(16) *Movement from the preembarkation quarantine facility to the port of embarkation.* The llamas and alpacas were moved from the preembarkation quarantine facility to the port of embarkation in a means of conveyance which, immediately prior to loading the llamas and alpacas, was cleaned and disinfected under the supervision of, and in the presence of, a full-time salaried employee of the exporting country's national veterinary services with a disinfectant specified in § 71.10 of this chapter. The movement from the preembarkation quarantine facility to the port of embarkation was by the most expeditious route to prevent possible exposure to disease in transit. From the time of cleaning and disinfecting the means of conveyance through the unloading of the llamas and alpacas for export to the United States, there were no other animals aboard the means of conveyance.

(b) *Quarantine upon arrival.* (1) As a condition of entry into the United States, llamas and alpacas from any country listed in § 94.1(d) of this chapter shall be quarantined at the Harry S Truman Animal Import Center for not less than 40 days, counting from the date of arrival at the Harry S Truman animal Import Center.

(2) All llamas and alpacas from any country listed in § 94.1(d) of this chapter shall test negative to the virus neutralization and virus infection associated antigen serological tests for foot-and-mouth disease twice, at an interval of no less than 21 days, during quarantine at the Harry S Truman Animal Import Center.

(3) All llamas and alpacas from any country listed in § 94.1(d) of this chapter shall test negative to a virus isolation procedure using oesophageal-pharyngeal tissue samples. The tissue samples shall be collected from the esophageal-pharyngeal area, using the probang procedure, within 7 days following arrival of the llamas and alpacas at the Harry S Truman Animal Import Center.

(4) In order to qualify for release from quarantine, llamas and alpacas from any country listed in § 94.1(d) of this chapter shall also test negative to any test duplicative of the tests required under paragraph (a) of this section and any other tests as may be determined necessary by the Administrator to determine their freedom from communicable diseases.

(5) Llamas and alpacas from any country listed in § 94.1(d) of this chapter shall be quarantined with sentinel animals during the entire time the llamas and alpacas remain at the Harry S Truman animal Import Center. The ratio of sentinel animals to imported llamas and alpacas shall be one pig and one calf per eight imported llamas and alpacas. The sentinel animals shall be observed for a minimum of 40 days for clinical signs of communicable disease and shall test negative to the virus neutralization and virus infection associated antigen serological tests for foot-and-mouth disease twice, at an interval of no less than 21 days, during quarantine at the Harry S Truman Animal Import Center. The sentinels shall also undergo any other tests that may be deemed necessary by the Administrator. The last serological test for foot-and-mouth disease will be performed a minimum of 21 days following initial exposure to the imported llamas and alpacas.

(6) The importer shall reimburse the United States Department of Agriculture for all costs, excluding capital expenditures at the Harry S Truman Animal Import Center, associated with the importation and entry into the United States of llamas and alpacas from any country listed in § 94.1(d) of this chapter.

(c) *Llamas and alpacas refused entry.* a llama or alpaca imported or offered for entry into the United States that is not accompanied by a health certificate as required by paragraph (a) of this section or that is found upon inspection at the Harry S Truman Animal Import Center to be affected with a communicable disease or to have been exposed to a communicable disease, shall be refused entry and shall be handled thereafter in accordance with 21 U.S.C. 103 or quarantined, or otherwise disposed of as the Administrator may direct.

Done in Washington, DC, this 25th day of September 1990.

James W. Glosser,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 90-22998 Filed 9-27-90; 8:45 am]

BILLING CODE 3410-34-M

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9 CFR Part 94

[Docket No. 89-209]

Change In Disease Status of Chile Because of Foot-and-Mouth Disease

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the animal import regulations by adding Chile to the list of countries declared to be free of rinderpest and foot-and-mouth disease. No outbreaks of rinderpest have ever occurred in Chile, and we have determined that foot-and-mouth disease has been eradicated there. We are also adding Chile to the list of countries that, although declared free of rinderpest and foot-and-mouth disease, are subject to special restrictions on the importation of meat and other animal products from ruminants or swine into the United States. This revision relieves certain prohibitions and restrictions on the importation, from Chile into the United States, of ruminants and swine, and of fresh, chilled, and frozen meats of these animals.

However, Chile is not included in the lists of countries declared to be free of hog cholera and swine vesicular disease. Therefore, the restrictions imposed on the importation of swine and swine products because of these diseases remain in effect for Chile.

A companion rule appearing in this issue of the **Federal Register** ("Llamas and Alpacas Imported From Chile and Certain Other Countries Declared Free of Rinderpest and Foot-and-Mouth Disease," Docket Number 89-216) adds certain health certification and quarantine upon arrival requirements for llamas and alpacas imported from Chile, as well as from any other country in which rinderpest or foot-and-mouth disease has been known to exist and that is added to the list of countries declared free of rinderpest and foot-and-mouth disease following the effective date of this document.

EFFECTIVE DATE: October 29, 1990.

FOR FURTHER INFORMATION CONTACT: Dr. Harvey A. Kryder, Jr., Acting Chief Staff Veterinarian, Import-Export Products Staff, VS, APHIS, USDA, room 753, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, 301-436-7885.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 94 (referred to below as the regulations), among other things, regulate the importation into the United States of specified animals and animal products in order to prevent the introduction into the United States of various diseases, including rinderpest and foot-and-mouth disease (FMD). Section 94.1(a)(1) of the regulations provides that rinderpest or FMD exists in all countries of the world except those countries listed in § 94.1(a)(2).

On August 17, 1989, we published in the **Federal Register** (54 FR 33918-33920, Docket Number 88-216), a document proposing to (1) amend § 94.1 of the regulations by adding Chile to the list of countries declared to be free of

rinderpest and FMD, and (2) amend § 94.11 of the regulations by adding Chile to the list of countries free of rinderpest and FMD that are subject to special restrictions on the importation of their meat and other animal products from ruminants and swine into the United States. We solicited comments concerning the proposal for a 60-day period ending October 16, 1989.

To give interested persons additional time to prepare comments, we extended the comment period 30 days, to November 15, 1989, in a docket published in the **Federal Register** on October 12, 1989 (54 FR 41845–41846, Docket Number 89–183).

Based on the rationale set forth in the proposal and in this document, we are declaring Chile free of rinderpest and FMD. However, as explained in the companion rule that appears in this issue of the **Federal Register** ("Llamas and Alpacas Imported From Chile and Certain Other Countries Declared Free of Rinderpest and Foot-and-Mouth Disease," Docket Number 89–216) we are adding health certification and quarantine upon arrival requirements for llamas and alpacas imported from Chile, as well as from any other country in which rinderpest or foot-and-mouth disease has been known to exist and that is added to the list of countries declared free of rinderpest and foot-and-mouth disease following the effective date of this document. Countries subject to these requirements will be listed in a new paragraph (d) in § 94.1.

Because Chile is not recognized as being free of hog cholera and swine vesicular disease, swine and pork or pork products offered for importation into the United States from Chile will continue to be subject to the prohibitions and restrictions imposed in part 94 because of those diseases.

We have carefully considered the comments received in response to our proposal. In this document we discuss those comments that relate to our proposal to declare Chile free of FMD. Those comments that raise issues associated with another proposed rule, "Llamas and Alpacas Imported from Chile" (54 FR 39759–39765, Docket Number 89–116), are addressed in the final rule ("Llamas and Alpacas Imported From Chile and Certain Other Countries Declared Free of Rinderpest and Foot-and-Mouth Disease," Docket Number 89–216) that appears in this issue of the **Federal Register**. That document deals specifically with health certification and quarantine upon arrival requirements for llamas and alpacas from Chile, as well as from any other country in which rinderpest or foot-and-mouth disease has been known to exist and that is added to the list of countries declared free of rinderpest and foot-and-mouth disease following the effective date of this document.

Comments

We received approximately 750 comments. Among those who submitted comments were State departments of agriculture; llama/alpaca breeders and importers; llama/alpaca and other livestock associations; livestock producers; veterinary hospitals and clinics; State and Federal officials, including State veterinarians; members of Congress; State legislators; universities; game preserves; zoos; farm bureau organizations; and other interested organizations and individuals, including veterinarians and animal scientists.

A majority of the comments, approximately 90 percent of the total received, either opposed FMD-free status for Chile or stated that Chile should not be declared free of FMD unless llamas and alpacas exported from that country undergo a high security quarantine before entering the United States. Many of the commenters specifically recommended a 90-day quarantine, with sentinel animals and appropriate testing, at the Harry S. Truman Animal Import Center (HSTAIC). This center is a maximum security quarantine facility located in Key West, Florida. It was established for the importation of animals, including those not otherwise eligible to be imported into the United States because they are from countries in which exotic diseases, such as FMD, exist. As previously mentioned, matters concerning the use of HSTAIC, length of quarantine, and other requirements for llamas and alpacas from Chile are not addressed in this document, but in the companion rule ("Llamas and Alpacas Imported From Chile and Certain Other Countries Declared Free of Rinderpest and Foot-and-Mouth Disease," Docket Number 89–216) that appears in this issue of the **Federal Register**.

The remainder of the comments, approximately 10 percent of the total received, either favored the proposed rule, requested an extension of the comment period, or requested additional information.

Commenters who opposed the proposed rule or called for the implementation of high security quarantine requirements shared the belief that the importation of llamas and alpacas from Chile would pose an unacceptable risk of introducing FMD into the United States. The issues raised by these commenters are discussed below.

Many commenters stated that Chile should not be declared free of FMD because that country has a history of repeated outbreaks of this disease. They asserted that these outbreaks are proof that Chile will be incapable of consistently maintaining FMD-free status. Other commenters stated that Chile will be unable to remain free of FMD because a silent, undetectable reservoir of FMD exists in its cattle and camelid populations. A large number of commenters stated that Chile's ability to remain free of FMD is compromised by the common borders it shares with Peru, Bolivia, and Argentina, countries in which FMD exists; that these borders are poorly patrolled and that there is routine smuggling of potentially FMD-infected animals across these borders into Chile; that FMD could also cross these borders into Chile via air transmission or via contaminated objects such as clothing or vehicles; and that llamas and alpacas smuggled into Chile from countries in which FMD exists could be selected for export to the United States or might commingle with llamas and alpacas destined for export to the United States. Some commenters stated that Chile does not have reliable method of monitoring and reporting FMD; that an FMD outbreak in Chile is imminent because Chile imports live ruminants and swine from countries in which FMD exists under conditions less restrictive than would be required for importation into the United States, and also because Chile imports meat and meat products from countries in which FMD exists. Other commenters stated that Chile and other countries that share common borders with countries in which FMD exists should be required to remain free of FMD for 3, 4, or 5 years—instead of the current 1-year period—before the Animal and Plant Health Inspection Service (APHIS) considers declaring them FMD-free.

We are making no changes, based on these comments, to our proposal to declare Chile free of rinderpest and FMD.

We disagree that Chile's past FMD-outbreaks are a sure indication that the country's current FMD-prevention efforts will prove unsuccessful. Chile suffered two FMD outbreaks during the last decade, in 1984 and 1987. In both cases, all infected and exposed animals were destroyed and eradication measures successfully completed. Information and documents submitted by the Government of Chile establish that laws and regulations are in effect in Chile and are administered in such a manner as to protect Chile against the introduction of rinderpest or FMD

through the importation of animals, meat, and other animal products from countries where FMD or rinderpest exists.

Since the country's last FMD outbreak in 1987, Chile has strengthened its disease-prevention efforts. The country instituted a program to identify all of the country's llamas and alpacas with official eartags. Annual inspections will keep this identification system up-to-date. Chile has also increased the number of FMD inspections conducted on its livestock population, including camelids; established an animal depopulation zone between itself and Argentina, and reduced the number of Chilean livestock entering the summer pasture areas near the Chile-Argentine border. Chilean livestock are identified, inspected, and tested for FMD upon entering and leaving these pasture areas.

Commenters' assertions that a silent, undetectable reservoir of FMD exists in the Chilean cattle and camelid populations appear to be unsubstantiated. Chile's domestic animal population was not the source of the two FMD outbreaks that occurred in Chile during the 1980's. In both instances, the disease was introduced into the country from outside sources.

Further, while no country's borders are completely impenetrable, it is our view that Chile has an effective program for controlling its borders with Argentina, Peru, and Bolivia to prevent the introduction of FMD via the smuggling of livestock and camelids into Chile. Surveillance along Chile's borders is a cooperative effort between Chile's Federal veterinary service, the Federal police, customs officials, and international police. In addition to its border control system, Chile also maintains a series of internal checkpoints along its roadways and highways. We have also determined that Chile has a reliable animal disease surveillance and reporting system, as evidenced by the swiftness with which Chile's 1987 FMD outbreak was reported to the United States and to the rest of the world.

We are aware that Chile imports live ruminants, swine, meat, and meat products from countries in which FMD exists. This is why we are adding Chile to the list in § 94.11(a) of countries free of rinderpest and FMD that are subject to special restrictions on the importation of meat and other animal products form ruminants and swine into the United States. The countries listed in § 94.11(a) are subject to these special restrictions because they (1) supplement their national meat supply by importing fresh, chilled, or frozen meat of ruminants or swine from countries in which rinderpest or FMD exists; (2) have a common land border with countries in which rinderpest or FMD exists; or (3) import ruminants or swine from countries in which rinderpest or FMD exists under conditions less restrictive than would be acceptable for importation into the United States.

We disagree with commenter statements concerning the length of time that Chile should be required to remain free of FMD before being designated by APHIS as an FMD-free country. Based on Departmental experience, it has been determined that a 1-year period of no FMD cases is sufficient to ensure that the disease has been completely eradicated, since the disease would manifest itself within that period of time if it had not been successfully eradicated. Chile's last FMD outbreak occurred more than 3 years ago.

Several commenters stated that determining the FMD status of South American countries should be done on a regional basis; that is, Chile should not be given FMD-free status until all countries in South America, or at least the llama and alpaca-producing countries in South America, are free of FMD.

It is not the purpose of this rule to review the Department's criteria for determining the disease status of countries. We are therefore making no changes based on these comments. We have determined that Chile has met the Department's criteria for being declared free of FMD.

Several commenters stated that APHIS should not consider granting FMD-free status to Chile until more research has been conducted on FMD in llamas and alpacas. Other commenters stated that we should not declare Chile free of FMD because we have not examined the risks associated with this action.

We are making no changes, based on these comments, to our proposal to declare Chile free of rinderpest and FMD. We have examined the risks associated with declaring Chile free of FMD and have determined that this action will not result in a significant risk of introducing animal diseases exotic to the United States. We based this determination on information supplied to us by Chilean veterinary officials, on first-hand observation of Chile's disease prevention programs, on the restrictions we are implementing concerning meat and other animal products of ruminants and swine imported from Chile, and on the requirements in the final rule ("Llamas and Alpacas Imported From Chile and Certain Other Countries Declared Free of Rinderpest and Foot-and-Mouth Disease," Docket Number 89-216) which is published in this issue of the Federal Register and which imposes restrictions upon the importation of llamas and alpacas into the United States from Chile.

We disagree with the conclusions drawn in a preliminary probabilistic risk assessment submitted to us by one commenter. The assessment's conclusion that an FMD-infected animal would pass undetected through U.S. quarantine once every 2 years appears to be unrealistic, given the fact that this FMD introduction rate exceeds the FMD introduction rate experienced by Chile in recent years. We believe the assessment contains numerous factual errors, methodological errors, and questionable assumptions, and, therefore, overestimates the risk associated with the importation into the United States of llamas and alpacas from Chile.[1]

Several commenters stated that Chile should not be declared free of FMD because the importation of llamas and alpacas from Chile would flood the United States market, hurting or destroying the llama/alpaca industry in this country. Other commenters stated that llamas and alpacas from Chile are genetically inferior to domestic llamas and alpacas, and that the breeding of these inferior animals with domestic animals would reduce the quality of the llama/alpaca population in the United States, causing a price decline that would hurt domestic breeders.

We are making no changes based on these comments. These reasons do not appear to be adequate for refusing to declare Chile free of FMD. The regulations in 9 CFR part 94 are established pursuant to animal quarantine and related laws that generally provide authority to take action to prevent the introduction or dissemination of certain diseases. These statutory provisions do not provide authority to establish regulations based merely on factors relating to economic competition or genetics. Although we consider the economic impact of our regulations in accordance with Executive Order 12291 and the Regulatory Flexibility Act, we do not have authority to prohibit or restrict the importation of llamas and alpacas to protect domestic breeders from competition or to ensure that the genetic base of the llamas and alpaca

[1] A copy of our analysis of the preliminary probabilistic risk assessment referred to above can be obtained by writing to the Administrator, c/o Dr. Gary P. Combs, Chief, Program Evaluation and Planning, APHIS, USDA, room 803, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782.

population in the United States is not changed.

A large number of commenters stated that Executive Order 12372 was ignored during this rulemaking process.

We disagree. Executive Order 12372 is intended to apply to Federal financial assistance and direct Federal development programs and activities of the Department of Agriculture. This rule does not involve matters of this nature. In this document we have therefore omitted the reference to Executive Order 12372. However, it should be noted that APHIS regularly cooperates with State and local officials in carrying out its Federal regulatory program.

Some commenters stated that this rulemaking process is subject to the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*), and that we have failed to meet the requirements of this act concerning the preparation of various environmental documents. One commenter stated that the National Environmental Policy Act is triggered by this rulemaking process, in part, because an outbreak of FMD in the United States could affect wild animal populations, thereby necessitating disease control measures that could have a significant impact upon the environment.

We disagree with the commenters' assertions concerning the National Environmental Policy Act. We have prepared a special environmental assessment to evaluate the environmental implications of this action. Our special environmental assessment concludes that this action will have no environmental impact, and that an environmental impact statement need not be prepared. This assessment supports our initial determination that the environment is not affected by the regulatory change we are making.[2]

A small number of commenters stated that we violated the Administrative Procedure Act by failing to effect meaningful participation by the public during this rulemaking process. Specifically, these commenters asserted that APHIS failed to respond to certain Freedom of Information Act requests in a timely manner, thereby impeding the public's ability to provide meaningful comments on the proposed rule.

We do not believe the public was impeded from commenting on the proposed rule. The Department has made a good faith effort to provide information to all those who requested it, and to provide this information in as timely a manner as circumstances would allow.

One commenter stated that we should redefine the parameters by which animals are permitted into the United States; another commenter stated that we should strengthen the risk assessment criteria we use in determining the impact of importing plants, animals, and plant/animal products from areas with exotic pest infestations; and several commenters stated that we must create more disease status levels or categories—as opposed to the current "disease free" or "not free" system—in order to make our regulations more flexible.

We are making no changes based on these comments. During this rulemaking proceeding we have focused exclusively on those issues relating to the rinderpest and FMD status of a particular country. It is not the purpose of this rule, nor would it be feasible as a part of this rulemaking proceeding, to undertake a revision of the Department's animal import regulations in their entirety. Nor is it the purpose of this rule to undertake a review of the criteria used by the Department in its risk analysis process, or to amend the Department's regulations concerning disease status categories. It should be noted, however, that the Department's policies and regulations undergo a continuous process of review and revision. Although the above comments fall outside the scope of this particular rulemaking proceeding, we will give them careful consideration when reviewing those Departmental policies and regulations to which they more closely relate.

Several commenters asserted that certain Chilean officials may have a financial interest in llama and alpaca exportations, and may therefore not report an FMD outbreak should one occur. Other commenters asserted that APHIS officials are being bribed to obtain FMD-free status for Chile.

We are making no changes based on these comments. The commenters provided no evidence to support these assertions, and the Department is aware of no information that is available to support or disprove these assertions.

Several commenters asserted that the decision to declare Chile free of FMD was based on political considerations.

We disagree. The decision to declare Chile free of FMD was based on our determination that Chile has met the requirements for FMD-free status.

A number of commenters questioned various aspects of the economic analysis that appeared in our proposed rule under the heading, "Executive Order 12291 and Regulatory Flexibility Act." However, changing circumstances have required us to make substantial revisions in that analysis. Following is a discussion of those comments that raised issues dealing specifically with our economic analysis as it appeared in our proposed rule (54 FR 33918–33920, Docket Number 88–216).

Many commenters stated that our analysis was incomplete in that it failed to examine the proposal's potential economic impact upon llama and alpaca breeders.

We agree that the analysis appearing in our proposed rule to declare Chile free of FMD (54 FR 33918–33920, Docket Number 88–216) did not discuss the potential economic effect of our proposed action on breeders of llamas and alpacas in the United States. Although our original analysis contains this information, it was inadvertently omitted from our published proposal.[3] The information is no longer relevant with respect to this rulemaking proceeding, however, and has therefore been excluded from the economic analysis contained in this document.

Other commenters questioned our statements that 228 importers may be interested in importing llamas and alpacas from Chile; that we expected most llamas and alpacas imported during the first several years to be kept by importers for breeding purposes and not sold for immediate financial gain; and that Chile would continue to limit the number of llamas and alpacas it quarantines at any one time, which would in turn limit the number of llamas and alpacas available for export to the United States in any one year.

Upon further consideration, we agree that these statements may not have been an accurate forecast of impending developments. They are no longer included in our analysis.

A number of commenters questioned our conclusions that other countries would absorb some of the llama/alpaca importations from Chile, thereby

[2] A copy of the special environmental assessment prepared in connection with the proposed rule entitled, "Change in Disease Status of Chile Because of Foot-and-Mouth Disease" (54 FR 33918–33920, Docket Number 88–216) and of the administrative determination prepared in connection with the proposed rule entitled, "Llamas and Alpacas Imported From Chile" (54 FR 39759–39765, Docket Number 89–116) can be obtained by writing to the Administrator, c/o Michael T. Werner, Deputy Director, Environmental Documentation; Biotechnology, Biologics, and Environmental Documentation; APHIS, USDA, room 828, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782.

[3] A copy of the economic analysis prepared in connection with our proposed rule to declare Chile free of FMD (54 FR 33918–33920, Docket Number 88–216) can be obtained by writing to the Administrator, c/o Kevin Shea, Chief, Policy Analysis and Development, APHIS, USDA, room 865, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782.

reducing the number that would be imported to the United States in any one year.

We disagree. Llamas and alpacas have gained popularity not only in the United States, but in other countries as well. Competition for these animals is intense, and a number of countries are working on regulations to import them. We therefore believe that only a portion of Chile's llama/alpaca exports would be available to the United States market.

Other commenters stated that our analysis was based on assumptions and provided no evidence to support its conclusion that increased llama and alpaca importations would not have a significant economic impact upon a substantial number of small entities.

We disagree. We based our analysis on information available to the Department. This information is included in the rulemaking record.

Several commenters stated that our analysis failed to consider the economic impact of the proposed rule on the entire U.S. livestock industry in the event an FMD-infected animal were to be imported into the United States from Chile.

We based our analysis on what we believed would be the direct consequences of our proposed rule on small entities. We anticipated, at the time the analysis was produced, that importers and breeders of llamas and alpacas in the United States would be the only entities directly affected by our proposed rule.

Several commenters stated that we used insufficient economic data in arriving at our determination that the proposal is not a major rule, and that we produced no analysis to support our determination. These commenters stated that the proposal should be rewritten as a major rule, since an FMD outbreak in the United States could have an impact on the economy of over $100 million. Commenters argued that the damage to the United States llama/alpaca industry and other livestock industries, the cost of eradication, the negative effect on the exporting capacity of the United States, and other factors would combine to produce an economic impact of billions of dollars.

We are making no changes based on these comments, since they appear to be based on the assumption that an FMD outbreak will occur in the United States as a result of the adoption of our proposed rule. We did not use this assumption when making our determination that this action is not a major rule. Our determination that this action is not a major rule is basd exclusively on what we believe will be the effects of declaring Chile free of FMD.

Miscellaneous

Commenters' recommendations we are implementing in the companion rule (Docket Number 89-216, "Llamas and Alpacas Imported From Chile and Certain Other Countries Declared Free of Rinderpest and FMD," which appears in this issue of the Federal Register) have required us to revise our analysis concerning the economic impact of this rule on small entities. This analysis appears below under the heading, "Executive Order 12291 and Regulatory Flexibility Act."

Executive Order 12291 and Regulatory Flexibility Act

We are issuing this rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this rule will have an effect on the economy of less than $100 million; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and will not cause a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

We expect that the amount of cattle, sheep and other ruminants imported from Chile as a result of this rule will be negligible. We also expect that the amount of fresh, chilled, or frozen meats of ruminants imported from Chile as a result of this rule will be negligible.

During the previous periods when Chile was recognized as being free of FMD, no cattle, sheep, or goats, or fresh, chilled, or frozen meats obtained from these animals were imported from Chile. Further, there is little or no demand in the United States for these animals or products from Chile. This rule will therefore have little or no impact on the small entities in the United States that deal with these products.

There is a demand in the United States for llamas and alpacas. These animals have attained a great deal of popularity during the last several years. Two groups of entities would face potential economic impacts in the event more llamas and alpacas were to be imported from Chile into the United States: Those entities in the United States who import llamas or alpacas for financial gain, and those entities in the United States who breed llamas or alpacas for financial gain.

Prior to the adoption of this rule and its companion rule adding health certification and quarantine upon arrival requirements for llamas and alpacas from any country in which rinderpest or FMD has been known to exist and that is added to the list of countries declared free of rinderpest the FMD following the effective date of this rule (see Docket Number 89-216, "Llamas and Alpacas Imported From Chile and Certain Other Countries Declared Free of Rinderpest and FM," which appears in this issue of the Federal Register), llamas and alpacas imported into the United States from Chile were required—during those periods when Chile was not recognized as being free of FMD—to undergo embarkation quarantine in Chile, under APHIS supervision, as well as a 90-day quarantine at the Harry S Truman Animal Import Center upon arrival in the United States. The cost of Chilean veterinary supervision of the embarkation quarantine has been approximately $350 per head. The cost of APHIS supervision of the embarkation quarantine and the costs associated with a 90-day quarantine at HSTAIC have ranged from $5,500 per head for 50 animals to $2,000 per head for 480 animals.

We are adding Chile to the list of countries declared free of rinderpest and FMD. Small importers involved in llama and alpaca importations may benefit economically from this action, since they may be able to import and sell more llamas and alpacas than they have in the past. Other factors, however, could substantially limit the number of llamas and alpacas entering the United States, thereby limiting the economic benefits experienced by importers.

The primary factor that may limit these potential benefits is that llamas and alpacas from Chile will be required to undergo quarantine at HSTAIC, as discussed earlier in this docket. We estimate that the quarantine space available at HSTAIC will allow a maximum of 1,200 llamas and alpacas to be processed through this facility during any one year. It is unlikely, however, that this many llamas and alpacas will be processed through HSTAIC due to the competition for quarantine space there.

In addition, the demand for llamas and alpacas has increased in other countries as well as the United States. The intense international competition that has developed for these animals will, we believe, limit the number of llamas and alpacas available for importation into the United States.

Therefore, even though HSTAIC is capable of processing 1,200 llamas and alpacas per year, the factors discussed above lead us to believe that this figure may not be a realistic projection of yearly llama and alpaca importations from Chile. Actual import levels could be as low as 300 to 600 animals per year.

We estimate that the cost of complying with the health certification requirements in Chile will be approximately $375 per head, while the quarantine upon arrival requirements are expected to cost approximately $1,000 to $4,000 per head in the United States. The cost of meeting the requirements in the United States will depend, in part, on the number of llamas and alpacas that are processed through HSTAIC at any one time. The requirements as presented in the companion rule (Docket Number 89-216, "Llamas and Alpacas Imported from Chile and Certain Other Countries Declared Free of Rinderpest and FMD," appearing in this issue of the Federal Register) along with their associated costs, should not have a significant economic impact upon importers. These entities will already be realizing an overall reduction in importation costs because they will no longer be required to pay the cost of USDA supervision services in Chile, and because the quarantine period in the United States is being shortened.

At this time it is not possible for us to estimate how many small entities are engaged in the llama/alpaca importing business, or how many will eventually choose to enter this field. However, we believe this number will be small when compared to the total number of animal importers operating in the United States.

The economic impact of this rule upon small llama/alpaca breeders in the United States will be influenced entirely by the reaction of consumers to an increased supply of llamas and alpacas. We cannot, with certainty, predict how consumers will react to this situation.

As the supply of llamas and alpacas increases, prices for these animals may drop, and breeders may face economic losses. However, the extent of their losses would depend on the extent of the price decline. If consumers in the United States respond to the increased supply by paying considerably less for these animals, then breeders would face greater economic losses. If consumers respond by paying only slightly less, then breeders' losses would be minimized. Consumers may not respond to the increased supply at all. In this event, prices would remain constant and breeders would suffer no losses.

If breeders and importers are two mutually exclusive groups, the economic impact of this rule on breeders could be negative, as discussed above. Some breeders, however, may opt to expand their breeding stock by importing Chilean llamas and alpacas for substantially less than they could purchase comparable, domestically-produced llamas and alpacas. In this way, a portion of their losses as breeders may be offset by their gain as importers. However, we do not know to what extent, if any, breeders and importers are mutually exclusive groups.

Based on the information available to us, we believe that an increase in the supply of llamas and alpacas in the United States may eventually produce a price decline for these animals. We do not believe the price decline would be drastic. We estimate that the llama and alpaca population in the United States is between 20,000 and 45,000, and is growing at the rate of approximately 7,000 per year. The importation of 1,200 llamas and alpacas from Chile in a single year represents approximately 17 percent of domestic production figures. Importation levels of 300 to 600 animals per year represent approximately 8 percent of domestic production figures. We do not believe that an 8 to 17 percent annual increase over domestic production levels is likely to produce a flooded llama/alpaca market in the United States.

In summary, a growing domestic production rate combined with increased llama/alpaca importations may eventually produce a price decline for llamas and alpacas in the United States, but the decline would likely be moderate.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

This rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Part 94

Animal diseases, Imports, Livestock and livestock products, Meat and meat products, Milk, Poultry and poultry products, African swine fever, Exotic newcastle disease, Foot-and-mouth disease, Fowl pest, Garbage, Hog cholera, Rinderpest, Swine vesicular disease.

Accordingly, 9 CFR part 94 is amended as follows:

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), NEWCASTLE DISEASE (AVIAN PNEUMOENCEPHALITIS), AFRICAN SWINE FEVER, AND HOG CHOLERA: PROHIBITED AND RESTRICTED IMPORTATIONS

1. The authority citation for part 94 continues to read as follows:

Authority: 7 U.S.C. 147a, 150ee, 161, 162, 450; 19 U.S.C. 1306; 21 U.S.C. 111, 114a, 134a, 134b, 134c, and 134f; 31 U.S.C. 9701; 42 U.S.C. 4331, 4332; 7 CFR 2.17, 2.51, and 371.2(d).

§ 94.1 [Amended]

2. In § 94.1, paragraph (a)(2) is amended by adding "Chile," immediately after "Channel Islands,".

3. In § 94.1, a new paragraph (d) is added to read as follows:

§ 94.1 Countries where rinderpest or foot-and-mouth disease exists; importations prohibited.

* * * * *

(d)(1) The following countries are countries in which rinderpest or foot-and-mouth disease has been known to exist and that are declared free of rinderpest and foot-and-mouth disease on or after September 28, 1990: Chile.

(2) No llama or alpaca shall be imported or entered into the United States from any country listed in paragraph (d)(1) of this section, unless in accordance with § 92.435 of this chapter.

§ 94.11 [Amended]

4. In § 94.11, paragraph (a) is amended by adding "Chile," immediately after "Channel Islands,".

Done in Washington, DC, this 25th day of September 1990.

James W. Glosser,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 90-22999 Filed 9-27-90; 8:45 am]

BILLING CODE 3410-34-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 85F-0555]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Gellan Gum

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of gellan gum as a stabilizer

and thickener in frostings, glazes, icings, jams, and jellies. This action is in response to petitions filed by Kelco, a Division of Merck & Co., Inc.

DATES: Effective September 28, 1990; written objections and requests for a hearing by October 29, 1990.

ADDRESSES: Written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Blondell Anderson, Center for Food Safety and Applied Nutrition (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–426–9463.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of January 7, 1986 (51 FR 687), FDA announced that a food additive petition (FAP 6A3903) had been filed by Kelco, a Division of Merck & Co., Inc., P.O. Box 23176, San Diego, CA 92123, proposing that 21 CFR part 172 be amended to provide for the safe use of gellan gum as a stabilizer and thickener in confections and frostings. Upon further review of that petition, FDA determined that the petition was seeking approval for use of gellan gum in frostings, glazes, and icings, and not for use in confections generally (including candies). In the **Federal Register** of December 2, 1987 (52 FR 45867), FDA announced that Kelco had filed a second food additive petition (FAP 7A4022) for the use of gellan gum in all foods. The agency did not receive comments on either notice. The latter petition is currently under scientific review. Subsequent to the filing of the second petition, the company amended their first petition (FAP 6A3903) to include jams and jellies.

FDA has evaluated data in the petition (FAP 6A3903) and other relevant material. The agency concludes that the proposed food additive use is safe, and that the regulations should be amended by adding new 21 CFR 172.665 to Subpart G as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before October 29, 1990 file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: Secs. 201, 401, 402, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 348, 371, 376).

2. New § 172.665 is added to subpart G to read as follows:

§ 172.665 Gellan gum.

The food additive gellan gum may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is a high molecular weight polysaccharide gum produced from *Pseudomonas elodea* by a pure culture fermentation process and purified by recovery with isopropyl alcohol. It is composed of tetrasaccharide repeat units, each containing one molecule of rhamnose and glucuronic acid, and two molecules of glucose. The glucuronic acid is neutralized to a mixed potassium, sodium, calcium, and magnesium salt. The polysaccharide may contain up to 5 percent of acyl (glyceryl and acetyl) groups as the 0-glycosidically linked esters.

(b) The strain of *P. elodea* is nonpathogenic and nontoxic in man and animals.

(c) The additive is produced by a process that renders it free of viable cells of *P. elodea*.

(d) The additive meets the following specifications:

(1) Positive for gellan gum when subjected to the following identification tests:

(i) A 1-percent solution is made by hydrating 1 gram of gellan gum in 99 milliliters of distilled water. The mixture is stirred for about 2 hours, using a motorized stirrer and a propeller-type stirring blade. A small amount of the above solution is drawn into a wide bore pipet and transferred into a solution of 10-percent calcium chloride. A tough worm-like gel will form instantly.

(ii) To the 1-percent distilled water solution prepared for identification test (i), 0.50 gram of sodium chloride is added. The solution is heated to 80 °C with stirring, held at 80 °C for 1 minute, and allowed to cool to room temperature without stirring. A firm gel will form.

(2) Residual isopropyl alcohol (IPA) not to exceed 0.075 percent as determined by the procedure described in the Xanthan Gum monograph, the "Food Chemicals Codex," 3d Ed. (1981), p. 347, which reads:

IPA Standard Solution. Transfer 500.0 milligrams (mg) chromatographic quality isopropyl alcohol into a 50-milliliter (ml) volumetric flask, dilute to volume with water, and mix. Pipet 10 ml of this solution into a 100-ml volumetric flask, dilute to volume with water, and mix.

Tert-Butyl Alcohol (TBA) Standard Solution. Transfer 500.0 mg of chromatographic quality *tert*-butyl alcohol into a 50-ml volumetric flask, dilute to volume with water, and mix. Pipet 10 ml of this solution into a 100-ml volumetric flask, dilute to volume with water, and mix.

Mixed Standard Solution. Pipet 4 ml each of the *IPA Standard Solution* and of the *TBA Standard Solution* into a 125-ml graduated Erlenmeyer flask, dilute to about 100 ml with water, and mix. This solution contains approximately 40 micrograms (μg) each of isopropyl alcohol and *tert*-butyl alcohol per ml.

Sample Preparation. Disperse 1 ml of a suitable antifoam emulsion, such as Dow-Corning G–10 or equivalent, in 200 ml of water contained in a 1000-ml 24/40 round-bottom distilling flask. Add about 5 grams (g) of the sample, accurately weighed, and shake for 1 hour on a wrist-action mechanical shaker. Connect the flask to a fractionating column and distill about 100 ml, adjusting the heat so that foam does not enter the column. Add 4.0 ml of *TBA Standard Solution* to the distillate to obtain the *Sample Preparation.*

Procedure. Inject about 5 microliters (μl) of the *Mixed Standard Solution* into a suitable gas chromatograph equipped with a flame-ionization detector and a 1.8 meters (m)×3.2 millimeters (mm) stainless steel column packed with 80/100-mesh Porapak QS or equivalent. The carrier is helium flowing at 80 ml per minute (min). The injection port temperature is 200 °C, the column temperature is 165 °C, and the detector temperature is 200 °C. The retention time of isopropyl alcohol is about 2 min, and that of *tert*-butyl alcohol about 3 min.

Determine the areas of IPA and TBA peaks, and calculate the response factor, f, by the formula A_{IPA}/A_{TBA}, in which A_{IPA} is the area of the isopropyl alcohol peak, and A_{TBA} is the area of the *tert*-butyl alcohol peak.

Similarly, inject about 5 μl of the *Sample Preparation*, and determine the peak areas, recording the area of the isopropyl alcohol peak as a a_{IPA}, and that of the *tert*-butyl alcohol peak as a_{TBA}. Calculate the isopropyl alcohol content, in parts per million (ppm), in the sample taken by the formula $(a_{IPA}\times 4000)/(f\times a_{TBA}\times W)$, in which W is the weight of the sample taken in grams.

(e) The additive is used or intended for use in accordance with current good manufacturing practice as a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter. The additive may be used in the following foods when standards of identity established under section 401 of the Federal Food, Drug, and Cosmetic Act do not preclude such use:

(1) Glazes, icings, and frostings and

(2) Jams and jellies.

(f) To assure safe use of the additive:

(1) The label of its container shall bear, in addition to other information required by the Federal Food, Drug, and Cosmetic Act, the name of the additive and the designation "food grade".

(2) The label or labeling of the food additive container shall bear adequate directions for use.

Dated: September 19, 1990.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 90–22955 Filed 9–27–90; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Parts 510 and 558

Animal Drugs, Feeds, and Related Products; Tylosin, Tylosin/Sulfamethazine

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to remove those portions reflecting approval of three new animal drug applications (NADA's), one held by Simonsen Mill-Rendering Plant, Inc., which provides for the use of a tylosin Type A medicated article, and the other two NADA's held by Arkansas Micro Specialties, Inc., one of which provides for the use of a tylosin Type A medicated article and the other of which provides for the use of a tylosin/sulfamethazine Type A medicated article. In a notice published elsewhere in this issue of the Federal Register, FDA is withdrawing approval of the NADA's.

EFFECTIVE DATE: October 9, 1990.

FOR FURTHER INFORMATION CONTACT: Mohammad I. Sharar, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4093.

SUPPLEMENTARY INFORMATION: In a notice published elsewhere in this issue of the Federal Register, FDA is withdrawing approval of Simonsen's NADA 96–776, which provides for the use of a tylosin Type A medicated article to make a Type C swine feed, and Arkansas Micro Specialties' NADA 139–600, which provides for the use of a tylosin Type A medicated article to make a Type C medicated swine, beef cattle, or chicken feed, and NADA 139–601, which provides for the use of a tylosin/sulfamethazine Type A medicated article to make a Type C medicated swine feed. Since Simonsen Mill-Rendering Plant, Inc., is no longer the sponsor of any approved NADA's, 21 CFR 510.600(c) is amended by removing the entries for the firm. This document also amends 21 CFR 558.625 (b)(26) and (b)(86), and 558.630(b)(10) to reflect withdrawal of approval of the NADA's.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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 parts 510 and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 376).

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entry "Simonsen Mill-Rendering Plant, Inc.," and in the table in paragraph (c)(2) by removing the entry "034418".

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

§ 558.625 [Amended]

4. Section 558.625 *Tylosin* is amended by removing and reserving paragraph (b)(26) and (b)(86).

§ 558.630 [Amended]

5. Section 558.630 *Tylosin and sulfamethazine* is amended in paragraph (b)(10) by removing "047863,".

Dated: September 21, 1990.

Gerald B. Guest,

Director, Center for Veterinary Medicine.

[FR Doc. 90–23038 Filed 9–27–90; 8:45 am]

BILLING CODE 4160–01–M