

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

Food Safety and Inspection Service

9 CFR Part 327

[Docket No. 01–029P]

RIN 0583–AC91

Addition of San Marino to the List of Countries Eligible To Export Meat and Meat Products to the United States

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to add San Marino to the list of countries eligible to export meat and meat products to the United States. Reviews of San Marino's laws, regulations, and other written materials show that its meat processing system meets requirements equivalent to all provisions in the Federal Meat Inspection Act (FMIA) and its implementing regulations.

Although a foreign country may be listed as eligible to export meat and meat products, products from that country must also comply with all other U.S. requirements, including those of the U.S. Customs Service and the restrictions under Title 9, part 94 of the Animal and Plant Health Inspection Service (APHIS) regulations that relate to the importation of meat and meat products from foreign countries into the United States. FSIS and APHIS work closely together to ensure that meat and meat products imported into the United States comply with the regulatory requirements of both agencies.

Establishments that would be certified under this proposed regulation would only be exporting pork products to the United States. Pork products from San Marino may be imported into the United States only if these products are from swine slaughtered in certified slaughter establishments located in other countries eligible to export meat to the United States and are processed in

certified establishments in San Marino. All meat products exported from San Marino to the United States would be subject to reinspection at the U.S. ports-of-entry by FSIS inspectors as required by law.

DATES: Comments must be received on or before October 12, 2004.

ADDRESSES: FSIS invites interested persons to submit comments on this proposed rule. Comments may be submitted by any of the following methods:

- Mail, including floppy disks or CD-ROM's, and hand-or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 300 12th Street, SW., Room 102 Cotton Annex, Washington, DC 20250.
- Federal eRulemaking Portal: Go to <http://www.regulations.gov>. Follow the online instructions at that site for submitting comments.

All submissions received must include the Agency name and docket number 01–029P.

All comments submitted in response to this proposal, as well as research and background information used by FSIS in developing this document, will be available for public inspection in the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday. The comments also will be posted on the Agency's Web site at <http://www.fsis.usda.gov/OPPDE/rdad/FRDockets.htm>.

FOR FURTHER INFORMATION CONTACT: Ms. Sally White, Director, International Equivalence Staff, Office of International Affairs; (202) 720–6400.

SUPPLEMENTARY INFORMATION:

Background

FSIS is proposing to amend the Federal meat inspection regulations to add San Marino to the list of countries eligible to export meat and meat products to the United States.

Section 20 of the FMIA (21 U.S.C. 620) prohibits the importation into the United States of carcasses, parts of carcasses, meat or meat food products of cattle, sheep, swine, goats, horses, mules, or other equines which are capable of use as human food that are adulterated or misbranded. The FMIA also requires that livestock from which imported meat products are produced be slaughtered and handled in connection with slaughter in accordance

with the Humane Slaughter Act (7 U.S.C. 1901–1906). Imported meat products must be in compliance with part 327 of title 9, Code of Federal Regulations (9 CFR part 327) to ensure that they meet the standards provided in the FMIA. 9 CFR 327.2 establishes the procedures by which foreign countries wanting to export meat and meat products to the United States may become eligible to do so.

Section 327.2(a) requires authorities in a foreign country's meat inspection system to certify that (1) the system provides standards equivalent to those of the United States and (2) the legal authority for the system and its implementing regulations are equivalent to those of the United States. Specifically, a country's regulations must impose requirements equivalent to those of the United States in the following areas: (1) Ante-mortem and post-mortem inspection; (2) official controls by the national government over plant construction, facilities, and equipment; (3) direct and continuous supervision of slaughter activities, where applicable, and product preparation by official inspection personnel; (4) separation of establishments certified to export from those not certified; (5) maintenance of a single standard of inspection and sanitation throughout certified establishments; (6) official controls over condemned product; and (7) requirements of a Hazard Analysis and Critical Control Point (HACCP) system within certified establishments.

Section 327.2 also requires a meat inspection system maintained by a foreign country, with respect to establishments preparing products in that country for export to the United States, to ensure that those establishments and their meat products comply with requirements equivalent to the provisions of the FMIA and the meat product inspection regulations. Foreign country authorities must be able to ensure that all certifications required under part 327 of the meat product inspection regulations (Imported Products) can be relied upon before USDA-FSIS will grant approval to export meat products to the United States.

In addition to meeting the certification requirements, a foreign country's inspection system must be evaluated by FSIS before eligibility to

export meat products can be granted. This evaluation consists of two processes: a document review and an on-site review. The document review is an evaluation of the laws, regulations, and other written materials used by the country to operate its meat inspection program. To help the country in organizing its material, FSIS gives the country questionnaires asking for detailed information about the country's inspection practices and procedures in five risk areas, which are the focus of the evaluation. These five risk areas comprise sanitation, animal disease, slaughter/processing, residues, and enforcement. FSIS evaluates the information to verify that the critical points in the five risk areas are addressed satisfactorily with respect to standards, activities, resources, and enforcement. If the document review is satisfactory, an on-site review is scheduled using a multi-disciplinary team to evaluate all aspects of the country's inspection program, including laboratories and individual establishments within the country.

The process of determining equivalence is described fully on the FSIS Web site at <http://www.fsis.usda.gov/OPPDE/IPS/EQ/EQProcess.htm>. Besides relying on its initial determination of a country's eligibility, coupled with ongoing reviews to ensure that products shipped to the United States are safe, wholesome and properly labeled and packaged, FSIS randomly samples imported meat and poultry products for reinspection as they enter the United States.

Evaluation of the San Marino Inspection System

In response to a request from San Marino in 1997 for approval to export meat and meat products to the United States, FSIS conducted a thorough review of the San Marino meat inspection system to determine if it was equivalent to the U.S. meat inspection system. First, FSIS compared San Marino's meat inspection laws and regulations with U.S. requirements. The study concluded that the requirements contained in San Marino's meat inspection laws and regulations are equivalent to those mandated by the FMIA and implementing regulations. FSIS then conducted an on-site review of the San Marino meat inspection system in operation. The FSIS review team concluded that San Marino's implementation of meat processing standards and procedures was equivalent to those of the United States.

All meat products exported to the United States from San Marino will be subject to reinspection at the ports-of-

entry for transportation damage, labeling, proper certification, general condition and accurate count. Other types of inspection will also be conducted, including examining product for defects and performing laboratory analyses to detect chemical residues or microbial contamination.

Products that pass reinspection will be stamped with the official mark of inspection and allowed to enter U.S. commerce. If they do not meet U.S. requirements, they will be "Refused Entry" and must be re-exported, destroyed or allowed entry for the purpose of converting to animal food.

Accordingly, FSIS is proposing to amend § 327 of the Federal meat inspection regulations to add San Marino as a country from which meat and meat products may be eligible for import into the United States. As a country eligible to export meat products to the United States, the government of San Marino would certify to FSIS those establishments wishing to export such products to the U.S. and operating according to U.S. requirements. FSIS would retain the right to verify that establishments certified by the San Marino government are meeting the U.S. requirements. This would be done through annual on-site reviews of the establishments while they are in operation.

Although a foreign country may be listed as eligible to export meat and meat products, products from that country must also comply with all other U.S. requirements, including those of the U.S. Customs Service and the restrictions under Title 9, part 94 of the Animal and Plant Health Inspection Service (APHIS) regulations that relate to the importation of meat and meat products from foreign countries into the United States. The Agency notes that APHIS has classified San Marino as having a substantial risk associated with Bovine Spongiform Encephalopathy (BSE). Although pork is the specific product proposed for import into the United States from San Marino, FSIS considered BSE risk in its evaluation process. APHIS is responsible for keeping foreign animal diseases out of the United States. APHIS sets forth restrictions on the importation of any fresh, frozen, and chilled meat, meat products, and edible products from countries in which certain animal diseases exist. Those products that APHIS has restricted from entering the United States will be refused entry.

FSIS and APHIS work closely together and communicate regularly to ensure that meat and meat products imported into the United States comply with the

regulatory requirements of both agencies.

The full report on San Marino can be found on the FSIS Web site at <http://www.fsis.usda.gov/OPPDE/Far/index.htm>.

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.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. It has been determined to be not significant for purposes of E.O. 12866 and therefore, has not been reviewed by the Office of Management and Budget (OMB).

There is only one establishment in San Marino that has applied to export meat products to the United States. This establishment would export non-shelf stable cooked meat products. U.S. imports from this establishment are expected to total approximately 500,000 pounds per year.

U.S. firms export small amounts of pork and poultry products to San Marino. Table A reports the most current information, from 1996–2000, on U.S. exports of poultry and pork products to San Marino. Poultry exports were highest in 1994, before declining and eventually falling to zero. Poultry exports reappeared again in 1998, but again at relatively low levels. Between 1994 and 2000, U.S. firms exported pork products to San Marino only once, in 1994. Since then, there have been no further exports of pork products.

Adoption of this proposed rule would continue to open trade between the U.S. and San Marino. This proposed rule would also increase the U.S. food supply.

The impact of this proposed rule on U.S. consumers is voluntary in that consumers will not be required to purchase meat products produced and processed in San Marino, although they may choose to do so. Expected benefits from this type of proposed rule would accrue primarily to consumers in the form of competitive prices due to a larger market variety of meat products. The volume of trade stimulated by this proposed rule, however, will likely be so small as to have little effect on supply and prices. Consumers, apart from any change in prices, would

benefit from increased choices in the marketplace.

The costs of this rule will accrue primarily to producers in the form of greater competition from San Marino.

Again, it must be noted that the volume of trade stimulated by this rule would be very small, likely having little effect on supply and prices. Nonetheless, it is possible that U.S. firms that produce

products that would compete with San Marino imports could face short-term difficulty. However, in the long run, such firms could adjust their product mix in order to compete effectively.

TABLE A.—U.S. EXPORTS OF POULTRY AND PORK PRODUCTS TO SAN MARINO 1996–2000

Calendar year	Quantity (tons)	Value (\$1,000)	Average price per ton
Poultry:			
1996	0	\$0.00	NA
1997	0	0.00	NA
1998	68	68	\$1.00
1999	24	14	0.58
2000	69	55	0.80
Pork:			
1996	0	\$0.00	NA
1997	0	0.00	NA
1998	0	0.00	NA
1999	0	0.00	NA
2000	0	0.00	NA

Effect on Small Entities

The Administrator, FSIS, has made an initial determination that this proposed rule will not have a significant impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601). This proposed rule would add San Marino to the list of countries eligible to export meat products into the United States. Currently, only one San Marino establishment has applied to export product to the United States. This establishment is planning to export approximately 500,000 pounds of non-shelf stable cooked meat products to the United States per year. The volume of trade stimulated by this rule would be very small, likely having little effect on supply and prices. Therefore, this proposed rule is not expected to have a significant impact on small entities that produce these types of products domestically.

Paperwork Requirements

No new paperwork requirements are associated with this proposed rule. Foreign countries wanting to export livestock products to the United States are required to provide information to FSIS certifying that its inspection system provides standards equivalent to those of the United States and that the legal authority for the system and its implementing regulations are equivalent to those of the United States before they may start exporting such product to the United States. FSIS collects this information one time only. FSIS gave San Marino questionnaires asking for detailed information about the country's inspection practices and procedures to assist the country in organizing its

materials. This information collection was approved under OMB number 0583–0094. The proposed rule contains no other paperwork requirements.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. In an effort to ensure that this notice comes to the attention of the public—including minorities, women, and persons with disabilities—FSIS will announce it on-line through the FSIS Web page located at <http://www.fsis.usda.gov>. The Regulations.gov Web site is the central online rulemaking portal of the United States government. It is being offered as a public service to increase participation in the Federal government's regulatory activities. FSIS participates in Regulations.gov and will accept comments on documents published on the site. The site allows visitors to search by keyword or Department or Agency for rulemakings that allow for public comment. Each entry provides a quick link to a comment form so that visitors can type in their comments and submit them to FSIS. The Web site is located at <http://www.regulations.gov>.

FSIS also will make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and other types of information that could affect or would be of interest to our constituents and stakeholders. The update is communicated via Listserv, a free e-mail subscription service consisting of industry, trade, and farm groups,

consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. The update also is available on the FSIS Web page. Through Listserv and the Web page, FSIS is able to provide information to a broader and more diverse audience.

List of Subjects in 9 CFR Part 327

Imports, Meat and meat products.

For the reasons set out in the preamble, 9 CFR part 327 would be amended as follows:

PART 327—IMPORTED PRODUCTS

1. The authority citation for part 327 would continue to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

§ 327.2 [Amended]

2. Section 327.2 would be amended by adding “San Marino” in alphabetical order to the list of countries in paragraph (b).

Done in Washington, DC, on August 1, 2004.

Barbara J. Masters,
Acting Administrator.

[FR Doc. 04–18567 Filed 8–12–04; 8:45 am]

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