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**DEPARTMENT OF AGRICULTURE**

**Food Safety and Inspection Service**

**9 CFR Part 557**

**[Docket No. FSIS-2018-0031]**

**RIN [0583-AD75]**

**Eligibility of Thailand to Export Siluriformes Fish and Fish 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 amend the Siluriformes fish inspection regulations to list Thailand as a country eligible to export Siluriformes fish and fish products to the United States. FSIS is proposing this action because the Agency has reviewed Thailand's laws, regulations, and inspection system as implemented and has determined that Thailand's Siluriformes fish inspection system is equivalent to the system that the United States has established under the Federal Meat Inspection Act (FMIA) and its implementing regulations.

Under this proposal, only raw Siluriformes fish and fish products produced in certified Thailand establishments would be eligible for export to the United States. All such products

would continue to be subject to re-inspection at U.S. points-of-entry by FSIS inspectors.

**DATES:** Submit comments on or before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

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

- Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or to 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, 1400 Independence Avenue SW, Mailstop 3758, Room 6065, Washington, DC 20250-3700.

- Hand- or courier-delivered submittals: Deliver to 1400 Independence Avenue SW, Room 6065, Washington, DC 20250-3700.

*Instructions:* All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2018-0031. 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, call (202)720-5627 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Room 6065, Washington, DC 20250-3700.

**FOR FURTHER INFORMATION CONTACT:** Roberta Wagner, Assistant Administrator, Office of Policy and Program Development; Telephone: (202) 205-0495.

**SUPPLEMENTARY INFORMATION:**

**Background**

FSIS is proposing to amend its regulations at 9 CFR 557.2(b)(1) to add Thailand as a country eligible to export Siluriformes fish and fish products to the United States (for convenience, in this proposed rule, "Siluriformes fish and fish products" will be shortened to "Siluriformes fish"). Although Thailand has been allowed to export these products to the United States under the conditions described below, Thailand is not currently listed in the Code of Federal Regulations (CFR) as eligible to export Siluriformes fish to the United States.

**Transitional Period**

On December 2, 2015, FSIS published the final rule, "Mandatory Inspection of Fish of the Order Siluriformes and Products Derived from Such Fish" (80 FR 75590). The final rule established a mandatory inspection system for fish of the order Siluriformes and products derived from these fish. The final

regulations implemented the provisions of the 2008 and 2014 Farm Bills, which amended the FMIA, mandating FSIS inspection of Siluriformes fish.

The final rule provided an 18-month period, from March 1, 2016, to September 1, 2017, for both the U.S. domestic Siluriformes fish industry and international trading partners to transition from the regulatory requirements of the U.S. Food and Drug Administration (FDA), the agency formerly responsible for regulatory oversight of Siluriformes fish, to the regulatory requirements of FSIS. By March 1, 2016, FSIS required foreign countries to submit written documentation identifying a list of establishments that had been exporting and would continue exporting Siluriformes fish to the United States. In addition, by March 1, 2016, FSIS required foreign countries to submit written documentation to demonstrate that they had laws or other legal measures in place that provide authority to regulate the growing and processing of fish for human food, and to assure compliance with FDA's good manufacturing practices, Hazard Analysis and Critical Control Point (HACCP) requirements, sanitation control procedures, and other regulatory requirements in 21 CFR part 123, *Fish and Fishery Products*.

FSIS recognized the foreign countries' initial documentation until the end of the transitional period on September 1, 2017. Foreign countries that wished to continue

exporting after September 1, 2017, were required to submit documentation substantiating the equivalence of their Siluriformes fish inspection system to that of the United States. Foreign countries that submitted complete equivalence documentation by September 1, 2017, were permitted to continue exporting Siluriformes fish until such time that FSIS determines if their Siluriformes fish inspection systems are equivalent to the U.S. system.

Thailand submitted its initial documentation in February 2016, which allowed it to continue exporting Siluriformes fish during the transitional period. In April 2017, Thailand submitted a completed Self-Reporting Tool (SRT), the questionnaire that FSIS uses to assess the equivalence of a foreign country's food safety inspection system.

FSIS stated in the final rule that, during the transitional period, it would reinspect imported Siluriformes fish and test for species identification and residues on at least a quarterly basis for each foreign establishment eligible to export Siluriformes fish to the U.S. (80 FR 75608). FSIS conducted random and targeted sampling and testing of imported Siluriformes fish during the transitional period, and on August 2, 2017, began reinspecting all shipments of Siluriformes fish, with random sampling for species and residue testing. As a result of the testing, FSIS found a residue violation in a

shipment of Siluriformes fish exported from Thailand. When imported product fails FSIS testing, the product is refused entry and the designated competent authority of the foreign government's inspection system is notified and further shipments of product from the foreign establishment are placed under either an increased or intensified level of sampling. FSIS notified the Thailand Department of Fisheries (DOF), the central competent authority for food inspection, of the residue violation, and in response, DOF stated that the processor would be suspended until DOF inspectors could re-audit the processor's HACCP system.

#### **Statutory and Regulatory Basis for Proposed Action**

Siluriformes fish are an amenable species under the FMIA (21 U.S.C. 601(w)(2)). The FMIA prohibits importation into the United States of adulterated or misbranded meat and meat food products (21 U.S.C. 620). Under the FMIA and its implementing regulations, Siluriformes fish imported into the United States must be from foreign countries that maintain an inspection system that ensures compliance with requirements equivalent to all the inspection, sanitary, quality, species verification, and residue standards, and all other provisions of the FMIA which are applied to official establishments in the United States. The regulatory requirements for foreign countries to become eligible to export Siluriformes fish and fish products to the United

States are provided in 9 CFR 557.2, which cross-references 9 CFR 327.2, the regulations for the import of other products also subject to the FMIA. As noted above, FSIS has allowed Thailand to continue shipping product while FSIS made the determination concerning whether the country's inspection system is equivalent to that of FSIS.

Section 557.2(a) (cross-referencing 9 CFR 327.2(a)(2)(i), (a)(2)(i), (a)(2)(ii)(C)-(I), (a)(2)(iii)-(iv), and (a)(3)), requires a foreign country's inspection system be authorized by legal authority that imposes requirements equivalent to those of the United States, specifically with respect to: (1) official controls by the national government over establishment construction, facilities, and equipment; (2) direct official supervision of the preparation of product to assure that product is not adulterated or misbranded; (3) separation of establishment operations for product certified for export from product that is not certified; (4) requirements for sanitation at certified establishments and for sanitary handling of product; (5) official controls over condemned materials; (6) a HACCP system; and (7) any other requirements found in the FMIA and its implementing regulations.

In addition to a foreign country's legal authority and regulatory requirements, the inspection program must achieve a level of public health protection equivalent to that achieved by

the U.S. program. Specifically, the inspection 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) competent, qualified inspectors; (4) enforcement and certification; (5) administrative and technical support; (6) inspection, sanitation, quality, species verification, and residue standards; and (7) any other inspection requirements required by the regulations in Subchapter F - Mandatory Inspection of Fish of the Order Siluriformes and Products of Such Fish, which cross-references 9 CFR 327.2(a)(2)(i)).

The foreign country's inspection system must ensure that establishments preparing Siluriformes fish for export to the United States comply with requirements equivalent to those of the FMIA and the regulations promulgated thereunder. The foreign country certifies the establishments as having met the required standards and notifies FSIS about establishments that are certified or removed from certification.

As discussed above, a foreign country's inspection system must be evaluated by FSIS to determine its eligibility to export

Siluriformes fish to the United States. 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 affect its inspection program. FSIS requests that countries provide information about their inspection systems through the Self Reporting Tool (SRT). The SRT can be found on the FSIS web site at *2016 Siluriformes SRT*. The SRT is a standardized questionnaire that FSIS provides to foreign governments to gather information that characterizes foreign inspection systems. Through the SRT, FSIS collects information on practices and procedures in six areas, known as equivalence components:

- (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),
- (3) Government Sanitation,
- (4) Government HACCP Systems,
- (5) Government Chemical Residue Testing Programs, and
- (6) Government 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>.

Under the regulations, foreign countries must be listed in the CFR as eligible to export Siluriformes fish to the United States. FSIS engages in rulemaking to list a country as eligible. Countries found eligible to export Siluriformes fish to the United States are listed in the regulations at 9 CFR 557.26(b) (1). Once listed, the eligible country is required to certify that establishments meet the requirements to export Siluriformes fish 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 conducts 100 percent re-inspection of those products at points-of-entry before they enter the U.S. commerce.

#### **Evaluation of Thailand's Siluriformes Fish Inspection System**

In April 2017, Thailand requested that FSIS conduct a review of its Siluriformes fish inspection system and submitted the documentation to formally establish its eligibility to export Siluriformes fish to the United States. FSIS conducted a document review of Thailand's Siluriformes fish inspection

system to determine whether it was equivalent to that of the United States. FSIS concluded, based review of the submitted documentation, that Thailand's laws, regulations, control programs, and procedures were equivalent to those of the United States.

Accordingly, in May 2018, FSIS proceeded with an on-site audit of Thailand's Siluriformes fish inspection system. The purpose of the on-site audit was to verify that DOF effectively implemented a Siluriformes fish inspection system equivalent to that of the United States. FSIS audited each of the four establishments then certified to export Siluriformes fish to the United States, one pre-harvest operation, and one cold storage facility. During the visits to the four establishments, none were producing Siluriformes fish for export to the United States. However, FSIS auditors were able to conduct observation of DOF inspection at two of the four establishments and to perform document reviews.

The May 2018 audit of Thailand's Siluriformes fish inspection system identified several deficiencies that the DOF was requested to address. Among other things, the audit found that the DOF did not have regulatory requirements for establishments to maintain daily records documenting the monitoring of the Sanitation Standard Operating Procedures (SOPs), although the establishments did document and maintain sanitation records.

Also, the DOF did not have regulatory requirements for establishments to develop HACCP verification procedures for direct observation of monitoring activities and corrective actions, resulting in no performance of the procedure by the establishments. Furthermore, because only two out of the four establishments FSIS visited during the May 2018 audit were operational, auditors were unable to verify the full implementation of Thailand's food safety inspections system. At the audit exit meeting, the DOF committed to addressing the preliminary findings.

On June 27, 2018, FSIS sent the DOF the draft final audit report, and advised that, in order to verify the full implementation of Thailand's Siluriformes fish inspection system, it would be necessary to schedule a follow up on-site visit.

On June 28, 2018, FSIS sent a follow-up letter proposing a follow-up on-site audit of Thailand's Siluriformes fish inspection system in August 2018. The letter explained that the objective of the follow-up audit was to verify any corrective actions or changes to Thailand's food safety inspection system as a result of the findings of the first audit and that the scope of the audit would be limited to aspects of Thailand's national inspection system.

FSIS conducted the follow-up audit between August 27 and 31, 2018, visiting the three establishments currently certified to export Siluriformes fish to the United States (Thailand delisted one establishment prior to the follow-up audit). The follow-up audit focused on the inspections system's ability to control hazards and prevent non-compliances that threaten food safety. FSIS auditors visited all three establishments certified by the DOF to export products to the United States. During this audit, all certified establishments were able to perform operations. The FSIS auditors were able to see production of Siluriformes fish, in addition to the implementation of corrective actions in response to the deficiencies found in the May onsite audit.

The FSIS auditors determined that Thailand's food safety inspection system governing fish of the order Siluriformes and their products are being implemented as documented in the SRT and according to their corrective actions responses. A review and analysis of each component with corrective actions by the FSIS auditors did not identify any findings representing an immediate threat to public health.

In summary, FSIS has completed the document review, on-site audit, follow-up audit with verification of corrective actions as part of the equivalence process, and determined that all outstanding issues have been resolved. FSIS has concluded that, as implemented, Thailand's inspection system for Siluriformes

fish is equivalent to that of the United States. The full report on Thailand's Siluriformes fish inspection system 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, Thailand intends to certify three establishments as eligible to export Siluriformes fish to the United States. Thailand's eligibility applies to the export of raw Siluriformes fish only. Should this rule become final, the government of Thailand must certify to FSIS those establishments that wish to export Siluriformes fish to the United States and that operate in accordance with requirements equivalent to that of the United States (9 CFR 557.2(a)). FSIS will verify that the establishments certified by Thailand's government are meeting the United States requirements through verification audits of Thailand's Siluriformes fish inspection system.

Although a foreign country may be listed in FSIS regulations as eligible to export Siluriformes fish products to the United States, the exporting country's products must be found to comply with all other applicable requirements of the United States. Accordingly, Siluriformes fish exported from Thailand will continue to be subject to re-inspection at U.S. points-of-entry for, but not limited to, transportation damage,

product and container defects, labeling, proper certification, general condition, and accurate count. In addition, FSIS is, and will continue, to 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 for a subset of Thailand's Siluriformes fish imported into the United States. Products that pass re-inspection 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 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/phis-import-component/phis-implementation-letter-to-importers/ct\\_index](http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/phis-import-component/phis-implementation-letter-to-importers/ct_index).

**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 proposed rule has been designated as 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 Proposed Rule**

If this rule is finalized, establishments in Thailand would be listed as eligible to export raw Siluriformes fish to the United States. Adoption of this rule is not expected to have quantified costs associated with it because the rule would maintain existing trade between the United States and Thailand in Siluriformes fish. The United States has historically imported Siluriformes fish from Thailand. Over the last 5 years, total sales from Thailand Siluriformes fish imports only averaged 0.017 percent of U.S. domestic production, and constituted only 0.009 percent of total United States consumption, Table 1. In 2016, Thailand exported 3.5 times more Siluriformes fish to the United States than average, but these exports still accounted for only 0.027 percent of total domestic consumption, Table 1. These amounts are unlikely to have any

substantive effect on U.S. production or prices for domestically harvested Siluriformes fish.

**Table 1. Summary of Siluriformes Fish Sales**

	2013	2014	2015	2016	2017	5 Year Average
	<b>Millions of Dollars</b>					
<b>Total U.S. Imports<sup>1</sup></b>	\$363.42	\$346.66	\$351.13	\$405.61	\$381.89	\$369.74
<b>Total U.S. Domestic Production<sup>2</sup></b>	\$356.73	\$351.94	\$363.61	\$385.99	\$379.71	\$367.60
<b>Total U.S. Exports<sup>1</sup></b>	\$4.69	\$3.99	\$4.95	\$4.80	\$6.18	\$4.92
<b>Total U.S. Consumption<sup>3</sup></b>	\$715.46	\$694.60	\$709.79	\$786.80	\$755.43	\$732.41
<b>Total U.S. Imports<sup>1</sup> from Thailand</b>	\$0.04	\$0.02	\$0.01	\$0.21	\$0.04	\$0.06
<b>Thailand as % of U.S. Imports</b>	0.012%	0.005%	0.003%	0.052%	0.010%	0.017%
<b>Thailand as % of U.S. Domestic Production</b>	0.012%	0.005%	0.003%	0.054%	0.010%	0.017%
<b>Thailand as % of U.S. Consumption</b>	0.006%	0.002%	0.002%	0.027%	0.005%	0.009%

Data Source: U.S. Census Bureau Trade Data

<sup>1</sup>Import and Export Data Accessed from USDA Foreign Agricultural Service: Global Agricultural Trade System: <https://apps.fas.usda.gov/gats/default.aspx>

<sup>2</sup>U.S. Production Data Accessed from USDA National Agricultural Statistics Service: Quick Stats: <https://quickstats.nass.usda.gov/>

<sup>3</sup>U.S. Consumption data is assumed to equal Imports + Domestic Production - Exports

### **Expected Benefits of the Proposed Rule**

If finalized, this rule would result in the continued opportunity for trade between the United States and Thailand. The volume of trade is likely to continue to be small and is

expected to have little or no effect on U.S. Siluriformes fish production or prices. U.S. consumers, however, are expected to continue to have access to more choices when purchasing Siluriformes products. The rule would, therefore, maintain choices for U.S. consumers and promote economic competition.

#### **Regulatory Flexibility Act Assessment**

The FSIS Administrator has made a preliminary determination that this proposed rule would not have a 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 rule would maintain existing trade.

#### **Executive Order 13771**

Consistent with E.O. 13771 (82 FR 9339, February 3, 2017), this proposed rule facilitates regulatory cooperation with foreign governments. Therefore, if finalized as proposed, this rule is expected to be an E.O. 13771 deregulatory action.

#### **Paperwork Reduction Act**

No new paperwork requirements are associated with this proposed rule. Foreign countries wanting to export Siluriformes fish 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 Thailand with a questionnaire, referred to as the self-reporting tool (SRT), 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. Constituent Updates are 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 notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

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**List of Subjects in 9 CFR Part 557**

Imported products.

For the reasons set out in the preamble, FSIS is proposing to further amend 9 CFR part 557, as proposed to be amended elsewhere in this issue of the Federal Register, as follows:

**PART 557—IMPORTATION**

1. The authority citation for part 557 continues to read as follows:

Authority: 21 U.S.C. 601-602, 606-622, 624-695; 7 CFR 2.7, 2.18, 2.53.

**§ 557.2 [Amended]**

2. Section 557.2 is amended by adding "Thailand" in alphabetical order to the list of countries in paragraph (b) (1).

Paul Kiecker,

Acting Administrator.

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