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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 557

[Docket No. FSIS-2018-0031]

RIN 0583-AD74

Eligibility of Thailand to Export Siluriformes Fish and Fish Products to the United States

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Siluriformes fish inspection regulations to list Thailand as a country eligible to export Siluriformes fish and fish products to the United States. FSIS 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 final rule, only raw Siluriformes fish and fish products produced in certified Thailand establishments are eligible for export to the United States. All such products are subject to re-inspection at U.S. points-of-entry by FSIS inspectors.

DATES: *Effective Date:* [INSERT DATE 30 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Terri Nintemann, Assistant Administrator, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture; Telephone: (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

On September 19, 2018, FSIS proposed to amend its regulations at 9 CFR 557.2(b)(1) to add Thailand as a country eligible to export raw Siluriformes fish to the United States (83 FR 47532) (for convenience, in this final 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 in the proposed rule (83 FR 47533), Thailand is not currently listed in the Code of Federal Regulations (CFR) as eligible to export Siluriformes fish to the United States. FSIS proposed to add Thailand to the regulations as eligible to export such products after the Agency conducted a documentary review of Thailand's laws, regulations, and Siluriformes fish inspection system, as well as an in-country audit of the system, and determined that Thailand's Siluriformes fish inspection system is equivalent to the U.S. system established under the

FMIA and its implementing regulations. This final rule is consistent with the provisions of the proposed rule.

Statutory and Regulatory Basis for Final Action

As explained in the proposed rule (83 FR 45733), 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 the inspection, sanitary, quality, species verification, and residue standards requirements in the United States, and all other provisions of the FMIA that are applied to official establishments in the United States. The regulatory requirements for foreign countries to become eligible to export Siluriformes fish 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.

Section 557.2(a) (cross-referencing 9 CFR 327.2(a)(1), (a)(2)(i), (a)(2)(ii)(C)-(I), (a)(2)(iii)-(iv), and (a)(3)), requires that 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 the sanitary handling of product; (5) official controls over condemned materials; (6) a Hazard Analysis Critical Control Point (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. inspection 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).

Annually, the foreign country certifies the establishments as fully meeting the required standards and notifies FSIS about establishments that are removed from certification (9 CFR 557.2, cross-referencing 9 CFR 327.2(a)(3)).

Evaluation of Thailand's Siluriformes Fish Inspection System

As discussed in the proposed rule (83 FR 47534), in April 2017, based on Thailand's request, FSIS conducted a document review of Thailand's Siluriformes fish inspection system to determine whether that system was equivalent to that of the United States. Based on its review of the submitted documentation, which included Thailand's laws, regulations, and inspection procedures, FSIS concluded that Thailand's inspection system is equivalent to that in the United States for raw Siluriformes fish products, specifically Siluriformes fish that fall within the FSIS product categories "Raw Product - Intact" and "Raw Product - Non-Intact." Both product categories are defined in the "FSIS Product Categorization" document, which was developed to assist foreign governments in accurately identifying the type of meat and poultry products exported to

the U.S., this document can be found on the FSIS website at:
https://www.fsis.usda.gov/shared/PDF/FSIS_Product_Categorization.pdf.

Accordingly, between May 7 and 11, 2018, FSIS proceeded with an initial on-site audit of Thailand's Siluriformes fish inspection system. The purpose of the on-site audit was to verify whether Thailand's Department of Fisheries (DOF), the Central Competent Authority (CCA) for food inspection, effectively implemented a Siluriformes fish inspection system equivalent to that of the United States. FSIS's initial audit included four slaughter and processing establishments that were exporting Siluriformes fish to the U.S., at that time, and one cold storage facility connected to one of the establishments. However, during the visits to the four establishments, none were processing Siluriformes fish for export to the United States. As discussed in the proposed rule (83 FR 47534), the May 2018 audit identified several deficiencies that FSIS requested the DOF address. FSIS sent the DOF the draft final audit report, and advised that for FSIS to verify the full implementation of Thailand's Siluriformes fish inspection system, it would be necessary to schedule a follow-up on-site audit. FSIS conducted the follow-up audit between August 27 and 31, 2018, visiting the three certified processing establishments exporting Siluriformes fish to the United States at that time (Thailand had delisted

one processing establishment prior to the follow-up audit). Based on the follow-up audit, FSIS concluded that, as implemented, Thailand's inspection system for Siluriformes fish is equivalent to that of the United States.

For more detailed information on FSIS's evaluation of Thailand's Siluriformes fish inspection system, see the proposed rule (83 FR 47534) 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>.

Final Rule

After considering the comments received on the proposed rule, discussed below, FSIS concludes that Thailand's Siluriformes fish inspection system is equivalent to the United States inspection system. Therefore, FSIS is amending its Siluriformes fish inspection regulations to list Thailand as a country eligible to export Siluriformes fish to the United States (9 CFR 557.2(b)(1)). As is stated above, under FSIS's Siluriformes fish import regulations, Thailand must certify to FSIS that those establishments that wish to export Siluriformes fish to the United States are operating under requirements equivalent to those of the United States (9 CFR 557.2(a)).

Although a foreign country may be listed in FSIS regulations as eligible to export Siluriformes fish to the United States,

the exporting country's products must also comply with all other applicable requirements of the United States. Accordingly, Siluriformes fish exported from Thailand will continue to be subject to re-inspection by FSIS 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 will continue to conduct other types of re-inspection activities, such as taking product samples for laboratory analysis to detect drug and chemical residues and pathogens, as well as to identify product species and composition. 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 the U.S. Food and Drug Administration (FDA)), depending on the violation. FSIS import re-inspection activities can be found on the Agency's website at:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/port-of-entry-procedures>.

Responses to Comments

FSIS received 23 comments from producers, a distributor, trade associations, a consumer interest group, a commercial workers union, and individuals. The issues raised in the comments and the Agency responses are summarized below.

The Effectiveness of Thailand's Inspection System and Ongoing Verification of Compliance

Comment: Comments from trade associations, the consumer interest group, the commercial workers union, and individuals questioned whether Thailand's Siluriformes fish inspection system is equivalent to that of the United States and whether Siluriformes fish processed under that system would be safe for consumption in the United States. One of the trade associations submitted peer-reviewed articles concerning the use of antibiotics in aquaculture in Southeast Asia.

Response: FSIS made its equivalence determination for Thailand's Siluriformes fish inspection system based on sound science and in accordance with U.S. international obligations and its own equivalence process. FSIS has an in-depth and rigorous equivalence process, through which it systematically determines whether a foreign country's inspection system achieves a level of public health protection equivalent to that achieved by the U.S. inspection system. Accordingly, the equivalence process does not require the exporting country to develop and implement the same procedures as those of the United

States. Once a country is considered to have an equivalent food safety inspection system, the FSIS equivalence process includes performing an annual records review and on-going on-site audits of the country's inspection system at least every three years to verify whether the country's inspection system continues to be equivalent to FSIS's inspection system.

Regarding antibiotic residues as discussed above, FSIS performs an annual records review for each country that has been deemed to have an equivalent inspection system to that of the United States which includes, in part, a review of the country's sampling and testing for residues; in short, FSIS annually verifies the adequacy of each equivalent country's residue testing program. In addition, FSIS conducts point-of-entry re-inspection of all imported Siluriformes fish, which can include product sampling and testing for microbial, chemical and other hazards. FSIS may conduct laboratory analysis for the detection of chemical residues that may result from the use of drugs and pesticides, or from incidents involving environmental contaminants. FSIS analyzes imported Siluriformes fish for over 100 chemical compounds, which include drugs, aminoglycosides, antifungal drugs, metals and pesticides. Products that pass re-inspection are stamped with the official mark of inspection and allowed to enter U.S. commerce. If they do not meet U.S.

requirements, they are refused entry into U.S. commerce and must be exported, destroyed, or converted to animal food.

On-site Audit

Comment: The commercial workers union and the consumer interest group expressed concerns over the deficiencies found during the initial on-site audit and the number of Thai establishments audited. In addition, these two commenters expressed concern over the number of establishments that were delisted prior to the initial on-site audit.

Response: The findings of the initial on-site audit conducted May 7-11, 2018, were shared with Thailand's CCA. The audit findings did not present the potential to endanger public health, as most of the findings involved recordkeeping and technical clarifications. The CCA committed to addressing the audit findings as presented within 30 days.

On August 27-31, 2018, FSIS performed a follow-up audit of Thailand's food safety system governing Siluriformes fish. The purpose of the follow-up audit was to observe the production of Siluriformes fish, in addition to the implementation of corrective actions to the deficiencies noted during the initial May 2018 audit. Prior to the August 2018 follow-up audit, Thailand had requested that FSIS remove five establishments from the list of eight establishments eligible to export Siluriformes fish to the United States. FSIS's August 2018 on-site follow-up

audit included the three remaining establishments; all three establishments were processing Siluriformes fish and were found to be performing all operations in accordance with equivalence documentation submitted to FSIS by Thailand's CCA.

It is important to note that FSIS equivalence determinations are based on the foreign country's inspection system, not on an individual establishment's system. To be eligible to export Siluriformes fish to the United States, the foreign country's inspection system must ensure that establishments preparing these products for export to the United States comply with requirements equivalent to those of the FMIA and supporting regulations. Thailand's inspection system meets these requirements. The foreign country certifies the establishments as meeting the required standards and notifies FSIS about establishments that are certified or removed from certification. Thailand's inspection system currently meets all these requirements. FSIS will verify that the system continues to meet requirements through annual CCA submissions, on-going audits, and point-of-entry re-inspection and sampling and testing.

Low-trade volume in Thailand and the associated cost to the United States economy

Comment: Three individuals noted that stopping trade with Thailand would not impact the United States' economy because

Thailand has a low-trade volume. These commenters also argued that continuing trade with Thailand would negatively impact public health and therefore the economy. However, several producers supporting the proposed rule stated that continued trade with Thailand would maintain certainty in the market.

Response: FSIS agrees that Thailand has a low-trade volume, but disagrees that continued trade with Thailand will negatively impact public health or the economy. As mentioned above, FSIS ensures a foreign country's inspection system achieves an equivalent level of public health protection to FSIS's inspection system through a robust equivalence process and point-of-entry re-inspection and testing. Because Thailand is likely to continue to maintain a low trade volume, continued trade with Thailand will not harm the economy and will instead provide continued market stability that is beneficial to the U.S. economy.

Executive Orders (E.O.s) 12866 and 13563

E.O.s 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). 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 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 Final Rule

This final regulatory impact analysis updates the preliminary regulatory impact analysis by including the most recent year's (2018) trade data. This final rule is not expected to have quantified costs because it maintains the existing trade in Siluriformes fish between the United States and Thailand. The United States has historically imported Siluriformes fish from Thailand. Therefore, market conditions, including prices and supplies, are not expected to be impacted by this rule. From 2014 to 2018, total sales from Thailand Siluriformes fish imports only averaged 0.016 percent of U.S. domestic production, and constituted only 0.008 percent of total U.S. consumption, Table 1. In 2016, although Thailand exported 3.5 times more Siluriformes fish to the United States than their average, Thai Siluriformes fish still only accounted for 0.027 percent of total United States Siluriformes fish 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 Sales

	2014	2015	2016	2017	2018	5 Year Average
	Millions of Dollars					
Total U.S. Imports¹	\$346.66	\$351.13	\$405.61	\$381.89	\$547.10	\$406.48
Total U.S. Domestic Production²	\$351.94	\$363.61	\$385.99	\$379.71	\$360.40	\$368.33
Total U.S. Exports¹	\$4.00	\$4.95	\$4.80	\$6.18	\$3.89	\$4.76
Total U.S. Consumption³	\$694.60	\$709.79	\$786.80	\$755.43	\$903.61	\$770.04
Total U.S. Imports¹ from Thailand	\$0.02	\$0.01	\$0.21	\$0.04	\$0.02	0.06
Thailand as % of U.S. Imports	0.005%	0.003%	0.052%	0.010%	0.004%	0.015%
Thailand as % of U.S. Domestic Production	0.005%	0.003%	0.054%	0.010%	0.006%	0.016%
Thailand as % of U.S. Consumption	0.002%	0.002%	0.027%	0.005%	0.002%	0.008%

Data Source: U.S. Census Bureau Trade Data

* Numbers in table may not sum to totals due to rounding

¹ Import and Export Data Accessed from USDA Foreign Agricultural Service:
Global Agricultural Trade System:

<https://apps.fas.usda.gov/gats/default.aspx/>

² U.S. Production Data Accessed from USDA National Agricultural Statistics
Service: Quick Stats: https://quickstats.nass.usda.gov/results/6F6BAB14-7014-365B-ACEA-CA35C184329B?pivot=short_desc/

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

Expected Benefits of the Final Rule

This final rule will result in the continued opportunity for trade between the United States and Thailand. The volume of trade is likely to continue to be low 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 fish. The rule will, therefore, maintain choices for U.S. consumers and promote economic competition.¹

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 economic impact on a substantial number of small entities in the United States, because, as stated above, the final rule will maintain existing trade. The trade volume is expected to remain within historical bounds, with little or no effect on all U.S. establishments, regardless of size.

Executive Order (E.O.) 13771

Consistent with E.O. 13771 (82 FR 9339, February 3, 2017), this final rule facilitates regulatory cooperation with foreign

¹ Sea Grant Delaware Seafood Health Facts: Making Smart Choices accessed on 7/27/2018 <https://www.seafoodhealthfacts.org/description-top-commercial-seafood-items/pangasius>

governments. Therefore, this final rule is an E.O. 13771 deregulatory action.

Paperwork Reduction Act

No new paperwork requirements are associated with this final 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 the 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 the country in organizing its materials. This information collection was approved under OMB number 0583-0153. The final rule contains no other paperwork requirements.

Executive Order (E.O.) 12988, Civil Justice Reform

This final rule has been reviewed under E.O. 12988, Civil Justice Reform. Under this rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) no administrative proceedings will be required before parties may file suit in court challenging this rule.

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 on-line 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 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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U.S. Department of Agriculture
Director, Office of Adjudication
1400 Independence Avenue, SW

Washington, DC 20250-9410

Fax: (202) 690-7442

E-mail: program.intake@usda.gov

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

List of Subjects in 9 CFR Part 557

Imported products.

For the reasons set out in the preamble, FSIS amends 9 CFR part 557 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 at the end of paragraph (b)(1).

Done at Washington, DC:

Carmen M. Rottenberg,

Administrator.

[FR Doc. 2019-24058 Filed: 11/4/2019 8:45 am; Publication Date: 11/5/2019]