

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 Parts 94 and 96

[Docket No. 97-002-1]

Change in Disease Status of Italy, Except the Island of Sardinia, Because of African Swine Fever

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to declare Italy, with the exception of the island of Sardinia, free of African swine fever. This proposed action appears to be appropriate because there have been no confirmed outbreaks of African swine fever in Italy, except on the island Sardinia, since 1983. This proposed action would relieve certain restrictions on the importation into the United States of pork and pork products from all regions of Italy except Sardinia. However, because hog cholera and swine vesicular disease exist in Italy, and because Italy, as a member state of the European Union, has certain trade practices regarding live swine and pork and pork products that are less restrictive than are acceptable to the United States, the importation into the United States of live swine and pork and pork products from Italy would continue to be subject to certain restrictions.

DATES: Consideration will be given only to comments received on or before August 11, 1997.

ADDRESSES: Please send an original and three copies of your comments to Docket No. 97-002-1, 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. 97-002-1. 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 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, swine vesicular disease, hog cholera, and African swine fever (ASF). These are dangerous and destructive communicable diseases of ruminants and swine.

Section 94.8 of the regulations states that ASF exists or is reasonably believed to exist in all the countries of Africa and in Brazil, Cuba, Haiti, Italy, Malta, and Portugal. Paragraph (a) of § 94.8 provides that no pork or pork products may be imported into the United States from those countries (referred to below as ASF countries) unless the pork or pork product:

- Is fully cooked in accordance with § 94.8(a)(1); or
- Is not otherwise prohibited importation into the United States and is consigned directly from the U.S. port of entry to an approved establishment for further processing, as provided by § 94.8(a)(2); or
- Is derived from swine raised and slaughtered in a country where ASF is not known or believed to exist and is handled and processed in accordance with § 94.8(a)(3).

Also, § 94.17 provides, in part, that dry-cured pork products may be imported into the United States from ASF countries 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 ASF countries may not be imported into the United States because the regulations in 9 CFR 92.505(a) require, among other things, that live domestic swine be accompanied by a certificate showing that the entire country of origin of the swine is free of ASF and other specified diseases. The importation of swine casings from ASF countries is likewise prohibited by 9 CFR 96.2(a) unless the swine casings originated in a country free of ASF and were processed in the ASF country at a facility that meets the criteria of § 94.8(a)(3)(iv) of the regulations.

The Government of Italy has requested that the U.S. Department of Agriculture recognize Italy, with the exception of the island of Sardinia, as free of ASF. We will consider declaring a country free of ASF 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 ASF in Italy, outside of the island of Sardinia, occurred in 1983.

The Animal and Plant Health Inspection Service (APHIS) has reviewed the documentation submitted by the Government of Italy in support of its request, and a team of APHIS officials traveled to Italy in February 1997 to conduct an on-site evaluation of Italy's animal health program with regard to ASF. The evaluation consisted of a review of Italy's veterinary services, laboratory and diagnostic procedures, vaccination practices, and administration of laws and regulations intended to prevent the introduction of communicable animal diseases into Italy, and from Sardinia into the rest of Italy. (Details concerning the February 1997 on-site evaluation are available upon written request from the person listed under **FOR FURTHER INFORMATION CONTACT**.) After reviewing the documentation provided by Italy and the data gathered during the on-site visit by APHIS officials, we believe that Italy, with the exception of Sardinia, qualifies to be recognized as free of ASF.

Therefore, we are proposing to amend § 94.8 of the regulations by removing Italy, except the island of Sardinia, from the list of ASF countries. This proposed action would result in pork and pork products from all parts of Italy except Sardinia no longer being subject to the restrictions found in § 94.8 of the regulations. Another effect of this proposed action would be that swine

casings that originated in or were processed in any region of Italy other than Sardinia would no longer be subject to the restrictions in 9 CFR 96.2(a).

However, Italy is still considered to be affected with hog cholera and swine vesicular disease, so pork and pork products from anywhere in Italy offered for importation into the United States would remain subject to the restrictions in § 94.9 for hog cholera and in § 94.12 for swine vesicular disease. Similarly, dry-cured pork products from Italy would continue to be subject to the regulations in § 94.17 due to hog cholera and swine vesicular disease. In addition, pork and pork products from Italy would continue to be subject to the restrictions in § 94.11 because Italy is one of the countries 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 trade with countries affected with rinderpest or FMD or because they have a common land border with a country affected with rinderpest or FMD. Finally, declaring all of Italy except Sardinia free of ASF would not relieve any of the current restrictions in 9 CFR part 92 on the importation into the United States of live swine from Italy because Italy remains affected with hog cholera and swine vesicular disease.

Miscellaneous

The regulations in § 94.8 and § 96.2 refer in several instances to "a country" or "any country" listed in § 94.8 as being affected with ASF. Because this proposed rule would designate only a portion of Italy—i.e., the island of Sardinia—as being affected with ASF, it would no longer be accurate to refer to "countries" listed in § 94.8. Therefore, for the purposes of accuracy and consistency, we would amend those sections to include the words "or part of a country" after each reference to countries listed in § 94.8.

We are also proposing to redesignate the footnotes in part 94 so that the footnotes would be numbered consecutively by part, rather than by section. We are also proposing to amend § 94.17(a) to correct a reference to "paragraph (i) of this subpart" by replacing it with a reference to "paragraph (i) of this section."

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not

been reviewed by the Office of Management and Budget.

This proposed rule would amend the regulations in part 94 by removing Italy, except the island of Sardinia, from the list of countries where ASF exists or is reasonably believed to exist. This action would relieve certain restrictions on the importation of pork and pork products into the United States from all areas of Italy except the island of Sardinia. However, because hog cholera and swine vesicular disease exist in Italy, and because Italy, as a member state of the European Union, has certain trade practices regarding live swine and pork and pork products that are less restrictive than are acceptable to the United States, the importation into the United States of live swine and pork and pork products from Italy would continue to be subject to restrictions. For this reason, no live swine, or fresh, chilled, or frozen pork would be imported from Italy as a result of this rule change.

Entities in the United States likely to be affected by this proposed rule are those entities engaged in the production of swine and processed pork products. According to the Small Business Administration (SBA) definition, a "small entity" in the production of swine is an entity whose total annual sales are less than \$0.5 million. Under this definition, approximately 96.3 percent of domestic producers are considered to be small entities. According to the SBA definition, a small entity in the production of pork products, including meat packing plants, is an entity employing fewer than 500 workers. In 1992, the most recent year for which complete figures are available, over 95 percent of pork processors of all types were considered small entities.

It is possible that imports of processed pork products would be affected if this proposed rule is adopted, but we believe any change would be minimal. Italy has not been declared free of swine vesicular disease or hog cholera, so there would continue to be restrictions on the importation into the United States of pork and pork products, including dry-cured pork products, from anywhere in Italy. Given those continuing restrictions, we believe any potential increase in imports of processed pork products derived from Italian swine would be minimal. The economic impact of a slight increase in those imports on U.S. swine producers and processors of pork and pork products is likewise expected to be minimal.

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

9 CFR Part 94

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

9 CFR Part 96

Imports, Livestock, Reporting and recordkeeping requirements.

Accordingly, 9 CFR parts 94 and 96 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).

§ 94.4 [Amended]

2. In § 94.4, in the introductory text of paragraph (b)(8) and in paragraph (b)(8)(i)(C), footnotes 1 and 2 and their references in the text would be redesignated as footnotes 2 and 3, respectively.

§ 94.6 [Amended]

3. Section 94.6 would be amended as follows:

a. In paragraph (c)(2), footnote 1 and its reference in the text would be redesignated as footnote 4.

b. In the introductory text of paragraph (d), footnote 2 and its

reference in the text would be redesignated as footnote 5.

c. In paragraph (d)(1)(ix)(C)(1), footnote 3 and its reference in the text would be redesignated as footnote 6.

§ 94.8 [Amended]

4. Section 94.8 would be amended as follows:

a. In the introductory text of the section, footnote 1 and its reference in the text would be redesignated as footnote 7, and, in the text of newly redesignated footnote 7, the words "or a part of a country" would be added after the word "country" the first time it appears.

b. In the introductory text of the section, the words "All the countries of Africa, Brazil, Cuba, Haiti, Italy, Malta, and Portugal" would be removed and the words "All the countries of Africa; Brazil, Cuba, Haiti, Malta, and Portugal; and the island of Sardinia, Italy" would be added in their place.

c. In the introductory text of paragraph (a), the words "or part of a country" would be added after the word "country".

d. In paragraph (a)(3)(i)(A), the words "or part of a country" would be added after the word "country".

e. In paragraph (a)(3)(i)(B), footnote 2 and its reference in the text would be redesignated as footnote 8, and the words "country listed" would be removed and the words "country or part of a country listed" would be added in their place.

f. In paragraph (a)(3)(iv)(A), the words "or parts of countries" would be added after the word "countries".

g. In paragraph (a)(3)(v), the words "or part of a country" would be added after the word "country".

h. In paragraph (c), the words "or part of a country" would be added after the word "country".

§ 94.9 [Amended]

5. In § 94.9, paragraph (a), footnote 1 and its reference in the text would be redesignated as footnote 9, and in paragraph (b)(3) footnote 2 and its reference in the text would be redesignated as footnote 10.

§ 94.12 [Amended]

6. In § 94.12, paragraph (b)(1)(iii)(B), footnote 1 and its reference in the text would be redesignated as footnote 11, and in paragraph (b)(3) footnote 2 and its reference in the text would be redesignated as footnote 12.

§ 94.16 [Amended]

7. In § 94.16, paragraph (b)(2), footnote 1 and its eight references in the text would be redesignated as footnote 13.

§ 94.17 [Amended]

8. In § 94.17, in paragraph (a), the word "subpart" would be removed and the word "section" would be added in its place, and in paragraph (e), footnote 1 and its reference in the text would be redesignated as footnote 14.

§ 94.18 [Amended]

9. In § 94.18, in paragraph (c)(2), footnote 1 and its reference in the text would be redesignated as footnote 15, and in paragraph (d)(1), footnote 2 and its reference in the text would be redesignated as footnote 16.

PART 96—RESTRICTION OF IMPORTATIONS OF FOREIGN ANIMAL CASINGS OFFERED FOR ENTRY INTO THE UNITED STATES

10. The authority citation for part 96 would continue to read as follows:

Authority: 21 U.S.C. 111, 136, and 136a; 7 CFR 2.22, 2.80, and 371.2(d).

§ 96.2 [Amended]

11. In § 96.2, paragraph (a) would be amended by adding the words "or part of a country" after the word "country" each time it appears.

Done in Washington, DC, this 5th day of June 1997.

Bobby R. Acord,

Acting Administrator, Animal and Plant Health Inspection Service.

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 304, 308, 310, 320, 327, 381, 416, and 417

[Docket No. 97-025N]

Generic HACCP Models and Guidance Materials Available for Review and Comment

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of availability and request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) has developed 13 generic Hazard Analysis and Critical Control Point (HACCP) models and has revised its Guidebook for the Preparation of HACCP Plans and its Hazards and Controls Guide for Meat and Poultry Products to assist meat and poultry establishments in the development of their HACCP systems. The models, Guidebook, and Guide will be available for review and study by interested members of the public. FSIS

is soliciting public comments on the models and other guidance materials to determine their appropriateness and useability, especially by owners of "small" and "very small" establishments.

DATES: Written comments on the models, Guidebook, and Guide must be submitted on or before August 11, 1997.

ADDRESSES: The models, Guidebook, and Guide may be viewed in the FSIS Docket Reading Room, Room 102 Cotton Annex Building, 300 12th Street, SW., Washington, DC 20250-3700 and at Government Depository Libraries throughout the country. Comments on the models and other documents should be directed to Ms. Diane Moore, FSIS Docket Clerk, at the above address. Paper copies of the complete set of materials are available from the Public Outreach Office, Room 1180, South Agriculture Building, 1400 Independence Avenue, SW., Washington, DC 20250-3700. To obtain a paper copy of the Guidebook, Guide, and appropriate model(s), please mail your request indicating the number and title of the document to the Public Outreach Office at the above address; or FAX to (202) 720-9063.

FOR FURTHER INFORMATION CONTACT: Ms. Patricia F. Stolfa, Assistant Deputy Administrator, Regulations & Inspection, in the Office of Policy, Program Development and Evaluation, Food Safety and Inspection Service, at (202) 205-0699, FAX (202) 401-1760.

SUPPLEMENTARY INFORMATION: On July 25, 1996, FSIS published a final rule, "Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems" (61 FR 38806). This rule introduces sweeping changes to the meat and poultry inspection system and directly targets pathogenic organisms on those products that can cause foodborne illness. In the preamble to the proposed rule, FSIS announced that it would develop 13 generic HACCP models to facilitate preparation of mandated HACCP plans, especially by "small" and "very small" establishments, and to reduce costs associated with developing HACCP plans. FSIS said that the models would be available in draft form for public comment, and in final form at least six months before HACCP implementation. HACCP will be implemented in "small" and "very small" plants in the years 1999 and 2000 respectively.

The following generic HACCP models and guidance materials are available: HACCP-1, Guidebook for the Preparation of HACCP Plans; HACCP-2, Meat and Poultry Products Hazards and Control Guide; HACCP-3, Generic