

**D. Executive Order 12866**

This amendment does not meet the criteria for a “significant regulatory action” as specified in Executive Order 12866.

**E. Executive Order 13132**

The rule will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, DHS has determined that this final rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

**F. Executive Order 12988 Civil Justice Reform**

This rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

**G. Paperwork Reduction Act**

The Department of Homeland Security is modifying OMB Control Number 1651–0111, Arrival and Departure Record, to allow eligible Poland passport holders to use the Electronic System for Travel Authorization (ESTA) to apply for authorization to travel under the VWP prior to departing for the United States. CBP uses the information to assist in determining if an applicant is eligible for travel under the VWP. The Department is requesting emergency processing of this change to 1651–0111 as the information is essential to the mission of the agency and is needed prior to the expiration of time periods established under the PRA. Because of the designation of Poland for participation in the VWP, the Department is requesting OMB approval of this information collection in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507).

The addition of Poland to the Visa Waiver Program will result in an estimated annual increase to information collection 1651–0111 of 300,000 responses and 75,000 burden hours. The total burden hours for ESTA, including Poland, is as follows:

*Estimated annual reporting burden:* 3,625,000 hours.

*Estimated number of respondents:* 14,500,000 respondents.

*Estimated average annual burden per respondent:* 15 minutes.

**List of Subjects in 8 CFR Part 217**

Air carriers, Aliens, Maritime carriers, Passports and visas.

**Amendments to the Regulations**

For the reasons stated in the preamble, DHS amends part 217 of title 8 of the Code of Federal Regulations (8 CFR part 217) as set forth below.

**PART 217—VISA WAIVER PROGRAM**

■ 1. The general authority citation for part 217 continues to read as follows:

**Authority:** 8 U.S.C. 1103, 1187; 8 CFR part 2.

■ 2. In § 217.2(a), the definition of “Designated country” is revised to read as follows:

**§ 217.2 Eligibility.**

(a) \* \* \*

*Designated country* refers to Andorra, Australia, Austria, Belgium, Brunei, Chile, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Monaco, the Netherlands, New Zealand, Norway, Poland, Portugal, Republic of Korea, San Marino, Singapore, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Taiwan, and the United Kingdom. The United Kingdom refers only to British citizens who have the unrestricted right of permanent abode in the United Kingdom (England, Scotland, Wales, Northern Ireland, the Channel Islands, and the Isle of Man); it does not refer to British overseas citizens, British dependent territories’ citizens, or citizens of British Commonwealth countries. Taiwan refers only to individuals who have unrestricted right of permanent abode on Taiwan and are in possession of an electronic passport bearing a personal identification (household registration) number.

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**Kevin McAleenan,**

*Acting Secretary.*

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**DEPARTMENT OF AGRICULTURE**

**Food Safety and Inspection Service**

**9 CFR Part 327**

[Docket No. FSIS–2016–0002]

RIN [0583–AD64]

**Eligibility of the People’s Republic of China (PRC) To Export to the United States Poultry Products From Birds Slaughtered in the PRC**

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

**ACTION:** Final rule.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) is amending the Federal poultry products inspection regulations to add the People’s Republic of China (PRC) as eligible to export to the United States poultry products from birds slaughtered in the PRC. FSIS has reviewed the PRC’s poultry laws, regulations, and inspection system, as implemented, and has determined that they are equivalent to the Poultry Products Inspection Act (PPIA), the regulations implementing this statute, and the United States’ food safety system for poultry. Under this final rule, slaughtered poultry, or parts or other products thereof, processed in certified PRC establishments, are eligible for export to the United States. All such products are subject to reinspection at United States ports of entry by FSIS inspectors.

**DATES:** Effective December 9, 2019.

**FOR FURTHER INFORMATION CONTACT:** Roberta Wagner, Assistant Administrator, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, 1400 Independence Avenue SW, Washington, DC 20250–3700; Telephone: (202) 205–0495.

**SUPPLEMENTARY INFORMATION:**

**Background**

On June 16, 2017, FSIS published a proposed rule in the **Federal Register** (82 FR 27625) to amend FSIS’s poultry products inspection regulations to list the PRC as eligible to export to the United States poultry products from birds slaughtered in the PRC. FSIS proposed this action after the Agency conducted a documentary review of the PRC’s laws, regulations, and poultry slaughter inspection system, as well as an in-country audit of the system, and determined that it is equivalent to the U.S. system established under the Poultry Products Inspection Act (PPIA) and its implementing regulations. This final rule is consistent with the provisions of the proposed rule.

The PRC is already eligible to export processed poultry products to the United States if the products are derived from poultry slaughtered in the United States or in other countries with a poultry slaughter inspection system equivalent to that of the United States. Under this final rule, the PRC is eligible to export to the United States poultry products derived from birds slaughtered in the PRC. The PRC may not export raw poultry at this time because of restrictions owing to animal disease risk put in place by the USDA Animal and

Plant Health Inspection Service (APHIS). Regarding processed poultry, the PRC may only export Fully Cooked-Not Shelf Stable products, because FSIS has only assessed information and audited the government controls for the production of products under this processing category.<sup>1</sup> The PRC would need to submit additional information for FSIS to review, and would likely need to undergo an additional audit before FSIS would allow the PRC to export other processed poultry products to the United States.

As explained in the proposed rule, under the PPIA and implementing regulations, poultry and poultry products imported into the United States must be produced under standards for safety, wholesomeness, and labeling that are equivalent to those of the U.S. system (21 U.S.C. 466). 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.

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

The country's inspection program must also impose requirements equivalent to those of the United States with respect to: (1) Organizational structure and staffing in certified establishments to ensure uniform

enforcement of laws and regulations; (2) national government control and supervision 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)).

#### Evaluation of the PRC's Poultry Inspection System

In 2004, at the request of the PRC, FSIS conducted a document review of the PRC's poultry (slaughter and processing) inspection system, concluding that the PRC's laws, regulations, control programs, and procedures were equivalent to those of the United States. FSIS proceeded with an on-site audit to verify that the PRC's General Administration of Quality Supervision, Inspection, and Quarantine (AQSIQ), which was the PRC's central competent authority (CCA) in charge of food inspection, had effectively implemented a poultry inspection system equivalent to that of the United States.<sup>2</sup> However, FSIS identified problems involving sanitation, slaughter, processing, residue controls, supervision, and enforcement. In 2005, FSIS conducted a follow-up on-site audit and concluded that the PRC had satisfactorily addressed the previous audit findings for poultry processing only.

In 2006, FSIS published a final rule in the **Federal Register** making the PRC eligible to export poultry products to the United States, but only from birds slaughtered under Federal inspection in the United States or other countries eligible to export slaughtered poultry products to the United States (71 FR 20867, April 24, 2006). Shortly after the publication, Congress prohibited FSIS from allowing poultry products to be imported from the PRC (see Sec. 733 of Pub. L. 110–161). In 2009, Congress removed this prohibition.

In June 2010, FSIS experts traveled to the PRC to collect information related to legislation applicable to the country's poultry inspection system, including the PRC's 2009 Food Safety Law. In December 2010, FSIS conducted separate but concurrent on-site audits of the PRC's poultry slaughter and

processing inspection systems. FSIS reviewed the effectiveness of the PRC's food safety program based on whether the following equivalence components were addressed satisfactorily with respect to standards, activities, resources, and enforcement: (1) Government Oversight (*e.g.*, Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (*e.g.*, Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government HACCP Systems; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The auditors concluded that the PRC was able to meet the principal requirements for the equivalence components of Government Sanitation and Government Chemical Residue Testing Programs. However, FSIS identified systemic inadequacies in both the slaughter and processed poultry inspection systems regarding the other four equivalence components. For example, FSIS found that the CCA lacked a standardized method to assign inspection personnel to slaughter facilities and also utilized establishment-paid inspectors to conduct official inspection duties. The CCA responded by developing a comprehensive corrective action plan addressing the findings.

In March 2013, FSIS conducted follow-up on-site audits to verify whether the PRC had implemented the corrective actions proffered in response to the previous audit findings. Based on the audit findings, FSIS concluded that the PRC's processed poultry inspection system was equivalent to the U.S. system and announced that the PRC could export processed poultry products to the United States. However, FSIS also found that the CCA had not adequately addressed all of FSIS's concerns about its poultry slaughter inspection system. Specially, the CCA still lacked a standardized method to assign inspection personnel to slaughter facilities on the basis of objective measurements. The CCA responded to these concerns, stating that it would implement changes to its poultry slaughter inspection system.

In May 2015, FSIS conducted an on-site audit to verify whether the CCA adopted the necessary corrective measures to its poultry slaughter inspection system. Based on the audit, FSIS concluded that the PRC had satisfactorily addressed all issues of concern that FSIS had raised in its 2013 audit of the PRC poultry slaughter

<sup>1</sup> See FSIS Product Categorization guide, available at: <https://www.fsis.usda.gov/wps/wcm/connect/abfb595d-7fc7-4170-b7be-37f812882388/Product-Categorization.pdf?MOD=AJPERES>.

<sup>2</sup> Since FSIS completed its preliminary determination regarding equivalence of the PRC's poultry inspection system, the PRC has reorganized and renamed its CCA, now organized under the General Administration of Customs of the People's Republic of China. This reorganization has no substantive impact on FSIS' determination of equivalence.

inspection system and had met the FSIS equivalence criteria for all six components.

On August 21, 2014, FSIS published the final rule *Modernization of Poultry Slaughter Inspection* (79 FR 49566). The rule created regulatory changes that apply to all poultry slaughter establishments and established a new optional post-mortem inspection system, the New Poultry Inspection System (NPIS). On August 11, 2016, the PRC sent a letter to FSIS outlining the changes that were made to the PRC's poultry inspection system to achieve equivalency with the new U.S. regulations. These included requirements that establishments have procedures to ensure that carcasses with visible fecal contamination do not enter the chiller and prerequisite programs to prevent contamination of carcasses and parts by enteric pathogens and visible fecal material. The PRC also stated in the letter that it had adopted the U.S. requirements for NPIS. On September 1, 2016, the PRC sent copies of its updated inspection manuals to FSIS. The letter and the relevant portions of the inspection manuals are available at: [www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/proposed-rules](http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/proposed-rules). FSIS reviewed the submitted letter and updated manuals and determined that the PRC's poultry slaughter inspection system is equivalent to the U.S. system in regard to the *Modernization of Poultry Slaughter Inspection* requirements.

Consequently, on June 16, 2017, FSIS published a proposal to find that the PRC's poultry slaughter inspection system is equivalent to the United States' system and, therefore, to remove from the regulations the limitation that the products must originate from birds slaughtered under Federal inspection in the United States or in a country eligible to export slaughtered poultry products to the United States. For more detailed information on FSIS's evaluations of the PRC's poultry inspection system see the proposed rule (82 FR 27625) and for the full audit reports, go to: <http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports>.

In November 2018, FSIS conducted an audit of PRC's poultry inspection system, reviewing the inspection and regulation by the PRC of both poultry processing and slaughter. FSIS identified no significant problems and the PRC poultry inspection system was again found to be equivalent. FSIS will publish the findings from this audit in the future.

## Final Rule

After considering the comments received on the proposed rule, discussed below, FSIS concludes that the PRC's poultry inspection system is equivalent to the United States' inspection system for poultry and poultry products. Therefore, FSIS is amending its poultry products inspection regulations to permit imports from the PRC of poultry products, derived from birds slaughtered in the PRC (9 CFR 381.196(b)). Under FSIS's import regulations, the PRC must certify to FSIS that those establishments that wish to export poultry product to the United States are operating under requirements equivalent to those of the United States (9 CFR 381.196(a)).

Although a foreign country may be listed in FSIS regulations as eligible to export poultry products to the United States, the exporting country's products must also comply with all other applicable requirements of the United States, including those of APHIS. These requirements include restrictions under 9 CFR part 94 of APHIS's regulations, which regulate the export of poultry products from foreign countries to the United States to control the spread of specific animal diseases.

Also, under this final rule, all poultry and poultry products exported to the United States from the PRC will be subject to reinspection by FSIS at United States ports of entry for, but not limited to, transportation damage, product and container defects, labeling, proper certification, general condition, and accurate count. FSIS also will conduct other types of reinspection activities, such as sampling and testing product to detect any drug or chemical residues or pathogens that may render the product unsafe or any species or product composition violations that would render the product economically adulterated. Products that pass reinspection will be stamped with the official mark of inspection and allowed to enter U.S. commerce. If they do not meet U.S. requirements, they will be refused entry and within 45 days will have to be returned to the country of origin, destroyed, or converted to animal food (subject to approval of the Food and Drug Administration (FDA)), depending on the violation. The import reinspection activities can be found on the FSIS website at: <http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/port-of-entry-procedures>.

Under current congressional appropriations,<sup>3</sup> poultry products permitted for importation under this final rule may not be used in the school lunch program under the Richard B. Russell National School Lunch Act (42 U.S.C. 1751 *et seq.*), the Child and Adult Care Food Program under section 17 of such Act (42 U.S.C. 1766), the Summer Food Service Program for Children under section 13 of such Act (42 U.S.C. 1761), or the school breakfast program under the Child Nutrition Act of 1966 (42 U.S.C. 1771 *et seq.*). In addition, poultry products from birds slaughtered in the PRC will be eligible for importation into the United States only if they are from animals slaughtered on or after the effective date of this final rule.

Finally, within one year of the effective date of this final rule, FSIS will conduct an ongoing equivalence audit of the PRC's poultry inspection system. During the audit, FSIS auditors will verify that the PRC's CCA has implemented its food safety inspection system as described in the Self-Reporting Tool and supporting documentation. FSIS auditors will visit government offices, establishments, and laboratories to verify that the CCA has implemented its inspection system as documented and verify that the country's system of controls remains equivalent to the U.S. inspection system. FSIS will be conducting such audits for all newly equivalent countries within one year of the effective date of the final rules granting equivalence. This policy results from an Agency response to a September 2017 audit of FSIS equivalence processes by the USDA Office of Inspector General (*Evaluation of Food Safety and Inspection Service's Equivalency Assessments of Exporting Countries: Audit Report 24601-0002-21*).

## Summary of Comments and Responses

FSIS received 96 comments from trade associations representing meat and poultry processors, consumer interest groups, a foodborne illness research center, a large food-processing corporation, and individual consumers. Comments from the meat and poultry industry and two individual consumers supported the proposed rule. Comments from the consumer interest groups and most individual consumers opposed the proposal. The following is a brief summary of the relevant issues raised in the comments and FSIS's responses.

<sup>3</sup> See Section 749, Consolidated Appropriations Act, 2019, Public Law 116-6, enacted February 15, 2019.

*Comment:* Two consumer interest groups and many individual consumers opposed the rule because of reported outbreaks of avian influenza in the PRC. A consumer interest group stated that even if cooking killed the avian influenza virus, consumers should not have to consume poultry from birds that were sick.

*Response:* To export poultry products to the United States, countries need to meet APHIS requirements for animal disease prevention and control. APHIS uses several methods to ensure that harmful animal diseases do not enter the United States. These include actively monitoring the animal disease status of foreign countries and maintaining lists of countries and regions considered to be free (or not free) of certain diseases. If an animal disease is found to exist in a country (or a region within a country) that exports meat, poultry, or egg products to the United States, APHIS requires specific processing steps to ensure that any product from that country or region will not cause the disease to be transmitted to the United States (see 9 CFR part 94).

In addition to these monitoring and processing provisions, APHIS requires imported meat, poultry, and egg products to have accompanying documentation regarding their origin, animal disease status, degree of processing, and intended use. At the U.S. border, Customs and Border Protection (CBP) officials verify that such documentation is accurate and that the products do not pose an animal disease transmission risk. These steps take place before FSIS reinspects imported product for food safety and other regulatory compliance. All meat and poultry products that APHIS restricts from entering the United States because of animal disease concerns will be refused entry by CBP.

As FSIS explained in the proposed rule, APHIS has classified China as a region where highly pathogenic avian influenza (HPAI) exists. APHIS also does *not* currently list the PRC as a region free of Exotic Newcastle Disease. Therefore, before a shipment of poultry products may be presented for FSIS reinspection at the port of entry, it must have been processed in a manner sufficient to inactivate these viruses if they were present in the meat, in accordance with APHIS requirements at 9 CFR 94.6. FSIS reinspection of this imported poultry, in addition to the equivalent PRC inspection system, ensures that the product is otherwise safe, wholesome, and unadulterated.

Any poultry intended for export to the United States from certified establishments in the PRC will be

subject to ante-mortem and post-mortem inspection (see 9 CFR part 381, subparts J and K), and will be subject to reinspection at United States ports of entry for any conditions which may render the product adulterated or misbranded.

*Comment:* Individuals and consumer interest groups opposed to the rule questioned whether FSIS can ensure that poultry slaughtered in the PRC will be safe for consumption in the United States. Many individual commenters, three consumer interest groups, and a foodborne illness research center argued that the PRC cannot ensure that their poultry products are safe, because the PRC has produced and exported unsafe products in the past. These commenters were concerned that establishments in the PRC would use antibiotics and chemicals that are banned in the United States; poultry products would contain antibiotic resistant pathogens and harmful residues; similar standards of sanitation would not be maintained; or the products would not be properly labeled. Two consumer interest groups and a few individuals stated that on-site audits would not ensure that exporting establishments meet U.S. requirements. A consumer interest group questioned how the PRC will ensure that each province consistently enforces food safety requirements since the PRC is such a large country. Another such group was concerned that the PRC would certify establishments that do not meet U.S. requirements. One individual expressed concern that residues of a certain type of antibiotic would remain in products.

*Response:* FSIS has determined that this rule will not adversely affect human health. FSIS explained in a 2006 proposed rule, and again in 2013, its determination that the poultry processing system in the PRC is equivalent to the United States' system. Under FSIS's regulations, initial eligibility to export poultry products to the United States depends on the results of FSIS's documentary reviews and on-site audits of a foreign poultry inspection system. Once the country becomes eligible to ship product to the United States, it is required to continue to submit such documents and other information related to the foreign inspection system as FSIS may find necessary to determine a foreign country's eligibility (9 CFR 381.196(a)(2)(iii)).

During these reviews and audits, FSIS verifies that foreign inspection systems: Have in place a chemical residue control program that is organized by the national government; include random sampling of chemical residues,

including veterinary drugs, identified by the exporting country or by FSIS as potential contaminants; and employ methods to deter recurrence of chemical residue violations. FSIS reviewed the PRC's chemical residue program and found that it met FSIS's equivalence criteria. In addition, once the country begins shipping product, the product is subject to reinspection, which includes periodic testing for residues.

Under the regulations, only those establishments that an official of the PRC's poultry inspection system certifies as fully complying with requirements equivalent to the provisions of the PPIA and the regulations issued thereunder will be eligible to export to the United States. As with other countries that FSIS has found equivalent, the PRC may certify any poultry establishment within its territory. The PRC will be required to renew these certifications annually (9 CFR 381.196(a)(3)). The PRC is required to ensure that certified establishments separate, by time or space, product destined for export to the United States from product intended for distribution domestically. All establishments certified by the PRC are subject to review by FSIS, which may terminate the eligibility of an establishment, if it does not comply with FSIS equivalence regulations or if current information about the establishment cannot be obtained (9 CFR 381.196(a)(3)). All certified establishments and records relevant to their certification and operation will be available for on-site and documentary audits by U.S. officials.

The regulations also require that a foreign inspection system, such as that of the PRC, maintain a program to ensure that the requirements equivalent to those in the United States are met. Specifically, the regulations require that a representative of the foreign inspection system periodically visit each establishment certified as complying with requirements equivalent to those of the PPIA and implementing regulations. The regulations also require that this representative prepare written reports documenting findings concerning compliance with requirements equivalent to those of the poultry inspection system in the United States (9 CFR 381.196(a)(2)(iv)). FSIS will evaluate these reports during audits.

Furthermore, each consignment of poultry products exported to the United States from a foreign country must be accompanied by a foreign inspection certificate that certifies that the products: Are sound, healthful, wholesome, clean and otherwise fit for

human food; are not adulterated and have not been treated with and do not contain any dye, chemical, preservative, or ingredient not permitted by FSIS's regulations; have been handled only in a sanitary manner in the foreign country; and are otherwise in compliance with requirements at least equal to those in the PPIA and FSIS's regulations (9 CFR 381.197). Thus, a representative of the Chinese government must certify that the product is not adulterated, does not contain harmful ingredients, and has undergone adequate cooking and processing, as necessary.

In addition to evaluating the PRC's eligibility and performing ongoing audits to ensure that products shipped to the United States are safe, wholesome, and properly labeled and packaged, every shipment of poultry products exported to the United States from the PRC will be subject to reinspection at points of entry for transportation damage, labeling, proper certification, general condition, and accurate count. Other types of inspection will be conducted regularly, including testing for pathogens, residues, and species.

Products that pass reinspection will be stamped with the official mark of inspection and allowed to enter U.S. commerce. If they do not meet U.S. requirements, they will be refused entry and must be re-exported, destroyed, or converted to animal food. Imported poultry products are to be treated as domestic product upon entry into the United States.

*Comment:* Many individual commenters stated that they preferred to purchase only domestically produced poultry products. Other individuals and two consumer interest groups expressed concern that poultry products from the PRC would not be subject to labeling requirements indicating the country of origin.

*Response:* All poultry product imports are required to bear on the container in which they are shipped and their immediate container the name of their country of origin, as well as the number assigned by the foreign meat inspection system to the establishment in which they were prepared (9 CFR 381.205--206). When an imported product is further prepared or processed, the labeling requirements for the resultant product are the same as for domestic product. The addition of a country-of-origin labeling statement is not required by FSIS on further-processed product, although the Agency would approve product labels with the original country-of-origin statement if

they are truthful and not misleading and meet all of FSIS's labeling requirements.

*Comment:* Several individuals expressed a general concern about on-farm practices in China regarding animal raising and feed. Other individuals believed that poultry from the PRC would not be treated humanely.

*Response:* FSIS is not authorized to mandate production practices on farms, either domestically or as a condition of permitting imports from foreign countries. FSIS regulates the safety of poultry products through its regulatory requirements that apply to slaughter and processing facilities, as well as products in commerce. These include HACCP, sanitation controls, ante- and post-mortem inspection by government inspectors, residue sampling, and *Salmonella* and *Campylobacter* performance standards, all of which are included in the evaluation process for foreign country equivalence.

Poultry are not subject to the Humane Methods of Slaughter Act (HMSA) of 1978 (7 U.S.C. 1901, *et seq.*), which requires that humane methods be used for handling and slaughtering livestock. FSIS requires, however, that poultry be handled in a manner that is consistent with good commercial practices, which means they should be treated humanely (see 70 FR 56624, September 28, 2005, *Treatment of Live Poultry Before Slaughter*). FSIS verified that the PRC implements good commercial practices equivalent to those required in domestic establishments.

*Comment:* A few individuals and a consumer interest group opposed to the rule questioned the timing of the publication of the proposed rule. These commenters argued that FSIS only determined that the PRC was equivalent to re-open U.S. trade of beef products with the PRC. A consumer interest group questioned whether a particular foreign establishment would be certified because it sponsored trips for foreign officials. Several commenters who supported the rule argued that FSIS conducted a rigorous and lengthy assessment of the PRC's poultry inspection system. These commenters also argued that the proposed rule was consistent with U.S. international trade obligations.

*Response:* FSIS made its equivalence determination based on sound science, and in accordance with international obligations of the United States. The PPIA and the World Trade Organization's Sanitary and Phytosanitary Measures Agreement provide that countries with equivalent inspection systems may export poultry products to the United States. As FSIS explained in the proposed rule, the

Agency reviewed the PRC's laws, regulations, and poultry slaughter inspection system as implemented before determining that the PRC's poultry slaughter inspection system is equivalent to the United States' system.

*Comment:* Many individuals and a consumer interest group expressed support for U.S. domestic poultry production, with an emphasis on local, free-range, poultry. A few commenters were concerned that the PRC would export a large amount of poultry products, resulting in negative effects on domestic poultry producers. One individual asked which domestic industry segments were unlikely to be competitive due to lower labor costs in the PRC. However, comments from the poultry industry argued that the proposed rule would not have a significant impact on their business because the United States is the largest and most efficient poultry producer in the world and has a comparative advantage due to access to cheap, high-quality feed and birds. According to these comments, the United States is also a technological leader in poultry genetics and breeding, feed-compounding, and animal health practices.

*Response:* As explained in more detail in the economic impact analysis below, FSIS believes the domestic poultry industry will be competitive with poultry from the PRC. Recently, labor costs in the PRC have been rising, which together with high feed costs have pushed the wholesale price of chicken in the PRC to be higher than in the United States. FSIS also does not believe that this rule will adversely affect the U.S. poultry industry, because the volume of trade that results from this rule will likely be small and have little effect on supply and prices.

*Comment:* One consumer interest group questioned whether FSIS was interacting with the correct PRC government agency. Another such group asserted that FSIS should not find the PRC equivalent because it operated parallel systems for domestic poultry products and products intended for export.

*Response:* FSIS's equivalence regulations require that before permitting poultry product imports from a foreign country, it find that the country's poultry inspection system complies with requirements equivalent to the PPIA and its implementing regulations, with respect to establishments preparing products for export to the United States (9 CFR 381.196(a)). While FSIS was evaluating the PRC's food safety system for poultry exports, that system was administered

by AQSIQ, the PRC's CCA at that time, in charge of food inspection and implementing a poultry inspection system equivalent to that of the United States. As noted above, the PRC's General Administration of Customs has taken over the functions of the prior CCA, but the reorganization did not result in substantive changes to the PRC's inspection system. The China Food and Drug Administration is responsible for food safety for domestically produced poultry products. As described above, FSIS has conducted a rigorous, comprehensive review of the Chinese food safety system and will continue to verify that the PRC maintains an equivalent inspection system through document review, systems audits, and reinspection of each shipment of poultry from the PRC.

*Comment:* Two consumer interest groups stated that an establishment in the PRC audited by FSIS was reported in the media as running at higher line speeds than those permitted under FSIS's poultry inspection system. One of these groups asserted that FSIS had only audited the way in which the PRC planned to run its inspection system, instead of observing the system in operation.

*Response:* As stated in the 2015 audit report, FSIS observed the audited establishments in operation, including the establishment referred to by these commenters. The audit included verification of adequate line speeds, as documented in FSIS's audit report. The PRC's system, as documented and observed, includes line speeds that comply with FSIS's requirements. After the final rule publishes, if the establishment mentioned in these comments is certified by the PRC, it must operate at line speeds in conformance with the inspection system FSIS reviewed and determined equivalent when producing product intended for export to the United States.

*Comment:* A consumer interest group questioned why a document on FSIS's website was not fully translated.

*Response:* The document the commenter referred was posted as supporting document to the proposed rule and is available here: <https://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/proposed-rules>. It relates to the PRC's compliance with FSIS's final rule, *Modernization of Poultry Slaughter Inspection* (79 FR 49565, August 21, 2014). It is completely translated by AQSIQ, except for a short introductory letter, which does not affect the content.

*Comment:* Commenters also raised concerns regarding Chinese labor practices and working conditions, the

use of a certain pesticide in the United States, greenhouse gases produced by agricultural activities, and FSIS's previous determination that the PRC is eligible to export processed poultry to the United States if the products are derived from poultry slaughtered in the United States or in other countries eligible to slaughter and export poultry to the United States.

*Response:* These comments are either beyond the scope of this rulemaking or outside FSIS's authority. This rule is based on FSIS's determination that the PRC's poultry slaughter system is able to provide a level of protection equivalent to the United States' inspection system.

#### **Executive Orders 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 (E.O.) 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been designated a "non-significant" regulatory action under section 3(f) of E.O. 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget under E.O. 12866.

#### *Expected Costs of the Final Rule*

The costs of the final rule will accrue primarily to domestic poultry producers in the form of greater competition from the PRC. In the short run, the volume of trade stimulated by this final rule is likely to be small because the PRC only intends to certify five slaughter establishments to provide poultry to certified processing establishments to export fully-cooked poultry products to the United States. Data from the PRC show that these five slaughter establishments will supply poultry to five processing establishments that the PRC will certify as eligible to ship product to the U.S. (three of them intend to export cooked chicken quarter-legs and chicken breasts, one to export cooked duck legs and duck breasts, and one to export roasted boneless duck to the United States).<sup>4</sup>

<sup>4</sup> Data is from the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China, November 2015. The projected annual production of these chicken and duck products at these five processing establishments will be about 838 million pounds

According to the data, the projected volume of exports to the United States will be about 324 million pounds per year for the next five years.<sup>5</sup> Given that the United States domestic annual production volume of ready-to-eat, fully-cooked poultry is about 12,325 million pounds,<sup>6</sup> the projected cooked poultry products from the PRC would only be about 2.6 percent of total United States production in the next five years.<sup>7</sup> The immediate impact on U.S. consumers and domestic processors is likely to be minor, as the low volume of trade is likely to have little effect on supply and prices.

In the long run, domestic producers will probably start to feel competitive pressure of competition if more PRC establishments become certified to export to the United States. However, FSIS believes the domestic poultry industry will be competitive with poultry from the PRC. Recently, labor costs in the PRC have been rising,<sup>8</sup> and the rising labor costs together with high feed costs have pushed the wholesale price of chicken in the PRC to be higher than the United States.<sup>9</sup> Comments from three poultry trade associations on the proposed rule also asserted that the United States is the largest and most efficient poultry producer in the world. According to the poultry trade associations, the United States has a comparative advantage in poultry production and marketing.

#### *Expected Benefits of the Final Rule*

The PRC is the second largest poultry producing country in the world, trailing closely behind the United States.<sup>10</sup> If the

per year, which could be sold in the PRC or to other foreign countries.

<sup>5</sup> Data is from the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China, November 2015.

<sup>6</sup> Calculated from PHIS data in November 2015. This number cannot be divided by species. If we adjusted it by the proportions of chicken and ducks in total domestic slaughtered poultry, which is 88.3 percent, the volume would be about 10,833 million pounds per year.

<sup>7</sup> If we use 10,833 million pounds (see previous footnote) as the denominator, the projected PRC export would be about 3 percent of United States domestic production of fully-cooked chicken and duck.

<sup>8</sup> Gale, F. and C. Arnade. (2015). Effects of Rising Feed and Labor Costs on China's Chicken Price. *International Food and Agribusiness Management Review*, Vol 18, Special Issue A. 137-150.

<sup>9</sup> Ibid. In addition, the unit price of exported poultry meat and products from China is much higher than that from the U.S. in 2016 and 2017, according to Global Trade Atlas data. We downloaded the data from <https://www.gtis.com>, and it will be available upon request.

<sup>10</sup> See Food Outlook, Food and Agricultural Organization (FAO) of the United Nations, October 2015, p. 49, at <http://www.fao.org/3/a-i5003e.pdf>, accessed 1/11/2016. Also see the same publication

PRC begins to export other poultry products (for example, if APHIS allows the PRC to export raw chicken products)<sup>11</sup> to the United States and more PRC establishments become certified to be eligible, consumers will likely benefit from more choices and more competitive prices in the marketplace; producers will likely benefit from efficiency gains as they have to become more efficient to be competitive.<sup>12</sup> The Agency did not quantify the value of these benefits because of the lack of predictability associated with the many factors that heavily influence trade patterns and volume. These factors include results of Sanitary and Phytosanitary Standards issues (e.g. the avian influenza), exchange rates,<sup>13</sup> and domestic political and economic conditions.

This rule will likely increase trade between the United States and the PRC in poultry products. In the short run, however, the impact is likely to be small as the expected volume of trade stimulated by this rule is likely to be small (see Expected Costs section above).

#### Regulatory Flexibility Act Assessment

The FSIS Administrator certifies that, for the purposes of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), this final rule will not have a significant impact on a substantial number of small entities in the United States. The expected trade volume will be small, with little or no effect on all U.S. establishments, regardless of size.

#### Executive Order 13771

Consistent with E.O. 13771 (82 FR 9339, February 3, 2017), this final rule facilitates regulatory cooperation with foreign governments. Therefore, this rule is an E.O. 13771 deregulatory action.

#### 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. This information collection was approved under OMB number 0583-0153. The rule contains no other paperwork requirements.

#### E-Government Act

FSIS and USDA are committed to achieving the purpose 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 citizens access to Government information and services, and for other purposes.

#### Additional Public Notification

FSIS will officially notify the World Trade Organization's Committee on Sanitary and Phytosanitary Measures (WTO/SPS Committee) in Geneva, Switzerland, of this rule and will announce it online through the FSIS web page located at: <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/interim-and-final-rules>.

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication online through the FSIS web page located at: <http://www.fsis.usda.gov/federal-register>.

FSIS will also announce and provide a link to it 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 *Constituent 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 email 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 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.

**Email:** [program.intake@usda.gov](mailto: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 in 9 CFR Part 381

Imported products.

For the reasons set out in the preamble, FSIS is amending 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. In § 381.196, amend paragraph (b) by removing the footnote 2 designation following "People's Republic of China."

Done at Washington, DC.

**Carmen M. Rottenberg,**  
Administrator.

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of June 2017, p.122, at <http://www.fao.org/3/a-i7343e.pdf>, accessed 1/8/2018.

<sup>11</sup> As mentioned above, APHIS has classified the PRC as a region affected by certain animal diseases, so the PRC will only be allowed to export cooked poultry products to the United States.

<sup>12</sup> It is well-established that international trade benefits trade partners because it allows countries to specialize in producing products at which they have a comparative advantage.

<sup>13</sup> The exchange rate affects the relative prices of exports and imports.