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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service, USDA.

9 CFR Part 94

[Docket No. 96–027–2]

Change in Disease Status of the Czech Republic and Italy Because of Rinderpest and Foot-and-Mouth Disease

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are declaring the Czech Republic and Italy free of rinderpest and foot-and-mouth disease and adding these two countries 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 their meat and other animal products into the United States. This rule removes the prohibition on the importation into the United States, from the Czech Republic and Italy, of live ruminants and fresh, chilled, and frozen meat from ruminants and relieves restrictions on the importation of milk and milk products from ruminants from these two countries. However, because the Czech Republic and Italy are not declared to be free of certain diseases of swine, including hog cholera and swine vesicular disease, the importation from these countries of swine and fresh, chilled, and frozen meat from swine continues to be restricted.

EFFECTIVE DATE: October 21, 1996.

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 20737–1228, (301) 734–3399.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 94 (referred to below as the regulations) govern 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, foot-and-mouth disease (FMD), bovine spongiform encephalopathy, African swine fever, hog cholera, and swine vesicular disease. These are dangerous and destructive communicable diseases of ruminants and swine.

Section 94.1(a)(1) of the regulations provides that rinderpest or FMD exists in all countries of the world except those listed in § 94.1(a)(2), which have been declared to be free of these diseases. We will consider declaring a country to be free of rinderpest and FMD if, among other things, there have been no cases of these 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 country for at least the previous 1-year period.

On July 9, 1996, we published in the Federal Register (61 FR 35987–35990, Docket No. 96–027–1) a proposal to amend the regulations by adding the Czech Republic and Italy to the list in § 94.1(a)(2) of countries declared free of rinderpest and FMD and to the list in § 94.11(a) of countries that are declared free of rinderpest and FMD but that are subject to special restrictions on the importation of their meat and other animal products into the United States. The proposal would remove the prohibition on the importation into the United States, from the Czech Republic and Italy, of live ruminants and fresh, chilled, and frozen meat from ruminants and would relieve restrictions on the importation, from these two countries, of milk and milk products from ruminants.

We solicited comments concerning our proposal for 60 days ending September 9, 1996. We did not receive any comments. The facts presented in the proposed rule still provide the basis for this final rule.

Therefore, based on the rationale set forth in the proposed rule, we are adopting the provisions of the proposal as a final rule without change.

Effective Date

This is a substantive rule that relieves restrictions and, pursuant to the provisions of 5 U.S.C. 553, may be made effective less than 30 days after publication in the Federal Register. This rule removes the prohibition on the importation into the United States, from the Czech Republic and Italy, of live ruminants and fresh, chilled, or frozen meat from ruminants and relieves restrictions on the importation, from these two countries, of milk and milk products from ruminants. We have determined that approximately 2 weeks are needed to ensure that the Animal and Plant Health Inspection Service personnel at ports of entry receive official notice of this change in the regulations. Therefore, the Administrator of the Animal and Plant Health Inspection Service has determined that this rule should be effective 15 days after publication in the Federal Register.

Executive Order 12866 and Regulatory Flexibility Act

This 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 rule alters the restrictions placed upon imports of live ruminants and meat, meat products, and dairy products derived from ruminants from the Czech Republic and Italy. The regulations in 9 CFR part 94 describe prohibited and restricted importations due to rinderpest, FMD, and other animal diseases. APHIS has determined that the Czech Republic and Italy meet the criteria for being recognized as free of rinderpest and FMD. However, because the Czech Republic and Italy share land borders and maintain trading relationships with FMD-affected countries, imports into the United States of live ruminants and meat, meat products, and dairy products derived from ruminants from the Czech Republic and Italy continue to be restricted under this rule. The rule does not relieve any restrictions imposed on the importation of swine and pork products because the Czech Republic and Italy are still considered to be affected with hog cholera and swine vesicular disease, and Italy is also considered to be affected with African swine fever.

We anticipate that the quantity of imports of live cattle, sheep, and goats from the Czech Republic and Italy into the United States will be minimally affected by the rule. Live cattle imports will still be restricted due to the trade practices of the Czech Republic and Italy and the fact that these countries share land borders with FMD-affected countries. In addition, the cattle industries in the Czech Republic and Italy are small relative to the enormous domestic market. Cattle inventories for 1994 were estimated to be 2.5 million head for the Czech Republic, 7.5 million head for Italy, and over 100 million head for the United States. Also, of the 2.5 million cattle and calves imported into the United States in 1994, more than 99 percent were from Canada and Mexico.

The population of sheep and goats in the Czech Republic is also very small relative to that of the United States (less than 2.5 percent of the size of the U.S. population in 1993). Italy has a sheep population that is slightly higher than that of the United States (11.7 million head in Italy and 10.9 million head in the United States in 1993). However, Italy is a strong net importer of sheep and goats (190,556 head imported and only 1,450 exported in 1993), while the United States is a strong net exporter of sheep and goats (28,420 head imported and 894,100 head exported in 1993). Of the few sheep that the United States does import, more than 99 percent are from Canada and Mexico.

The Czech Republic exports few live ruminants to the United States. In 1994, less than 0.0001 percent of the total value of total U.S. imports of live ruminants were from the Czech Republic. Italy exported no live ruminants to the United States in 1994. In fact, the United States did not import any cattle or sheep from the European Union in 1994. Neither Eastern nor Western Europe are usual sources of live ruminants for the United States, and any increase in ruminant importations from the Czech Republic or Italy prompted by this rule are likely to be negligible. Therefore, the impact on small domestic farmers of cattle, sheep, and goats is likely to be minimal.

Czech production of beef, veal, mutton, and goat meat in 1994 was about 2 percent of the size of U.S. production. Italian production of beef, veal, mutton, and goat meat in 1994 was about 1.2 million metric tons, or about 11 percent of the U.S. production of 11.3 million metric tons. The United States imports very little in the way of ruminant meat and ruminant meat products from Eastern or Western Europe in general. Moreover, more than 88 percent of the imports of ruminant meat and ruminant meat products that come into the United States are from Australia, Canada, and New Zealand. It is unlikely that either the Czech Republic or Italy will be willing or able to redirect a significant portion of its ruminant meat production for export exclusively to the United States as a result of the rule, given that restrictions remain in place for imports into the United States. Even if the Czech Republic were able to redirect its entire production of these products for export to the United States, this production was only one-fifth the size of total U.S. imports of these products in 1994. Moreover, Italy is a significant net importer of beef, veal, mutton, and other products such as offal and meat extracts. Therefore, any effect of the rule on domestic prices or supplies is likely to be negligible, and thus the impact on small domestic producers will be minimal.

We also anticipate that the effect of the rule on the importation of dairy products from the Czech Republic and Italy will be minimal. Czech production of dairy products is small relative to that of the United States. In 1993, Czech dairy product production was about 5 percent of the value of U.S. production. The United States imports little in the way of dairy products from the Czech Republic or from Eastern Europe in general. In 1994, U.S. imports of dairy products were valued at $963.4 million; of this total, less than 5 percent originated in Eastern Europe and less than 0.1 percent in the Czech Republic. The Czech Republic is a significant producer and exporter of butter. However, butter is already exempt from the provisions of 9 CFR part 94 and thus will be unaffected by the rule. For dairy products in general, Italy is a significant net importer and not likely to be willing or able to redirect a significant portion of its production exclusively to the United States, which is a significant net exporter. Italy's major dairy export to the United States is cheese. Because solid cheeses are already exempt from the provisions of 9 CFR part 94, there is no reason to believe that imports of cheese will increase significantly due to this rule. For these reasons and given the fact that restrictions will remain in place, it is unlikely that the rule will significantly alter imports of dairy products into the United States. Therefore, the impact on small domestic dairy producers should be minimal.

Any effects of the rule on importers of embryos, semen, other genetic material, or breeding animals is also likely to be minimal. We anticipate that, after the rule becomes effective, there could be an initial increase in the volume of these products flowing into the United States to diversify the genetic composition of domestic cattle. (In particular, there has been a great deal of interest expressed in obtaining genetic material of beef cattle from Italy.) However, any temporary increase in volume will most likely be small relative to total U.S. imports of these products. The United States is a net exporter of both bovine semen and cattle embryos. In 1994, the value of U.S. bovine semen and cattle embryo imports was $4.3 million and $266,000, respectively, while U.S. exports of bovine semen and cattle embryos were valued at $7.9 million and $6.4 million, respectively. Given this trade balance and the size differences between the U.S. and Czech and Italian cattle industries, the amount imported of each type of genetic material is likely to be minimal and have a minimal impact on small domestic cattle producers.

In conclusion, declaring the Czech Republic and Italy free of rinderpest and FMD will likely have a negligible impact on domestic small entities. Imports from the Czech Republic and Italy of ruminants and ruminant products continue to be restricted. In addition, the U.S. markets for these products are large relative to the Czech and Italian markets, and Italy is a net importer of most of these products. Under these conditions, it is unlikely that either the Czech Republic or Italy will be willing or able to redirect a significant portion of the production of these products exclusively to the United States.

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.

Executive Order 12988

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

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the information collection or recordkeeping requirements included in this final rule have been approved by the Office of Management and Budget (OMB). The

assigned OMB control number is 0579–0015.

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 is amended as follows:

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), VELOGENIC VISCEROTROPIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, HOG CHOLERA, AND BOVINE SPONGIFORM ENCEPHALOPATHY: 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, 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).

§ 94.1 [Amended]

2. In § 94.1, paragraph (a)(2) is amended by adding the words ''Czech Republic,'' immediately after the words ''Costa Rica,'' and by adding the word ''Italy,'' immediately after the word ''Ireland,''.

§ 94.11 [Amended]

3. In § 94.11, the first sentence in paragraph (a) is amended by adding the words ''Czech Republic,'' immediately after the word ''Chile,'' and by adding the word ''Italy,'' immediately after the word ''Hungary,''.

Done in Washington, DC, this 30th day of September 1996.

A. Strating,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 96–25503 Filed 10–3–96; 8:45 am]

BILLING CODE 3410–34–P

9 CFR Part 113

[Docket No. 92–124–2]

Viruses, Serums, Toxins, and Analogous Products; Antibody Products

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: This rule amends the regulations by revising the designation for a group of standard requirements from ''Blood Origin Products'' to ''Antibody Products;'' revising five of the six existing standard requirements in the group; removing the sixth; and adding a new standard requirement for products intended for the treatment of failure of passive transfer. These amendments are necessary in order to update the standard requirements for veterinary biological products and to provide for their regulation in a manner that is more consistent with current scientific knowledge and understanding.

EFFECTIVE DATE: November 4, 1996

FOR FURTHER INFORMATION CONTACT: Dr. David A. Espeseth, Deputy Director, Veterinary Biologics, BBEP, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1237, (301) 734–8245.

SUPPLEMENTARY INFORMATION:

Background

In accordance with the regulations in 9 CFR part 113 (hereinafter referred to as ''the regulations''), standard requirements are prescribed for the preparation of veterinary biological products. A standard requirement consists of specifications, procedures, and test methods that define the standards of purity, safety, potency, and efficacy for a veterinary biological product. Where a standard requirement for a product does not exist, production procedures and specifications for purity, safety, and potency of a biological product are provided in an Outline of Production filed with the Animal and Plant Health Inspection Service (APHIS). For consistency of review and uniformity of standards, standard requirements are codified in the regulations.

In recent years, the number of license applications received by APHIS for antibody products has increased substantially. Historically, the antibody source material for most of these products has been blood. Increasingly, however, the Agency is being presented with products for licensure that are derived from other sources such as colostrum, milk, and eggs. Standard requirements for many of these products are not codified in the regulations, and many of the products are not adequately addressed by the general requirements for blood origin products in § 113.450.

On July 23, 1993, we published in the Federal Register (58 FR 39462–39467, Docket No. 92–124–1) a proposed rule that would update the regulations to provide more consistent licensing standards and more appropriate product-indication statements that, in turn, should provide greater guidance to manufacturers and lead to more reliable products.

We solicited comments concerning our proposal for 60 days ending September 21, 1993. We received twelve sets of comments by that date. They were from eight manufacturers of veterinary biological products, three consultants, and a national trade association.

One commenter asked what the impact of the rule would be on a product that is currently licensed by APHIS as a veterinary biological but for which no biologic-type claim (i.e., a claim that a product functions through an immunologic mechanism to diagnose, prevent, or alleviate animal disease) is made, overtly or by implication. The commenter noted that the proposed regulations do not seem to specifically address this category of product. In response to the commenter, APHIS notes that these type of products were licensed at the request of producers for use in the nonspecific treatment of anemia, hemorrhage, or shock that may follow injury to horses. The regulations referred to such products as ''normal serum.'' This regulation does not specifically address normal serum because it is not a product which is required to be licensed. Therefore, no new licenses shall be issued for normal serum, which is not intended to affect the immune mechanism. APHIS will work with the producers of any such product that may be currently licensed to resolve any questions involving these type of products. No change to the regulations is made in response to this comment.

One commenter criticized the proposed nomenclature for products intended for the treatment of failure of passive transfer (FPT) proposed in § 113.450(b)(3). The commenter asserted that to refer to these products as ''IgG'' is misleading because such products may contain ''many other protective factors.'' In response to the commenter, APHIS believes the nomenclature proposed for products for the treatment of FPT is appropriate for this category of biological product. The reason for this is that FPT is most commonly defined as a below normal level of circulating, maternally derived immunoglobulin G (IgG) in the neonate, the awareness that IgG is measured in the establishment of product efficacy and potency, and the understanding that the ''other protective factors'' (i.e., substances other than immunoglobulins) cited are at best very poorly characterized. No change to the regulations is made in response to this comment.

Three commenters suggested other changes to proposed § 113.450(c). Two of the commenters stated that the proposed regulations precluded the use of slaughterhouse blood as an antibody