

# Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

#### 9 CFR Part 94

[Docket No. 95-055-1]

#### Change in Disease Status of Germany Because of Swine Vesicular Disease

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

**ACTION:** Proposed rule.

**SUMMARY:** We are proposing to declare Germany free of swine vesicular disease. As part of this proposed action, we would add Germany to the list of countries that, although declared free of swine vesicular disease, are subject to restrictions on pork and pork products offered for importation into the United States. Declaring Germany free of swine vesicular disease appears to be appropriate because there have been no confirmed outbreaks of swine vesicular disease in Germany since 1981. This proposed rule would relieve certain restrictions on the importation of pork and pork products into the United States from Germany. However, because Germany shares common land borders with countries affected by swine vesicular disease, imports pork products from countries affected by swine vesicular disease, and is still considered to be affected with hog cholera, the importation into the United States of pork and pork products from Germany would continue to be restricted.

**DATES:** Consideration will be given only to comments received on or before October 30, 1995.

**ADDRESSES:** Please send an original and three copies of your comments to Docket No. 95-055-1, 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. 95-055-1. 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, Import/Export Products, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737-1231, (301) 734-8695.

#### 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 animal diseases, including rinderpest, foot-and-mouth disease (FMD), bovine spongiform encephalopathy, African swine fever, hog cholera, and swine vesicular disease (SVD). These are dangerous and destructive communicable diseases of ruminants and swine.

Section 94.12(a) of the regulations provides that SVD is considered to exist in all countries of the world except those listed in § 94.12(a), which have been declared to be free of SVD. We will consider declaring a country to be free of SVD if there have been no reported cases of the disease in that country for at least the previous 1-year period. The last case of SVD in Germany that was confirmed by laboratory procedures occurred in 1981. Clinical symptoms similar to SVD were recognized in a herd in Germany in 1985, and that case was reported as SVD by the Regional Veterinary Officer in Germany, but laboratory tests failed to confirm SVD. There have been no reports of SVD in Germany since that time. Based on Germany's apparent current and recent freedom from SVD, the Government of Germany has requested that the U.S. Department of Agriculture (USDA) recognize Germany to be free of SVD.

The Animal and Plant Health Inspection Service (APHIS) reviewed the documentation submitted by the Government of Germany in support of its request. A team of APHIS officials traveled to Germany in September 1993 to conduct an on-site evaluation of the country's animal health program with

regard to the foot-and-mouth disease (FMD) and rinderpest situation in Germany. The evaluation consisted of a review of Germany's veterinary services, laboratory and diagnostic procedures, vaccination practices, and administration of laws and regulations intended to prevent the introduction of FMD and rinderpest into Germany. We believe that the 1993 on-site evaluation was sufficient to provide APHIS with a complete picture of Germany's animal health program with regard to SVD, as well. Therefore, we have used the findings of the 1993 on-site evaluation as part of the basis for this proposed rule. (Details concerning the 1993 on-site evaluation are available upon written request from the person listed under **FOR FURTHER INFORMATION CONTACT**.)

Based on the information discussed above, we are proposing to amend § 94.12(a) by adding Germany to the list of countries declared free of SVD. This action would relieve certain requirements on the importation of pork and pork products from Germany.

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

Germany supplements its national pork supply by importing fresh, chilled, and frozen pork from countries where SVD is considered to exist. In addition, Germany has common land borders with Belgium, Czechoslovakia, France, the Netherlands, and Poland. These countries are designated in § 94.12(a) as countries where SVD exists. As a result, even though Germany appears to qualify for designation as a country free of SVD, there is potential for pork and pork products produced in Germany to be commingled with the fresh, chilled, or frozen meat of animals from a country 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 Germany be subject to the restrictions specified in § 94.13 of the regulations and to the applicable requirements contained in the regulations of the USDA's Food Safety and Inspection Service at 9 CFR chapter III. Section 94.13 requires, in part, that pork and pork products 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 as well as a certification issued by a full-time salaried veterinary official of the national government of the exporting country, stating that certain precautions have been satisfied 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 country in which SVD is considered to exist.

Because hog cholera exists in Germany, the importation of pork and pork products from Germany would continue to be subject to the restrictions in § 94.9 for pork and pork products from countries where hog cholera exists. The importation of live swine, except for wild swine, from Germany would continue to be prohibited due to hog cholera, in accordance with § 94.10. 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 adding Germany to the list of countries that have been declared free of SVD. This action would relieve certain restrictions on the importation of pork and pork products into the United States from Germany. However, other requirements would continue to restrict the importation of live swine and pork and pork products.

Because of the continued presence of hog cholera in Germany, nearly all of the current U.S. restrictions on the importation of pork and pork products would remain unchanged. The only area of pork importation that may be affected should Germany be declared free of SVD is cured and dried pork imports. A lengthy curing and drying period is required at present for pork and pork products originating from countries

with SVD (see 9 CFR 94.17). The restriction for hog cholera is much shorter, requiring that the meat be thoroughly cured and fully dried for a period of not less than 90 days so that the product is shelf stable without refrigeration (see 9 CFR 94.9).

A shorter and less costly curing and drying period for pork and pork products could lead to Germany's increased participation in the U.S. market, depending on the competitiveness of the market for imported cured and dried pork and pork products. However, the impact for U.S. importers and consumers is not expected to be significant. In the fiscal year 1993-94, Germany exported 232 tons of prepared or preserved pork to the United States, which amounted to only 0.25 percent of the total quantity imported into the United States. The effect of this proposed rule on U.S. domestic prices or supplies or on U.S. businesses, including small entities, is expected to be negligible.

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 12778

This proposed rule has been reviewed under Executive Order 12778, 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

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been approved by the Office of Management and Budget (OMB), and there are no new requirements. 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 would be 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 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 2.17, 2.51, and 371.2(d).

#### § 94.12 [Amended]

2. In § 94.12, paragraph (a) would be amended by adding "Germany," immediately after "Finland,".

#### § 94.13 [Amended]

3. In § 94.13, the introductory text, the first sentence would be amended by adding "Germany," immediately after "Denmark,".

Done in Washington, DC, this 22nd day of August 1995.

**Lonnie J. King,**

*Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 95-21288 Filed 8-28-95; 8:45 am]

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Food and Drug Administration

#### 21 CFR Part 101

[Docket No. 95P-0003]

#### Food Labeling: Health Claims; Sugar Alcohols and Dental Caries; Correction

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a proposed rule that appeared in the **Federal Register** of July 20, 1995 (60 FR 37507). The document proposed to authorize the use, on food labels and in food labeling, of health claims on the association between sugar alcohols and the nonpromotion of dental caries and to exempt sugar alcohol-containing foods from certain provisions of the health claims general requirements regulation. The document was published with some errors. This document corrects those errors.

**DATES:** Written comments by October 3, 1995. The agency is proposing that any