same requirements for cattle entering at other ports. Therefore, there is no additional risk of introduction and spread of fever ticks or introduction and spread of tick fever.

Two commenters stated that tick fever outbreaks have occurred in areas of the United States and Europe above the 36° N line of latitude, which contradicts the findings in the risk assessment. One of these commenters asked that the risk assessment be revised to address this issue.

There has never been an outbreak of fever ticks or tick fever within the United States above the 36° N line of latitude that has been conclusively linked to cattle imported from Mexico. As mentioned in the risk assessment, the environment above the 36° N line of latitude is not conducive for the establishment of fever ticks, even in the case that some ticks might make it across the border. This is because fever ticks thrive in tropical and subtropical climates; at temperatures below 20 °C, the reproductive ability of female ticks appears to be impaired.

As noted by the commenter, tick fever outbreaks have been reported in areas of Europe above the 36° N line of latitude (i.e., Finland, the Netherlands, Romania, and Slovenia); however those outbreaks were due to species of *Babesia* (*Babesia divergens* and *B. jakimovi*) that are transmitted via a different, non-*Boophilus* species of tick (*Ixodes ricinus*) capable of thriving in more northern climates. Neither these *Babesia* species nor this tick species are indigenous to the United States, although similar tick species such as *I. (dammini) scapularis* and *I. pacificus* are present that feed on deer and mice, and are capable of spreading another

species of *Babesia*, *B. microti*. However, unlike with other *Babesia* species that cause tick fever, humans and not cattle are the intermediate hosts for *B. microti*.

One commenter expressed concern that the restriction limiting the importation of cattle that have been infested with fever ticks or exposed to fever ticks or tick-borne diseases to the State of Texas was lifted without allowing for public comment.

As stated in the proposed rule, the passage of the North American Free Trade Agreement (NAFTA) Implementation Act removed the statutory provisions that limited the importation of cattle only into the State of Texas. Following the passage of the NAFTA Implementation Act, our permitting procedures were modified to allow cattle that had been infested with or exposed to fever ticks to be moved from Mexico into States other than Texas under the conditions described in § 93.427(b)(2). However, we did not make a corresponding change in the regulations to reflect the statutory amendment. We sought to rectify this error in this rulemaking, which also allowed the public the opportunity to comment on the removal of the restriction.

Several commenters expressed concern regarding acaricide-resistant ticks present in Mexico. One commenter suggested that we require Mexico to standardize their tick treatment protocol for exported cattle according to the recommendations of the Binational Tick Committee, which requires a 400 ppm Amitraz immersion.

Although there is a concern about acaricide-resistant ticks in Mexico, the resistance has proven to be due to the inappropriate use of acaricides. The Mexican Government has developed a pesticide resistance management program to minimize the development and spread of resistant tick populations. We expect that these changes will ensure that acaricides continue to be an effective treatment for cattle imported into the United States. Cattle from Mexico are currently being treated with at least a 400 ppm Amitraz treatment before entering the United States.

Several commenters stated that the Cattle Fever Tick Eradication Program must be fully funded and implemented.

We will continue to seek full funding of our tick eradication program and, in the event of a fever tick outbreak, will take appropriate action to eliminate the outbreak.

One commenter asked if more information was available about the economic effects of the proposed rule on small businesses. Another commenter stated that a cost-benefit analysis should

be conducted before the proposed rule is finalized. One commenter stated that our estimate of the costs of eradicating ticks from infested herds is inadequate because it is based on 2005 data and because it did not include the costs of replacing animals lost to tick fever.

The initial regulatory flexibility analysis in the proposed rule provided all the information that was available to us regarding the potential economic effects of the proposed rule on small businesses. The cost data in the regulatory flexibility analysis was based on the most current data available at the time of drafting. Although some of this data might be from 2005, this does not impact the regulatory flexibility analysis. Despite the costs, we will continue to use all the resources at our disposal to prevent the introduction and dispersal of tick fever into the United States. Moreover, we note that there has never been an outbreak of tick fever in the United States that was conclusively linked to Mexican-origin cattle.

One commenter expressed concern that the United States could experience lost export markets because it does not follow World Organization of Animal Health (OIE) guidelines with regard to tick fever. In particular, the commenter mentioned the OIE guidelines recommending that a country limit its imports to animals that have resided since birth in a zone recognized as free from tick fever or to animals that have tested negative for tick fever in the preceding month, and that have been treated with an acaricide prior to shipment.

In order for bovine babesiosis to persist in cattle populations in the United States, three factors must simultaneously exist: Agent, host, and environment. In the absence of all three elements, it is still possible for disease to be detected occasionally, but difficult for the infection to persist in a population. Fever ticks are currently confined to quarantined areas within Texas and movement restrictions are in place to prevent the movement of cattle from Mexico into the quarantined areas. As stated in the risk assessment, in the absence of vector ticks, tick-borne diseases cannot be spread and, therefore, will gradually disappear from an infected herd. Therefore, even if an animal was a carrier of tick fever, because there are no vectors to transmit the disease within the United States outside of the quarantined areas and because there are restrictions in place to prevent the movement of Mexican cattle into or through tick quarantine areas, it is unlikely that tick fever would be introduced and spread within the United States. We are not aware of

having lost any export markets due to not complying with OIE guidelines. Moreover, we do not believe it is necessary to limit U.S. cattle imports to animals that have resided since birth in a zone recognized as free from tick fever or to those cattle that have tested negative for tick fever prior to importation.

Several commenters stated that the prohibition on the movement of tick-infested cattle into the area of Texas quarantined for cattle tick fever must be maintained.

We agree with the commenter, as we are continuing eradication efforts in that area of Texas. Therefore, this rule continues the prohibition on the movement from Mexico of tick-infested cattle or cattle that have been exposed to fever ticks or tick-borne diseases into the quarantined areas of Texas.

Several commenters stated that APHIS should work closely with Mexico to ensure that new cattle-handling facilities, including the port at San Luis, AZ, are properly managed, equipped, and funded to prevent the spread of cattle fever ticks into the United States and that port staff are adequately trained. One commenter stated that all port staff should be full-time and that APHIS should conduct regular reviews of procedures at the port at San Luis, AZ.

All ports on the Mexican border are staffed by APHIS as well as employees of the Mexican Government, and APHIS guidelines are in place to ensure consistency and close coordination between the two groups. In addition, APHIS has standard operating procedures in place that detail proper tick inspection procedures. All ports are staffed with full-time employees, and port facility reviews are conducted on a regular basis to make sure the facilities themselves and the procedures they employ are adequate to prevent the introduction of cattle fever ticks into the United States. The San Luis port, like all other ports that handle Mexican cattle, will undergo an inspection and approval process prior to being opened for trade.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, without change.

Effective Dates

This is a substantive rule that relieves restrictions and, pursuant to the provisions of 5 U.S.C. 553, may be made effective less than 30 days after publication in the **Federal Register**.

Immediate removal of the provision in § 93.427(b) that limited the admission of certain Mexican-origin cattle to parts of

Texas will make our regulations consistent with the NAFTA Implementation Act and with our permitting procedures, which were modified following the passage of the NAFTA implementation Act.

However, we are delaying, indefinitely, the effective date of the addition of San Luis, AZ, to the list in § 93.427(b) of ports through which cattle that have been infested with fever ticks or exposed to fever ticks or tick-borne diseases may be imported from Mexico, pending construction of new facilities and APHIS inspection of those facilities to confirm that they are properly equipped to allow for the necessary chute inspection, dipping, and testing of cattle.

Executive Order 12866 and Regulatory Flexibility Act

This final rule has been reviewed under Executive Order 12866. The 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.

In accordance with 5 U.S.C. 604, we have performed a final regulatory flexibility analysis, which is set out below, regarding the economic effects of this rule on small entities.

For the purpose of this analysis, and following Small Business Administration (SBA) guidelines, the potentially affected entities are classified as Beef Cattle Ranching and Farming (North American Industry Classification System 112111). By SBA standards, farms in this category are considered small if annual receipts are not more than \$750,000. According to the 2002 Census of Agriculture, of the 664,431 beef cattle farms, 659,009, or 99 percent, had annual receipts of less than \$500,000 and are therefore considered small. Cattle imported into the United States from Mexico are generally purchased by stocker operations before they are shipped to feedlots. While there is no economic information available on the number, size, or distribution of the stocker operations, it is reasonable to assume they are small given that 99 percent of beef cattle ranches and farms in general are small entities.

From 2000 to 2006, an average of 45,258 cattle per year entered through the port of San Luis, Arizona.³ Historically, 80 percent of U.S. cattle imports from Mexico have gone to Texas and New Mexico. Between 2003 and 2008, over 6.5 million cattle entered the United States from Mexico at various

³ Source: Centers for Epidemiology and Animal Health Import Tracking System.

ports. The ports with the largest volume of cattle imports between 1994 and 2003 were Santa Teresa/El Paso (26.64 percent), Presidio (18.12 percent), and Nogales (14.24 percent). Only 5.95 percent of U.S. cattle imports from Mexico came through San Luis.⁴ To date, the San Luis port has only received 8,000 head of cattle in 2008. As mentioned in the addendum to the risk assessment, San Luis' western location makes it inconvenient, and therefore unlikely, that there will be a major shift in cattle movements from existing ports in Texas and New Mexico.

Any positive effects of the rule for small entities in the San Luis area, such as increased volumes of business for firms that transport cattle, are expected to be largely matched by business declines for firms operating from the Texas and New Mexico ports. Cattle importers who find it advantageous to use the San Luis port will be positively affected. There may also be positive effects at the Texas and New Mexico ports if the diversion of imports to San Luis of cattle that have been infested with fever ticks or exposed to fever ticks or tick-borne diseases reduces operational delays when the demand for imports is beyond the capacity of those border facilities; however, APHIS has no information on whether such periods of insufficient capacity have occurred, and if so, how frequently.

The final rule will increase the number of cattle operations allowed to receive cattle from Mexico that have been infested with fever ticks or exposed to fever ticks or tick-borne diseases. A larger number of more widely distributed U.S. entities will be afforded the opportunity to benefit from importing these cattle. Establishment of San Luis, AZ, as a port of entry for cattle from Mexico that have been infested with fever ticks or exposed to fever ticks or tick-borne diseases will also make these cattle more readily accessible for entities to the west of Texas; transport costs from the port of entry will be lower because the cattle will be moved over shorter distances.

The Mexican Government has requested that a land-border port be established on the Mexico-Arizona border to move cattle that have been infested with fever ticks or exposed to fever ticks or tick-borne diseases from Mexico to the United States. APHIS has determined that with the construction of new facilities at the port of San Luis, this request can be satisfied given that the new port will be equipped to handle

cattle that have been infested with fever ticks or exposed to fever ticks or tick-borne diseases. The potential impacts for affected U.S. cattle operations, most of which are small entities, are expected to be positive. This rule does not contain any new reporting, recordkeeping, or compliance requirements. There are no significant alternatives to the rule that will accomplish the stated objectives.

Executive Order 12988

This final 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 final rule contains no new 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 93.427 is amended, effective January 2, 2009 by revising paragraph (b)(2) to read as follows:

§ 93.427 Cattle from Mexico.

* * * * *

(b) * * *

(2) Cattle that have been exposed to splenetic, southern, or tick fever, or that have been infested with or exposed to fever ticks, may be imported from Mexico for admission into the United States, except into areas of Texas quarantined because of said disease or tick infestation as specified in § 72.5 of this chapter, either at one of the land border ports in Texas listed in § 93.403(c) or at the port of Santa

Teresa, NM, provided that the following conditions are strictly observed and complied with:

(i) The cattle shall be accompanied by a certificate issued in accordance with § 93.405(a), and showing that the veterinarian issuing the certificate has inspected the cattle and found them free from fever ticks and any evidence of communicable disease, and that, as far as it has been possible to determine, they have not been exposed to any such disease, except splenetic, southern, or tick fever, during the 60 days immediately preceding their movement to the port of entry.

(ii) The cattle shall be shown by a certificate issued in accordance with § 93.405(a) to have been dipped in a tickicidal dip within 7 to 12 days before being offered for entry.

(iii) The importer, or his or her duly authorized agent, shall first execute and deliver to an inspector at the port of entry an application for inspection and supervised dipping wherein he or she shall agree to waive all claims against the United States for any loss or damage to the cattle occasioned by or resulting from dipping, or resulting from the fact that they are later found to be still tick infested; and also for all subsequent loss or damage to any other cattle in the possession or control of such importer which may come into contact with the cattle so dipped.

(iv) The cattle when offered for entry shall receive a chute inspection by an inspector. If found free from ticks they shall be given one dipping in one of the permitted dips listed in § 72.13(b) of this chapter under the supervision of an inspector 7 to 14 days after the dipping required by paragraph (b)(2)(ii) of this section. The selection of the permitted dip to be used will be made by the port veterinarian in each case. If found to be infested with fever ticks, the entire lot of cattle shall be rejected and will not be again inspected for entry until 10 to 14 days after they have again been dipped in the manner provided by paragraph (b)(2)(ii) of this section.

(v) The conditions at the port of entry shall be such that the subsequent movement of the cattle can be made without exposure to fever ticks.

* * * * *

■ 3. Section 93.427 is further amended, with an effective date pending further notice, by revising paragraph (b)(2) introductory text to read as follows:

§ 93.427 Cattle from Mexico.

* * * * *

(b) * * *

(2) Cattle that have been exposed to splenetic, southern, or tick fever, or that

⁴ Source: Live cattle imports by Port of Entry from Mexico into the United States: Data and Models, New Mexico State University, August 2005.

have been infested with or exposed to fever ticks, may be imported from Mexico for admission into the United States, except into areas of Texas quarantined because of said disease or tick infestation as specified in § 72.5 of this chapter, either at one of the land border ports in Texas listed in § 93.403(c) or at the port of Santa Teresa, NM, provided that the following conditions are strictly observed and complied with:

* * * * *

Done in Washington, DC, this 22nd day of December 2008.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E8-31212 Filed 12-31-08; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA-2008-N-0039]

New Animal Drugs for Use in Animal Feeds; Tiamulin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of two supplemental new animal drug applications (NADAs) filed by Novartis Animal Health US, Inc. The supplemental NADAs provide for

removal of a 250-pound weight restriction and the addition of a reproductive caution statement to labeling of tiamulin medicated feeds used for the treatment or control of certain bacterial enteric diseases in swine.

DATES: This rule is effective January 2, 2009.

FOR FURTHER INFORMATION CONTACT:

Cindy L. Burnsteel, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8341, e-mail: cindy.burnsteel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408, filed a supplement to NADA 139-472 for DENAGARD (tiamulin) Medicated Premixes used for the treatment or control of certain bacterial enteric diseases in swine. Novartis Animal Health US, Inc., also filed a supplement to NADA 141-011 for the use of DENAGARD (tiamulin) Medicated Premixes and Chlortetracycline Type A medicated articles to manufacture 2-way combination drug medicated swine feeds used for the treatment or control of certain bacterial enteric diseases. The supplemental NADAs provide for removal of a 250-pound weight restriction and the addition of a reproductive caution statement to labeling. The supplemental NADAs are approved as of December 9, 2008, and 21 CFR 558.600 is amended to reflect the approval.

Approval of these supplemental NADAs did not require review of additional safety or effectiveness data or

information. Therefore, a freedom of information summary is not required.

The agency has determined under 21 CFR 25.33 that these actions are of a type that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801 808.

List of Subjects in 21 CFR Part 558

Animal drugs, animal feeds.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

■ 2. In § 558.600, revise paragraphs (d)(2) and (e)(1)(i) to read as follows:

§ 558.600 Tiamulin.

* * * * *

(d) * * *

(2) The effects of tiamulin on swine reproductive performance, pregnancy, and lactation have not been determined.

* * * * *

(e) * * *

(1) * * *

Tiamulin grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 10		For increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration. Not for use in swine weighing over 250 pounds.	058198

* * * * *

* * * * *

Dated: December 22, 2008.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. E8-31128 Filed 12-31-08; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA-2008-N-0517]

Medical Devices; Immunology and Microbiology Devices; Classification of Enterovirus Nucleic Acid Assay

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying enterovirus nucleic acid assay into class II (special controls). The special control that will apply to the device is the guidance document entitled "Class II Special Controls Guidance Document: Nucleic Acid Amplification Assay for the Detection of Enterovirus RNA" (ribonucleic acid). The agency is classifying the device into class II (special controls) in order to provide a