

# Rules and Regulations

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## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

#### 9 CFR Part 94

[Docket No. 01-094-1]

#### Change in Disease Status of Japan Because of BSE

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

**ACTION:** Interim rule and request for comments.

**SUMMARY:** We are amending the regulations by adding Japan to the list of regions where bovine spongiform encephalopathy exists because the disease has been detected in a native-born animal in that region. The effect of this action is restriction on the importation of ruminants that have been in Japan and meat, meat products, and certain other products of ruminants that have been in Japan. This action is necessary to help prevent the introduction of bovine spongiform encephalopathy into the United States.

**DATES:** This rule is effective retroactively to September 10, 2001. We invite you to comment on this docket. We will consider all comments that we receive by December 17, 2001.

**ADDRESSES:** Please send four copies of your comment (an original and three copies) to: Docket No. 01-094-1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. 01-094-1.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except

holidays. To be sure someone is there to help you, please call (202) 690-2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at <http://www.aphis.usda.gov/ppd/rad/webrepor.html>.

**FOR FURTHER INFORMATION CONTACT:** Dr. Gary Colgrove, Chief Staff Veterinarian, National Center for Import and Export, Sanitary Issues Management Staff, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737-1231; (301) 734-4356.

#### SUPPLEMENTARY INFORMATION:

##### Background

The regulations in 9 CFR parts 93, 94, 95, and 96 (referred to below as the regulations) govern the importation of certain animals, birds, poultry, meat, other animal products and byproducts, hay, and straw into the United States in order to prevent the introduction of various animal diseases, including bovine spongiform encephalopathy (BSE).

BSE is a neurological disease of bovine animals and other ruminants and is not known to exist in the United States. It appears that BSE is primarily spread through the use of ruminant feed containing protein and other products from ruminants infected with BSE. Therefore, BSE could become established in the United States if materials carrying the BSE agent, such as certain meat, animal products, and animal byproducts from ruminants, are imported into the United States and are fed to ruminants in the United States. BSE could also become established in the United States if ruminants with BSE are imported into the United States.

Sections 94.18, 95.4, and 96.2 of the regulations prohibit or restrict the importation of certain meat and other animal products and byproducts from ruminants that have been in regions in which BSE exists or in which there is an undue risk of introducing BSE into the United States. In § 94.18, paragraph (a)(1) lists the regions in which BSE exists. Paragraph (a)(2) lists the regions that present an undue risk of introducing BSE into the United States because their import requirements are less restrictive than those that would be

acceptable for import into the United States and/or because the regions have inadequate surveillance. Paragraph (b) of § 94.18 prohibits the importation of fresh, frozen, and chilled meat, meat products, and most other edible products of ruminants that have been in any region listed in paragraphs (a)(1) or (a)(2). Paragraph (c) of § 94.18 restricts the importation of gelatin derived from ruminants that have been in any of these regions. Section 95.4 prohibits or restricts the importation of certain byproducts from ruminants that have been in any of those regions, and § 96.2 prohibits the importation of casings, except stomach casings, from ruminants that have been in any of these regions. Additionally, the regulations in 9 CFR part 93 pertaining to the importation of live animals provide that the Animal and Plant Health Inspection Service may deny the importation of ruminants from regions where a communicable disease such as BSE exists and from regions that present risks of introducing communicable diseases into the United States (see § 93.404(a)(3)).

On September 10, 2001, Japan reported a suspected case of BSE in a native-born animal, and on September 22, 2001, Japan confirmed their diagnosis in a report to the Office International des Epizooties. Therefore, in order to reduce the risk of introducing BSE into the United States, we are amending § 94.18 (a)(1) by adding Japan to the list of regions where BSE is known to exist. The effect of this action is a restriction on the importation of ruminants that have been in Japan and on the importation of meat, meat products, and certain other products and byproducts of ruminants that have been in Japan. We are making this amendment effective retroactively to September 10, 2001, which is the date that BSE was reported in a native-born animal in that region.

#### Emergency Action

This rulemaking is necessary on an emergency basis to prevent the introduction of BSE into the United States. Under these circumstances, the Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest and that there is good cause under 5 U.S.C. 553 for making this rule effective less than 30 days after publication in the **Federal Register**.

We will consider comments that are received within 60 days of publication of this rule in the **Federal Register**. After the comment period closes, we will publish another document in the **Federal Register** that will include a discussion of any comments we receive and any amendments we are making to the rule as a result of the comments.

#### **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 under Executive Order 12866.

This emergency situation makes timely compliance with section 604 of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) impracticable. We are currently assessing the potential economic effects of this action on small entities. Based on that assessment, we will either certify that the rule will not have a significant economic impact on a substantial number of small entities or publish a final regulatory flexibility analysis.

#### **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 retroactive effect to September 10, 2001; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

#### **Paperwork Reduction Act**

This interim rule contains no 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, we are amending 9 CFR part 94 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 continues to read as follows:

**Authority:** 7 U.S.C. 450, 7711, 7712, 7713, 7714, 7751, and 7754; 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 371.4.

#### **§ 94.18 [Amended]**

2. In § 94.18, paragraph (a)(1) is amended by adding, in alphabetical order, the word "Japan,".

Done in Washington, DC, this 10th day of October 2001.

**W. Ron DeHaven,**

*Acting Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 01-25953 Filed 10-15-01; 8:45 am]

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### **DEPARTMENT OF AGRICULTURE**

#### **Food Safety and Inspection Service**

#### **9 CFR Parts 317 and 381**

**[Docket No. 97-001TF]**

**RIN 0583-AC35**

#### **Elimination of Requirements for Partial Quality Control Programs; Certification of Scales**

**AGENCY:** Food Safety and Inspection Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) is amending its regulations governing the certification for accuracy of scales used in federally inspected meat and poultry establishments. Under the final rule, official establishments may rely on State or local certification or data from documented procedures that demonstrate compliance with the National Institute of Standards and Technology Handbook 44. This final rule addresses an issue raised after publication of the May 30, 2000, final rule "Elimination of Requirements for Partial Quality Control (PQC) Programs," by clarifying that establishments may rely on data from documented procedures, and that FSIS will verify establishment compliance with regulations on the accuracy of scales based on data maintained by the establishments.

**EFFECTIVE DATE:** This final rule is effective November 15, 2001.

**FOR FURTHER INFORMATION CONTACT:** Daniel L. Engeljohn, Ph.D., Director, Regulations Development and Analysis Division, Office of Policy, Program Development, and Evaluation, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250-3700; (202) 720-5627, fax number (202) 690-0486.

#### **SUPPLEMENTARY INFORMATION:**

#### **Background**

On May 30, 2000, FSIS published the final rule "Elimination of Requirements for Partial Quality Control Programs" (65 FR 34381). The final rule, which became effective August 28, 2000, removed from the Federal meat and poultry products inspection regulations the remaining requirements pertaining to partial quality control (PQC) programs. A PQC program, as distinguished from a total quality control (TQC) system, controls a single product, operation, or part of an operation in a meat or poultry establishment. A TQC system controls all products and processes in an establishment. The final rule removed the design requirements for PQC programs and the requirements for establishments to have PQC programs for certain products or processes. The final rule was intended to make the regulations more consistent with the Pathogen Reduction (PR)/Hazard Analysis and Critical Control Points (HACCP) regulations and to give federally inspected establishments greater flexibility to adopt new technologies and methods that will improve food safety and other consumer protections.

#### **Status of Establishment PQC Programs**

After publication of the final rule, some establishments asked the Agency whether they could continue to use their PQC programs, including PQC programs for net weight. Some persons who contacted the Agency asked specifically about the status of PQC programs that control net weight. Some establishments believed that, if such programs were rescinded, their products would be subject to lot inspection by FSIS. FSIS answered that the final rule does not rescind PQC programs for net weight. Establishments can continue to use PQC programs for net weight, and the Agency will verify their compliance with net weight requirements based on data from such programs.

Others asked whether the Agency would recognize TQC system data or PQC net weight program data regarding the testing of scales. They referred to the fact that the final rule removes the requirement for an establishment to have a total quality control (TQC) system provision for net weight or a partial quality control (PQC) program for net weight control in lieu of displaying, on or near its scales, a valid certification from a State or local weights and measures authority or from