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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: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending 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 the foreign inspection and foreign establishment certificate processes. The Agency is also removing from the regulations the discontinued "streamlined" import inspection procedures for Canadian product and is requiring Sanitation Standard Operating Procedures (SOPs) at official import inspection establishments.

In addition to the regulatory amendments outlined above, FSIS is discontinuing 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: Effective Date: [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Compliance Date: Revised Import Inspection Application (FSIS Form 9540-1): [INSERT DATE 180 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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SUPPLEMENTARY INFORMATION:

Executive Summary

On November 27, 2012, FSIS issued a proposed rule to amend the meat, poultry, and egg products import regulations to provide for the import component of the Agency's Public Health Information System (PHIS). The PHIS is an electronic data analytic system, launched to collect, consolidate, and analyze data in order to improve public health.

In addition to providing for the PHIS Import Component, FSIS proposed to amend the regulations to delete overly prescriptive formatting and narrative requirements for foreign establishments and inspection certificates and to make the certificate requirements the same for imported meat, poultry, and egg products. The Agency also proposed to require additional information on these certificates so it would have complete foreign establishment and product information to determine eligibility and reinspection.

The proposed rule also amended the regulations to require that official import inspection establishments comply with Sanitation Standard Operating Procedures (SOPs) to prevent the direct contamination or adulteration of products. The proposal also deleted certain streamlined inspection procedures for products imported from Canada. The streamlined procedures were implemented 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. However, FSIS suspended the use of these procedures in 1992.

In addition to the proposed regulatory amendments, FSIS announced 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 within 30 days and clarified its policy

of addressing imported product that is not presented for reinspection.

This rule finalizes all of the proposed amendments, with the following modifications and clarifications:

- The final rule changes the proposed foreign establishment certification regulations (9 CFR 327.2(a)(3) and 381.196(a)(3)) to provide that when a foreign government certifies a foreign establishment for which the preceding year's certificate information has not changed, the certificate or certification only needs to list the date, the foreign country, the foreign establishment's name, and the foreign official's title and signature (for paper certificates only). Also, the final rule will not require the foreign official's title for electronic foreign establishment certifications because this information is required in an electronic certification agreement and Memorandum of Understanding (MOU) between FSIS and the foreign country.
- The final rule revises the foreign inspection certificate regulations (9 CFR 327.4, 381.197, and 590.5915) to require that foreign governments provide the names and addresses of the "importer or consignee" and the "exporter or consignor." The Agency is also clarifying that "the process category" is an example of the type of

product produced, not additional required information. This final rule also amends the proposal to require the seal of the foreign government on paper foreign inspection certificates. In addition, the final rule will not require the foreign official's name and title for electronic foreign inspection certifications because, as discussed above for foreign establishment certifications, this information is required in an electronic certification agreement and MOU between FSIS and the foreign country.

The benefits of the final rule include reduced data-entry time for import inspectors, streamlined existing import documentation requirements, and increased effectiveness of import inspection regulations. An additional potential benefit is that the rule provides the option to file mandatory import application data electronically. Compared to the old paper-based application, FSIS estimates that it will take 6 additional minutes to complete the new paper-based application and an additional minute to submit an electronic application. Monetizing this time, FSIS estimates the industry wide cost to complete the new application is about \$77,000 per year. The Agency expects few or no costs to arise from the Sanitation SOPs or the removal of regulatory provisions for the streamlined import inspection system for Canadian products.

Background

On November 27, 2012, FSIS published the proposed rule, "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" (77 FR 70714). In it, the Agency proposed to amend the meat, poultry, and egg products import regulations to provide for the PHIS Import Component, an electronic alternative to the paper-based import inspection application and imported product foreign inspection and foreign establishment certificate processes.

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 the 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.

PHIS Import Component

On May 29, 2012, FSIS launched the PHIS Import Component, which 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 Import Component enables United States importers to file for FSIS inspection in advance of arrival of shipments destined to the United States.

PHIS and the Automated Commercial Environment (ACE) Interface

FSIS has actively participated in the development of the International Trade Data System (ITDS), an electronic information exchange capability, or "single-window," through which businesses will transmit data required by participating agencies for the importation or exportation of cargo. The goal of the ITDS is to eliminate redundant data reporting and replace multiple filings, many of which are on paper. As part of the ITDS initiative, the U.S. Customs and Border Protection (CBP) developed the Automated Commercial Environment (ACE), a United States commercial trade processing system that automates border processing of shipments of amenable products. The ACE system provides a single, centralized, online access point that connects the trade community and partner government agencies. The ACE system interfaces with the PHIS Import Component and electronically transfers CBP entry data on meat, poultry, and egg products to FSIS but does not yet provide all of the

required FSIS information.

Since the implementation of the PHIS Import Component, the Agency has collaborated with CBP to develop the capability to collect and transfer, through the ACE/PHIS Import Component interface, all of the FSIS required information through a Partner Government Agency (PGA) Message Set, which will eliminate the need to submit a paper application for import inspection. In March 2013, the Agency published a Federal Register Notice, "Electronic Filing of Import Inspection Applications for Meat, Poultry, and Egg Products: Availability of Draft Compliance Guide and PGA Message Set Pilot Program," announcing the availability of a compliance guide on the PGA Message Set and a pilot program intended to test the transfer of FSIS data from the ACE/PGA Message Set to the PHIS Import Component (<http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2012-0037.pdf>). The compliance guide, which FSIS developed in conjunction with CBP, provides specific guidance to industry to take advantage of the "single window" initiative. FSIS began piloting the PGA Message Set with two brokers in April 2014.

On December 13, 2013, CBP published a Federal Register Notice, "National Customs Automation Program (NCAP) Test Concerning the Submission of Certain Data Required by the Environmental Protection Agency and the Food Safety and Inspection Service Using the Partner Government Agency Message

Set Through the Automated Commercial Environment (ACE),” which announced the testing of electronic filings of import data using the Automated Commercial Environment (ACE) Partner Government Agency (PGA) Message Set and the Automated Broker Interface (ABI) to transmit the data (78 FR 75931). On February 19, 2014, President Obama signed an Executive Order that mandates the completion of the ITDS by December 2016

(<http://www.whitehouse.gov/the-press-office/2014/02/19/executive-order-streamlining-exportimport-process-america-s-businesses>).

FSIS considers any electronic data transferred from ACE into the PHIS Import Component as certified by the applicant. FSIS also 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.

Proposed and Final Regulatory Amendments

Foreign Establishment Certificate

As discussed in the proposed rule (77 FR 70714), the meat and poultry products import regulations require that an official of the foreign inspection system determine and certify, on an annual basis, 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 proposed rule also explained that the annual foreign establishment certificate regulations prescribe a narrative format that requires the foreign establishment's 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 for its egg products to be imported into the United States, the country is listed in 9 CFR 590.910(b). As discussed in the proposed rule (77 FR 70716), because the egg products import regulations do not require foreign establishment certification, FSIS did not propose eligibility requirements for foreign egg product plants. The Agency intends to propose foreign egg product plant certification requirements in a separate rulemaking.

FSIS proposed (77 FR 70716) to amend the meat and poultry foreign establishment certificate regulations to provide concise regulatory language, delete the prescriptive narrative certificate statement, 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 proposed to require the species and type of products produced and the process category. FSIS also proposed to provide for the electronic transmittal of foreign establishment certifications to FSIS from foreign governments, in lieu of paper-based foreign establishment certifications.

This rule finalizes the proposed amendments to the foreign establishment certification regulations (9 CFR 327.2 (a)(3) and 381.196(a)(3)), with minor modifications. FSIS proposed that slaughter and processing establishments must address the species and type of products produced at the establishment and the process category. In this final rule, in response to comments, the Agency is clarifying that "the process category" is an example of the type of product produced, not additional information. Therefore, the last sentence of the regulatory text in proposed 9 CFR 327.2(a)(3) and 381.196(a)(3) is changed in this final rule to provide that slaughter and processing establishment certifications must address the species and type of products produced at the establishment (e.g., the process category).

FSIS also proposed to require the foreign official's title on foreign establishment certificates and electronic certifications. However, because foreign countries that utilize electronic certification (eCert) identify the foreign official's title in an Interconnection Security Agreement (ISA) and a Memorandum of Understanding (MOU) with FSIS, the Agency reconsidered requiring this information for electronic certifications. In this final rule, for foreign governments that utilize eCert to transmit foreign establishment certifications, the foreign official's title will not be required information.

In addition, since actively exporting foreign establishment information is stored in the PHS Import Component's foreign establishment profile, the Agency reconsidered requiring all of the information on a yearly basis. To minimize the burden to foreign countries, FSIS determined that, for foreign establishments that have no changes to the previous year's certification information, foreign governments only have to provide the date, the foreign country, the foreign establishment name, and, for paper certificates, the foreign official's title and signature. The Agency is amending 9 CFR 327.2(a)(3) and 381.196(a)(3) to add subparagraph (i) to list the requirements for a new establishment, or any establishment for which information from last year's information has changed, and

subparagraph (ii) to list the establishment certification requirements for establishments listed the preceding year that have no changes to the required information.

Imported Product Foreign Inspection Certificates

As discussed in the proposed rule (77 FR 70714), the meat, poultry, and egg products import regulations require a foreign inspection certificate for every shipment of product that is offered for import into the United States (9 CFR 327.4, 381.197, and 590.915). Depending on the type of product to be imported, the regulations provide four different 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 meat and poultry foreign inspection certificate regulations prescribe a narrative statement and format, certifying that the product was derived from livestock or poultry that received ante-mortem and post-mortem veterinary inspection at the time of slaughter in establishments certified to export their products to the United States, is not adulterated, and is in compliance with requirements equivalent to the U.S. domestic requirements. The regulations also require specific information about the product. Meat and poultry products foreign inspection certificates are required to be in the form illustrated in 9 CFR 327.4(a) and (b) and 381.197(b),

the 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 (9 CFR 327.4(c) and (d)).

The egg products foreign inspection certification regulations (9 CFR 590.915) contain a list of required information and require certification that the product was produced under the approved regulations, requirements, and continuous inspection of the government of the exporting country.

FSIS proposed to amend the meat, poultry, and egg product foreign inspection certification regulations to clarify and simplify the foreign inspection certificate requirements; to require the same information for meat, poultry, and egg product certificates; and to delete the prescriptive narrative and format requirements for the meat and poultry foreign inspection certificates (77 FR 70716). The Agency proposed to delete the requirement that the meat certificate 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. In addition, the Agency proposed to delete the requirement that the certificate identify the city where the establishment is located, because the foreign establishment number provides sufficient information to identify that city. The Agency also

proposed to require the identity and address of the consignee, consignor, exporter, and importer and to delete the product "destination" requirement because it would be replaced with the "consignee address." In addition, the Agency proposed to amend the foreign inspection certification regulations to provide for the electronic transmittal of foreign inspection certifications.

The proposed meat, poultry, and egg products foreign inspection certification regulations (9 CFR 327.4, 381.197, and 590.915) require: the date, name, and title of the official authorized to issue inspection certificates for products that are offered for import into the United States; the foreign country of export and the producing foreign establishment number; 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; the product's description, including the process category, the product category, and the product group; the name and address of the consignor; the name and address of the exporter; the name and address of the consignee; the name and address of the importer; the number of units (pieces or containers) and the shipping or identification mark on the units; the net weight of each lot; and any additional information the Administrator requests to determine whether the product is eligible to be imported into the United States.

This rule finalizes the proposed amendments to the foreign inspection certificate regulations with minor modifications. In response to comment, FSIS reconsidered requiring the names and addresses of the consignor, exporter, consignee, and importer, as this information is redundant and may not be consistent with international data standards. Therefore, the Agency is modifying 9 CFR 327.4(e), 381.197(e), and 590.915(e) to require the names and addresses of the "importer or consignee" and the "exporter or consignor." In addition, in proposing to delete the seal requirements for paper foreign inspection certificates, FSIS anticipated that paper certificates would be replaced by secure electronic government-to-government transmission of foreign inspection certification data. However, until a foreign government has the capability to electronically transmit foreign inspection certification data, the Agency will continue to require that paper foreign inspection certificates bear the official seal of the foreign government agency responsible for the inspection of the product, to ensure the authenticity of the certificate. Therefore, the regulations will continue to require that paper foreign inspection certificates bear the official seal of the foreign government (9 CFR 327.4(d), 381.197(d), and 590.915(d)).

In addition, FSIS proposed to require the foreign official's name and title on the electronic foreign inspection

certification. However, as discussed above for foreign establishment certification, foreign countries that utilize eCert identify the foreign official's name and title in an ISA and MOU. Therefore, in this final rule, for foreign governments utilizing eCert to transmit foreign inspection certification, the foreign official's name and title will not be required information.

Import Inspection Application

As discussed in the proposed rule (77 FR 70715), 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). Before the PHIS Import Component implementation, applicants submitted FSIS Form 9540-1, "Import Inspection Application and Report," for meat and poultry products and FSIS Form 5200-8, "Import Request Egg Products" for egg products, to FSIS import inspection program personnel.

FSIS proposed to amend the imported product inspection application regulations (9 CFR 327.5, 381.198, and 590.920) to require applicants to 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 (77 FR 70717). The Agency revised the application to include egg products and additional information the Agency needs to accurately assign reinspection tasks and sampling of the

product. In addition, the Agency proposed to provide the option of submitting the application electronically or in paper.

As discussed above, the PHIS Import Component interfaces with CBP's ACE system and receives a limited amount of data needed to complete the inspection application. FSIS inspection program personnel enter the additional required data into the PHIS Import Component by using information from the paper Import Inspection Application. The PGA Message Set will electronically collect and transfer all FSIS-specific data fields from ACE to PHIS. For applicants that electronically file entries with CBP, including the PGA Message Set, this entry will replace the paper inspection application. Applicants that do not file the PGA Message Set data or that do not electronically file entries with CBP can continue to submit paper applications to FSIS inspection personnel at an official import inspection establishment. Paper applications must be provided to FSIS at the time the entry is filed, in advance of the presentation of the shipment at the official import inspection establishment.

When the revised Import Inspection Application (FSIS Form 9540-1) receives final approval from OMB, FSIS will post the form on its Website. FSIS will provide applicants with six months from the date of this final rule to transition from the current to the revised form.

Prior Notification of Imported Product

As discussed in the proposed rule (77 FR 70717), the meat, poultry, and egg products import regulations require that the importer apply for the inspection of imported product as far as possible in advance of the anticipated arrival of each consignment (9 CFR 327.5(b), 381.198(a), and 590.920).

FSIS proposed 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 (proposed 9 CFR 327.5(b), 381.198(b), and 590.920(b)).

This rule finalizes the proposed amendments.

Streamlined Inspection Procedures for Canadian Products

As discussed in the proposed rule (77 FR 70715), for participating Canadian establishments, the meat and poultry import regulations provide "streamlined" inspection procedures on a voluntary basis (9 CFR 327.5 (d) and 381.198(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. The 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. However, because of issues raised in a 1990 General Accounting Office (now known as the Government Accountability Office, or GAO) report about the streamlined procedures, in 1992, the Agency suspended using the streamlined inspection procedures for Canadian product (77 FR 70717).

FSIS proposed (77 FR 70717) to delete the discontinued streamlined procedures provided in 9 CFR 327.5(d) and 381.198(b). The Agency also proposed to amend 9 CFR 327.1 and 381.195, to revise paragraph designations and 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."

This rule finalizes the proposed amendments.

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

As discussed in the proposed rule (77 FR 70715), 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 proposed (77 FR 70718) to amend 9 CFR 327.6(e) to require that an official import inspection establishment must, in order to receive a grant of inspection, meet the Sanitation SOP requirements in 9 CFR 416.11 through 416.17.

In addition, the Agency proposed to amend the poultry products regulations (9 CFR 381.199) to parallel the meat import regulations to require that all poultry products offered for import be inspected only at an official establishment or at an official import inspection establishment approved by the Administrator. The Agency also proposed to amend the requirements for the conditions of approval (9 CFR 327.6(b), (c), (d), (f), (g), and (h)).

The Agency also proposed to amend 9 CFR 381.1, "Definitions" to include the definition of "Official Import Inspection Establishment," to parallel the definition in 9 CFR 301.2. and 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).

For imported egg products, importers are advised of the point where inspection will be made (9 CFR 590.925(a)). The Agency did not propose amendments to the egg products regulations but will be proposing amendments to the imported egg products regulations in a separate rulemaking.

This rule finalizes the proposed amendments. As discussed in the proposal (77 FR 70718), official import inspection establishments operating under a grant of inspection must develop and implement written Sanitation SOP within 60 days of the publication of this final rule.

Other Proposed Amendment

As discussed in the proposed rule (77 FR 70718), FSIS proposed 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."

This rule finalizes the proposed amendment.

Discontinued Import Practice and Enforcement Notification

In the proposed rule, in addition to the proposed regulatory amendments outlined above, FSIS announced that it would end two of its imported meat, poultry, and egg products reinspection practices (77 FR 70718). These practices will end on the effective date of this rule.

30-day Guarantee Foreign Inspection Certificate Replacement

As discussed in the proposed rule, when official foreign inspection certificates are lost in transit or contain errors, FSIS will discontinue its practice of reinspecting imported product based on the foreign government's guarantee to replace lost or incorrect foreign inspection certificates (77 FR 70718). If certificates 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 File (PDF) by email (importinspection@fsis.usda.gov) or by an expedited mail service. FSIS will only reinspect imported product upon receipt of the replacement foreign inspection certificate.

Failure to Present (FTP) Imported Product for Reinspection

Imported meat, poultry and egg products are considered "in-commerce" when they are off-loaded at a location other than the official import inspection establishment or the official establishment designated on the import inspection application.

As discussed in the proposed rule, imported product that has bypassed FSIS import reinspection and entered commerce

constitutes a "failure to present" (FTP) and violates the Acts (77 FR 70718). In response to comments requesting that the Agency provide clarification concerning activities that trigger FTP determinations and the disposition of FTP products in general, the Agency is providing further clarification on its FTP product enforcement policies. As discussed in the proposed rule, when a product has been identified as a FTP, FSIS will request, through CBP, a redelivery of the shipment and appropriate penalties. Any imported product that has not been presented for reinspection at the official FSIS establishment identified on the Import Inspection Application is considered a FTP.

If FTP product has been removed from the original cartons or further processed, FSIS will initiate a regulatory control action on all applicable FTP product, including any further processed product that contains the FTP product for appropriate disposition (i.e., destruction).

Comments and Responses

FSIS received 14 comments in response to the proposed rule. The comments were from domestic and foreign trade associations, private citizens, foreign government agencies, and a consumer advocacy organization.

General Support

Most comments supported the proposal to provide an electronic method of processing import inspection applications and foreign inspection certificates. The comments stated that the PHIS Import Component offered the promise of increased efficiency and better use of resources, and that it expedited the processing of imported products. A commenter stated that the proposed amendments would harmonize requirements across meat, poultry and egg products and removed unnecessary prescriptive narratives and formatting for foreign inspection and establishment certificates. A commenter also supported the Sanitation Standard Operating Procedures (Sanitation SOPs) requirements at official import inspection establishments because it would harmonize food safety requirements between official establishments and official import inspection establishments.

PHIS Import Component System Operation and Required Information

Comment: Because the PHIS Import Component launched in May 2012, before the publication of the proposed rule, some commenters familiar with the system expressed concern about its efficiency. In the event of system breakdowns, importers requested the Agency's commitment to work with the industry to ensure that shipments are cleared. Several domestic trade associations stated that delays involving the PHIS Import Component will lead to added overtime inspection charges for

refused entries, data entry, and system downtime that will negatively affect the industry. One trade association asked if FSIS would redefine overtime based on PHIS.

Response: The PHIS Import Component is a significant new information technology (IT) application and its implementation was a major initiative. As with any new system, there was an initial period of transition and adjustment for inspection personnel and industry. When the Agency launched the PHIS Import Component, it cancelled the long-standing Import Manual of Procedures and issued FSIS Import PHIS Directives to provide inspection personnel with instructions on their duties (http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/directives/phis_directives). In January 2013, PHIS Directive 9500.1, "Contingency Plan for Import Reinspection When the Public Health Information System (PHIS) is Unavailable," was updated to provide guidance on obtaining reinspection assignments when the system is not accessible (http://www.fsis.usda.gov/wps/wcm/connect/dbdd4bb4-2601-44b3-a855-282253304988/PHIS_9500.1.pdf?MOD=AJPERES). The Agency is committed to resolving PHIS Import Component operational issues and ACE/PHIS Import Component data transfer problems. Because brokers can submit entries well in advance the shipment's presentation for import reinspection, there should be no problem in completing the FSIS reinspection in a timely fashion. The

Agency has no plans to redefine overtime as it relates to the PHIS Import Component.

Comment: Foreign governments and a trade association asked that FSIS consult with foreign authorities to determine how long they will need to make the changes to comply with the foreign establishment certification and foreign inspection certification requirements in the final rule. Foreign governments stated that they needed sufficient time to change their IT operating systems to collect the newly required data and to be able to submit data electronically to FSIS.

Several commenters asked if FSIS would work with industry, foreign countries, and brokers in submitting the new data requirements on the foreign establishment and foreign inspection certifications, and the Import Inspection Application before enforcement actions would be taken based on incomplete information.

Response: Many of the amendments in this final rule have been implemented voluntarily. In March 2012, before implementing the Import PHIS Component, FSIS sent letters to the competent authorities of all eligible foreign countries, notifying them of the changes in foreign establishment and the foreign inspection certification requirements

(<http://www.fsis.usda.gov/wps/wcm/connect/d5f3ad49-133c-4a21-b0d9->

5975c9e3e838/PHIS Letter to Foreign Countries 03202012.pdf?MOD=AJPERES&CACHEID=d2e89cb3-0581-45b5-8190-489bd4d7d36e). In April 2012, FSIS sent letters to importers providing them with information on changes in certification requirements, product categorization, and import reinspection presentation and sampling at official import inspection establishments (<http://www.fsis.usda.gov/wps/wcm/connect/165e4c94-5fcf-4aab-abc7-1bec486b8f33/PHIS Letter to Importers 04182012.pdf?MOD=AJPERES&CACHEID=e2ca0872-608b-43c0-be2e-79002cbb65e9>).

In addition, FSIS conducted several outreach sessions with industry and foreign governments to provide information on the PHIS Import Component, including the information requirements.

Because of the letters, the outreach sessions, the implementation of the PHIS Import Component in May 2012, and the publication of the November 2012 proposed rule, some foreign governments have already made the changes needed to provide the foreign establishment and foreign inspection certifications. This final rule will be effective 60 days from the date of publication, and FSIS does not foresee any additional impact on foreign governments. However, FSIS will conduct teleconference calls or hold meetings to address requests for clarification or further information specific to individual foreign country's needs.

As discussed above, the Agency is providing applicants with six months, from the date of this final rule, to transition from the current to the revised Import Inspection Application. In addition, the Agency is conducting a pilot program, which started in April 2014, that tests the electronic transfer of all FSIS-specific data elements included in the PGA Message Set to the PHIS Import Component.

Foreign Establishment Certification

Comment: Several commenters asked for general guidelines to assist foreign governments with completing foreign establishment certification requirements. Commenters specifically requested that the Agency explain the new "type of products produced" and "process category" information. A foreign government asked that FSIS confirm that the "process category" will be the same as that used for the Electronic Certification (eCert) exchange.

Response: Some of the foreign establishment certification information is not new, e.g., the date; the foreign establishment name, address, and number; and the foreign official's title and signature. Some of the information that is new, such as the foreign country, the type of operations conducted at the establishment (e.g., slaughter, processing, storage, or export certification), and the establishment's eligibility status (e.g., new, listed as eligible the previous

year, delisted, relisted (if previously delisted)), does not need explanation. For slaughter and processing establishments, FSIS proposed requiring the species, the type of product produced, and the process category. The March 2012 letters to foreign countries discussed above included an "FSIS Product Categorization" appendix document that identified the nine (9) process categories in 9 CFR 417.2(b).

In this final rule, the Agency is amending the regulatory text to clarify that the "process category" is an example of the type of product produced. The "process category" is the same information that would be provided through eCert, the electronic government-to-government exchange that is currently utilized by two foreign countries.

Comment: Two foreign countries asked if the "eligibility status" was necessary because they provide FSIS with establishment notifications throughout the year. One foreign country stated that the new establishment information is already supplied in various forms to FSIS; specifically, the FSIS Self Reporting Tool (SRT) captures the types of products produced and the process category at each foreign establishment. One trade organization asked whether FSIS will require a foreign government that exports or wishes to begin exporting product to the U.S. to complete the SRT, and whether FSIS will add that requirement to the regulations. The commenter also asked how

FSIS will verify the data from the annual certification and other systems, such as the SRT.

Response: The "eligibility status" information is necessary to ensure the appropriate and efficient reinspection, enforcement, and audit planning activities, and any changes in eligibility status need to be updated as necessary and reported annually. The FSIS SRT collects and catalogs information submitted by foreign countries during the initial and on-going equivalence process. FSIS will not include the SRT in the regulations. FSIS requests that countries complete the SRT to collect and evaluate the information countries are required to submit to FSIS to be eligible to import product to the U.S. (9 CFR 327.2, 381.196, and 590.910). On January 25, 2013, FSIS published a Federal Register Notice, "Ongoing Equivalence Verifications of Foreign Food Regulatory Systems," that describes the methodology the Agency is using to conduct ongoing verification of foreign country's regulatory food safety systems and includes a discussion of the SRT (<http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2012-0049.pdf>). FSIS is evaluating comments on that notice and is considering necessary changes to its equivalence verification procedures. FSIS will respond to comments and clarify issues commenters raised on the January 25, 2013, notice in an upcoming Federal

Register notice. The Agency will verify annual establishment certification data during foreign audit activities.

Comment: One trade association asked how FSIS will handle establishment certification data errors, given that errors may cause trade delays.

Response: If there are foreign establishment certification data errors, e.g., the product is from a foreign establishment that is not listed in the PHIS Import Component, FSIS will contact the competent authority in the foreign country to resolve the issue.

Comment: One foreign country asked whether FSIS intended to request separate lists of eligible foreign establishments based on species and products.

Response: FSIS has no intention to request separate lists of eligible foreign establishments based on species and products. It intends to maintain an accurate list of eligible foreign establishments, which will include the name and establishment number, the eligible species, the type of operations (e.g., slaughter, processing, or storage), and the types of products produced, based on the process categories. This information will be maintained in the PHIS foreign country profile and published on the FSIS Website.

Foreign Inspection Certificate

Comment: Domestic trade associations stated that many countries will use different foreign inspection certificate formats, causing import inspectors to question shipment certification and delaying reinspection. The commenters asked whether FSIS will issue a compliance guide for foreign governments to follow so that reinspections are not delayed because import inspectors question certificates. One trade organization recommended that FSIS establish a standard for acceptable foreign inspection certificates.

Response: FSIS requires specific foreign inspection certificate information (9 CFR 327.4, 381.197, and 590.915); however, there are no formatting requirements. As instructed in FSIS Directive 9900.1, "Imported Product Shipment Presentation," inspection program personnel with questions about information in a foreign inspection certificate, or about the certificate's validity are to contact their supervisor. If a significant number of foreign inspection certificates are noncompliant with these regulations, FSIS may issue compliance guidelines to assist foreign countries.

Foreign countries can use the Codex Alimentarius generic model official certificate as a guideline for organizing the required data elements on an official certificate. The certificate guideline can be found on the Codex Alimentarius

Website at: <http://www.codexalimentarius.org/standards/list-of-standards/>.

Comment: Trade associations asked whether FSIS will issue guidelines to assist foreign governments in completing the process category, product category, and product group portion of the foreign inspection certificate.

Response: FSIS provided guidance on the process categories, product categories, and product groups in letters sent to foreign countries and industry before the PHIS Import component was implemented. This information is currently available on the FSIS Website

[http://www.fsis.usda.gov/wps/wcm/connect/d5f3ad49-133c-4a21-b0d9-5975c9e3e838/PHIS Letter to Foreign Countries 03202012.pdf?MOD=AJPERES&CACHEID=d2e89cb3-0581-45b5-8190-489bd4d7d36e](http://www.fsis.usda.gov/wps/wcm/connect/d5f3ad49-133c-4a21-b0d9-5975c9e3e838/PHIS_Letter_to_Foreign_Countries_03202012.pdf?MOD=AJPERES&CACHEID=d2e89cb3-0581-45b5-8190-489bd4d7d36e). In addition, the Agency is developing compliance guidelines to further assist in providing the required information. The industry guidance will be posted on the Agency's Website, and the foreign government guidance will be sent to the competent authority of the foreign government.

Comment: Commenters questioned how FSIS will handle any delays caused by data entry errors on foreign inspection certificates. A commenter asked how FSIS will certify shipments when the electronic foreign certificate is unavailable through

the PHIS Import Component and asked whether FSIS inspection personnel would clear shipments if they were presenting with a digital image, photocopy, or fax copy of the foreign inspection certificate. The commenter also asked how FSIS would handle replacement certificates.

Response: If there are data entry errors on the foreign inspection certificate, the shipment will either be refused entry or will be held by FSIS until the replacement certificate has been issued by the competent authority in the foreign country. FSIS Directive 9900.1, "Imported Product Shipment Presentation," instructs FSIS inspection personnel to "fail" the Certification Type-of-Inspection (TOI) in PHIS and ask the applicant if they intend to rectify the issue (e.g., through replacement certificates) or allow the shipment to remain refused entry. The directive also instructs inspection personnel on how to proceed according to the applicant's response (e.g., replacement certification or refused-entry disposition).

Foreign governments that electronically transmit their foreign inspection certificates generally do so well in advance of the shipment's arrival at the United States port-of-entry so any unexpected disruption in transmission of the data into PHIS should have minimal impact with timely reinspection of the shipments at port-of-entry.

When a shipment from a country that does not certify electronically is presented to FSIS, the Agency will need an original paper certificate to clear the shipment. For countries that do not have electronic certification, FSIS will accept replacement certificates in an alternative format, such as through e-mail (e.g., digital image) from the foreign government to FSIS.

Comment: One trade association asked whether the original foreign inspection certificates will be needed when countries provide the certificates electronically.

Response: FSIS will no longer require a paper copy of the foreign inspection certificate when the competent authority in the foreign country certifies the shipment data electronically.

Comment: Commenters asked why FSIS was requiring importer, exporter, consignee, and consignor information on the foreign inspection certificate when this information may be redundant, is not useful for enforcement action, and is not consistent with United Nations Centre for Trade Facilitation and Electronic Commerce (UNCEFACT) international Electronic Certification (eCert) data standards and message structure, which requires only the name and contact details of the "importer or consignee" and "exporter or consignor." One foreign country asked whether the new foreign inspection certificate requirements affect the current eCert data exchange.

Response: Although other parties are involved, the United States importer of record is required to control and present shipments to FSIS for reinspection. Therefore, FSIS requires importer information. FSIS requires exporter information because the exporter is the party responsible for sending the consignment (or shipment). However, FSIS acknowledges that proposing to require the importer, exporter, consignee, and consignor information is redundant and not consistent with international standards. Therefore, the Agency is amending the final rule to require information of the "importer or consignee" and "exporter or consignor."

The new data requirements may impact the current electronic data exchange as a result of having to map the new data elements between systems, though this issue has been addressed with the two countries that currently provide electronic certification data to the PHIS Import Component.

Comment: A consumer advocacy organization stated that FSIS should continue to require the product destination address if that address differs from the consignee's business address. The commenter also stated that FSIS should continue to require the foreign government's seal on foreign inspection certificates, as it serves to authenticate the government document.

Response: Because of the way shipments are manifested, there may be several consignees for one entry. Requiring an

"importer or consignee" address, rather than the product destination address, provides sufficient information without compromising product control or information necessary for enforcement. In proposing to delete the seal requirements, FSIS anticipated that, as the electronic capabilities of the United States and its trading partners evolved, official seals would be replaced by secure data transmissions subject to security agreements between governments. However, in this final rule, until a foreign government has the capability to electronically transmit foreign inspection certification data, the Agency will continue to require that paper foreign inspection certificates bear the official seal of the foreign government agency responsible for the inspection of the product, to ensure the authenticity of the certificate.

Comment: One foreign government agency stated that, although the eCert data exchange with FSIS has been in place for months, the Agency has not conducted preliminary paperwork checks on certificates in the time available before presentation of product.

Response: Although FSIS has access to the data elements certified electronically in advance of the shipment arrival, most discrepancies with the certificates cannot be detected until the product is presented for reinspection. FSIS will consider performing preliminary verification on certificate

information, recognizing that the final check will occur when the entry is filed and the shipment presented.

Import Inspection Application

Comment: Commenters asked whether the revised FSIS Form 9540-1, "Import Inspection Application," would be available before or after the regulations are finalized so that exporters could begin creating application templates and adjusting to the new information requirements. A domestic trade association stated that FSIS should be more transparent in the development of the application. Several commenters also asked whether the Agency is moving forward with implementing the Partnering Government Agency (PGA) Message Set data collected through the U.S. Customs and Border Protection's (CBP) Automated Commercial Environment (ACE) system. The commenter stated that the use of the PGA Message Set data would reduce inspector data entry, thereby minimizing delays obtaining reinspection assignments.

Response: Before the PHIS Import Component was implemented in May 2012, FSIS notified foreign countries, importers, customs brokers, and official import inspection establishments of the new information in the revised Import Inspection Application (FSIS Form 9540-1) and provided a draft of the revised form. In addition, FSIS consulted with several major customs brokers when revising the application.

As discussed above, the Agency has finalized the draft revised Import Inspection Application (FSIS Form 9540-1). As discussed in the Paperwork Reduction Act section below, FSIS has submitted the form to OMB for final approval. When the form receives final OMB approval, the Agency will post the form on its website at:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/interim-and-final-rules>. The Agency is providing six months from the date of the publication of this final rule for applicants who continue to file paper applications to transition to the revised form and for applicants to update any templates they use to collect application information. In addition, the Agency began piloting the PGA message set with two brokers in April 2014.

Comment: One commenter asked whether FSIS would be updating FSIS directives and notices to give inspection program personnel guidance on the new data elements for the Import Inspection Application.

Response: All FSIS Import Directives (9000 Series) were revised before the implementation of the PHIS Import Component and are available on the FSIS Website (http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/directives/phs_directives). In addition, inspection program personnel have been entering inspection application information

into the PHIS Import Component since its implementation in May 2012. The Agency is updating the Import Directives to reflect the Agency's reorganization but does not believe it needs to provide further instruction on the new data elements to its inspection program personnel.

Comment: Commenters questioned the timeframes for completing the revised paper-based Import Inspection Application (an additional 6 minutes when compared to the old version) and for filing the application electronically rather than submitting a paper-based application (an additional 1 minute). The commenters stated that it would take much longer and asked for the justification of the timeframes and the economic analysis based on the additional timeframes.

Response: As discussed in the Benefits and Costs section of the proposed rule (77 FR 70718), specifically Footnote 2, the Agency provided the time frames. Staff members conducted data entry simulation (i.e., entered data using the different formats) to estimate the additional time necessary to complete the revised paper-based Import Inspection Application and to electronically enter information into the ACE. The estimated additional time, the estimated number of Import Inspection Applications, and wage data from the Bureau of Labor Statistics provided the basis for the cost estimates to complete the paper-based application and electronically file the application.

Comment: One comment asked whether FSIS would increase staffing to enter data from the Import Inspection Application into the PHIS Import Component. One comment stated that the increase in the amount of data entry results in inspection assignment delays. Another comment asked whether FSIS will accept paper applications when the PHIS Import Component is unavailable, and what procedures are in place to distinguish between inspection applications filed electronically or by paper.

Response: FSIS does not intend to increase staffing for Import Inspection Application data entry. As FSIS inspection personnel have become more familiar with the PHIS Import Component, data entry time has decreased. Since implementation of the component, system enhancements have allowed more efficient data entry. When the PGA Message Set is implemented, the additional data elements needed to complete the Import Inspection Application will be transferred from ACE to the PHIS Import Component, eliminating the need for manual data entry by FSIS inspection personnel. When the PHIS Import Component is unavailable, FSIS Directive 9500.1, "Contingency Plan for Import Reinspections When the Public Health Information System (PHIS) is Unavailable," instructs inspection personnel to verify the eligibility of the shipment and appropriate "types of inspection" according to the defined rates of inspection under

the contingency plan. When the system becomes available, inspection personnel retrieve and complete the application in PHIS and proceed with requesting the assignments and entering the results of the inspection tasks that were performed. The PHIS Import Component tracks behind the user interface the method by which the application was received, i.e., whether it was entered manually or received from ACE.

Comment: One commenter wanted to know what action FSIS would take if a shipment arrives for reinspection before the paper import inspection application arrives.

Response: This final rule requires that Import Inspection Applications be submitted to FSIS in advance of the shipment's arrival at the official import inspection establishment, but no later than when the entry is filed with CBP (9 CFR 327.5(b), 381.198(b), and 590.920(b)). Inspection program personnel will first check the PHIS Import Component to confirm that the shipment made entry with CBP. For minor or inadvertent prior notice violations, FSIS will consider utilizing outreach (e.g., education and communication) with the IOR, and proceed with the reinspection if the entry is confirmed and a copy of the Import Inspection Application, along with the original foreign inspection certificate is submitted. However, if the violation reflects a history of repeated conduct of a similar nature by an IOR who has been notified of such violations, the shipment may

be refused entry. It should be noted that applicants filing entry with the PGA Message Set will meet this prior notice requirement.

Comment: Comments from domestic trade associations stated that some data elements are the same for the import inspection application and the foreign inspection certificate, however the information may differ between the application and the certificate, e.g., a corporate address listed on the certificate, a company address on the application. The commenters asked which information, if different, would take precedence. One trade association asked how differences in data elements would be handled, e.g., a foreign country uses one Harmonized Tariff Schedule (HTS) code and a broker uses another.

Response: The Import Inspection Application is completed by an applicant, usually an importer or customs broker. Therefore, if there is any discrepancy in importer or consignee information between the Import Inspection Application and the Foreign Inspection Certificate, FSIS would rely on the information provided on the Import Inspection Application. For importers and brokers participating in the PGA Message Set, FSIS would rely on any importer or consignee information electronically transferred from ACE to the PHIS Import Component. For any product-based information, the foreign inspection certificate information, which is certified by an

official of the foreign government, would take precedence over information provided on the Import Inspection Application. The HTS Code used by customs brokers must accurately represent the imported product. The HTS Code is filed with CBP when the entry is made, and transferred by CBP's ACE system into the PHIS Import Component. Therefore, the HTS code filed with CBP is the code that will take precedence.

Comment: Trade associations asked FSIS to clarify what HTS code will be required on the Import Inspection Application, since multiple HTS codes could be used for a specific product. The commenters also requested that FSIS clarify how new HTS codes will be made available to brokers.

Response: Customs brokers, when filing for entry with CBP, identify the HTS code for the entry, and those HTS codes are transferred from ACE to the PHIS Import Component. FSIS requires all the applicable HTS codes associated with the Import Inspection Application to be listed on the form (9 CFR 327.5, 381.198, and 590.920). For applicants that will utilize the PGA Message Set, ACE will prompt the filer to provide additional FSIS data elements (PG Records) for HTS codes that FSIS has identified as amenable product. CBP manages changes to the Harmonized Tariff Schedule.

Comment: One commenter asked that FSIS define the "production codes" information required on the Import Inspection Application.

Response: The revised Import Inspection Application (FSIS Form 9540-1), requests the "production date(s)," the date that the product was produced. If "production codes" are used on the product, they need to be translated into dates on the inspection certificate. However, the dates are only necessary if the foreign establishment has been delisted or relisted (9 CFR 327.2, 381.196).

Comments: One trade association asked how FSIS will process informal entries, because they may not use CBP's ACE system.

Response: Applicants (importers or consignees) are required to submit an Import Inspection Application to FSIS to apply for the reinspection of any amenable product offered for entry (9 CFR 327.5, 381.199, and 590.920). When an informal entry is made, i.e., an entry that does not utilize CBP's ACE system, CBP inputs the data into its electronic systems. FSIS receives the electronic data for informal entries via the Interconnectivity Web Services (IWS).

Prior Notification of Imported Product

Comment: One domestic trade association stated that FSIS should issue clear and consistent prior notification guidance

and enforcement instructions to inspection program personnel. Other domestic trade associations stated that FSIS should clarify whether its import policies are aligned with CBP's, and whether there will be allowances for legitimate, mitigating circumstances, e.g., when ACE is not operational. In addition, these commenters asked that the Agency explain the consequences of failing to provide notification.

Response: When this final rule becomes effective, the applicant will be required to submit an Import Inspection Application in advance of the shipment's arrival, but no later than when the entry is filed with CBP (9 CFR 327.5, 381.198, 590.920). FSIS is committed to working through any ACE-to-PHIS Import Component data transfer problems to avoid any delays in completing reinspection. As discussed above, FSIS will take necessary enforcement actions if an importer repeatedly fails to provide prior notice to FSIS, should the need arise.

Comment: One trade association stated that airline shipments utilize manifests or air bills for entry into the United States, which often do not translate into ACE system entries. The commenter stated that FSIS should provide guidance to inspection program personnel on how to handle airline shipments.

Response: Air shipments are accompanied by manifests or air bills that report cargo to CBP; however, air shipment

entries are processed the same way as other modes of transportation. Meat, poultry, and egg products shipments are identified by FSIS-specific HTS codes, the CBP entry data transfers from ACE to the PHIS Import Component, and inspection program personnel proceed with their reinspection activities.

Canadian Streamlined Inspection Procedures

Comment: Commenters stated that, since the United States and Canada currently have the U.S.-Canada Regulatory Cooperation Council (RCC) and the Beyond-the-Border (BtB) initiatives underway, the Agency should reconsider deleting the Canadian Streamlined Inspection procedures. One commenter asked FSIS to retain the streamlined procedures because reintroducing the streamlined procedures through future rulemaking may be more challenging than leaving the existing regulations in place. One comment stated that the streamlined procedures should not be deleted but amended to provide future flexibility for other countries. One comment stated that deleting the streamlined inspection procedures was a good housekeeping measure, and that the Agency should proceed with caution in moving forward too hastily with any pilot programs.

Response: As discussed in the preamble of the proposed rule (77 FR 70717), the Canadian Streamlined Inspection Procedures were codified in 1989 to further the goal of the 1988 U.S.-Canada Free Trade Agreement to reduce trade restrictions

between the United States and Canada. However, because of concerns raised in a Government Accountability Office (GAO) report, FSIS suspended use of these inspection procedures in 1992.

The 2011 RCC and BtB initiatives were launched to explore more effective approaches to regulation that enhance the economic competitiveness and well-being of the United States and Canada, while maintaining high standards of public health and safety, and environmental protection. To further these initiatives, in July 2012, FSIS announced that it would conduct a BtB Action Plan pre-clearance initiative pilot program that would consider alternative methods for reviewing import documents before the shipments arrival at the United States border and alternative methods for releasing shipments destined for further processing at FSIS establishments. To date, the BtB pilot program has not begun. The Agency will evaluate the BtB pilot program when it is complete and will seek public input before taking any action or effecting any changes more broadly. Current FSIS regulations require reinspection of all imported shipments but are flexible enough to allow, in appropriate circumstances, these activities to occur in official establishments, egg product plants, or official import inspection establishments. To this extent, the regulations are consistent with the objective of the BtB pilot project.

Consequently, FSIS is finalizing the proposed deletion of the Canadian Streamlined Inspection Procedures.

Sanitation Standard Operating Procedures (Sanitation SOPs)

Comment: Commenters questioned whether FSIS would withdraw or withhold inspection from official import establishments that fail to develop and implement Sanitation SOPs within the 60 days after publication of the final rule.

Response: FSIS does not anticipate that official import inspection establishments will delay or fail to develop Sanitation SOPs within 60 days after the publication of this final rule (the effective date) because, in practice, these establishments maintain these procedures during the reinspection of imported product. FSIS clearly explained in the proposed rule's preamble (77 FR 70717) and regulatory text (9 CFR 304.3 and 381.22) that official import inspection establishments would be required to develop and implement Sanitation SOPs. If an official import inspection establishment does not develop and implement Sanitation SOPs by the effective date of this final rule, the Agency may withhold inspection, under its Rules of Practice (9 CFR 500.3(a)(3)), until the official import inspection establishment meets the requirements of 9 CFR 304.3 and 381.22.

Comment: One foreign government asserted that reinspecting products at official import inspection establishments may

preclude the opportunity for a more flexible future approach to import inspection, e.g., inspecting products while they are still at the port. The commenter stated that reinspection at port facilities would be less costly and less trade-restrictive, and that this is the predominant international practice.

Response: Conducting reinspection at official import inspection establishments does not preclude FSIS from considering alternative approaches to reinspecting imported product. FSIS requires reinspection of all products offered for entry (9 CFR 327.6 (a), 381.199(a), and 590.925(a)), and it is the Agency's policy to perform import reinspection activities at official import inspection establishments in close proximity to a port-of-entry, thus minimizing costs to importers.

Foreign Inspection Certificate Replacement

Comment: Domestic trade associations stated that replacement certificates are not overly burdensome to the industry, as long as the foreign country's competent authority is able to quickly transmit the replacement certification through the PHIS Import Component. One commenter stated that the Agency should provide options for expedited reinspections for importers that do not use the PHIS Import Component, or when the PHIS Import Component is unavailable. A comment from a foreign government requested that FSIS clarify what constitutes

a "short time frame" for lost foreign inspection certificates or certificates that contain mistakes.

Response: As FSIS explained in the preamble to the proposed rule, replacement foreign inspection certificates can easily be replaced by emailing a PDF of the certificate to importinspection@fsis.usda.gov or sending the certificate by expedited mail service (77 FR 70718). Foreign countries that use eCert can resend foreign inspection certification electronically. FSIS inspection program personnel will proceed with import reinspection activities only when they receive either the paper replacement certificate, or the electronic certification. Foreign countries are required to ensure that foreign inspection certificates accompany product (9 CFR 327.4, 381.197, and 590.915). Therefore, it is not appropriate for FSIS to designate a specific timeframe to foreign countries for replacing the certificate.

Failure to Present (FTP)

Comment: Several domestic trade associations requested that FSIS define "in-commerce," for purposes of imported product that has bypassed reinspection and entered commerce. These commenters also requested clarification on whether transporting and storing imported product at a U.S. warehouse prior to reinspection would be considered a FTP.

Response: The importer is required to present all imported meat, poultry, and egg products for reinspection upon entry into the United States (9 CFR 327.6, 381.199, and 590.925). Once imported product leaves the official import inspection establishment, it is considered "in-commerce," unless it is moved to another location under the control of the official import inspection establishment (e.g., under company seal).

If the FTP product shipment is delivered to the end user in the United States, the imported product, or any product produced from the ineligible product, may be subject to FSIS recall or destruction. FSIS does not permit storing of imported meat, poultry, and egg products in a warehouse or other facility prior to reinspection, unless the warehouse or facility has the same physical address as the official import inspection establishment and it is physically connected to the official import establishment.

Comment: A domestic trade association requested that FSIS alert import companies to potential FTP product problems as soon as they are discovered.

Response: FSIS inspection program personnel are instructed in FSIS Directive 9900.1

http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/PHIS_9900.1.pdf to notify the applicant electronically through the PHIS Import Component when a shipment has not arrived at the official

import inspection establishment by the Estimated Date of Arrival (EDA) recorded on the import inspection application.

Comment: Domestic trade associations requested clarification on whether storing a product shipment at an official import inspection establishment pending reinspection is an FTP. These commenters also asked FSIS to clarify if imported product in a truck driven past an official import inspection establishment after hours of operations to a rest stop 10 miles away for the weekend would be considered an FTP.

Response: FSIS does not consider a product shipment stored at an official import inspection establishment pending reinspection to be an FTP. Establishment managers notify FSIS import inspection personnel of the shipment's arrival so that the status of the shipment can be changed to "On Premises" in the PHIS Import Component. If a truck is driven past an official import inspection establishment to a rest stop, the product shipment would not be considered FTP if it arrives at the official import inspection establishment by the EDA, provided the shipment is intact and has not been off-loaded.

Comment: Trade associations asked if FTP product guidelines will be available to importers, brokers, and I-houses for correlation.

Response: FSIS is currently developing compliance guidelines that will include FTP product guidance for the

importers, customs brokers, and official import inspection establishments, and will post the guidelines on the FSIS Website as soon as they are available.

Other Comments

Preclearance Sampling

Comment: A foreign government commented that FSIS should collect the samples before the product is shipped to the United States so that the consignment could remain at the foreign establishment pending the results of the testing.

Response: FSIS's port-of-entry sampling is designed to monitor the performance and effectiveness of the foreign inspection system, and the Agency will continue to sample imported shipments before their entry into U.S. commerce. The foreign country has the opportunity to collect samples under its own sampling programs.

Stamping of Product

Comment: One foreign government requested that FSIS explain the justification for manually stamping every carton of product in a consignment.

Response: As required in 9 CFR 327.10(b) and 381.204(a), the outside containers of all products offered for entry from any foreign country (excluding Canada) that are accompanied with a foreign inspection certificate, are found not to be adulterated or misbranded, and are otherwise eligible for entry

into the United States, shall be marked with the official inspection legend prescribed in 9 CFR 327.26 and 381.204(b). The stamping of imported product was not addressed in the proposed rule and is outside the scope of this final rule.

FSIS Jurisdiction in Facilities

Comment: Two trade associations asked FSIS to define where, within an official import inspection establishment, inspection program personnel would have jurisdiction.

Response: As provided in 9 CFR 304.2(a), when FSIS gives notice to the applicant granted inspection, the notice includes the limits of the establishment's premises, including official import inspection establishments, to which the grant pertains. In addition, the owner or operators of the official import inspection establishment must provide adequate facilities and equipment for examination of the imported product presented to FSIS personnel (9 CFR 327.6 (e)). FSIS inspection personnel have authority to enter any areas of the premises in order to monitor and verify compliance with these conditions.

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 final rule

The changes made by this final 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 final rule streamlines existing import

documentation requirements by making the foreign inspection certificate consistent among meat, poultry, and egg products. In addition, the final 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 will require the source country and establishment number when the source materials originate from a country other than the exporting country. The additional information will help FSIS 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 final rule may have a cost impact on the industry. However, the Agency believes the impacts of the final rule will be very small, if any. The possible impacts include:

(1) The electronic foreign inspection and foreign establishment certificates and the electronic import inspection application. Under this final rule, the industry will have the option of filing Import Inspection Applications electronically, and foreign governments will have the option of submitting

electronic inspection and foreign establishment certifications and data. As this is a voluntary option, FSIS assumes industry will chose to file electronically only if the benefits to them surpass their costs.

(2) Additional information entry. This final rule 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, i.e., paper or electronic.

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.¹ Updated Agency data show that there are, on average, a total of 108,140 applications per year that will be filed electronically using the ACE, and that 2,300 applications per year will be completed manually.² Therefore, the total additional time for electronically filing the application will be 1,802 hours ($108,140 * 1/60 = 1,802$) and the additional time for completing

¹ Time estimates from the International Policy Division (currently the International Relations and Strategic Planning Staff (IRSPS)), Office of Policy and Program Development, FSIS, USDA.

² Number of applications from the Automated Import Inspection System (AIIS) and the Public Health Information System, FSIS, USDA.

the new paper-based application will be 232 hours ($2,317 * 6/60 = 232$). Monetizing these hours by \$38 per hour³, the estimated cost to complete the new application would be about \$77,000 ($\$38 * (232 + 1,802)$) per year.

(3) Sanitation Standard Operating Procedures (SOPs) as a condition of approval for official import inspection establishments. The final rule clarifies that official import inspection establishments must have developed written Sanitation SOPs before being granted approval. 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, requiring Sanitation SOPs will have little cost impact (including recordkeeping cost impact) on the industry.

(4) The final rule removes the regulatory provisions for the streamlined import inspection system for Canadian product. Since the procedures have been obsolete since 1992, removing the regulatory provisions will have no significant economic impact.

Regulatory Flexibility Analysis

The FSIS Administrator certifies that, for the purposes of the Regulatory Flexibility Act (5 U.S.C. 601-602), this final

³ Bureau of Labor Statistics "Occupational Employment & Wages" Database, May 2012. Animal Production Managers, all other \$48.51 @ 47.6% time; General and Operations Managers \$37.22 @ 26.2% time; Food scientists and technologists \$18.45 @ 26.2% time = \$38.00 Managerial Median hourly wage.

rule will 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 will continue to accept paper applications. Similarly, the other changes in the final rule will not result in significant costs to industry and, therefore, will not have a significant impact on a substantial number of small entities.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this final 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 final 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(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the information collection requirement associated with this final rule has been submitted for approval to the Office of Management and Budget (OMB). This information collection request is at OMB awaiting approval. FSIS will collect no information associated with this rule until the information collection is approved by OMB.

Copies of this information collection assessment can be obtained from Gina Kouba, Paperwork Reduction Act Coordinator, Food Safety and Inspection Service, USDA, 1400 Independence Avenue, SW., Room 6077, South Building, Washington, DC 20250-3700; (202) 690-6510.

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](http://www.fsis.usda.gov/regulations&policies/ProposedRules/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/wps/portal/fsis/programs-and-services/email-subscription-service>.

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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Mail:

U.S. Department of Agriculture
Director, Office of Adjudication
1400 Independence Avenue, SW
Washington, DC 20250-9410

Fax: (202) 690-7442

E-mail: program.intake@usda.gov

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

List of Subjects

9 CFR Part 304

Meat inspection.

9 CFR Part 327

Imports.

9 CFR Part 381

Poultry and poultry products.

9 CFR Part 590

Eggs and egg products.

For the reasons discussed in the preamble, FSIS is amending 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 Procedures, as required by part 416 of this chapter, and written recall procedures as required by part 418 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.

(i) For a new establishment, or any establishment for which information from last year's electronic certification or paper certificate has changed, the certification or certificate must contain: the date; the foreign country; the foreign establishment's name, address, and foreign establishment number; the foreign official's title and signature (for paper certificates only); the type of operations 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 products produced at the establishment (e.g., the process category).

(ii) If the establishment information provided on the preceding year's electronic foreign establishment certification or paper certificate, as required in paragraph (a)(3)(i) of this section, has not changed, the certification or certificate must contain: the date, the foreign country, the foreign establishment's name, and the foreign official's title and signature (for paper certificates only).

* * * * *

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; bear the official seal of the foreign government responsible for the inspection of the product, and the name, title, and signature of the official authorized to issue inspection certificates for products imported to the United States.

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

- (1) The date;
- (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 importer or consignee;
- (6) The name and address of the exporter or consignor;

- (7) The number of units (pieces or containers) and the shipping or identification mark on the units;
- (8) The net weight of each lot; and
- (9) Any additional information the Administrator requests to determine whether the product is eligible to be imported into the United States.

7. Revise §327.5 to read as follows:

§ 327.5 Import inspection application.

(a) Applicants must submit an 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 form.

(b) Import inspection applications for each consignment must be submitted (electronically or on 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 electronic inspection system shall be consulted for reinspection instructions. The electronic inspection system 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 the electronic inspection system.

* * * * *

(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 import inspection 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 definition 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 establishment or an official import inspection establishment, must have developed written Sanitation Standard Operating Procedures, as required by part 416 of this chapter, and written recall procedures as required by part 418 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 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.

(i) For a new establishment or any establishment for which information from last year's electronic certification or paper certificate has changed, the certification or 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 certificates 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 products produced at the establishment (e.g., the process category).

(ii) If the establishment information provided on the preceding year's electronic foreign establishment certification or paper certificate, as required in paragraph (a)(3)(i) of this section, has not changed, the certification or certificate must contain: the date, the foreign country, the foreign establishment's name, the foreign official's title and signature (for paper certificates only).

* * * * *

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 official seal of the foreign government responsible for the inspection of the product, and the name, title, and signature of the official authorized to issue inspection certificates for products imported to the United States.

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

(1) The date;

(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 importer or consignee;

(6) The name and address of the exporter or consignor;

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

(8) The net weight of each lot; and

(9) Any additional information the Administrator requests to determine whether the product is eligible to be imported into the United States.

15. Revise § 381.198 to read as follows:

§ 381.198 Import inspection application.

(a) Applicants must submit an 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 form.

(b) Import inspection applications for each consignment must be submitted (electronically or on 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 paragraph (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 electronic inspection system shall be consulted for reinspection instructions. The electronic inspection system 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 the electronic inspection system.

* * * * *

(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 Meat, Poultry and Egg Product Inspection Directory, 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 this part.

(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 official seal of the foreign government responsible for the inspection of the product, and the name, title, and signature of the official authorized to issue the inspection certificates for products imported into the United States.

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

- (1) The date;
- (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 importer or consignee;
- (6) The name and address of the exporter or consignor;
- (7) The number of units (pieces or containers) and the shipping or identification mark on the units;

(8) The net weight of each lot; and

(9) Any additional information the Administrator requests to determine whether the product is eligible to be imported into the United States.

19. Revise § 590.920 to read as follows:

§ 590.920 Import inspection application.

(a) Applicants must submit an 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 form.

(b) Import inspection applications for each consignment must be submitted (electronically or on 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: September 11, 2014.

Alfred V. Almanza,

Administrator

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