

processing can demonstrate a compelling need by submitting a statement certified by the requester to be true and correct to the best of such person's knowledge and belief and that satisfies the statutory and regulatory definitions of compelling need. Requesters shall be notified within ten (10) calendar days after receipt of such a request whether expedited processing or an appeal of a denial of a request for expedited processing, was granted. As used in this section, *compelling need* means:

(1) That a failure to obtain requested records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual; or

(2) With respect to a request made by a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity.

Dated: November 7, 1997.

**Solly Thomas,**

*Executive Director.*

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## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

#### 9 CFR Part 94

[Docket No. 97-086-1]

### Changes in Disease Status of Belgium, France, Greece, Luxembourg, Portugal, and Spain

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

**ACTION:** Proposed rule.

**SUMMARY:** We are proposing to declare Luxembourg and Portugal free of rinderpest and foot-and-mouth disease; Greece free of rinderpest; France, Greece, Luxembourg, and Spain free of exotic Newcastle disease; Portugal free of African swine fever; and Belgium, France, and Portugal free of swine vesicular disease. These proposed actions are based on a request from the European Commission's Directorate General for Agriculture and on our review of the supporting documentation supplied with that request. These proposed actions would relieve some restrictions on the importation into the United States of certain animals and animal products from those countries. However, because of the status of those countries with respect to other diseases, and because of other factors that could

result in a risk of introducing animal diseases into the United States, the importation into the United States of animals and animal products from those countries would continue to be subject to certain restrictions.

**DATES:** Consideration will be given only to comments received on or before January 13, 1998.

**ADDRESSES:** Please send an original and three copies of your comments to Docket No. 97-086-1, Regulatory Analysis and Development, PPD, APHIS, suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comments refer to Docket No. 97-086-1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are requested to call ahead on (202) 690-2817 to facilitate entry into the comment reading room.

**FOR FURTHER INFORMATION CONTACT:** Dr. John Cougill, Staff Veterinarian, Products Program, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737-1231, (301) 734-8695; or e-mail: jcougill@aphis.usda.gov.

#### SUPPLEMENTARY INFORMATION:

##### Background

The regulations in 9 CFR part 94 (referred to below as the regulations) prohibit or restrict the importation of specified animals and animal products into the United States in order to prevent the introduction of various animal diseases, including foot-and-mouth disease (FMD), rinderpest, exotic Newcastle disease (END), African swine fever (ASF), hog cholera, swine vesicular disease (SVD), and bovine spongiform encephalopathy (BSE). These are dangerous and destructive communicable diseases of ruminants, swine, and poultry.

In this document, we are proposing to declare Luxembourg and Portugal free of FMD and rinderpest; Greece free of rinderpest; France, Greece, Luxembourg, and Spain free of END; Portugal free of ASF; and Belgium, France, and Portugal free of SVD. We are proposing these actions in response to a request submitted to the Animal and Plant Health Inspection Service (APHIS) in July 1997 by the European Commission's (EC's) Directorate General for Agriculture. With its request, the EC's Directorate General for Agriculture provided supporting documentation that included information about the capability of each country's veterinary

services, laboratory and diagnostic procedures, vaccination practices, and the administration of laws and regulations to ensure against the introduction of the diseases of concern into each country through the importation of live animals, meats, and animal products.

Since this request was received and reviewed by APHIS, we have published a final rule and policy statement in the **Federal Register** that establish procedures for recognizing regions, rather than only countries, for the purpose of importing animals and animal products into the United States, and that establish procedures by which regions may request permission to export animals and animal products to the United States under specified conditions, based on the regions' disease status (see 62 FR 56000-56033, October 28, 1997, Dockets 94-106-8 and 94-106-9). The final rule is scheduled to become effective on November 28, 1997. The request from the EC addressed by this proposed rule is not a request to recognize regions, rather than countries, nor a request to establish new import conditions based the disease status of any region. Therefore, as we explained we would do in our final rule and policy statement on regionalization, we have handled and evaluated this request in the traditional framework of recognizing a country as free or not free of a specified disease. If this proposed rule is adopted, the current regulations regarding importation of animals and animal products from regions "free" of a specified disease will apply.

##### Luxembourg and Portugal Free of Rinderpest and FMD

Section 94.1(a)(1) of the regulations provides that rinderpest or FMD exists in all regions of the world except those listed in § 94.1(a)(2), which have been declared to be free of those diseases. The regulations in § 94.1(b) prohibit, with certain specific exceptions, the importation into the United States of any ruminant or swine, or any fresh, chilled, or frozen meat of any ruminant or swine, that is from any region where rinderpest or FMD exists, or that has entered a port in or otherwise transited a region where rinderpest or FMD exists. Furthermore, the regulations in § 94.2 restrict the importation of fresh, chilled, or frozen products other than meat, and milk and milk products, of ruminants or swine that originate in or transit a region where rinderpest or FMD exists. Additionally, the importation of organs, glands, extracts, and secretions of ruminants or swine originating in a region where rinderpest

or FMD exists is restricted under the regulations in § 94.3, and the importation of cured or cooked meat from a region where rinderpest or FMD exists is restricted under the regulations in § 94.4. Finally, the regulations in 9 CFR part 98 restrict the importation of ruminant and swine embryos and animal semen from a region where rinderpest or FMD exists.

We will consider declaring a region to be free of rinderpest and FMD if, among other things, there have been no cases of those diseases reported there for at least the previous 1-year period and no vaccinations for rinderpest or FMD have been administered to swine or ruminants in that region for at least the previous 1-year period. There has never been a reported case of rinderpest in Luxembourg or Portugal, and the last reported cases of FMD in Luxembourg and Portugal occurred in 1964 and 1984, respectively. Both Luxembourg and Portugal have prohibited vaccinations for rinderpest and FMD since 1991.

We have reviewed the documentation submitted by the EC's Directorate General for Agriculture in support of its request that Luxembourg and Portugal be declared free of rinderpest and FMD. Based on that documentation, we believe that Luxembourg and Portugal qualify to be designated as free of rinderpest and FMD. Therefore, we are proposing to add Luxembourg and Portugal to the list in § 94.1(a)(2) of regions declared free of rinderpest and FMD. This proposed action would remove the rinderpest- and FMD-based prohibition on the importation from Luxembourg and Portugal of live ruminants and fresh, chilled, or frozen meat from ruminants and would relieve restrictions on the importation, from these two countries, of milk and milk products from ruminants. However, the importation of fresh, chilled, or frozen meat and edible products other than meat (excluding gelatin, milk, and milk products) from ruminants that have been in Portugal would continue to be restricted under § 94.18 because Portugal is listed in § 94.18 as a region in which BSE exists. Additionally, the importation from Luxembourg and Portugal of live swine and fresh, chilled, or frozen meat from swine would continue to be restricted under § 94.9 of the regulations because these countries have not been declared free of hog cholera.

We are also proposing to add Luxembourg and Portugal to the list in § 94.11(a) of regions declared free of rinderpest and FMD that are subject to special restrictions on the importation of their meat and other animal products into the United States. The regions

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 regions that are designated in § 94.1(a) as infected with rinderpest or FMD; or (2) have a common land border with regions designated as infected with rinderpest or FMD; or (3) import ruminants or swine from regions designated as infected with rinderpest or FMD under conditions less restrictive than would be acceptable for importation into the United States.

Both Luxembourg and Portugal supplement their national meat supplies by the importation of fresh, chilled, or frozen meat of ruminants and swine from regions designated in § 94.1(a)(1) as regions in which rinderpest or FMD exists. Furthermore, both Luxembourg and Portugal import live ruminants and swine from regions not recognized as being free of FMD under conditions less restrictive than would be acceptable for importation into the United States. As a result, even though we propose to designate Luxembourg and Portugal as being free of rinderpest and FMD, the meat and other animal products produced in these countries may be commingled with the fresh, chilled, or frozen meat of animals from a region in which rinderpest or FMD exists, resulting in an undue risk of introducing rinderpest or FMD into the United States.

Therefore, we are proposing that meat and other animal products of ruminants and swine and the ship stores, airplane meals, and baggage containing these meat or animal products imported into the United States from Luxembourg and Portugal be subject to the restrictions specified in § 94.11 of the regulations, in addition to other applicable requirements of the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) at 9 CFR Chapter III. Section 94.11 generally requires that the meat and other animal products of ruminants and swine be: (1) Prepared in an inspected establishment that is eligible to have its products imported into the United States under the Federal Meat Inspection Act; and (2) accompanied by an additional certificate, issued by a full-time salaried veterinary official of the national government that is responsible for the health of the animals within the exporting region, assuring that the meat or other animal products have not been commingled with or exposed to meat or other animal products originating in, imported from, or transported through a region where rinderpest or FMD exists.

### **Greece Free of Rinderpest**

Although Greece does not appear to qualify to be declared free of both rinderpest and FMD, the EC's Directorate General for Agriculture has requested that Greece be declared free of rinderpest. As noted above with regard to both rinderpest and FMD, we will consider declaring a region to be free of rinderpest if, among other things, there have been no cases of the disease reported there for at least the previous 1-year period and no vaccinations for rinderpest have been administered to swine or ruminants in that region for at least the previous 1-year period. There has not been a reported case of rinderpest in Greece since 1926, and vaccinations for that disease have been prohibited in Greece since 1991.

We have reviewed the documentation submitted by the EC's Directorate General for Agriculture in support of its request that Greece be declared free of rinderpest. Based on that documentation, we believe that Greece qualifies to be designated as free of rinderpest. We are, therefore, proposing to amend § 94.1(a) to designate Greece as a region free of rinderpest. To do so, we are proposing to add a new paragraph § 94.1(a)(3) in which Greece's status as a region free of rinderpest would be designated.

However, because Greece would be declared free of rinderpest only, and not FMD, the prohibitions and restrictions found in §§ 94.1(b), 94.2, 94.3, and 94.4 on the importation from Greece of ruminants and swine, and fresh, chilled, or frozen meat of ruminants and swine; products other than meat; milk and milk products; organs, glands, extracts, and secretions; and cured or cooked meat of ruminants or swine would continue to apply.

### **France, Greece, Luxembourg, and Spain Free of END**

Section 94.6(a)(1) of the regulations provides that END is considered to exist in all regions of the world except those listed in § 94.6(a)(2), which have been declared to be free of END. The importation into the United States of any carcasses, or parts or products of carcasses, of poultry, game birds, or other birds that are from a region where END is considered to exist, or that have been imported from or moved into or through any region where END is considered to exist, is subject to the restrictions contained in § 94.6(c). In addition, the importation into the United States of eggs (other than hatching eggs) laid by poultry, game birds, or other birds that are from a region where END or *Salmonella*

*enteritidis* (SE) phage-type 4 is considered to exist or that have been imported from or moved into or through any region where END or SE phage-type 4 is considered to exist is subject to the restrictions contained in § 94.6(d). Poultry eggs for hatching imported from a region where END exists must be quarantined in accordance with § 93.209(b).

We will consider declaring a region to be free of END if there have been no reported cases of the disease in that region for at least the previous 1-year period. There has been no documented case of END in France, Greece, or Spain during the reporting period that began in 1994, and there has been no reported case of END in Luxembourg since 1995.

APHIS has reviewed the documentation submitted by the EC's Directorate General for Agriculture in support of its request that France, Greece, Luxembourg, and Spain be declared free of END. Based on that documentation, we believe that France, Greece, Luxembourg, and Spain qualify to be designated as free of END. Therefore, we are proposing to amend § 94.6(a)(2) by adding France, Greece, Luxembourg, and Spain to the list of regions declared free of END. This proposed action would relieve the restrictions of § 94.6(c) on the importation of carcasses, or parts or products of carcasses, of poultry, game birds, or other birds from those countries, and would relieve the END-specific restrictions of § 94.6(d)(1)(ix) on the importation of eggs (other than hatching eggs) laid by poultry, game birds, or other birds from those countries. This proposed action would also relieve the quarantine requirements of § 93.209(b) for poultry hatching eggs imported from France, Greece, Luxembourg, and Spain.

#### **Portugal Free of ASF**

Section 94.8 of the regulations states that ASF exists or is reasonably believed to exist in all the regions of Africa; in Brazil, Cuba, Haiti, Malta, and Portugal; and on the island of Sardinia, Italy. Paragraph (a) of § 94.8 provides that no pork or pork products may be imported into the United States from a region where ASF exists unless the pork or pork product meets certain specified conditions. Also, § 94.17 provides, in part, that dry-cured pork products may be imported into the United States from a region where ASF exists if the dry-cured pork products meet the conditions specified in that section.

In addition to the restrictions on pork and pork products contained in the regulations in part 94, live domestic swine from a region where ASF exists

may not be imported into the United States because the regulations in 9 CFR 93.505(a) require, among other things, that live domestic swine be accompanied by a certificate showing that the entire region of origin of the swine is free of ASF and other specified diseases. The importation of swine casings from regions where ASF exists is likewise prohibited by 9 CFR 96.2(a) unless the swine casings originated in a region free of ASF and were processed in the region where ASF exists at a facility that meets the criteria of § 94.8(a)(3)(iv) of the regulations.

We will consider declaring a region free of ASF if there have been no reported cases of the disease in that region for at least the previous 1-year period. The last case of ASF in Portugal occurred in 1993.

APHIS has reviewed the documentation submitted by the EC's Directorate General for Agriculture in support of its request that Portugal be declared free of ASF. Based on that documentation, we believe that Portugal qualifies to be designated as free of ASF. Therefore, we are proposing to amend § 94.8 by removing Portugal from the list of regions in which ASF exists or is reasonably believed to exist. This proposed action would result in the importation of pork and pork products from Portugal no longer being subject to the restrictions found in § 94.8 of the regulations. Another effect of this proposed action would be that the importation of swine casings that originated in or were processed in Portugal would no longer be subject to the restrictions in 9 CFR 96.2(a).

However, Portugal is still considered to be affected with hog cholera, so the importation of pork and pork products from Portugal would remain subject to the restrictions in § 94.9 for hog cholera. Similarly, the importation of dry-cured pork products from Portugal would continue to be subject to the regulations in § 94.17 due to hog cholera. In addition, the importation of pork and pork products from Portugal would continue to be subject to the restrictions in § 94.11 because, as discussed above with respect to our proposal to declare Portugal free of rinderpest and FMD, Portugal would be listed in § 94.11(a) as a region that has been declared free of rinderpest and FMD, but from which the importation of all meat and other animal products is restricted due to the nature of its requirements for importing animal products from with regions affected with rinderpest or FMD or because they have a common land border with a region affected with rinderpest or FMD. Finally, declaring Portugal free of ASF would not relieve any of the current

restrictions in 9 CFR part 93 on the importation into the United States of live swine from Portugal because Portugal remains affected with hog cholera.

#### **Belgium, France, and Portugal Free of SVD**

Section 94.12(a) of the regulations provides that SVD is considered to exist in all regions of the world except those listed in § 94.12(a), which have been declared to be free of SVD. Paragraph (b) of § 94.12 provides that no pork or pork products may be imported into the United States from a region where SVD exists unless the pork or pork product meets certain specified conditions and is not otherwise prohibited importation into the United States by the regulations.

We will consider declaring a region to be free of SVD if there have been no reported cases of the disease in that region for at least the previous 1-year period. The last cases of SVD in Belgium, France, and Portugal were reported in 1993, 1983, and 1995, respectively.

APHIS has reviewed the documentation submitted by the EC's Directorate General for Agriculture in support of its request that Belgium, France, and Portugal be declared free of SVD. Based on that documentation, we believe that Belgium, France, and Portugal qualify to be designated as free of SVD. Therefore, we are proposing to amend § 94.12(a) by adding Belgium, France, and Portugal to the list of regions declared free of SVD. This proposed action would relieve certain restrictions on the importation of pork and pork products from those countries.

However, Belgium, France, and Portugal are still considered to be affected with hog cholera, so pork and pork products from those countries offered for importation into the United States would remain subject to the restrictions in § 94.9 for hog cholera. The importation of live swine, except for wild swine, from Belgium, France, and Portugal would likewise continue to be prohibited due to hog cholera in accordance with § 94.10. Similarly, dry-cured pork products from Belgium, France, and Portugal would continue to be subject to the regulations in § 94.17 due to hog cholera. In addition, pork and pork products from Belgium, France, and Portugal would continue to be subject to the restrictions in § 94.11 because Belgium, France, and Portugal are among the regions listed (or, in the case of Portugal, would be listed) in § 94.11(a) that have been declared free of rinderpest and FMD, but from which the importation of all meat and other

animal products is restricted due to the nature of their requirements for importing animal products from regions affected with rinderpest or FMD or because they have a common land border with a region affected with rinderpest or FMD. (Portugal is not currently on the list in § 94.11(a), but, as discussed above, we are proposing to add Portugal to that list as part of our proposal to declare Luxembourg and Portugal free of rinderpest and FMD.)

We are also proposing to amend § 94.13 by adding Belgium, France, and Portugal to the list of regions that have been declared free of SVD, but from which the importation of pork and pork products is restricted. The regions listed in § 94.13 are subject to these restrictions because they: (1) Supplement their national pork supply by importing fresh, chilled, or frozen pork from regions where SVD is considered to exist; (2) have a common border with regions where SVD is considered to exist; or (3) have certain import requirements that are less restrictive than are acceptable to the United States.

Belgium, France, and Portugal all supplement their national pork supplies by importing fresh, chilled, or frozen pork from regions where SVD is considered to exist. In addition, France has a common land border with Italy, which is designated in § 94.12(a) as a region where SVD exists. Furthermore, Belgium, France, and Portugal have certain import requirements that are less restrictive than are acceptable to the United States. As a result, even though Belgium, France, and Portugal appear to qualify for designation as regions free of SVD, there is potential for pork and pork products produced in Belgium, France, and Portugal to be commingled with fresh, chilled, or frozen pork from a region where SVD exists. This potential for commingling constitutes an undue risk of introducing SVD into the United States.

Therefore, we are proposing that pork and pork products, as well as any ship's stores, airplane meals, and baggage containing such pork, offered for importation into the United States from Belgium, France, or Portugal be subject to the restrictions specified in § 94.13 of the regulations and to the applicable requirements contained in the FSIS regulations at 9 CFR chapter III. Section 94.13 requires, in part, that pork and pork products, except those treated in accordance with § 94.12(b), be: (1) Prepared in an inspected establishment that is eligible to have its products imported into the United States under the Federal Meat Inspection Act; and (2) accompanied by a foreign meat

inspection certificate and a certification issued by a full-time salaried veterinary official of the national government that is responsible for the health of the animals within the exporting region, stating that certain precautions have been taken so that the pork or pork product has not been commingled with or exposed to animals, pork, or pork products originating in, or transported through, a region in which SVD is considered to exist.

#### Miscellaneous

In §§ 94.3 and 94.4, reference is made to articles "originating in any region designated in § 94.1." Although the intent of those sections is to restrict the importation of certain articles from regions where rinderpest or FMD exists, the phrase "designated in § 94.1" could also be interpreted as referring to those regions declared free of rinderpest and FMD, since those regions are listed in § 94.1(a)(2). To make the intent of those two sections clear, we are proposing to amend those sections so that they refer to "regions where rinderpest or foot-and-mouth disease exists, as designated in § 94.1." We would also amend §§ 94.1(c) and 94.11(a), where reference is made to § 94.1(a); for the sake of accuracy, those paragraphs should specifically refer to § 94.1(a)(2).

#### Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. For this action, the Office of Management and Budget has waived its review process required by Executive Order 12866.

This proposed rule would amend the regulations in part 94 by declaring Luxembourg and Portugal free of rinderpest and FMD; Greece free of rinderpest; France, Greece, Luxembourg, and Spain free of END; Portugal free of ASF; and Belgium, France, and Portugal free of SVD.

#### Pork and Pork Products and Swine

Although this proposed rule would declare Luxembourg and Portugal free of rinderpest and FMD; Greece free of rinderpest; Belgium, France, and Portugal free of SVD; and Portugal free of ASF, all those countries are still considered affected with hog cholera, and Greece is still considered to be affected with FMD. Because of this, this proposed rule would not lead to any substantive relaxation of restrictions imposed on the importation of pork and pork products and live swine from those countries, as these products would continue to be restricted based on the presence of hog cholera and, in the case of Greece, FMD. Therefore, the effect of

this proposed rule on the importation of pork and pork products and live swine would be minimal, and thus the potential impact on the domestic producers of pork and pork products and swine would be minimal.

#### Ruminants and Ruminant Products

This proposed rule would declare Greece free of rinderpest, but that country is still considered to be affected with FMD. Similarly, Portugal would be declared free of rinderpest and FMD, but that country is still considered to be affected with BSE. Because imports of ruminants and ruminant products from regions with FMD and BSE are restricted, this proposed rule would not lead to a substantive change in the restrictions imposed on the importation of ruminants and ruminant products from Greece and Portugal.

By declaring Luxembourg free of rinderpest and FMD, this proposed rule would reduce the restrictions placed on the importation of ruminants and ruminant products from Luxembourg. However, that proposed change in disease status should have a minimal effect on the amount of ruminants and ruminant products imported into the United States from Luxembourg.

The cattle industry in Luxembourg is very small relative to the U.S. domestic market. Cattle and buffalo inventories for 1996 were more than 103 million head in the United States ("Agricultural Statistics," 1997), compared to fewer than 3.4 million in Belgium and Luxembourg (those two nations are reported collectively in the United Nations' Food and Agriculture Organization (FAO) Yearbook). Also, of the 2 million cattle and calves that were imported into the United States in 1996, more than 99 percent were from Canada and Mexico. Sheep and goat inventories are also much smaller in Luxembourg than in the United States. According to the FAO, there were 8.9 million sheep and 2 million goats in the U.S. in 1995, as opposed to 150,000 sheep and 9,000 goats in Belgium and Luxembourg. The United States is also a strong net exporter of sheep and goats, with 48,792 head imported and 397,395 head exported in 1996 ("World Trade Atlas," June 1997). Of the sheep that the United States does import, more than 99 percent are from Canada and Mexico ("World Trade Atlas," June 1997). Luxembourg exported no live ruminants to the United States in 1996. In fact, there were fewer than 100 cattle, sheep and goats imported from the European Union in 1996. Western Europe is not a significant source of live ruminants for the United States, and any importation of live ruminants from Luxembourg as

a result of this proposed rule likely would be negligible.

The effect of this proposed rule on the importation of ruminant meat and meat products should also be minimal. The 1995 production of beef, veal, mutton, lamb and goat meat for Belgium and Luxembourg was approximately 3 percent of the U.S. production of 11.6 million metric tons for that year ("FAO Yearbook," 1995). The United States imports only a small portion of its overall supply of these products, an amount equal to about 6 percent of production. In addition, the United States imports very little ruminant meat and meat products from Luxembourg or from Western Europe in general. Moreover, nearly 85 percent of the imports that come into the United States are from Australia, Canada, and New Zealand. Because we believe that it is unlikely that Luxembourg would export a significant portion of its comparatively small meat production exclusively to the United States, any effect on domestic prices or supplies would likely be negligible.

The importation of dairy products from Luxembourg into the United States should be at most minimally affected by this proposed rule. Dairy product production in Luxembourg is small relative to that of the United States. Milk production in Belgium and Luxembourg was less than 5 percent the size of U.S. production in 1995 ("FAO Yearbook," 1995). For dairy products in general, we believe that it is unlikely that Luxembourg would redirect a significant portion of its production exclusively to the United States, which is a significant net exporter of those products. Belgium and Luxembourg do export significant quantities of butter and dried milk, but those products may currently be exported to the United States under the current regulations. Therefore, the impact on domestic dairy producers should be minimal.

The potential effect of this proposed rule on the importation into the United States of ruminant embryos and animal semen would also likely be minimal. The United States is a net exporter of both bovine semen and cattle embryos. In 1996, the value of U.S. bovine semen and cattle embryo imports was \$7.7 million and \$701,000, respectively, while the value of U.S. exports of bovine semen and cattle embryos was \$63.1 million and \$12.6 million respectively ("World Trade Atlas," June 1997). Given this trade balance and the size difference between the cattle industries of the United States and Luxembourg, the amount imported of each will likely be minimal.

### **Bird and Poultry Products**

The proposed rule would declare France, Greece, Luxembourg, and Spain free of END. This proposed action would relieve restrictions on the importation of carcasses, or parts or products of carcasses, of poultry, game birds, or other birds from those countries, and would relieve certain restrictions on the importation of eggs (other than hatching eggs) laid by poultry, game birds, or other birds from those countries. This proposed action would also relieve the quarantine requirements for poultry hatching eggs imported from France, Greece, Luxembourg, and Spain.

Egg production in those four countries is considerable: In 1995, the reported egg production in Belgium and Luxembourg was 3,858 million; in France, 16,911 million; in Greece, 2,600 million; and in Spain, 9,983 million ("Agriculture Statistics," 1997). U.S. production is also large, 74,280 million in 1995. In addition, the U.S. imports few eggs, with the total amount being equal to less than 0.1 percent of U.S. production. We believe that it is unlikely that these countries would redirect a significant portion of their production toward such a small U.S. import market.

Total poultry meat production in France, Greece, Luxembourg, and Spain in 1995 was about 3.5 million metric tons, or about 26 percent the size of U.S. production of 13.8 million metric tons. However, the United States is a very strong net exporter of poultry meat, with imports of only 3,546 metric tons and exports of more than 2 million metric tons in 1996 ("World Trade Atlas," June 1997). Very few of the imports are from western Europe. Moreover, more than 99 percent of U.S. poultry meat imports originated in Canada. We do not expect that these countries would redirect a significant amount of poultry meat toward such a small U.S. import market.

### **Impact on Small Entities**

The Regulatory Flexibility Act requires that the Agency specifically consider the economic impact associated with the proposed rule on small entities. Those likely to be affected by this proposed rule are those entities engaged in the production of live swine, pork and pork products, live ruminants, meat, meat products, and dairy products derived from ruminants, and poultry products.

The Small Business Administration's (SBA's) definition of a "small" cattle, swine, or poultry farm is one whose total sales is less than \$0.5 million annually. In 1992, 97.8 percent of cattle

and calf farms would be considered small entities. The vast majority of the domestic hog and pig farms qualify as small entities (96.3 percent in 1992). Eighty-seven percent of poultry farms would be considered small entities in 1992 ("1992 Census of Agriculture," U.S. Department of Commerce, 1993).

The SBA's guidelines state that a "small" producer of poultry meat (Standard Industrial Classification (SIC) 2015, poultry slaughtering and processing) is one employing fewer than 500 workers. In 1992, 74 percent of 591 poultry slaughtering and processing establishments were considered small entities. These small entities accounted for approximately 30 percent of the total value of shipments of the industry, \$7.2 billion.

The SBA's guidelines state that a "small" producer of pork and ruminant products (part of SIC 2011 or 2013, meat packing plants) is one employing fewer than 500 workers. In 1992, 97 percent of the 1,367 meat packing establishments in SIC 2011 were considered small entities. These small establishments accounted for approximately 40 percent of the total value of shipments of the industry, \$50.4 billion. Ninety-eight percent of the 1,264 establishments in SIC 2013 were considered small entities in 1992. These producers accounted for 84 percent of the total value of shipments of the industry, \$19.97 billion.

Although the majority of the domestic entities potentially affected by this proposed rule are small, there should be only a minimal change in the level of imports that may compete with the output of these small entities, and thus there would be a minimal impact on any domestic producer of these products, whether small or large.

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

### **Executive Order 12988**

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

### **Paperwork Reduction Act**

This proposed 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 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

Accordingly, 9 CFR part 94 would be amended as follows:

#### PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, HOG CHOLERA, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

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

**Authority:** 7 U.S.C. 147a, 150ee, 161, 162, and 450; 19 U.S.C. 1306; 21 U.S.C. 111, 114a, 134a, 134b, 134c, 134f, 136, and 136a; 31 U.S.C. 9701; 42 U.S.C. 4331 and 4332; 7 CFR 2.22, 2.80, and 371.2(d).

2. Section 94.1 would be amended as follows:

a. In paragraph (a)(1), the words “or (a)(3)” would be added immediately after the words “paragraph (a)(2)”.

b. In paragraph (a)(2), the word “Luxembourg,” would be added immediately after the word “Japan,” and the word “Portugal,” would be added immediately after the word “Poland,”;

c. A new paragraph (a)(3) would be added to read as set forth below.

d. In the introductory text of paragraph (c), the words “paragraph (a) of” would be removed and the words “paragraph (a)(2) of” would be added in their place.

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

(a) \* \* \*

(3) The following regions are declared to be free of rinderpest: Greece.

\* \* \* \* \*

#### § 94.3 [Amended]

3. Section 94.3 would be amended by adding the words “where rinderpest or foot-and-mouth disease exists, as” immediately before the word “designated”.

#### § 94.4 [Amended]

4. In § 94.4(a), the introductory text of the paragraph would be amended by adding the words “where rinderpest or foot-and-mouth disease exists, as” immediately before the word “designated”.

#### § 94.6 [Amended]

5. In § 94.6, paragraph (a)(2) would be amended by adding the words “France, Greece,” immediately after the word “Finland,”; by adding the word “Luxembourg,” immediately after the word “Iceland,”; and by adding the word “Spain,” immediately after the words “Republic of Ireland,”.

#### § 94.8 [Amended]

6. In § 94.8, the introductory text of the section would be amended by removing the words “Malta, and Portugal” and adding in their place the words “and Malta”.

#### § 94.11 [Amended]

7. In § 94.11, paragraph (a), the first sentence would be amended by adding the word “Luxembourg,” immediately after the word “Japan,”; by adding the word “Portugal,” immediately after the word “Poland,”; and by removing the reference “§ 94.1” and adding the reference “§ 94.1(a)(2)” in its place.

#### § 94.12 [Amended]

8. In § 94.12, paragraph (a) would be amended by adding the word “Belgium,” immediately after the words “The Bahamas,”; by adding the word “France,” immediately after the word “Finland,”; and by adding the word “Portugal,” immediately after the word “Panama,”.

#### § 94.13 [Amended]

9. In § 94.13, the introductory text of the section would be amended by adding the word “Belgium,” immediately after the words “The Bahamas,”; by adding the word “France,” immediately after the word “Denmark,”; and by adding the word “Portugal,” immediately after the words “Northern Ireland,”.

Done in Washington, DC, this 12th day of November 1997.

**Terry L. Medley,**

*Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 97-30105 Filed 11-13-97; 8:45 am]

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Food and Drug Administration

#### 21 CFR Part 201

[Docket No. 77N-094W]

RIN 0910-AA01

#### Over the-Counter Drug Products Containing Analgesic/Antipyretic Active Ingredients for Internal Use; Required Alcohol Warning

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking that would establish alcohol warnings for all over-the-counter (OTC) drug products containing internal analgesic/antipyretic active ingredients labeled for adult use. The proposed warning statements advise consumers who have a history of heavy alcohol use or abuse to consult a physician for advice about the use of OTC internal analgesic/antipyretic drug products. A warning would be required for all OTC internal analgesic/antipyretic drug products marketed under an OTC drug monograph or an approved new drug application (NDA). FDA is issuing this notice of proposed rulemaking after considering the reports and recommendations of its Nonprescription Drugs Advisory Committee (NDAC) and Arthritis Drugs Advisory Committee (ADAC), public comments on the proposed rule for OTC internal analgesic, antipyretic, and antirheumatic drug products, and other available information.

**DATES:** Written comments by January 28, 1998. Written comments on the agency's economic impact determination by January 28, 1998. The agency is proposing that any final rule based on this proposal be effective 6 months after the date of its publication in the **Federal Register**.

**ADDRESSES:** Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Debbie L. Lumpkins, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2241.

**SUPPLEMENTARY INFORMATION:**