

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 Parts 304, 327, 381, and 590

[Docket No. FSIS-2009-0022]

RIN 0583-AD39

Electronic Import Inspection Application and Certification of Imported Products and Foreign Establishments; Amendments To Facilitate the Public Health Information System (PHIS) and Other Changes To Import Inspection Regulations

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to amend the meat, poultry, and egg products import regulations to provide for the Agency's Public Health Information System (PHIS) Import Component. The PHIS Import Component, launched on May 29, 2012, provides an electronic alternative to the paper-based import inspection application and imported product foreign inspection and foreign establishment certificate processes. In addition, the Agency is proposing to delete the discontinued "streamlined" import inspection procedures for Canadian product and to require Sanitation Standard Operating Procedures (SOPs) at official import inspection establishments. In addition to the proposed regulatory amendments outlined above, FSIS is announcing its intention to discontinue its practice of conducting imported product reinspection based on a foreign government's guarantee to replace a lost or incorrect foreign inspection certificate and is clarifying its policy of addressing imported product that is not presented for reinspection.

DATES: Submit comments on or before January 28, 2013.

ADDRESSES: FSIS invites interested persons to submit comments on this

proposed rule. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the online instructions at that site for submitting comments.

- *Mail, including CD-ROMs, etc.:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW., Mailstop 3782, Room 8-163A, Washington, DC 20250-3700.

- *Hand- or courier-delivered submittals:* Deliver to Patriots Plaza 3, 355 E. Street SW., Room 8-163A, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2009-0022. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

Docket: For access to background documents or comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E. Street SW., Room 8-164A, Washington, DC 20250-3700 between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Ms. Mary Stanley, Director, International Policy Division, Office of Policy and Program Development, FSIS, U.S. Department of Agriculture, 1400 Independence Avenue SW., Room 2125, Washington, DC 20250-3700, Phone: (202)720-0287.

SUPPLEMENTARY INFORMATION:

Background

The Federal Meat Inspection Act (FMIA) (21 U.S.C. 620) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 466) prohibit the importation of meat and poultry products into the United States if such products are adulterated or misbranded and unless they comply with all the inspection and other requirements of the Acts and regulations as are applied to domestic products. The Egg Products Inspection Act (EPIA) (21 U.S.C. 1046) prohibits the importation of egg products unless

they were processed under an approved continuous inspection system of the government of the foreign country of origin and comply with the other pertinent requirements of the Act and regulations as are applied to domestic products.

Foreign Establishment Certificate

The meat and poultry products import regulations require that an official of the foreign inspection system determine and certify, on an annual basis, only those foreign establishments that are eligible to have their products imported into the United States (9 CFR 327.2(a)(3) and 381.196(a)(3)). The certificate prescribes a narrative statement format for certifying that the establishments fully comply with all of the requirements applied to official establishments in the United States and otherwise meet the requirements of 9 CFR 327.2(a) and 381.196(a). The certificate must list the name, address, and control number (the establishment number assigned by the foreign inspection agency) of each establishment and include the foreign official's title, signature, and date.

The egg products import regulations require that egg products imported into the United States must be from foreign countries that comply with the EPIA and the applicable regulations (9 CFR 590.910). When FSIS determines that a foreign country is eligible to import egg products into the United States, the foreign country is listed in 9 CFR 590.910(b).

Imported Product Foreign Inspection Certificates

The meat, poultry, and egg products import regulations require a foreign inspection certificate for every shipment of product imported into the United States (9 CFR 327.4, 381.197, and 590.915). The regulations provide for four foreign product inspection certificates—a fresh meat and meat byproducts certificate, a meat food product certificate, a poultry product certificate, and an egg products certificate.

The regulations also prescribe a narrative statement and format, certifying that the product was derived from livestock and poultry that received ante-mortem and post-mortem veterinary inspections at the time of slaughter in establishments certified for importation of their products into the

United States, is not adulterated, and is in compliance with requirements equivalent to domestic requirements. The egg products inspection certificate must certify that the product was produced under the approved regulations, requirements, and continuous government inspection of the exporting country.

In addition, the regulations require specific information about the product, including the kind of product, the consignor and consignee (for meat and poultry product certificates), the importer and exporter (for egg product certificates), the weight, the identification marks on the product, the establishment number, the number of containers, and the shipping marks. The certificates must also include the date of certification and the name, title, and signature of the foreign official authorized to issue inspection certificates. Each foreign meat inspection certificate must be both in English and the language of the foreign country and bear the official seal of the national government agency responsible for the inspection of the product. The meat and poultry products foreign inspection certificate is required to be in the form illustrated in 9 CFR 327.4(a) and (b) and 381.197(b).

Import Inspection Application

The FSIS meat, poultry, and egg products import regulations require importers to apply for the inspection of imported product (9 CFR 327.5, 381.198, and 590.920).

Prior to the PHIS Import Component implementation, applicants submitting paper-based applications completed FSIS Form 9540-1, "Import Inspection Application and Report," for meat and poultry products and, for egg products, FSIS Form 5200-8, "Import Request Egg Products." The import inspection application forms were submitted to FSIS import inspection program personnel.

Prior Notification of Imported Product

The meat, poultry, and egg products import regulations require that the importer apply for the inspection of imported product as long as possible in advance of the anticipated arrival of each consignment (9 CFR 327.5(b), 381.198(a), and 590.920). Prior to the PHIS Import Component implementation, meat and poultry products applications (FSIS Form 9540-1) were submitted to import inspection personnel when the product was presented for reinspection at an official import inspection establishment. For egg products, applicants submitted the import inspection application (FSIS

Form 5200-8) to FSIS electronically by facsimile or email prior to the product entering the country.

Streamlined Inspection Procedures for Canadian Products

The meat and poultry product import regulations require that products be reinspected before they are allowed entry into the United States (9 CFR 327.6 and 381.199). The regulations require that every lot of imported product be given a visual inspection for appearance and condition, proper certification, and labeling compliance (9 CFR 327.6(a)(2) and 381.199(a)(2)). Reinspection levels and procedures are computer generated based on established sampling plans, or established sampling plans and established product and plant history (9 CFR 327.6(a)(3) and 381.199(a)(3)).

For participating Canadian establishments, the meat and poultry import regulations provide "streamlined" inspection procedures on a voluntary basis (9 CFR 327.5 (d) and 381.199(b)). Under these streamlined procedures, Canadian officials contact FSIS import offices directly for reinspection assignments. If the shipment is not designated for reinspection, it can proceed to the consignee for further distribution. If the shipment is designated for reinspection, Canadian officials select the samples according to USDA sampling tables and identify and place the samples in the vehicle for easy removal and reinspection by an FSIS import inspector. These streamlined procedures were provided in January 1989 to further the goal of the 1988 U.S.-Canada Free Trade Agreement to reduce trade restrictions between the United States and Canada.

Sanitation Standard Operating Procedures (SOPs) Requirements for Official Import Inspection Establishments

FSIS meat import regulations require that all imported products be inspected only at an official establishment or at an official import inspection establishment (9 CFR 327.6(b)). Owners or operators of establishments where imported product is inspected must furnish adequate sanitary facilities and equipment for examining the product and, as a condition for approval, must comply with the provisions of the sanitation regulations, 9 CFR 416.1 through 416.6 (9 CFR 327.6(e)). However, 9 CFR 327.6(e) does not require that official import inspection establishments comply with the Sanitation SOP requirements provided in 9 CFR 416.11 through 416.17.

FSIS poultry and egg products import regulations do not require product inspection only at an official establishment or official import inspection establishment. However, in practice, imported poultry and egg products are inspected only at official establishments or official import inspection establishments.

PHIS Import Component

FSIS launched the PHIS Import Component on May 29, 2012. The PHIS Import Component replaced the Agency's Automated Import Inspection System (AIIS) and integrated and automated its paper-based business processes into one comprehensive and automated data-driven import inspection system. The PHIS enables U.S. importers to file for FSIS inspection in advance of arrival of shipments destined to the United States. The PHIS also enables the receipt of electronic foreign health certificate information that provides a secure and timely advance notice of a foreign shipment certified by a foreign government.

Information on implementation of the PHIS Import Component is provided on the FSIS Web site at http://www.fsis.usda.gov/regulations_and_policies/PHIS_Import_Component/index.asp. FSIS is also coordinating with foreign countries to enable the electronic submission of the foreign establishment and foreign inspection certifications. Any updated information will be posted on the Agency's PHIS Import Component Web site.

PHIS and the Automated Commercial Environment (ACE) Interface

FSIS has actively participated in the development of the International Trade Data System (ITDS), a government-wide project to build an electronic "single-window" for collecting and sharing trade data for reporting imports and exports among federal agencies. The goal of the ITDS is to eliminate the redundant reporting of data, replacing multiple filings, many of which are on paper, with a single electronic filing. The U.S. Customs and Border Protection (CBP) has developed the Automated Commercial Environment (ACE), a U.S. commercial trade processing system that automates border processing of products. The ACE system connects the trade community and participating government agencies by providing a single, centralized, online access point. When applicants file entries with the CBP through ACE, relevant data is electronically distributed to appropriate government agencies.

The PHIS interfaces with the ACE, permitting the direct electronic transfer of imported meat, poultry, and egg products data directly into the PHIS Import Component. FSIS considers any electronic data transferred from ACE into the PHIS Import Component as certified by the applicant. In addition, FSIS considers any electronic records, digital images, data, or information from a foreign government for foreign inspection and foreign establishment certification to be equivalent to paper records and certified by the foreign government.

When developing, procuring, maintaining, or using electronic and information technology (EIT), federal agencies are required by Section 508(a)(1)(a) of the Rehabilitation Act of 1973 (29 U.S.C. 794d) to ensure that EIT is accessible to people with disabilities, including employees and members of the public. The PHIS Import Component meets these requirements.

Proposed Amendments

Foreign Establishment Certification

As discussed above, FSIS meat and poultry import inspection regulations require an official of the foreign government to determine and certify the foreign establishments that are eligible to export their products into the United States. The regulations require a prescriptive narrative statement certifying that the establishments fully meet the requirement of 9 CFR 327.2(a)(2)(i) and (ii) and 381.196(a)(2)(i) and (ii). The establishment certificate must also include: the date; the foreign country; the foreign establishment's name, address, and control number (the foreign establishment's number assigned by the foreign country); and the foreign official's title and signature.

FSIS is proposing to amend 9 CFR 327.2(a)(3) and 381.196(a)(3) to provide concise regulatory language, delete the prescriptive narrative statement on the certificate, and require (in addition to information listed above): the type of operations conducted at the foreign establishment (e.g., slaughter, processing, storage, exporting warehouse), and the establishment's eligibility status (i.e., identify establishments that have been added or delisted and subsequently relisted since the last annual certification). In addition, for slaughter and processing establishments, the Agency is proposing to require the species and type of products produced and the process category. This information is necessary to ensure that FSIS has complete information on the types of products

produced and the types of operations conducted in each foreign establishment.

Because the foreign establishment certification regulations are currently paper-based, FSIS is proposing to provide for the electronic transmittal of foreign establishment certifications to FSIS from foreign governments. FSIS will continue to require that foreign establishment certifications be renewed on an annual basis and that, consistent with current procedures, paper certificates, if used, be submitted to FSIS Headquarters.

As discussed above, the egg products import regulations provide for foreign country (not establishment) certification to export to the United States. FSIS is not proposing foreign establishment eligibility requirements for imported egg products at this time. The Agency will propose foreign establishment certification in a separate proposed rule, currently under development.

Imported Product Foreign Inspection Certificates

As discussed above, the foreign product inspection certificate regulations provide four types of certificates—a fresh meat and meat byproducts certificate, a meat food product certificate, a poultry product certificate, and an egg products certificate. The meat and poultry certificates contain a form with a prescriptive narrative statement certifying that the products listed on the certificate are in compliance with equivalent U.S. requirements in the Acts and regulations. The imported egg products foreign inspection certificate regulation specifies the required information.

To clarify and simplify the foreign inspection certificate requirement, FSIS is proposing to require the same information for meat, poultry, and egg products and delete the prescriptive narrative and format requirements for meat and poultry foreign inspection certificates. The meat and poultry products foreign inspection certificate's narrative statement reiterates the requirements in 9 CFR 327.2 and 381.196 with respect to ante-mortem and post-mortem inspection, establishment certification, sanitary handling of product, and requirements equivalent to those in Acts and relevant regulations, and therefore, is unnecessary. The prescriptive formatting requirements (i.e., certificate title, headings, lines) for meat and poultry foreign inspection certificates are also unnecessary.

The Agency is also proposing to delete the requirement that the meat

foreign inspection certificates bear the official seal of the government agency responsible for the inspection of the product and be in the language of the foreign country of origin (9 CFR 327.4(c) and (d)). The certificates must in English so they can be read by U.S. import inspectors, and the seal has no purpose. In addition, the Agency is proposing to delete the requirement that the meat and poultry inspection certificate identify the foreign city. The foreign establishment number provides sufficient information to identify the foreign city.

The egg products foreign inspection certificate requires the name and address of the importer and the exporter, but not the name and address of the consignee and the consignor. The meat and poultry products foreign inspection certificate requires the consignor and consignee addresses, but not the importer and exporter addresses. The "exporter" is the party in the foreign country that sold the product. The "importer" is the party in the United States to whom the overseas shipper sold the imported product. The "consignee" is the party that holds the product for sale or for delivery. The "consignor" is the party that delivers the product to the consignee. The Agency is proposing to amend its regulations to require the identity and address of the consignee, consignor, exporter, and importer and is proposing that this information be provided for meat, poultry, and egg product inspection certificates. The Agency is also proposing to delete the product "destination" requirement since it will be replaced with the "consignee address." This information provides additional contact information concerning who owns or is responsible for the product, where the product is coming from, and its destination.

In addition to the current required information, the Agency is proposing to require: the source country and foreign establishment number for the source material when the source materials originate from a country other than the exporting country; and the product's description, including the process category, the product category, and the product group.

The product's source information is needed to verify that the source materials are from countries and establishments eligible to export products to the United States, and that the product itself is eligible to be imported into the United States. The product description information, including the process category, the product category, and the product group provides further information about the

product and assists in accurately assigning product reinspections and laboratory testing. FSIS also collects this information in PHIS for domestic plants. Examples of process categories include: raw product (non-intact)—ground; raw product (intact)—not ground; thermally processed (commercially sterile); not heat treated (shelf stable); heat treated (shelf stable); fully cooked (not shelf stable); and heat treated but not fully cooked (not shelf stable). Within these process categories are the product categories, e.g., raw ground, comminuted, or otherwise non-intact (species); raw intact (species); not ready-to-eat otherwise processed (species); ready-to-eat dried meat; and ready-to-eat fully cooked (species). Within the product categories are the product groups, e.g., ground beef, hamburger, carcass, primals, sausage, ham, soups. FSIS will issue guidelines to assist foreign governments in completing the process category, product category, and product group portion of the foreign inspection certificate.

Because the foreign inspection certification regulations are currently paper-based, FSIS is proposing to amend the foreign product inspection certificate regulations to provide for the electronic transmittal of foreign inspection certifications. For electronic foreign inspection certifications, foreign governments will transmit data, which will serve as the certification that the product meets the FSIS regulatory requirements.

In addition, FSIS is proposing that the Administrator may specifically request any additional information necessary to determine whether the product is eligible to be imported into the United States. Such information may include, when appropriate, production date information. Production date information will be requested when restrictions have been placed on the country, the foreign establishment, or its products, to determine whether the product was produced in the foreign establishment during an eligible or ineligible timeframe. Import inspection personnel will notify the importer or the foreign official when additional information is required.

Import Inspection Application

The Agency has revised FSIS Form 9540–1, Import Inspection Application, to include egg products and additional information the Agency needs to accurately assign reinspection tasks and sampling of the product. FSIS will ensure that copies of this revised application are available to applicants in paper format.

FSIS is proposing to amend the imported product inspection application regulations (9 CFR 327.5, 381.198, and 590.920) to require that applicants submit FSIS Form 9540–1, Import Inspection Application, to import inspection personnel for the inspection of any product offered for entry into the United States. The Agency is also proposing to provide the option of submitting the application electronically or in paper.

As discussed above, the PHIS Import Component interfaces with the ACE, permitting the direct electronic transfer of relevant data from imported meat, poultry, and egg products entries submitted through ACE into the PHIS. Applicants that are filing at ports that are not under CBP control (e.g., American Samoa, Guam) can continue to submit paper import inspection applications to FSIS inspection personnel at an official import inspection establishment.

Prior Notification of Imported Product

As discussed above, FSIS requires importers to provide advance notice, as long in advance as possible, before the anticipated arrival of each consignment (9 CFR 327.5, 381.198, and 590.920). FSIS will continue to require advance notification but is proposing to revise the regulations to make clear that applicants must submit electronic or paper import inspection applications to FSIS in advance of the shipment's arrival but no later than when the entry is filed with CBP. Paper applications must be submitted to the official import establishment where the reinspection is to be performed.

Streamlined Inspection Procedures for Canadian Products

As discussed above, the meat and poultry import regulations provide streamlined inspection procedures for products imported from Canada (9 CFR 327.5 and 381.198). The Canadian streamlined procedures became effective January 1989.

In response to a congressional request, the General Accounting Office (now known as the Government Accountability Office, or GAO) reviewed, among other things, how the streamlined inspection procedures differed from past procedures, and how the procedures affected the imported product rejection rate between 1988 and 1989. The GAO issued its findings in July 1990.¹

¹ "Food Safety—Issues USDA Should Address Before Ending Canadian Meat Inspections," United States General Accounting Office Report to Congressional Requestors AO/RCED–90–176, July 1990.

In response to how the streamlined procedures differed from past procedures, the GAO reported that under the new procedures, Canadian shipments were no longer unloaded at a border inspection facility and given the routine visual inspection for general condition and labeling compliance. Canadian government inspectors called FSIS field offices to determine whether a shipment would be subject to comprehensive inspection. Shipments not assigned inspection could proceed directly to their delivery point. If the shipment was selected for a random comprehensive inspection, a Canadian inspector would select the sample, following FSIS instructions, and place it in an accessible location in the back of the truck, eliminating the need for unloading the entire vehicle. After passing through U.S. Customs, the shipment went to an import inspection facility where the selected samples were examined by an FSIS inspector. The GAO expressed concern that FSIS had no control procedure to ensure that samples were pulled in accordance with FSIS instructions. The FSIS inspectors union expressed concern about this procedure because it reduced the control its members had over the inspection process.

In response to how the streamlined procedures affected the rejection rates, GAO reported that the rates were higher in 1989 (the year the streamlined procedures were in effect) than in 1988. However, neither FSIS nor GAO could determine the cause and significance of the increased rejection rate. Because of issues raised in the GAO report, in 1992, the Agency suspended using the streamlined inspection procedures for Canadian product.

FSIS is proposing to delete the discontinued streamlined procedures provided in 9 CFR 327.5(d) and 381.198(b). The Agency is also proposing to amend 9 CFR 327.1 and 381.195, to revise paragraph designations and to remove specific references to "for product from eligible countries other than Canada" (9 CFR 327.1(a)(2) and 381.195(a)(2)) and delete paragraphs 9 CFR 327.1(a)(3) and 381.195(a)(3), that provide specific definitions for "product from Canada."

Sanitation Standard Operating Procedures (SOPs) Requirements for Official Import Inspection Establishments

As discussed above, 9 CFR 327.6(e) requires that official import inspection establishments, as a condition of approval, meet the sanitation requirements in 9 CFR 416.1 through 416.6. However, the requirements do

not include the Sanitation SOPs in 9 CFR 416.11 through 416.17. Sanitation SOPs are written procedures official establishments are required to develop, implement, and maintain to prevent the direct contamination or adulteration of meat or poultry products.

FSIS is proposing to amend 9 CFR 327.6 (e) to require that an official import inspection establishment must, in order to receive grant of inspection, meet the Sanitation SOPs requirements in 9 CFR 416.11 through 416.17. If this proposed amendment is finalized, official import inspection establishments operating under a grant of inspection must develop and implement written Sanitation SOPs within 60 days after of the publication of the final rule.

In addition, the Agency is proposing to amend the poultry products regulations (9 CFR 381.199) to parallel the meat import regulations requiring that all imported poultry products be inspected only at an official establishment or at an official import inspection establishment approved by the Administrator and the requirements for the conditions of approval (9 CFR 327.6(b), (c), (d), (f), (g), and (h)). Imported poultry products are currently reinspected at an official establishment or import inspection establishment, and this amendment is intended to clarify this requirement.

The Agency is also amending 9 CFR 381.1, "Definitions" to include the definition of "Official Import Inspection Establishment," to parallel the definition in 9 CFR 301.2.

In addition, FSIS is proposing to amend the "Conditions for receiving inspection" regulations (9 CFR 304.3(a) and 381.22(a)) to clarify that before being granted federal inspection, establishments and official import inspection establishments, must develop written sanitation Standard Operating Procedures (9 CFR 416.12 through 416.7).

Imported egg products are also inspected at official establishments or official import establishments. FSIS is not proposing amendments to the egg products import regulations at this time. The Sanitation SOP requirements for egg products are included in a separate proposed rule, currently under development.

Other Proposed Amendments

FSIS is proposing to amend the poultry products import regulations (9 CFR 381.195(a)(2)(ii)) to replace the meat import regulation citation (9 CFR 327.6) with the correct poultry products regulation citation (9 CFR 381.204), "Marking of poultry products offered for

entry; official import inspection marks and devices."

Discontinued Import Practice and Enforcement Notification

In addition to the proposed regulatory amendments outlined above, FSIS is announcing that it will end two practices involving imported meat, poultry, and egg products, as discussed below. FSIS is providing 60 days for comment on the changes to these practices.

30-Day Guarantee Foreign Inspection Certificate Replacement

As discussed above, meat, poultry and egg products imported into the United States must be accompanied by foreign inspection certificates (9 CFR 327.4, 381.197, and 590.915). Currently, when an official foreign inspection certificate is lost in transit or contains errors (e.g., wrong product name, species, or quantity of contents, missing foreign official signature), FSIS allows importers (applicants) to request that the foreign country replace the certificate. The foreign country can guarantee the replacement of the certificate within 30 days of the importer's (applicant's) request. When FSIS receives the foreign government's guarantee to replace the certificate, the Agency proceeds with reinspection and permits accepted imported product to enter U.S. commerce.

FSIS is announcing its intention to discontinue the practice of reinspecting imported product based on the foreign government's guarantee to replace the lost or incorrect foreign inspection certificate. If certifications are lost or contain mistakes, they can easily be replaced within a short timeframe. A replacement certificate can be sent to FSIS in a Portable Document Format (PDF) by email (importinspection@fsis.usda.gov) or by an expedited mail service, or it can be transmitted electronically through the PHIS. When the regulatory amendments in this proposal are finalized, FSIS will end its practice of reinspecting imported product based on the foreign government's guarantee to replace the foreign inspection certificate. FSIS will only reinspect imported product upon receipt of the foreign inspection certificate.

Failure To Present (FTP) Imported Product for Reinspection

Imported product destined for FSIS import reinspection may sometimes bypass reinspection and enter commerce, where it may be further processed into other products or be offered for sale to the consumer. This

bypassing of FSIS reinspection constitutes a "failure to present" (FTP) and violates the Acts.

Through the PHIS Import Component, FSIS is able to more effectively and efficiently monitor the movement of imported product. Therefore, when a shipment has been identified as FTP, FSIS will request, through the CBP, a re-delivery and appropriate penalties. If FSIS finds FTP product in distribution channels, the Agency will control the product (e.g., retain or detain the product) or request a recall of the product. If FSIS finds FTP product in an official establishment that is being used in further processed product, FSIS will condemn the FTP product and any further processed product that contains the FTP product. The FTP product that is contained intact in the original cartons from the foreign country can return to an official import inspection establishment, where the FSIS import inspection personnel will stamp the product as "refused entry."

Executive Order 12866 and Executive Order 13563

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a "significant regulatory action" under section 3(f) of Executive Order 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget.

Benefits and Costs of the Proposed Rule

The changes under this proposed rule are necessary to provide for the Agency's PHIS Import Component. The PHIS Import Component facilitates trade with foreign countries by providing the electronic exchange of import data and documentation. The PHIS Import Component interfaces with the ACE to provide the automatic transfer of all import-related data among FSIS and other government agencies that regulate trade, such as the CBP. This transfer of data creates new safety standards and strengthens existing ones.

The PHIS Import Component enables FSIS import inspection personnel to verify import shipments using electronic data. The Agency estimates that electronic imported product

information reduces the data-entry time for import inspectors by 50 to 60 percent. This does not mean that the Agency is going to reduce the number of import inspectors based on enhanced PHIS-related efficiencies. This proposed rule streamlines existing import documentation requirements by making the foreign inspection certificate consistent among meat, poultry, and egg products. In addition, the proposed rule updates the required information on applications and certificates to fortify the effectiveness of import inspection regulations. For example, for the import inspection application (FSIS Form 9540-1), the Agency is proposing to require the source country and establishment number when the source materials originate from a country other than the exporting country and the product's production dates. The additional information would help verify that source products are from countries and establishments eligible to export products to the United States, and that the product itself is eligible for importation. The additional information will also assist inspection and enforcement personnel in tracing, retrieving, and controlling product in the event of a recall.

Several changes under this proposed rule may have a cost impact on the industry. Should this proposed rule become final, the Agency believes the impacts will be very small, if any. The impacts would be as follows:

(1) *The electronic foreign inspection and foreign establishment certificates and the electronic import inspection application.* Under this proposed rule, the industry would have the option of filing import inspection applications electronically, and foreign governments would have the option of submitting electronic inspection and foreign establishment certifications and data. Since the electronic option is voluntary, applicants and the foreign countries would choose to file electronically only if it is beneficial to do so.

(2) *Additional information entry.* This proposed rule, if finalized, requires additional information for the import inspection application, which will increase the amount of time to fill out the application. The time needed to provide the additional information will depend on (1) the number of lots, and (2) how the information is entered.

Some of the information required on the new import inspection application is data that are required by other government agencies, such as CBP, and are entered by the applicant into the ACE system. The ACE electronically transmits data elements into PHIS, eliminating the need for entering all of

the data requested on the electronic form.

For applicants that submit a paper-based import inspection application, FSIS estimates that it will take 6 more minutes to complete the new application, based on a comparison between the old and the new paper-based application. FSIS also estimates that electronically filing the import inspection application will take, on average, an additional minute per application in comparison with the old paper-based application.² Agency data show that there are, on average, a total of 44,480 applications per year that will be filed electronically using the ACE, and that 2,317 applications per year will be completed manually.³ Therefore, the total additional time for electronically filing the application will be 741 hours ($44,480 * 1/60 = 741$) and the additional time for completing the new paper-based application will be 232 hours ($2,317 * 6/60 = 232$). Monetizing these hours by \$37 per hour,⁴ the estimated cost to complete the new application would be about \$36,000 ($\$37 * (232 + 741)$) per year.

(3) *Sanitation Standard Operating Procedures (SOPs) as a condition of approval for official import inspection establishments.* The proposed rule will clarify that official import inspection establishments must have developed written Sanitation SOPs before being granted approval. If this proposed amendment is finalized, official import inspection establishments will be given 60 days after the publication of the final rule to develop and implement written Sanitation SOPs. Since, in practice, many official import inspection establishments maintain sanitation SOPs during the reinspection of imported products, the proposed amendment requiring sanitation SOPs will have little cost impact (including recordkeeping cost impact) on the industry.

The proposed rule will remove the regulatory provisions for the streamlined import inspection system for Canadian product. Since the procedures have been obsolete since 1992, removing the regulatory

² Time estimate from International Policy Division, Office of Policy and Program Development, FSIS, USDA.

³ Number of applications from International Policy Division, Office of Policy and Program Development, FSIS, USDA.

⁴ Bureau of Labor Statistics "Occupational Employment & Wages" Database, May 2010. Animal Production Managers, all other \$51.54 @ 47.6% time; General and Operations Managers \$33.08 @ 26.2% time; Food scientists and technologists \$14.49 @ 26.2% time = \$37.00 Managerial Median hourly wage.

provisions will have no significant economic impact.

Regulatory Flexibility Analysis

The FSIS Administrator has made a preliminary determination that, for the purposes of the Regulatory Flexibility Act (5 U.S.C. 601-602) this proposed rule would not have a significant impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act. If small entities are unable to meet the requirements necessary to use the electronic import system, FSIS would continue to accept paper applications. Similarly, the other changes proposed in the rule would not result in significant costs to industry and, therefore, would not have a significant impact on a substantial number of small entities.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this proposed rule: (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) no retroactive proceedings will be required before parties may file suit in court challenging this rule.

Executive Order 13175

This proposed rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

Paperwork Reduction Act

In accordance with section 3507(j) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection requirement included in this proposed rule concerning the Import Inspection Application (FSIS Form 9540-1) was submitted to OMB for approval as part of the Public Health Information System (PHIS) information collection request. At that time, FSIS anticipated the changes to the Import Inspection Application that it is now proposing and described them in the PHIS information collection request to OMB, which approved the information collection and assigned it OMB control number 0583-0153.

In addition, FSIS has submitted an information collection to OMB for the new information collection associated with the proposed rule.

Title: Electronic Import Inspection
Type of Collection: New

Abstract: Under this proposed rule, FSIS is proposing to require foreign governments to submit additional information when submitting both the foreign establishment certificate and the foreign inspection certificate to FSIS in order for foreign establishments to be permitted to import product to the United States. The current information collection associated with these two certificates is approved under OMB control number 0583-0094.

FSIS is also proposing to require official import inspection establishments to develop, implement, and maintain written Sanitation Standard Operating Procedures (SSOPs), as provided in 9 CFR 416.11 through 416.17.⁵

Estimate of Burden: FSIS estimates that it will take 27.8 hours per foreign government (foreign establishment and foreign inspection certificates) and 157.6 hours per official import inspection establishment (SSOP requirements).

Respondents: Foreign governments (foreign establishment and foreign inspection certificates) and official import inspection establishments (SSOP requirements).

Estimated Number of Respondents: 30 foreign governments and 120 official import inspection establishments.

Estimated Number of Responses per Respondent: 556 responses per foreign government and 523 responses per official import inspection establishments annually.

Estimated Total Annual Burden on Respondents: 834 hours for foreign governments and 18,920 hours for official import inspection establishments for a total of 19,754 hours.

Copies of this information collection assessment can be obtained from John O'Connell, Paperwork Reduction Act Coordinator, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW., Room 6083, South Building, Washington, DC 20250-3700.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of FSIS's functions, including whether

the information will have practical utility; (b) the accuracy of FSIS's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent to both John O'Connell, Paperwork Reduction Act Coordinator, at the address provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253. To be most effective, comments should be sent to OMB within 60 days of the publication date of this proposed rule.

E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, *et seq.*) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

Additional Public Notification

FSIS will announce this rule online through the FSIS Web page located at http://www.fsis.usda.gov/regulations_&_policies/Proposed_Rules/index.asp

FSIS will also 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, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at http://www.fsis.usda.gov/News_&_Events/Email_Subscription/.

Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

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List of Subjects

9 CFR Part 304

Application for inspection; Grant of inspection

9 CFR Part 327

Imported products

9 CFR Part 381

Poultry products inspection regulations

9 CFR Part 590

Inspection of eggs and egg products (Egg Products Inspection Act)

For the reasons set discussed in the preamble, FSIS proposes to amend 9 CFR Chapter III as follows:

PART 304—APPLICATION FOR INSPECTION; GRANT OF INSPECTION

1. The authority citation for Part 304 continues to read as follows:

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

2. In § 304.3, revise paragraph (a) to read as follows:

§ 304.3 Conditions for receiving inspection.

(a) Before being granted Federal inspection, an official establishment or an official import inspection establishment must have developed written Sanitation Standard Operating

⁵ The "Benefits and costs of the proposed rule" section (above) did not include Sanitation Standard Operating Procedures (Sanitation SOPs) costs. While not currently required, in practice, Import Inspection Establishments maintain Sanitation SOPs; therefore, the proposed rule would not be adding any further costs to import inspection establishments. However, incorporating the Sanitation SOPs into FSIS's regulations requires OMB approval of the associated information collection burden. The cost analysis also did not address the expanded questions addressed to foreign governments because the costs would be experienced by foreign entities.

Procedures, as required by part 416 of this chapter.

* * * * *

PART 327—IMPORTED PRODUCTS

3. The authority citation for Part 327 continues to read as follows:

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

4. In § 327.1, revise paragraph (a) to read as follows:

§ 327.1 Definitions; application of provisions.

(a) When used in this part, the following terms are defined to mean:

(1) *Import (imported)*. To bring within the territorial limits of the United States whether that arrival is accomplished by land, air, or water.

(2) *Offer(ed) for entry*. The point at which the importer presents the imported product for reinspection.

(3) *Entry (entered)*. The point at which imported product offered for entry receives reinspection and is marked with the official mark of inspection, as required by § 327.26.

* * * * *

5. In § 327.2, revise paragraph (a)(3) to read as follows:

§ 327.2 Eligibility of foreign countries for importation of products into the United States.

(a) * * *

(3) Only those establishments that are determined and certified to the Agency by a responsible official of the foreign meat inspection system as fully meeting the requirements of paragraphs (a)(2)(i) and (ii) of this section are eligible to have their products imported into the United States. Establishment eligibility is subject to review by the Agency (including observations of the establishments by Program representatives at times prearranged with the foreign meat inspection system officials). Foreign establishment certifications must be renewed annually. Notwithstanding certification by a foreign official, the Administrator may terminate the eligibility of any foreign establishment for the importation of its products into the United States if it does not comply with the requirements listed in paragraphs (a)(2)(i) and (ii) of this section, or if current establishment information cannot be obtained. The Administrator will provide reasonable notice to the foreign government of the proposed termination of any foreign establishment, unless a delay in terminating its eligibility could result in the importation of adulterated or misbranded product. The electronic

foreign establishment certification or paper certificate must contain: the date; the foreign country; the foreign establishment's name, address, and foreign establishment number; the foreign official's title; the foreign official's signature (for paper certificate only); the type of operation(s) conducted at the establishment (e.g., slaughter, processing, storage, exporting warehouse); and the establishment's eligibility status (e.g., new or relisted (if previously delisted)). Slaughter and processing establishment certifications must address the species and type of product(s) produced at the establishment and the process category.

* * * * *

6. Revise § 327.4 to read as follows:

§ 327.4 Foreign inspection certificate requirements.

(a) Except as provided in § 327.16, each consignment imported into the United States must have an electronic foreign inspection certification or a paper foreign inspection certificate issued by an official of the foreign government agency responsible for the inspection and certification of the product.

(b) An official of the foreign government must certify that any product described on any official certificate was produced in accordance with the regulatory requirements in § 327.2.

(c) The electronic foreign inspection certification must be in English, be transmitted directly to FSIS before the product's arrival at the official import inspection establishment, and be available to import inspection personnel.

(d) The paper foreign inspection certificate must accompany each consignment, be submitted to import inspection personnel at the official import inspection establishment, be in English, and bear the signature of the official authorized to issue inspection certificates for products imported to the U.S.

(e) The electronic foreign inspection certification and paper foreign inspection certificate must contain:

(1) The date, name, and title of the official authorized to issue inspection certificates for products imported into the U.S.;

(2) The foreign country of export and the producing foreign establishment number;

(3) The species used to produce the product and the source country and foreign establishment number, if the source materials originate from a country other than the exporting country;

(4) The product's description, including the process category, the product category, and the product group;

(5) The name and address of the consignor;

(6) The name and address of the exporter;

(7) The name and address of the consignee;

(8) The name and address of the importer;

(9) The number of units (pieces or containers) and the shipping or identification mark on the units;

(10) The net weight of each lot; and

(11) Any additional information the Administrator requests to determine whether the product is eligible to be imported into the U.S.

7. Revise § 327.5 to read as follows:

§ 327.5 Import inspection application.

(a) Applicants must submit FSIS Form 9540–1, Import Inspection Application, to apply for the inspection of any product offered for entry. Applicants may apply for inspection using a paper or electronic application.

(b) Import inspection applications for each consignment must be submitted (electronically or paper) to FSIS in advance of the shipment's arrival at the official import establishment where the product will be reinspected, but no later than when the entry is filed with U.S. Customs and Border Protection.

(c) The provisions of this section do not apply to products that are exempted from inspection by §§ 327.16 and 327.17.

8. In § 327.6, revise paragraphs (a) and (e) to read as follows:

§ 327.6 Products for importation; program inspection, time and place; application for approval of facilities as official import inspection establishment; refusal or withdrawal of approval; official numbers.

(a)(1) Except as provided in §§ 327.16 and 327.17, all products offered for entry from any foreign country shall be reinspected by a Program inspector before they shall be allowed entry into the United States.

(2) Every lot of product shall routinely be given visual inspection by a Program import inspector for appearance and condition, and checked for certification and label compliance.

(3) The Public Health Information System (PHIS) shall be consulted for reinspection instructions. The PHIS will assign reinspection levels and procedures based on established sampling plans and established product and plant history.

(4) When the inspector deems it necessary, the inspector may sample and inspect lots not designated by PHIS.

* * * * *

(e) Owners or operators of official import inspection establishments must furnish adequate sanitary facilities and equipment for examination of such product. The requirements of §§ 304.2, 307.1, 307.2(b), (d), (f), (h), (k), and (l), and part 416 of this chapter shall apply as conditions for approval of establishments as official import inspection establishments to the same extent and in the same manner as they apply with respect to official establishments.

* * * * *

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

9. The authority citation for Part 381 continues to read as follows:

Authority: 7 U.S.C. 138f, 450; 21 U.S.C. 451–470; 7 CFR 2.7, 2.18, 2.53.

10. In § 381.1, in paragraph (b), add a definition for *Official establishment* in alphabetical order to read as follows:

§ 381.1 Definitions.

* * * * *

(b) * * *

Official import inspection establishment. This term means any establishment, other than an official establishment as defined in this paragraph where inspections are authorized to be conducted as prescribed in § 381.199.

* * * * *

11. In § 381.22, revise paragraph (a) to read as follows:

§ 381.22 Conditions for receiving inspection.

(a) Before being granted Federal inspection, an official establishments or an official import inspection establishment, must have developed written Sanitation Standard Operating Procedures, as required by part 416 of this chapter.

* * * * *

12. In § 381.195, revise paragraph (a) to read as follows:

§ 381.195 Definitions; requirements for importation into the United States.

(a) When used in this part, the following terms are defined to mean:

(1) *Import (imported).* To bring within the territorial limits of the United States whether that arrival is accomplished by land, air, or water.

(2) *Offer(ed) for entry.* The point at which the importer presents the imported product for reinspection.

(3) *Entry (entered).* The point at which imported product offered for entry receives reinspection and is marked with the official mark of inspection, as required by § 381.204.

* * * * *

13. In § 381.196, revise paragraph (a)(3) to read as follows:

§ 381.196 Eligibility of foreign countries for importation of poultry products into the United States.

(a) * * *

(3) Only those establishments that are determined and certified to the Agency by a responsible official of the foreign poultry inspection system as fully meeting the requirements of paragraphs (a)(2)(i) and (ii) of this section are eligible to have their products imported into the United States. Establishment eligibility is subject to review by the Agency (including observations of the establishments by Program representatives at times prearranged with the foreign meat inspection system officials). Foreign establishment certifications must be renewed annually. Notwithstanding certification by a foreign official, the Administrator may terminate the eligibility of any foreign establishment for the importation of its products into the United States if it does not comply with the requirements listed in paragraphs (a)(2)(i) and (ii) of this section, or if current establishment information cannot be obtained. The Administrator will provide reasonable notice to the foreign government of the proposed termination of any foreign establishment, unless a delay in terminating its eligibility could result in the importation of adulterated or misbranded product. The electronic foreign establishment certification or paper certificate must contain: the date; the foreign country; the foreign establishment's name, address, and foreign establishment number; the foreign official's title; the foreign official's signature (for paper certificate only); the type of operation(s) conducted at the establishment (e.g., slaughter, processing, storage, exporting warehouse); and the establishment's eligibility status (e.g., new or relisted (if previously delisted)). Slaughter and processing establishment certifications must address the species and type of product(s) produced at the establishment and the process category.

* * * * *

14. Revise § 381.197 to read as follows:

§ 381.197 Foreign inspection certificate requirements.

(a) Except as provided in §§ 381.207 and 381.209, each consignment imported into the United States must have an electronic foreign inspection certification or a paper foreign inspection certificate issued by an official of the foreign government agency responsible for the inspection and certification of the product.

(b) An official of the foreign government must certify that any product described on any official certificate was produced in accordance with the regulatory requirements in § 381.196.

(c) The electronic foreign inspection certification must be in English, be transmitted directly to FSIS before the product's arrival at the official import inspection establishment, and be available to import inspection personnel.

(d) The paper foreign inspection certificate must accompany each consignment, be submitted to import inspection personnel at the official import inspection establishment, be in English, and bear the signature of the official authorized to issue inspection certificates for products imported to the U.S.

(e) The electronic foreign inspection certification and paper foreign inspection certificate must contain:

(1) The date, name, and title of the official authorized to issue inspection certificates for products imported into the U.S.;

(2) The foreign country of export and the producing foreign establishment number;

(3) The species used to produce the product and the source country and foreign establishment number, if the source materials originate from a country other than the exporting country;

(4) The product's description, including the process category, the product category, and the product group;

(5) The name and address of the consignor;

(6) The name and address of the exporter;

(7) The name and address of the consignee;

(8) The name and address of the importer;

(9) The number of units (pieces or containers) and the shipping or identification mark on the units;

(10) The net weight of each lot; and

(11) Any additional information the Administrator requests to determine whether the product is eligible to be imported into the U.S.

15. Revise § 381.198 to read as follows:

§ 381.198 Import inspection application.

(a) Applicants must submit FSIS Form 9540–1, Import Inspection Application, to apply for the inspection of any product offered for entry. Applicants may apply for inspection using a paper or electronic application.

(b) Import inspection applications for each consignment must be submitted (electronically or paper) to FSIS in advance of the shipment's arrival at the official import establishment where the product will be reinspected, but no later than when the entry is filed with U.S. Customs and Border Protection.

(c) The provisions of this section do not apply to products that are exempted from inspection by §§ 381.207 and 381.209.

16. In § 381.199, revise paragraph (a) and add paragraphs (e) through (k) to read as follows:

§ 381.199 Inspection of poultry products offered for entry.

(a)(1) Except as provided in § 381.209 and paragraph (c) of this section, all slaughtered poultry and poultry products offered for entry from any foreign country shall be reinspected by a Program import inspector before they shall be allowed entry into the United States.

(2) Every lot of product shall routinely be given visual inspection for appearance and condition, and checked for certification and label compliance.

(3) The Public Health Information System (PHIS) shall be consulted for reinspection instructions. The PHIS will assign reinspection levels and procedures based on established sampling plans and established product and plant history.

(4) When the inspector deems it necessary, the inspector may sample and inspect lots not designated by PHIS.

* * * * *

(e) All products, required by this part to be inspected, shall be inspected only at an official establishment or at an official import inspection establishment approved by the Administrator as provided in this section. Such approved official import inspection establishments will be listed in the Directory of Meat and Poultry Inspection Program Establishments, Circuits and Officials, published by the Food Safety and Inspection Service. The listing will categorize the kind or kinds of product which may be inspected at each official import inspection establishment, based on the adequacy of the facilities for making such

inspections and handling such products in a sanitary manner.

(f) Owners or operators of establishments, other than official establishments, who want to have import inspections made at their establishments, shall apply to the Administrator for approval of their establishments for such purpose. Application shall be made on a form furnished by the Program, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC, and shall include all information called for by that form.

(g) Approval for Federal import inspection shall be in accordance with subpart D of part 381.

(h) Owners or operators of establishments at which import inspections of product are to be made shall furnish adequate sanitary facilities and equipment for examination of such product. The requirements of §§ 381.21 and 381.36, and part 416 of this chapter shall apply as conditions for approval of establishments as official import inspection establishments to the same extent and in the same manner as they apply with respect to official establishments.

(i) The Administrator is authorized to approve any establishment as an official import inspection establishment provided that an application has been filed and drawings have been submitted in accordance with the requirements of paragraphs (c) and (d) of this section and he determines that such establishment meets the requirements under paragraph (e) of this section. Any application for inspection under this section may be denied or refused in accordance with the rules of practice in part 500 of this chapter.

(j) Approval of an official import inspection establishment may be withdrawn in accordance with applicable rules of practice if it is determined that the sanitary conditions are such that the product is rendered adulterated, that such action is authorized by section 21(b) of the Federal Water Pollution Control Act, as amended (84 Stat. 91), or that the requirements of paragraph (e) of this section were not complied with. Approval may also be withdrawn in accordance with section 401 of the Act and applicable rules of practice.

(k) A special official number shall be assigned to each official import inspection establishment. Such number shall be used to identify all products inspected and passed for entry at the establishment.

PART 590—INSPECTION OF EGGS AND EGG PRODUCTS (EGG PRODUCTS INSPECTION ACT)

17. The authority citation for part 590 continues to read as follows:

Authority: 21 U.S.C. 1031–1056.

18. Revise § 590.915 to read as follows:

§ 590.915 Foreign inspection certificate requirements.

(a) Except as provided in § 590.960, each consignment imported into the United States must have an electronic foreign inspection certification or a paper foreign inspection certificate issued by an official of the foreign government agency responsible for the inspection and certification of the product.

(b) An official of the foreign government agency must certify that any product described on any official certificate was produced in accordance with the regulatory requirements § 590.910.

(c) The electronic foreign inspection certification must be in English, be transmitted directly to FSIS before the product's arrival at the official import inspection establishment, and be available to import inspection personnel.

(d) The paper foreign inspection certificate must accompany each consignment, be submitted to import inspection personnel at the official import inspection establishment, be in English, and bear the signature of the official authorized to issue the inspection certificates for products imported into the U.S.

(e) The electronic foreign inspection certification and paper foreign inspection certificate must contain:

(1) The date, name, and title of the official authorized to issue inspection certificates for products imported into the U.S.;

(2) The foreign country of export and the producing foreign establishment number;

(3) The species used to produce the product and the source country and foreign establishment number, if the source materials originate from a country other than the exporting country;

(4) The product's description including the process category, the product category, and the product group;

(5) The name and address of the consignor;

(6) The name and address of the exporter;

(7) The name and address of the consignee;

(8) The name and address of the importer;

(9) The number of units (pieces or containers) and the shipping or identification mark on the units;

(10) The net weight of each lot; and

(11) Any additional information the Administrator requests to determine whether the product is eligible to be imported into the U.S.

19. Revise § 590.920 to read as follows:

§ 590.920 Import inspection application.

(a) Applicants must submit FSIS Form 9450-1, Import Inspection Application, to apply for the inspection of any product offered for entry. Applicants may apply for inspection using a paper or electronic application.

(b) Import inspection applications for each consignment must be submitted (electronically or paper) to FSIS in advance of the shipment's arrival at the official import establishment where the product will be reinspected, but no later than when the entry is filed with U.S. Customs and Border Protection.

(c) The provisions of this section do not apply to products that are exempted from inspection by §§ 590.960 and 590.965.

Done at Washington, DC, on: October 25, 2012

Alfred V. Almanza,
Administrator.

[FR Doc. 2012-28751 Filed 11-26-12; 8:45 am]

BILLING CODE 3410-DM-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 381

[Docket No. FSIS-2012-0019]

RIN 0583-AD49

Eligibility of the Republic of Korea To Export Poultry 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 the Republic of Korea (Korea) to the list of countries eligible to export poultry products to the United States. Reviews by FSIS of Korea's laws, regulations, and inspection implementation show that its poultry inspection system requirements are equivalent to the Poultry Products Inspection Act (PPIA) and its implementing regulations. Under this

proposal, slaughtered poultry or parts or other products thereof processed in certified Korean establishments would be eligible for export to the United States. All such products would be subject to re-inspection at United States ports-of-entry by FSIS inspectors.

DATES: Comments must be received on or before January 28, 2013.

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

- *Federal eRulemaking Portal:* This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

- *Mail, including CD-ROMs, etc.:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW., Mailstop 3782, Room 8-163A, Washington, DC 20250-3700.

- *Hand- or courier-delivered submittals:* Deliver to Patriots Plaza 3, 355 E. Street SW., Room 8-163A, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2012-0019. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

Docket: For access to background documents or comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E Street SW., Room 8-164, Washington, DC 20250-3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Dr. Andreas Keller, Director, International Equivalence Staff, Office of International Affairs; telephone (202) 690-5646.

SUPPLEMENTARY INFORMATION:

Background

FSIS is proposing to amend its poultry products inspection regulations to add Korea to the list of countries eligible to export poultry products to the United States (9 CFR 381.196(b)). Korea is not currently listed as eligible to export such products to the United States.

Statutory Basis for Proposed Action

Section 17 of the PPIA (21 U.S.C. 466) prohibits importation into the United

States of slaughtered poultry, or parts or products thereof, of any kind unless they are healthful, wholesome, fit for human food, not adulterated, and contain no dye, chemical, preservative, or ingredient that renders them unhealthful, unwholesome, adulterated, or unfit for human food. Under the PPIA and the regulations that implement it, poultry products imported into the United States must be produced under standards for safety, wholesomeness, and labeling accuracy that are equivalent to those of the United States. Section 381.196 of Title 9 of the Code of Federal Regulations (CFR) sets out the procedures by which foreign countries may become eligible to export poultry and poultry products to the United States.

Section 381.196(a) requires a foreign country's poultry inspection system to include standards equivalent to those of the United States and to provide legal authority for the inspection system and its implementing regulations that is equivalent to that of the United States. Specifically, a country's legal authority and regulations must impose requirements equivalent to those of the United States with respect to: (1) Ante-mortem and post-mortem inspection by, or under the direct supervision of, a veterinarian; (2) official controls by the national government over establishment construction, facilities, and equipment; (3) direct and continuous official supervision of slaughtering of poultry and processing of poultry products by inspectors to ensure that product is not adulterated or misbranded; (4) complete separation of establishments certified to export from those not certified; (5) maintenance of a single standard of inspection and sanitation throughout certified establishments; (6) requirements for sanitation and for sanitary handling of product at establishments certified to export; (7) official controls over condemned product; (8) a Hazard Analysis and Critical Control Point (HACCP) system; and (9) any other requirements found in the PPIA and its implementing regulations (9 CFR 381.196(a)(2)(ii)).

In addition to a foreign country's legal authority and regulations, the program itself must be equivalent to the United States. Specifically, the program organized and administered by the national government must impose requirements equivalent to those of the United States with respect to: (1) Organizational structure and staffing, so as to ensure uniform enforcement of the requisite laws and regulations in all certified establishments; (2) ultimate control and supervision by the national government over the official activities of