



DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. **FSIS-2021-0001**]

Eligibility of Lithuania to Export Egg Products to the United States

AGENCY: Food Safety and Inspection Service (FSIS), U.S.

Department of Agriculture (USDA).

ACTION: Notice and response to comments.

SUMMARY: FSIS is announcing that Lithuania is eligible to export egg products to the United States. FSIS has reviewed Lithuania's laws, regulations, and inspection system, as implemented, and has determined that Lithuania's egg products inspection system is equivalent to the food safety inspection system for egg products that the United States has established under the Egg Products Inspection Act (EPIA) and its implementing regulations. Therefore, egg products produced in certified Lithuanian establishments are eligible for export to the United States. All such products will be subject to reinspection at U.S. points-of-entry by FSIS inspectors.

DATES: *Applicable:* Lithuania's egg products eligible for import to the United States will be added to the FSIS Import Library (<https://www.fsis.usda.gov/inspection/import-export/import-export-library>) on **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. Lithuania will be eligible to export to the United

States egg products produced in the country on or after **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development, telephone (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

On December 28, 2021, FSIS published a notice in the **Federal Register** (86 FR 73721) that announced that FSIS intended to add Lithuania to the list of countries eligible to export egg products to the United States. As explained in the notice, the EPIA prohibits the importation of egg products capable of use as human food into the United States unless they were processed under an approved inspection system of the government of the foreign country of origin and are labeled and packaged in accordance with, and otherwise comply with, the standards of the EPIA and regulations issued thereunder applicable to such articles within the United States (21 U.S.C. 1046(a)(2)). The regulatory requirements for foreign countries to become eligible to export egg products to the United States are provided in 9 CFR 590.910(a).

Section 590.910(a) requires a foreign country's inspection system to be authorized by a legal authority that imposes requirements equivalent to those of the United States, specifically with respect to labeling, packaging, sanitation, processing, facility requirements, and Government inspection.

The foreign country's inspection system must ensure that establishments preparing egg products for export to the United States comply with requirements equivalent to those of the EPIA and the regulations promulgated by FSIS under the authority of that statute. The foreign country is required to certify establishments as having met the required standards and to notify FSIS of those establishments that are either certified as eligible to export to the United States or removed from eligibility.

As part of the FSIS initial equivalence review process, FSIS evaluated the country's food safety inspection system for egg products to determine whether it is equivalent to FSIS', and therefore, eligible to export egg products to the United States. This evaluation consisted of two processes: A document review and an onsite review. The document review is an evaluation of the laws, regulations, and other written materials used by the country to affect its inspection program (9 CFR 327.2(a)(2)(iii), 381.196(a)(2)(iii), and 590.910(a)). The onsite review is an FSIS audit to verify the implementation of the country's food safety inspection system. These comprehensive processes are described more fully on the FSIS website at <https://www.fsis.usda.gov/inspection/import-export/equivalence>.

FSIS regulations (9 CFR 590.910(b)) provide that a list of countries eligible to export egg products to the United States be maintained at <https://www.fsis.usda.gov/inspection/import->

export/import-export-library. To verify that products imported into the United States are not adulterated or misbranded, FSIS reinspects all product imported under FSIS jurisdiction and samples a subset of those products for pathogens and residues at points-of-entry before they enter U.S. commerce.

Evaluation of the Lithuanian Egg Products Inspection System

FSIS explained in the December 28, 2021, **Federal Register** notice that FSIS conducted an onsite audit from October 24 to November 2, 2016, to verify that Lithuania's State Food and Veterinary Service (SFVS), the central competent authority (CCA) in charge of food inspection, effectively implemented an egg products inspection system equivalent to that of the United States (86 FR 73721). Details regarding that audit and subsequent actions resulting from it, including a follow-up audit conducted from July 15 to July 24, 2019, can be found in the December 28, 2021, notice. In the follow-up audit, FSIS evaluated the corrective action plans and Lithuania's inspection verification activities, based on the information Lithuania submitted, and determined that Lithuania had satisfactorily addressed all the audit findings and was able to meet FSIS requirements and equivalence criteria related to all six components (86 FR 73721).

FSIS' Equivalence Determination

After considering the comments received on the notice, discussed below, FSIS has concluded that Lithuania's egg products inspection system is equivalent to the United States'

inspection system for egg products. FSIS has added Lithuania to its list of eligible countries to export egg products to the United States on its website at:

<https://www.fsis.usda.gov/inspection/import-export/import-export-library>.

Lithuania is eligible to export to the United States egg products produced in certified Lithuanian establishments produced on or after **[INSERT DATE OF PUBLICATION IN FEDERAL REGISTER]**. FSIS maintains a country specific web page¹ on FSIS' website with a link to the country's certified establishments and a list of the process categories, product categories, and the product groups Lithuania is eligible to export to the United States. Although a foreign country may be listed on FSIS' website as eligible to export egg 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 USDA's Animal and Plant Health Inspection Service (APHIS). These requirements include restrictions under 9 CFR part 94 of the APHIS regulations, which regulate the importation of egg products from foreign countries into the United States to control the spread of specific animal diseases. All egg products exported to the United States from Lithuania will be subject to reinspection by FSIS at United States points-of-entry for, but not limited to, transportation damage, product and container defects, labeling, proper certification, general condition, and

¹ See: <https://www.fsis.usda.gov/inspection/import-export/import-export-library/lithuania>.

accurate count. FSIS also will conduct other types of reinspection activities, such as physical inspection of products to ensure product safety and taking product samples for laboratory analysis to detect any drug or chemical residues or pathogens that may render the product unsafe or other 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 United States commerce. If a product does not meet United States requirements, it 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:

[https://www.fsis.usda.gov/inspection/import-export/import-](https://www.fsis.usda.gov/inspection/import-export/import-guidance)

[guidance](https://www.fsis.usda.gov/inspection/import-export/import-guidance). Finally, within one year of the publication date of this **Federal Register** notice, FSIS intends to conduct an onsite audit of Lithuania's egg products inspection system to verify ongoing equivalence. During the audit, FSIS auditors will verify that Lithuania's CCA has implemented its food safety inspection system as described in the Self-Reporting Tool² and supporting documentation. FSIS will audit government offices, establishments, and laboratories to verify that the CCA has

² The Self-Reporting Tool (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. The SRT template can be found on the FSIS website at <https://www.fsis.usda.gov/guidelines/2022-0003>.

implemented its inspection system as documented and verify that the country's system of controls remains equivalent to the U.S. inspection system.

Summary of Comments and Responses

FSIS received three comments in response to the notice, one from a trade association representing U.S. egg farmers, one from a trade association representing U.S. egg products producers, and one from an individual. The two trade associations opposed the declaration of equivalence for Lithuania for the reasons discussed below. The individual asked about the importation of shell eggs from Lithuania. Because this notice does not deal with the importation of shell eggs from Lithuania, the comment is outside the scope of this notice and is not addressed. The following is a brief summary of the relevant issues raised in the comments and FSIS' responses.

Continuous Inspection

Comments: The trade association representing U.S. egg farmers and the trade association representing U.S. egg products producers questioned how FSIS will verify that continuous inspection, including the inspection of shell eggs prior to breaking, will be provided in a foreign egg products processing plant, as required by the EPIA. The trade association representing U.S. egg products producers noted that under the final rule "Egg Products Inspection Regulations" (85 FR 68640), "continuous inspection" was interpreted to provide for the presence of inspectors at official plants at the same frequency

that meat and poultry processing establishments have inspectors, i.e., at least once per production shift (daily inspection).

Response: FSIS will verify through Lithuania's (and other countries') documented foreign inspection procedures submitted to FSIS through the SRT and FSIS audits of the inspection systems that "continuous inspection" in foreign egg products establishments, including the inspection of shell eggs prior to breaking, is conducted by government inspectors who are present at the establishment at least once per production shift.

Hazard Analysis and Critical Control Point (HACCP)

Implementation

Comments: The trade association representing U.S. egg products producers asked if equivalence procedures would be implemented in Lithuania when the HACCP system requirements are implemented on October 31, 2022.

Response: FSIS has verified through Lithuania's SRT responses and documentation reviews that Lithuania has a documented inspection system, including requirements for Sanitation Performance Standards, Sanitation Standard Operating Procedures and HACCP, equivalent to FSIS' egg products inspection system under the new requirements of the final egg rule (see 85 FR 68640). Implementation of these requirements will be verified during the next audit.

Failure to Provide Government Oversight

Comments: The trade association representing U.S. egg producers argued that Lithuania is unable to demonstrate

adequate government oversight of its egg products inspection system. According to the trade association, the country may have shown that its laws, regulations, control programs, and procedures were equivalent to those of the United States in 2014, but Lithuania was unable to demonstrate adequate government oversight over its egg products inspection system in 2016 and 2019, considering the documentation reviews and onsite audits conducted by FSIS. The commenter noted that in 2016, FSIS concluded that the Lithuanian government was unable to demonstrate adequate government oversight regarding implementation and verification of its sanitation requirements. The commenter noted that in 2019, FSIS conducted a second onsite audit and found that actions to correct the 2016 deficiencies in the egg products plant were implemented and effective; however, the commenter further noted that in 2019, the Agency found that Lithuania could not demonstrate adequate government oversight regarding implementation and verification of its egg products requirements.

Response: FSIS' equivalence review process for Lithuania was not unique. Many countries submit multiple series of corrective actions to FSIS and undergo more than one onsite audit before they are found eligible to export meat, poultry, or egg products to the United States. As FSIS explained in the December 28, 2021, notice, the Lithuanian government addressed past concerns both with the egg products inspection system and with other products that they are eligible to export to the

United States. The corrective actions provided indicated that the country has addressed FSIS concerns (86 FR 73721). As is stated above, FSIS will follow up with an audit of Lithuania's egg products inspection system within one year of granting equivalence, which is standard policy for all countries granted new equivalence.

Economic Impact Analysis

As explained above, FSIS is listing Lithuania as a country eligible to export egg products to the United States. Given the limited market in the United States for Lithuania's egg products and Lithuania's projected low export volume, there is likely to be little, if any, impact on the United States economy.

In comparison to the United States, Lithuania is a small egg and egg products producer with limited capacity to export egg products. Between 2015 and 2019, Lithuania had an annual average of 3.2 million egg laying hens that produced 55,300 tons of eggs and imported 14,300 tons of eggs. During this same period, Lithuania consumed approximately 50,800 tons of eggs annually. The remaining eggs were exported as eggs or egg products, mainly to the European Union, of which Lithuania is a member. Of these exports, approximately 17.2 percent were in the form of egg products.³ According to the United Nations Comtrade Database, Lithuania, on average, exported 3,200 tons of egg

³ Lithuania's production, trade, and consumptions data are based on the Food and Agricultural Organization of the United Nations (FAO, 2021) Food Balance Sheet (FBS): available at <http://www.fao.org/faostat/en/#data/FBS>. FSIS calculated 17.2 percent as a five-year average based on 2015-19 FAO data (production plus imports minus consumption and assuming zero ending stock). The latest available FBS data for Lithuania is 2019.

products during 2017-2021. Assuming that the European Union will continue to be Lithuania's largest trading partner, the amount of egg products to be exported to the U.S. is likely to be less than 3,200 tons.⁴

From 2017 to 2021, the U.S. had an annual average of 387 million egg laying hens⁵ that produced 6.9 million tons of eggs, of which approximately 5.9 million tons were consumed domestically.⁶ While the U.S., on average, imported around 7,000 tons of egg products annually in this period, it was a net exporter of egg products.⁷

With only one establishment intending to export egg products to the U.S., Lithuanian egg products exports to the U.S. are likely to be small in comparison to the total U.S. egg products market, and are expected to have little or no effect on U.S. egg products supplies or their prices. U.S. consumers, however, are expected to enjoy more choices when purchasing egg products.

Effect on Small Businesses

⁴ United Nations Statistical Division, UN Comtrade Database, 2017-2021: available at <https://comtrade.un.org/data/>.

⁵ U.S. Chicken Layers Inventory are based on USDA National Agricultural Statistics Service (NASS) data for July 1st each year from 2015-19. The data were accessed from the USDA/NASS Quick Stats at: <https://quickstats.nass.usda.gov/results/B6EC799A-D857-338C-82DC-73C74B27755B>

⁶ U.S. Production and Consumption Data accessed from USDA/World Agricultural Supply and Demand Estimates (WASDE): <https://usda.library.cornell.edu/concern/publications/3t945q76s?locale=en>. WASDE's egg data are published in dozen; FSIS converted these data into tons using Grade A Large Egg Weight based on USDA/Agricultural Marketing Service conversion rate: accessed from https://www.ams.usda.gov/sites/default/files/media/Shell_Egg_Standard%5B1%5D.pdf.

⁷ U.S. Import and Export Data accessed from USDA Foreign Agricultural Service: Global Agricultural Trade System: <https://apps.fas.usda.gov/GATS/default.aspx>. Egg products are based on Harmonized System (HS) codes 040811, 040819, 040891, 040899, 350211, and 350219.

The FSIS Administrator has made a determination that this notice will 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.). The trade volume is expected to have little or no effect on all U.S. establishments, regardless of size.

Additional Public Notification

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

Congressional Review Act

Pursuant to the Congressional Review Act at 5 U.S.C. 801 *et seq.*, the Office of Information and Regulatory Affairs has determined that this notice is a not "major rule," as defined by 5 U.S.C. 804(2).

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Paul Kiecker,

Administrator.

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