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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 557

[Docket No. FSIS-2018-0029]

RIN [0583-AD74]

Eligibility of the Socialist Republic of Vietnam 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 the Socialist Republic of Vietnam (Vietnam) 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 Vietnam's laws, regulations, and inspection system as implemented and has determined that Vietnam'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 Vietnamese 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 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-2018-0029. 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 Vietnam 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 Vietnam has been allowed to export these products to the United States under the conditions described below, Vietnam 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 FSIS 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.

Vietnam submitted its initial documentation in February 2016, which allowed it to continue exporting Siluriformes fish during the transitional period. In August 2017, Vietnam 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 at least on a quarterly basis for each foreign establishment that exported 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. During the testing, FSIS found residue violations in shipments of

Siluriformes fish exported from Vietnam. 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 Vietnam's National Agro-Forestry-Fisheries Quality Assurance Department (NAFIQAD), the central competent authority for food inspection, of the residue violations, and in response, NAFIQAD investigated to determine the cause of the violations and provided corrective actions.

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 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 Vietnam 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 establishments 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 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 to export Siluriformes fish to the United States 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 Vietnam's Siluriformes Fish Inspection System

In August 2017, Vietnam 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 Vietnam's Siluriformes fish inspection system to determine whether that system was equivalent to that of the United States. FSIS concluded, based review of the submitted documentation, that Vietnam'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 Vietnam's Siluriformes fish inspection system. FSIS audited eight of the 13 establishments currently exporting Siluriformes fish to the U.S. The on-site audit also included visits to two farms where fish were raised and pre-harvest operations were conducted. The purpose of the on-site audit was to verify whether NAFIQAD effectively implemented a Siluriformes fish inspection system equivalent to that of the United States. Vietnam currently exports only raw Siluriformes fish to the United States.

The audit of Vietnam's Siluriformes fish inspection system did not identify any deficiencies that represented an immediate threat to public health. The audit did find that NAFIQAD inspectors were not identifying the establishment's failures to adequately document results of operational sanitation monitoring in all of the establishments FSIS visited. Specifically, at each establishment audited, the FSIS auditors found that the establishments were documenting operational sanitation monitoring; however, it was not at the frequency prescribed in the establishment's sanitation procedures. The audit also found that, in one establishment, the hazard analysis identified the

shipping step in its process, but did not identify all potential hazards associated with that step.

On June 29, 2018, FSIS sent NAFIQAD the draft final audit report, and requested a written response regarding any corrective actions undertaken and changes made to Vietnam's Siluriformes fish inspection system. On August 10, 2018, NAFIQAD responded with written comments and corrective actions.

In response to the finding that NAFIQAD inspectors did not identify establishment's failure to adequately document results of operational sanitation monitoring, NAFIQAD provided examples of monitoring forms and procedures, and stated that these documents showed that operational sanitation monitoring in establishments was performed and documented in accordance with the establishment's Sanitation Standard Operating Procedures once every one or two hours depending on production stage and establishments sanitation procedure. FSIS agrees that this frequency of monitoring is sufficient. The frequency and documentation of the monitoring of the sanitation operations must replicate the frequency and monitoring in the written sanitation procedures.

In response to the finding that one establishment's hazard analysis identified the shipping step, but not all potential hazards associated with that step, NAFIQAD explained that the establishment did not identify the hazards because the product

had been frozen and transported outside of the factory and that the establishment is revising its HACCP plan to include the hazard of pathogen growth.

In addition to the corrective actions discussed above, FSIS reviewed Vietnam's corrective action plan for all of the audit findings and concluded that all have been satisfactorily addressed.

In summary, FSIS has completed the document review, on-site audit, and verification of corrective actions as part of the equivalence process, and all outstanding issues have been resolved. FSIS has concluded that, as implemented, Vietnam's inspection system for Siluriformes fish is equivalent to that of the United States. The full report on Vietnam'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, Vietnam intends to certify thirteen establishments as eligible to export Siluriformes fish to the United States. Vietnam's eligibility applies to the export of raw Siluriformes fish only. Should this rule become final, the government of Vietnam 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 Vietnam's government are meeting the United States requirements through verification audits of Vietnam's Siluriformes fish inspection system.

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 be found to comply with all other applicable requirements of the United States. Accordingly, Siluriformes fish exported from Vietnam 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 Vietnam'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.

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 Vietnam 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 because the proposed rule maintains the

existing trade in Siluriformes fish between the United States and Vietnam. The United States has historically imported Siluriformes fish from Vietnam. Therefore, market conditions, including prices and supplies, are not expected to be impacted by this rule. From 2013 to 2017, 90.5 percent of total Siluriformes fish imports to the United States were from Vietnam, Table 1. Vietnamese Siluriformes fish accounted for 45.7 percent of U.S. consumption, Table 1.

Table 1. Summary of Siluriformes Fish Sales

	2013	2014	2015	2016	2017	5 Year Average
	Millions of Dollars					
Total U.S. Imports¹	\$363.42	\$346.66	\$351.13	\$405.61	\$381.89	\$369.74
Total U.S. Domestic Production²	\$356.73	\$351.94	\$363.61	\$385.99	\$379.71	\$367.60
Total U.S. Exports¹	\$4.69	\$3.99	\$4.95	\$4.80	\$6.18	\$4.92
Total U.S. Consumption³	\$715.46	\$694.60	\$709.79	\$786.80	\$755.43	\$732.41
Total U.S. Imports from¹ Vietnam	\$335.03	\$309.53	\$318.40	\$367.65	\$342.96	\$334.71
Vietnam as % of U.S. Imports	92.2%	89.3%	90.7%	90.6%	89.8%	90.5%
Vietnam as % of U.S. Domestic Production	93.9%	87.9%	87.6%	95.3%	90.3%	91.1%
Vietnam as % of U.S. Consumption	46.8%	44.6%	44.9%	46.7%	45.4%	45.7%

Data Source: U.S. Census Bureau Trade Data

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

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

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

Expected Benefits of the Proposed Rule

The proposed rule may qualitatively benefit industry by maintaining market stability and continued opportunity for trade between the United States and Vietnam. Consumers in the United States would continue to have access to more choices when purchasing Siluriformes fish, specifically of the family Pangasius, which are native to Vietnam, The People's Republic of China, and other neighboring Asian nations. Pangasius have a different flavor, color and texture than other Siluriformes fish found in the United States. The Siluriformes fish trade between the United States and Vietnam would maintain choices for consumers in the United States.¹

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

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>

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 Vietnam with a questionnaire, referred to as the 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 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 "Socialist Republic of Vietnam" in alphabetical order to the list of countries in paragraph (b)(1).

Paul Kiecker,

Acting Administrator.

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