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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 381

[Docket No. FSIS-2015-0016]

RIN 0583-AD58

Eligibility of Honduras to Export Poultry Products to the United States

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to add Honduras to the list of countries eligible to export poultry products to the United States. The FSIS review of Honduras' laws, regulations, and inspection system demonstrated that its poultry slaughter inspection system is equivalent to the system FSIS has established under the Poultry Products Inspection Act (PPIA) and its implementing regulations.

At this time, because Honduras advised FSIS that it intends to export raw poultry products, such as whole carcasses, to the United States, FSIS has only assessed Honduras' poultry slaughter establishments. Thus, should this proposed rule become final, Honduras would only be eligible to export raw poultry products to the United States. Should Honduras express interest

in exporting processed poultry product, such as cooked or canned product, to the United States, they would need to request an equivalence determination. Honduras would be required to submit additional records for FSIS to review and conduct an audit as appropriate.

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

DATES: Submit comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

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

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

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

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

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2015-0016. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

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

FOR FURTHER INFORMATION CONTACT:

Dr. Daniel Engeljohn, Assistant Administrator, Office of Policy and Program Development; Telephone: (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

FSIS is proposing to amend its poultry products inspection regulations to add Honduras to the list of countries eligible to export poultry products to the United States (9 CFR 381.196(b)). Honduras is not currently listed as eligible to export poultry products to the United States. Honduras is currently eligible for the export of raw and processed meat products. If this

proposed rule is finalized, establishments in Honduras will be eligible to export raw poultry to the United States. However, because of animal disease restrictions, Animal and Plant Health Inspection Service (APHIS) regulations restrict Honduras from shipping raw poultry product to the U.S. Newcastle disease (ND) is considered by APHIS to exist in all regions of the world except those listed in paragraph (a)(2) of 9 CFR section 94.6. Because Honduras is not listed, the APHIS regulation restricts the importation of poultry carcasses, meat, parts or products of carcasses, and eggs (other than hatching eggs) of poultry, game birds, or other birds from Honduras. Honduras has requested APHIS' recognition of their ND status as ND free, and APHIS is conducting a review and evaluation. If APHIS determines that the request can be safely granted, it will state its intent and make its evaluation available for public comment through a document published in the Federal Register.

Statutory Basis for Proposed Action

Section 17 of the PPIA (21 U.S.C. 466) prohibits importation into the United States of slaughtered poultry, or parts or products thereof, of any kind unless they are healthful, wholesome, fit for human food, not adulterated, and contain no dye, chemical, preservative, or ingredient that renders them unhealthful, unwholesome, adulterated, or unfit for human food. Under the PPIA and the regulations that implement it, poultry

products imported into the United States must be produced under standards for safety, wholesomeness, and labeling accuracy that are equivalent to those of the United States. Section 381.196 of Title 9 of the Code of Federal Regulations (CFR) sets out the procedures by which foreign countries may become eligible to export poultry and poultry products to the United States.

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

at establishments certified to export; (7) official controls over condemned product; (8) a Hazard Analysis and Critical Control Point (HACCP) system; and (9) any other requirements found in the PPIA and its implementing regulations (9 CFR 381.196(a)(2)(ii)).

In addition to a foreign country's legal authority and regulations, the program itself must be equivalent to the United States. Specifically, the program organized and administered by the national government must impose requirements equivalent to those of the United States with respect to: (1) Organizational structure and staffing, so as to ensure uniform enforcement of the requisite laws and regulations in all certified establishments; (2) ultimate control and supervision by the national government over the official activities of employees or licensees; (3) qualified inspectors; (4) enforcement and certification authority; (5) administrative and technical support; (6) inspection, sanitation, quality, species verification, and residue standards; and (7) any other inspection requirements (9 CFR 381.196(a)(2)(i)).

The foreign country's inspection system must ensure that establishments preparing poultry or poultry products for export to the United States, and their products, comply with requirements equivalent to those of the PPIA and the regulations promulgated by FSIS under the authority of that statute. The

foreign country certifies the appropriate establishments as having met the required standards and advises FSIS of those establishments that are certified or removed from certification. Before FSIS will grant approval to the country to export poultry or poultry products to the United States, FSIS must first determine that reliance can be placed on the certification of establishments by the foreign country.

As indicated above, a foreign country's inspection system must be evaluated by FSIS before eligibility to export poultry products to the United States can be granted. This evaluation consists of two processes: a document review and an on-site review. The document review is an evaluation of the laws, regulations, and other written materials used by the country to effect its inspection program. To help the country in organizing its material, FSIS provides the country with a series of questions asking for detailed information about the country's inspection practices and procedures in six areas or equivalence components: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Point (HACCP) Systems, (5) Chemical Residue Testing Programs, and (6) Microbiological Testing Programs. FSIS evaluates the information submitted to verify that the critical points in the six equivalence components are addressed satisfactorily with respect to standards, activities, resources,

and enforcement. If the document review is satisfactory, an on-site review is scheduled using a multi-disciplinary team to evaluate all aspects of the country's inspection program. This comprehensive process is described more fully on the FSIS Web site at

<http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/equivalence/equivalence-process-overview>.

The PPIA and implementing regulations require that foreign countries be listed in the CFR as eligible to export poultry products to the United States. FSIS must engage in rulemaking to list a country as eligible. Countries found eligible to export poultry or poultry products to the United States are listed in the poultry inspection regulations at 9 CFR 381.196(b). Once listed, it is the responsibility of the eligible country to certify that establishments meet the requirements to export poultry or poultry products to the United States and to ensure that products from these establishments are safe, wholesome, and not misbranded. To verify that products imported into the United States are safe, wholesome, and properly labeled and packaged, FSIS re-inspects and randomly samples those products before they enter the United States commerce.

Evaluation of the Honduran Poultry Inspection System

In 2003, the government of Honduras submitted an initial equivalence application and requested that FSIS conduct a review of Honduras' poultry slaughter inspection system to establish eligibility to export raw poultry products to the United States. FSIS conducted a document review of Honduras' poultry (slaughter) inspection system to determine whether that system was equivalent to that of the United States. Honduras only expressed interest in exporting raw poultry carcasses to the United States, and Honduras does not have a poultry processing establishment. Therefore, FSIS did not obtain documentation for an equivalence review of such a system. FSIS concluded on the basis of the review of Honduras' poultry slaughter system that Honduras' laws and regulations are equivalent to the Poultry Products Inspection Act (PPIA) and implementing regulations.

Accordingly, FSIS proceeded with an initial on-site audit of Honduras' poultry slaughter system in November 2005, to verify whether Honduras' National Plant and Animal Health Service (SENASA), which is Honduras' central competent authority for food inspection, effectively implemented a poultry inspection system equivalent to that of the United States. The audit resulted in the identification of systemic deficiencies within the following three equivalence components: Government Oversight, Sanitation, and HACCP. The audit found that SENASA did not have adequate government oversight and administrative

controls over the inspection system. Also SENASA did not properly stage the necessary number of post-mortem inspectors at the evisceration line. In addition, the audit found during pre-operational sanitation verification inspection, SENASA did not implement procedures to ensure all shackles checked in a 15 foot section were not free of protein residue, fat particles from the previous day's production and dried paint droplets. Likewise, the audit found that SENASA failed to verify whether establishments met HACCP requirements within the system. SENASA took corrective actions to address all of the audit findings, either at the time of the finding, or after the distribution of the Final Audit Report on March 7, 2006. FSIS reviewed the proffered corrective actions and determined that they would be sufficient to prevent re-occurrence.

FSIS conducted a second on-site audit in June 2009, to verify whether all outstanding issues identified during the previous audit had been resolved. The 2009 audit verified that the implementation of Honduras' corrective actions to the previous audit findings were implemented as described and were working as intended.

However, the 2009 audit resulted in the identification of systemic deficiencies that had not been identified in the previous audit. The deficiencies related to the equivalence components of Sanitation, HACCP, and Microbiological Testing

Programs. Specifically, the 2009 audit found that, with regard to Sanitation, SENASA did not implement procedures to verify adequate sanitation programs. With regard to HACCP, SENASA did not implement procedures to verify establishments met HACCP requirements. Finally, with regard to Microbiological Testing Programs, SENASA did not provide adequate controls over the implementation of laboratory quality systems associated with microbiological testing of product which is intended for export to the U.S.

After the 2009 on-site audit, Honduras developed a comprehensive corrective action plan to address the findings identified during the 2009 on-site audit. Its corrective actions included implementing new regulations, procedures, measures, and verification activities to ensure uniformity in conducting official inspection activities. FSIS reviewed Honduras' corrective action plan and concluded that Honduras had satisfactorily addressed all audit findings.

FSIS conducted a third on-site audit in September, 2014, to verify that Honduras had satisfactorily addressed all the findings of the November 2005 and June 2009 audits, and had met the FSIS criteria for all six equivalence components. The evaluation of all documentation provided by Honduras since the 2009 audit (corrective actions taken in response to the 2009 audit findings, regulatory updates, new performance standards,

new microbiological laboratory procedures/analyses) supported the decision to perform another audit. The auditor verified that all corrective actions to the 2009 audit findings were implemented as described, and working as intended. There were no new audit findings observed by the auditor during the 2014 on-site audit. The resolution of previous audit findings, and the absence of new audit findings supports the conclusion that the Honduran poultry regulatory system cumulatively achieves a level of protection equivalent to that provided by the United States' poultry inspection system.

In summary, FSIS has completed the document review, on-site audits, and verification of corrective actions as part of the equivalence process, and all outstanding issues have been resolved. FSIS has tentatively concluded that, as implemented, Honduras' poultry inspection system (slaughter) is equivalent to the United States' poultry inspection system. The full report on Honduras' poultry inspection system (slaughter) can be found on the FSIS Web site at <http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports/foreign-audit-reports>.

At this time, Honduras intends to certify only one establishment as eligible to export product to the U.S. The establishment intends to export raw poultry product. Should this

proposed rule become final, the government of Honduras must certify to FSIS those establishments that wish to export poultry products to the United States and that operate in accordance with requirements equivalent to that of the United States (9 CFR 381.196(a)). FSIS will verify that the establishments certified by Honduras' government are meeting the United States requirements through verification audits of Honduras' poultry inspection system.

Although a foreign country may be listed in FSIS regulations as eligible to export poultry to the United States, the exporting country's products must also comply with all other applicable requirements of the United States. These requirements include restrictions under 9 CFR part 94 of the United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) regulations, which also regulate the exportation of poultry products from foreign countries to the United States. At this time, APHIS does not allow Honduras to export raw poultry to the US because Honduras is not recognized by APHIS as a region free of Newcastle disease (ND).

If this proposed rule is adopted and should APHIS allow Honduras to export raw poultry to the US in the future, all slaughtered poultry, or parts and products thereof, exported to the United States from Honduras will be subject to re-inspection at the U.S. ports of entry for, but not limited to,

transportation damage, product and container defects, labeling, proper certification, general condition, and accurate count.

In addition, FSIS will conduct other types of re-inspection activities, such as taking product samples for laboratory analysis for the detection of drug and chemical residues, pathogens, species, and product composition. Products that pass re-inspection will be stamped with the official United States mark of inspection and allowed to enter United States commerce. If they do not meet United States requirements, they will be refused entry and within 45 days must be exported to the country of origin, destroyed, or converted to animal food (subject to approval of FDA), depending on the violation. The import re-inspection activities can be found on the FSIS Web site at

http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/phish-import-component/phish-implementation-letter-to-importers/ct_index.

Executive Order 12866 and 13563, and the Regulatory Flexibility Act

Executive Orders 12866 and 13563 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 proposed rule has been designated a "non-significant" regulatory action under section 3(f) of Executive Order 12866. Accordingly, the proposed rule has not been reviewed by the Office of Management and Budget under Executive Order (E.O.) 12866.

Expected Cost of the Proposed Rule

If this proposed rule is finalized, establishments in Honduras will be eligible to export raw poultry to the United States. However, because of animal disease restrictions, APHIS regulations currently prohibit Honduras from immediately shipping raw poultry product to the U.S. Honduras' establishments are currently eligible to export raw and processed beef and veal, raw and processed lamb and mutton, raw and processed goat as well as processed pork. According to data from the government of Honduras, if this proposed rule is finalized, Honduras intends to certify one establishment as eligible to export raw poultry to the United States.¹ The expected export volume for this establishment for the first

¹ Honduras currently has only two establishments certified for meat exports to the United States. Therefore, it is unlikely we will see a significant increase in the number of establishments eligible to export poultry from Honduras.

three years is 10,211 Metric Tons (MT). This is expected to increase to 11,231 MT in year four and 12,355 MT in year five.²

The U.S. poultry industry is one of the most competitive agricultural industries in the world. U.S. establishments slaughtered 17.9 million MT of young chickens in 2014.³ Approximately 3.0 million MT of young chickens slaughtered in the U.S. were exported in 2014. U.S. exports of young chicken comprised 31 percent of the market share among major traders in 2014.⁴

The importation of poultry products from Honduras is expected to have a minimal impact on the United States poultry market. Should the proposed rule become final, FSIS estimates Honduras' exports would comprise 0.6 percent (10,211 MT from Honduras compared to a U.S. slaughter volume of 17.9 million MT in 2014) of the United States market annually the first three years. FSIS estimates Honduras' exports would continue to comprise 0.6 percent of the United States market the fourth year and increase 0.7 percent the fifth year. FSIS projects that Honduras would not alter the United States poultry supply and would not have an impact on domestic poultry prices. Therefore, FSIS projects that establishments in the U.S. would not see the

² Source: Correspondence with the Government of Honduras.

³ Source: FSIS's Public Health Information System (PHIS)

⁴ USDA Foreign Agricultural Service. (October 2014). Livestock and Poultry: World Markets and Trade. Washington, DC.
http://apps.fas.usda.gov/psdonline/circulars/livestock_poultry.pdf

negative effects that could come from a decrease in price as a result of increased competition.

Companies based in Honduras that export to the United States or U.S. companies that export products from Honduras to the U.S. would incur standard costs such as export fees and freight and insurance costs. However, those companies would be willing to bear these costs because of the expected benefits associated with selling their products to the U.S.

Expected Benefits of the Proposed Rule

Should this proposed rule become final, we would see an increase in trade between Honduras and the United States. The volume of poultry exported from Honduras is likely to be small and is expected to have little to no effect on U.S. poultry supplies or prices. Therefore, consumers will not benefit from a decrease in price that would result from increased competition. However, Latin American preferences for dark meat complement American preferences for white meat. Therefore, Honduras' establishments will benefit if they export surplus white meat to the United States. While the export of white meat from Honduras may be minimal compared to overall U.S. consumption, these

exports may be significant enough in the long run to have an effect on domestic prices in Honduras.⁵

In addition, the Dominican Republic-Central America-United States Free Trade Agreement (CAFTA-DR), implemented in 2006, sought to level the playing field and increase trade between the United States and the six CAFTA-DR trading partners, including Honduras.⁶ If this proposed rule is finalized, we would see a fulfillment of those objectives, benefiting U.S. and Honduras' firms and consumers, especially within the agricultural sector. Providing market access in the U.S. to Honduras' establishments ensures similar access will be given to U.S. firms. American firms have already benefited from CAFTA-DR, with agricultural exports (including wheat, live animals and red meat) to Honduras nearly doubling (97 percent) between 2006 and 2014 and is expected to rise even further in the future.

Regulatory Flexibility Act Assessment

The FSIS Administrator has made a preliminary determination that this proposed rule will not have a

⁵ Haley, Mildred M. (May 2001). Changing Consumer Demand for Meat: The U.S. Example, 1970-2000. In A. Regmi, *Changing Structure of Global Food Consumption and Trade* (pp.41-48). (Economic Research Service Outlook No. WRS-01-1) Washington, DC.

⁶ United States Department of Agriculture. *FACT SHEET on Dominican Republic-Central America-United States Free Trade Agreement* (Release No. 0237.08). Retrieved on March 18, 2015 from <http://www.usda.gov/wps/portal/usda/usdamediafb?contentid=2008/09/0237.xml&printable=true&contentidonly=true>.

significant economic impact on a substantial number of small entities in the United States, as defined by the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) because, as stated above, the proposed rule would not have a significant effect on an U.S. establishments.

Paperwork Reduction Act

No new paperwork requirements are associated with this proposed rule. Foreign countries wanting to export poultry and poultry products to the United States are required to provide information to FSIS certifying that their inspection system provides standards equivalent to those of the United States, and that the legal authority for the system and their implementing regulations are equivalent to those of the United States. FSIS provided Honduras with questionnaires asking for detailed information about the country's inspection practices and procedures to assist that country in organizing its materials. This information collection was approved under OMB number 0583-0153. The proposed rule contains no other paperwork requirements.

E-Government Act

FSIS and the U.S. Department of Agriculture (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

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this Federal Register publication and officially notify the World Trade Organization's Committee on Sanitary and Phytosanitary Measures (WTO/SPS Committee) in Geneva, Switzerland, of this proposal on-line through the FSIS Web page located at:

<http://www.fsis.usda.gov/federal-register>.

FSIS also will make copies of this 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 our constituents and stakeholders. The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an e-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/subscribe>. Options range from recalls to export information, regulations, directives, and

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Washington, DC 20250-9410

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E-mail: program.intake@usda.gov

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List of Subjects in 9 CFR Part 381

Imported products.

For the reasons set out in the preamble, FSIS is proposing to amend 9 CFR part 381 as follows:

PART 381--POULTRY PRODUCTS INSPECTION REGULATIONS

1. 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.

§ 381.196 [Amended]

2. Section 381.196 is amended in paragraph (b) by adding "Honduras" in alphabetical order to the list of countries.

Done at Washington, DC, on: April 8, 2016.

Alfred V. Almanza,
Acting Administrator.

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