FINAL REPORT OF AN AUDIT CONDUCTED IN

LITHUANIA

JULY 15 THROUGH 24, 2019

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

MEAT AND EGG PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

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Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the United States Department of Agriculture's Food Safety and Inspection Service from July 15 through 24, 2019. The purpose of the meat products audit was to determine whether Lithuania's food safety inspection system governing meat remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. The purpose of the egg products audit was to determine whether Lithuania's egg products inspection system is equivalent to that of the United States. Lithuania currently exports ready-to-eat fully cooked, not shelf stable beef and pork products and thermally processed, commercially sterile (TPCS) beef and pork products to the United States.

The meat audit focused on six system 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, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs. The egg products audit excluded components 4 and 5 for which FSIS did not have requirements for egg products at the time of the audit.

An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors identified the following findings:

GOVERNMENT OVERSIGHT (e.g., Organization and Administration)

- The Central Competent Authority (CCA) was unable to demonstrate adequate government oversight regarding implementation and verification of its egg products requirements as evidenced by the Government Statutory Authority and Food Safety and Other Consumer Protection Regulations component findings described below.

GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS

- The FSIS auditors observed the following at the sole egg products establishment the CCA intends to certify as eligible for export to the United States:
  - The CCA personnel could not explain how the egg products pasteurization records presented during the audit supported that pasteurization requirements were met.
  - The establishment could not produce a current calibration certificate for one flow rate probe used during the pasteurization process at the time of the audit.
  - Multiple blood spots were observed on the yolks of multiple eggs with no actions taken by the official government veterinarians or establishment personnel to remove the blood spots or reject the affected egg products.
  - The establishment was not monitoring and documenting product temperature during heat treatment of dried whites.
  - Blocks of yeast used in the fermentation of egg products were stored in a refrigerator but lacked any labeling indicating the actual product contents.

GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM

- The CCA does not ensure HACCP records include the time of monitoring CCPs.

GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

- The CCA does not ensure support is maintained for the TPCS process, as evidenced by the failure of the sole establishment eligible to export TPCS product to the United States to maintain heat penetration or heat distribution data for the validation of their thermal process.

During the audit exit meeting on July 24, 2019, the CCA committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of Lithuania's meat and egg products food safety systems from July 15 through 24, 2019. The audit began with an entrance and exits meetings were held on July 15, 2019, and July 24, 2019, respectively, in Vilnius, Lithuania, during which the FSIS auditors discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – State Food and Veterinary Service (SFVS). Representatives from the CCA accompanied the FSIS auditors throughout the entire audit.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit of meat and initial equivalence verification audit of egg products. The audit objective was to determine whether the food safety system governing processed meat remains equivalent to that of the United States, and to verify whether the food safety system governing egg products is implemented as described in the FSIS self-reporting tool (SRT) and effective in providing an equivalent level of public health protection as achieved in the United States with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Lithuania is eligible to export the following categories of products to the United States:

Process Category	Product Category	Eligible Products[1]
Thermally Processed, Commercially Sterile	Thermally processed, commercially sterile	Corned (species); Other; Sausage; Soups; and Ham.
Fully Cooked - Not Shelf Stable	Ready-to-eat fully cooked meat	Diced/shredded; Hot dog products; Meat + nonmeat component, Nuggets, Other fully cooked not sliced product, Other fully cooked sliced product, Parts, Patties, Salad/spread/pate, Sausage products, Ham patties, Ham, Not sliced ham; and Sliced hot dog products.
Fully Cooked - Not Shelf Stable	Ready-to-eat fully cooked meat without subsequent exposure to the environment	Diced/shredded; Hot dog products; Meat + nonmeat component, Nuggets, Other fully cooked not sliced product, Other fully cooked sliced product, Parts, Patties, Salad/spread/pate, Sausage products, Ham patties, Ham, Not sliced ham; and Sliced hot dog products.

[1] All source meat used to produce products must originate from eligible countries and establishments certified to export to the United States. For processed meat products, meat includes the following species: beef, veal, goat, lamb, mutton, and pork.

The USDA's Animal and Plant Health Inspection Service (APHIS) recognizes Lithuania as free of foot-and-mouth disease and swine vesicular disease (with restrictions), negligible risk for bovine spongiform encephalopathy, low risk for classical swine fever, and subject to European Union zoning restrictions for African swine fever.

For the audit of the meat inspection system, FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, point-of-entry (POE) reinspection and testing results, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS over a three-year period, in addition to information obtained directly from the CCA through the SRT.

Determinations concerning program effectiveness focused on performance within the following six components upon which meat food safety system equivalence is based: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

Administrative functions were reviewed at CCA headquarters, two territorial offices, and four local inspection offices. The FSIS auditors evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

All three meat establishments certified to export to the United States, and one establishment that the CCA intends to certify for export to the United States (dependent upon initial equivalence for egg products), were included in the audit. This included two beef and pork slaughter and processing establishments, one egg processing establishment, and one establishment certified as a cold storage facility. The FSIS audit included evaluation of slaughter, RTE, and TPCS process categories. Lithuania currently exports thermally processed, commercially sterile (TPCS) beef and pork products; and ready-to-eat (RTE) fully cooked beef and pork products to the United States.

During the establishment visits, the FSIS auditors paid attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that threatens food safety. The FSIS auditors assessed the CCA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) 327.2.

Additionally, one government microbiological and residue laboratory was audited to verify its ability to provide adequate technical support to the food safety inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• SFVS, Vilnius
	Territorial	2	• Kėdainiai Territorial Office, Kėdainiai • Plungė Territorial Office, Plungė
Laboratories		2	• National Food and Veterinary Risk Assessment Institute, government microbiological and chemical, Vilnius
Beef and pork slaughter and processing establishments		2	• Establishment No. LT 17 EB, Biovela-Utenos Mesa, UAB, Utena • Establishment No. LT 53-04 EB, AB Krekenavos Agrofirma, Kėdainiai
Egg products establishment		1	• Establishment No. LT 68-09 EB, Baltic Egg Corporation, Plungė
Cold storage facility		1	• Establishment No. LT 19-30 EB, UAB Liūtukas ir Ko, Kaunas

FSIS performed the audit to verify the food safety inspection system met requirements equivalent to those under the specific provisions of United States' laws and regulations, in particular:

- The Federal Meat Inspection Act (21 United States Code [U.S.C.] 601 *et seq.*);
- The Humane Methods of Slaughter Act (7 U.S.C. 1901-1906);
- The Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*); and,
- The Meat and Egg Products Inspection Regulations (9 CFR).

The audit standards applied during the review of Lithuania's inspection system for processed meat and egg products included: (1) all applicable legislation originally determined by FSIS as equivalent as part of the initial review process, and (2) any subsequent equivalence determinations that have been made by FSIS under provisions of the World Trade Organization's *Agreement on the Application of Sanitary and Phytosanitary Measures*; and includes the following:

- Regulation European Commission (EC) No. 178/2002;
- Regulation (EC) No. 852/2004;
- Regulation (EC) No. 853/2004;
- Regulation (EC) No. 854/2004;
- Regulation (EC) No. 882/2004;
- Regulation (EC) No. 2073/2005;
- Regulation (EC) No. 1069/2009;
- Regulation (EC) No. 1099/2009;
- Regulation (EU) No. 142/2011;
- Council Directive No. 93/119/EC;
- Council Directive No. 96/22/EC; and
- Council Directive No. 96/23/EC.

III. BACKGROUND

From April 1, 2016 through March 31, 2019, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 831,073 pounds of meat from Lithuania. This included 276,219 pounds of TPCS beef and pork; 22,757 pounds of RTE fully cooked beef and pork without subsequent exposure to the environment; 532,056 pounds of RTE fully cooked beef and pork; and 41 pounds of raw intact beef exported by Lithuania to the United States. Of these amounts, additional types of inspection were performed on 121,145 pounds of meat, including testing for chemical residues and microbiological pathogens (*Listeria monocytogenes* [*Lm*] and *Salmonella* in RTE products), for which no products were rejected for issues related to public health.

The previous ongoing equivalence verification audit for meat in 2018 did not identify any systemic findings.

In November 2014, Lithuania requested an initial equivalence determination to export egg products to the United States and submitted SRT responses and supporting documents from December 2014 through May 2016. FSIS reviewed these documents and performed an on-site equivalence verification audit for egg products in 2016. FSIS identified the following findings during the 2016 audit:

GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)

- The FSIS auditor did not observe the full implementation of regulatory requirements cited in 9 CFR Part 590 by the CCA. The CCA was unable to demonstrate adequate government oversight regarding implementation and verification of its sanitary requirements as evident by the Government Sanitation component findings below.

GOVERNMENT SANITATION

- The FSIS auditor did not observe the establishment conduct candling procedures to detect eggs with cracked shells and interior defects.
- The FSIS auditor did not observe the establishment conduct washing, sanitizing, and drying dirty eggs.
- Some of the nest run eggs (shell eggs) loaded onto the breaking machine conveyor belt had adhering dirt and foreign material on the shell surface. These dirty eggs were in direct contact with each other and other eggs on the conveyor belt creating a potential for cross contamination between eggs and conveyor belt before breaking operations. The establishment's employees did not remove these eggs prior to the breaking operation.
- Following breaking, an accumulation of intact shell eggs or large fragments of broken shells was observed in the egg products containers, resulting in direct product contamination.
- Beaded condensate, dust on overhead structures, and pooling water on the floor were also observed. However, FSIS did not observe any direct product contamination on the day of the audit.

FSIS determined that Lithuania needed to submit additional supporting documentation to support their initial equivalence request for egg products. Throughout 2018 and 2019, the SFVS continued to provide supporting documents in response to FSIS requests. The current FSIS audit was to determine whether Lithuania's corrective actions in response to the prior findings were implemented and effective as well as to assess implementation of their egg products inspection system as described in the FSIS SRT. The FSIS auditors verified that the corrective actions for the 2016 Government Sanitation component findings were implemented and effective in resolving the findings. However, the FSIS auditors determined that the 2016 Government Oversight finding is not resolved.

During the audit, the FSIS auditors conducted interviews, reviewed records, and made observations to determine whether Lithuania's food safety inspection system governing processed meat and egg products is being implemented as documented in the country's SRT responses and supporting documentation.

The FSIS final audit reports for Lithuania's food safety inspection system are available on the FSIS website at: https://www.fsis.usda.gov/foreign-audit-reports.

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)

The first of six equivalence components the FSIS auditors reviewed was Government Oversight. FSIS import regulations require the foreign food safety inspection system to be organized by the national government in such a manner as to provide ultimate control and supervision over all official inspection activities; ensure the uniform enforcement of requisite laws; provide sufficient administrative technical support; and assign competent qualified inspection personnel at establishments where products are prepared for export to the United States.

The national government of Lithuania organizes and manages the food safety system. The CCA is the SFVS with responsibility for developing and implementing Lithuanian policy in the fields of food safety and quality as well as animal health and welfare as established by *Resolution 638*. The SFVS is headed by the Director, Chief Veterinary Officer of the Republic of Lithuania and consists of 14 departments. The Veterinary Sanitary Department (VSD) is responsible for the coordination of inspection of animal origin food products, including coordination and implementation of sampling plans; approval of food business operators; preparation of legal acts, standard operating procedures, and work instructions; and export control. The VSD also manages the EC's Rapid Alert System for Food and Feed (RASFF) coordination and notifications, analyzes inspection data, and provides methodological assistance and training of territorial SFVS specialists.

Since the last FSIS audit, the SFVS has undergone a reorganization, establishing ten regional SFVS offices, which now oversee 42 territorial SFVS offices. Formerly, the SFVS consisted of 52 territorial offices that were overseen directly by the SFVS headquarters. Regional offices are responsible for the supervision and coordination of territorial offices and territorial offices are responsible for the supervision and coordination of the Official Veterinarians (OVs). At the local level, government inspection personnel consist of OVs, who are responsible for conducting

inspection verification activities and enforcing regulatory requirements. Territorial SFVS offices are responsible for implementation of official controls, including staffing of establishments and enforcement of legislation.

The FSIS auditors' review of the oversight activities carried out at the SFVS headquarters and territorial offices verified that SFVS has the legal authority and responsibility to enforce inspection policy. The initial equivalence egg products audit included an on-site visit to the Plungė territorial office providing immediate oversight of the egg products establishment. The Telšiai regional office is responsible for periodic supervisory visits to the egg products establishment to ensure FSIS requirements are met. The Telšiai regional office oversees the Plungė territorial office that is responsible for oversight of the continuous inspection requirements. The ongoing equivalence meat audit included an on-site visit to the Kėdainiai territorial office providing oversight to one certified establishment. The Kaunas regional office oversees the Kėdainiai territorial office and is responsible for ensuring FSIS requirements are met.

The FSIS auditors reviewed noncompliance records at the audited establishments, which demonstrated that the OVs are identifying deficiencies and verifying that establishments take corrective actions within an appropriate amount of time. Noncompliances are documented in the Animal Food Information System (AFIS) inspection database, and can be reviewed at the territorial, regional, and headquarters levels to monitor trends of noncompliance. *Order B1-59, Rules for Inspection of Activities of Business Operators* establishes that corrective actions must be planned within 14 days of notification within the inspection report that identifies the deficiencies. The *Administrative Code of Lithuania* provides the SFVS the authority to issue sanctions to food business operators, including warnings, penalties and confiscation of products. *Order B1-12, Approval of the Procedure for the Application of Administrative Sanctions* defines the procedure for applying administrative sanctions to establishments.

The FSIS auditors verified that there have been no recalls since the last audit from establishments certified to export to the United States. *Order B1-308, Provision of Information on Unsafe Food or Potentially Unsafe Food, Food Contacts Articles or Materials or Feed* requires notification of customers within 24 hours of receipt of information on unsafe or potentially unsafe food. If adulterated or misbranded product is shipped, the territorial office will notify SFVS headquarters, which will communicate the information directly to FSIS. *Resolution 638* identifies SFVS as responsible for reporting information on unsafe food through the RASFF.

The FSIS auditors reviewed the meat export certification process at both the territorial office and establishment levels and verified that export certificates are completed, signed, and stamped by OVs after their inspection of the product and verification of the pre-shipment review. The OVs verify that acceptable residue and microbiological results are received prior to signing the export certificate. The FSIS auditors confirmed that the OV responsible for certifying products for export to the United States verifies that any source materials originate from establishments certified as eligible to export to the United States by checking the SFVS website which provides a link to FSIS' list of United States eligible foreign establishments and verifying that all export

requirements are met. Currently, all establishments certified to export to the United States are not receiving source material from any other establishments.

The FSIS auditors reviewed the establishment certification process according to *KT-6-9-D1, Procedure for the Approval of Conformity of the Business Operator of Food of Animal Origin Engaged in Exports to Third Countries and for the Certification of Products*, at the Plungė territorial SFVS office. The CCA maintains an export library with specific country requirements that is accessible to industry on their website (https://vmvt.lt/eksportas-importas/eksportas/sertifikatai). At the time of the audit, the certification process for egg products differed from that for meat products. However, the CCA representatives stated it was their intent to mirror the process described for meat and they would revise the work instructions accordingly. No concerns were identified during the review of these programs for meat products, except as noted in components four and six.

The FSIS auditors verified that the CCA is following the procedures for establishment certification as described. In addition, the FSIS auditors verified that SFVS has the authority to decertify establishments. The FSIS auditors determined through interviews with SFVS personnel that two establishments previously certified as eligible to export to the United States had their eligibility removed due to failure to correct SFVS-identified noncompliance.

The FSIS auditors verified that United States import requirements are communicated from SFVS headquarters to regional, territorial, and local inspection offices via email, through the electronic Document Management System (DMS). The DMS was demonstrated during audits of the territorial offices. The DMS is a secure system utilized by the CCA to ensure distribution of information and serves as a document repository. The head of the territorial office holds weekly meetings with territorial staff to review updated DMS information.

The Internal Audit Department of the SFVS conducts internal planned and unplanned audits of regional and territorial offices through document review and site visits, which are developed in an annual plan at the headquarters level each year. The regional and territorial office Senior Veterinary Inspectors (VIs) conduct annual HACCP audits of establishments, in which the HACCP and traceability systems are evaluated. Additionally, regional and territorial Senior VIs conduct yearly planned audits in all establishments to verify compliance with premise, HACCP system, traceability, sanitation, microbiological and residue testing, and byproducts requirements. The annual reviews also include evaluation of the performance of the OVs.

Territorial office Senior VIs also perform animal welfare audits twice per year, reviews of labeling requirements twice per quarter, and unplanned inspections in response to consumer complaints. Depending on the results of the audits, the frequency will be increased if deficiencies are identified. All reviews are documented within the AFIS and establishments are required to submit a corrective action plan within seven days when deficiencies are identified. The FSIS auditors reviewed documentation demonstrating the scope and results of annual and HACCP audits by the territorial and regional offices, in addition to corrective actions taken by the establishments and did not identify any concerns.

The SFVS has a single set of rules that apply to all establishments that includes EU legislation, national resolutions, laws, and orders. Additionally, SFVS officials use a quality management system, which consists of standard operating procedures and work instructions that provide guidance in implementing official controls. All establishments must adhere to Regulation (EC) Nos. 178/2002, 852/2004, 853/2004, 854/2004, 882/2004, and 2073/2005. The national legislation and implementing orders that govern establishments producing meat and egg products include the following:

- *Resolution 638*, which defines the regulatory responsibilies of SFVS,
- *Lithuania Hygiene Norm*, which defines sanitation requirements,
- *Law on Food No. VIII-1608*, which defines adulterated and misbranded product and the subsequent prohibitions for placing such food on the market, and
- *Order B1-59, Rules for Inspection of Activities of Business Operators*, which defines corrective action requirements.

Lithuania prescribes the specific procedures related to verification of United States regulatory requirements within *KT-2-3-2-D1 Continuous Official Veterinary Control of Meat Production Establishments Producing Meat Products Intended for Export to the USA. Order No. B1-299*, *On the Safety Requirements for Egg Products to be Exported to the United States,* requires that egg processing plants that export to the United States must adhere to the requirements in 9 CFR Part 590, Inspection of Eggs and Egg Products. The SFVS developed specific oversight and verification procedures as detailed in *KT-2-2-18-D1, Official Veterinary Control of Egg Packing and Egg Product Manufacturing Establishments,* and *KT-2-3-2-D2, Continuous Veterinary Inspection of Egg Processing Plants Producing Egg Products Intended for Export to the USA*. Both documents incorporate the requirements consistent with 9 CFR Part 590. The FSIS auditors assessed implementation of the above mentioned policies and procedures.

The 2016 FSIS egg products initial equivalence audit identified a finding due to insufficient government oversight of the implementation and verification of regulatory requirements adopted by the CCA based on specific deficiencies identified by the FSIS auditor. In response, the CCA revised *KT-2-2-18-D1* and increased the frequency for official periodic supervision at the egg processing establishment to four times each year. The current FSIS audit determined that the specific sanitation findings identified during the previous audit were adequately corrected. However, the current audit documents specific findings under Component 2 and the FSIS auditors determined that the prior finding related to government oversight was not adequately resolved and the current audit identified the following finding:

- The CCA was unable to demonstrate adequate government oversight regarding implementation and verification of its egg products requirements as evidenced by the Government Statutory Authority and Food Safety and Other Consumer Protection Regulations component findings described below.

The *Statute of the State Food and Veterinary Service* states that SFVS is funded and paid from the national Republic of Lithuania budget in accordance with the *Law on Public Service*. The FSIS auditors verified through document review that OVs assigned to establishments certified to export to the United States are paid by the national government.

The SFVS requires 300 hours of on-the-job practical training for OVs prior to being assigned to establishments. The OVs must demonstrate knowledge of EU, national, and United States requirements prior to being assigned to an establishment and must be competent in inspection responsibilities in the establishment to which they are assigned, which is demonstrated through an assessment. SFVS then issues an official order assigning each qualified OV to an establishment.

The SFVS headquarters administers annual training according to a plan, for 2019 detailed in *Order B1-67*. SFVS administers the training for territorial offices who are then responsible for training OVs. The FSIS auditors reviewed the most recent training that had been held for territorial offices and OVs and verified that training in United States requirements is occurring at least once per year. The hiring process was reviewed at territorial offices, and the FSIS auditors verified that the SFVS requires professional veterinary degrees of all OVs assigned to establishments.

The *Law on the Adjustment of Public and Private Interests in the Public Service* contains provisions to prevent conflicts of interest pertaining to employees hired by the SFVS.
The AFIS system is used to document government inspection verification activities and periodic supervisory reviews and allows for the collection of inspection information and allows for the analysis of information across the central, regional, and territorial levels. The SFVS inspection records were reviewed at the audited establishments, which are documented both on paper and within the AFIS system, demonstrating continuous inspection in the slaughter process and throughout the shift when processing operations were occurring.

The FSIS auditors verified through observation of post-mortem inspection that the SFVS maintains an adequate number of OVs staffing the slaughter line based on the line speed and daily slaughter volumes. Staffing plans were reviewed at territorial offices, which demonstrated that the territorial office plans for unscheduled absences of the assigned OVs at the establishments by using relief OVs. The FSIS auditors verified that when noncompliances were identified, the OVs documented such results and verified corrective actions implemented by the establishments.

The National Food and Veterinary Risk Assessment Institute (NFVRAI) provides technical support for the CCA including diagnostics of animal diseases, food and animal feed analysis, analysis of the safety and effectiveness of veterinary medicines and biocides for veterinary use, and scientific risk assessment and delivery of scientific opinion. The NFVRAI is the designated National Reference Laboratory for food, feed, and animal health in Lithuania. The NFVRAI is within the SFVS and is comprised of the institute in Vilnius as well as territorial branches in Kaunas, Klaipėda, Šiauliai, Panevėžys, and Telšiai.

The NFVRAI laboratories conduct analyses for all official samples. The Vilnius laboratory performs all official analyses of meat products, whereas the Klaipėda territorial branch performs analyses of all official egg products samples intended for export to the United States. In addition, the NFVRAI performs all analyses for chemical residues in livestock, meat, and egg products.

The National Accreditation Bureau (NAB) is the Lithuanian national accreditation service that is responsible for conducting accreditation audits to ensure implementation of the International Organization for Standardization (ISO) 17025, *General requirements for the competence of testing and calibration laboratories*. The FSIS auditors reviewed the most recent NAB accreditation certificate and verified that it is valid until May 5, 2020.

The NFVRAI has a flexible scope of accreditation for both microbiological and chemical residue methods. The current scope of accreditation includes ISO 6579-1:2017, *Microbiology of the food chain -- Horizontal method for the detection, enumeration and serotyping of Salmonella -- Part 1: Detection of Salmonella* method and ISO 11290-1, *Microbiology of the food chain. Horizontal method for the detection and enumeration of Listeria monocytogenes and of Listeria spp. -- Part 1: Detection method*, both recognized as equivalent methods to those used by FSIS for analysis of carcass swabs, environmental surfaces (food contact and non-food contact), RTE products, and egg products.

The NAB performs accreditation audits every five years, as well as annual audits of the NFVRAI. In addition, the NFVRAI performs annual internal audits according to their Quality Management System. The FSIS auditors evaluated the most recent NAB and internal audit reports. The NFVRAI implements written action plans addressing all internal and external audit findings and at the time of the audit no outstanding findings were identified.

The NFVRAI participates in proficiency testing through separate mechanisms. The NAB requires participation in proficiency testing for each method not less than once every five years. The NFVRAI participates in ongoing proficiency testing including those organized by EU Reference Laboratories. The laboratory also organizes and participates in proficiency testing using commercially available services. The FSIS auditors reviewed proficiency testing results for both the Vilnius and Klaipėda laboratories and confirmed that all results were satisfactory.

The FSIS auditors verified components of the NFVRAI quality control plan including qualifications and training of laboratory personnel, calibration and maintenance of instruments and equipment, document change control system, recordkeeping practices, and proper labeling and storage of reagents and kits. The FSIS auditors observed sample receiving and the issuance of a unique sample identification number, use of the laboratory information management system database, and overall conditions and practices in the laboratory.

Lithuania's legislation includes the provisions for ensuring collection of a reserve sample every time an official sample is collected. Through interviews with NFVRAI management, the FSIS auditors determined that the reserve samples are left at the establishment in the custody of the food business operator who has sole discretion on performing analysis on the reserve sample. NFVRAI management verbally stated that, for purposes of export to the United States, the official sample results are always conclusive and not subject to retesting. The CCA has established sample security methods to ensure chain of custody throughout delivery to the official government laboratory. Official samples are transported to the official laboratory by a government courier.

The FSIS auditors confirmed that the CCA ensures the NFVRAI official laboratories comply with ISO 17025 criteria through review of the NAB accreditation certificate, scope of accreditation, audit reports, review of the annual SFVS report, and review of internal audits conducted in accordance with ISO 17025 as well as the on-site visit to the Vilnius laboratory. The audit verified that Lithuania's meat and egg products inspection system is organized and administered by the national government, and that the SFVS inspection officials are assigned to enforce the laws and regulations governing meat and egg products. However, at the time of the audit, SFVS was unable to demonstrate adequate government oversight and verification that its orders and other national policies are being met to ensure that egg products are not adulterated as noted by the findings listed in Component Two of this report.

V. COMPONENT TWO: GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (e.g., INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)

The second of six equivalence components the FSIS auditors reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of each and every carcass and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; at least once per shift inspection during processing operations; periodic supervisory visits to official establishments; and egg products requirements.

The FSIS auditors verified that government inspection personnel perform humane handling verification activities in establishments certified to export to the United States at least once per shift. SFVS enforces *No. VII-500, Animal Welfare and Protection Law* and the FSIS auditors verified that OVs evaluate establishments' adherence to animal welfare requirements listed in *KT-2-2, Official Veterinary Control on Welfare Requirements of Animals at Time of Killing*. OVs also verify the requirements of Regulation (EC) No. 1099/2009. Additionally, territorial offices audit all slaughter establishments on at least an annual basis to verify compliance with animal welfare requirements.

The FSIS auditors verified that OVs perform ante-mortem inspection in establishments certified to export to the United States on all livestock in motion and at rest and are adhering to ante-mortem inspection procedures listed in *KT-2-3-1-D1, Evaluation Instruction of Meat and Other Slaughter Products for Food Industry in Slaughterhouses*. Through observations and review of ante-mortem inspection records, the FSIS auditors verified that OVs are identifying and documenting livestock with disease conditions and segregating animals identified as suspects which receive a more thorough examination and are slaughtered at the end of the day. If emergency slaughter of animals is necessary, such animals are also slaughtered at the end of the day and segregated from further processing for export to the United States.

The FSIS auditors verified that OVs perform post-mortem inspection for livestock, including zero tolerance inspection procedures through observation of inspection procedures and a review of post-mortem inspection records. Only OVs perform post-mortem inspection, and the FSIS auditors verified appropriate presentation, examination, identification of disease conditions,

segregation and condemnation procedures at each station for head, viscera, and carcass inspection, in accordance with *KT-2-3-1-D1, Evaluation Instruction of Meat and Other Slaughter Products for Food Industry in Slaughterhouses*. At carcass inspection, OVs inspect carcasses for fecal material, milk, and ingesta contamination as well as pathology, and ensure that carcasses are railed out and reprocessed prior to final inspection. The FSIS auditors also verified condemnation procedures, which included the disposal and denaturing of condemned carcasses and parts.

Supervisory reviews are conducted at least once per year in establishments producing meat for export to the United States, in accordance with *Order B1-33, Amendment of SFVS No. B1-31, on Approval of Guidelines for Official Control and Veterinary Supervision of Food Handling Entities*. The FSIS auditors reviewed records documenting the most recent supervisory visits conducted by Senior VIs from the territorial SFVS offices and verified that such visits are consistent with the above-mentioned procedures described and are documented within the AFIS system, which also allows for review by SFVS headquarters. Supervisory reviews include evaluation of the OVs for ante-mortem and post-mortem inspection, verification of United States export requirements, traceability, sanitation standard operating procedures (SOPs), HACCP, sampling, and documentation of inspection results. The FSIS auditors verified that the territorial level has the authority to require disciplinary action or require retraining for unsatisfactory performance reviews.

Supervisory reviews are conducted four times per year in egg processing establishments by a Senior VI from the territorial SFVS office in accordance with *Order B1-134, On the Amendment of Official Veterinary Control of Egg Packing and Egg Processing Plants*. The periodic supervisory visit reports are documented in the AFIS database and hard copy reports may be printed from AFIS. The periodic supervisory assessment is conducted according to Annex 6 of *KT-2-2-18-D1*. The FSIS auditors reviewed the most recent report dated June 5, 2019 and noted that no noncompliance was identified. The report did document specific remarks directed to the OV for minor issues that required attention.

The FSIS auditors verified that OVs perform labeling verification of each lot of product intended for export to the United States. In addition, official species verification testing of meat products is performed once per year. At the egg products establishment the FSIS auditors verified that the OV ensures that added ingredients are approved for use according to procedures in KT-2-3-2 that reference FSIS Directive 7120.1*, Safe and Suitable Ingredients Used in the Production of Meat, Poultry and Egg Products*.

The Animal Health and Welfare Department of the SFVS is responsible for remaining informed of APHIS animal disease status of Lithuania via the APHIS website and official communications. The department communicates information on any updates in disease status to the SFVS headquarters and territorial SFVS offices.

The FSIS auditors verified that procedures for the identification, removal, segregation, and disposal of specified risk materials are verified by the OVs on a daily basis, using implementation of 9 CFR 310.22 within *KT-2-3-2-D1, Continuous Official Veterinary Control of Meat Production Establishments Producing Meat Products Intended for Export to the USA*.

At the meat establishments, the FSIS auditors verified that the OVs are ensuring that establishments are adhering to requirements for each of the categories of condemned materials as required by Regulation (EC) No. 1774/2002, which classifies byproducts within three different categories. The OVs verify that containers used to store condemned materials are labeled with the appropriate category. The FSIS auditors also verified adherence to *Order B1-190, Animal By-Products and Processed Animal Products Management and Accounting Requirements,* which outlines the requirements for segregating, storing, and transporting inedible products.

Egg products establishments are required to comply with the CCA's *KT-2-2-18-D1* and *KT-2-3-2-D2* that directly reference 9 CFR 509.504(c) that requires placing all inedible eggs or egg products into containers clearly labeled "inedible" and containing denaturant. The FSIS auditors verified that the egg products establishment used blue inedible containers in processing areas and denatured contents with green dye. All inedible containers are washed in a separate washroom from that used for food contact equipment. Inedible materials are transferred to Category 3 animal byproduct containers and stored in a dedicated inedible room with its own dock door for load-out and transport to disposal.

The CCA provides requirements for continuous government inspection of the processing of egg products intended for export to the United States in *KT-2-3-2-D2, Continuous Veterinary Inspection of Egg Processing Plants Producing Egg Products Intended for Export to the USA*. The FSIS auditors confirmed the CCA's intent is to ensure continuous government inspection during all egg processing operations. The CCA requires submission of the intended production schedule in advance to ensure continuous government inspection. The FSIS auditors were unable to confirm staffing ensures continuous inspection because the country has not been determined equivalent and the establishment is not eligible to export to the United States.

At the meat establishments, the FSIS auditors verified that establishments maintain separation of product destined for export to the United States and other products, by means of separation by time and designated space for United States exports, which is verified by OVs on a daily basis. The CCA requires the egg products establishment to separate egg products intended for export to the United States from production for the domestic market. In addition, the egg products establishment is required to segregate production and products at all times. The FSIS auditors verified that the establishment has areas at receiving and storage labeled for exclusive use to store products intended for export to the United States. In addition, the candling machine and downstream sorting lines were designed to ensure only eggs meeting the requirements in 9 CFR Part 590 are eligible for breaking when production for export to the United States occurs. The FSIS auditors verified that the establishment segregated eligible eggs and labeled pallets with "JAV" indicating United States production.

The CCA has adopted the requirements of 9 CFR Part 590, *Inspection of Eggs and Egg Products*, as detailed in quality procedures *KT-2-2-18-D1* and KT-2-3-2-D2. The 2016 FSIS egg products audit identified multiple findings due to a failure on the part of the CCA to ensure the egg products requirements were met. Since the 2016 audit, the egg products establishment had installed automated candling equipment as well as automated shell egg washing and sanitizing equipment. The current FSIS audit identified that the CCA effectively ensured the establishment

had corrected the prior deficiencies. However, inadequate government verification of egg products requirements was identified as a repeat finding from the previous initial equivalence verification audit for egg products in 2016.

The CCA was unable to demonstrate adequate government oversight and verification that the egg products requirements detailed in their orders and other national policies were being fully met and adequate to ensure that egg products are not adulterated. The FSIS auditors identified the following findings that government inspection personnel failed to identify:

- The CCA personnel could not explain how the egg products pasteurization records presented during the audit supported that pasteurization requirements were met:
  - The establishment's pasteurization records presented to the FSIS auditors did not include data such as flow rate, total volume of the pasteurized lot, volume of the holding tubes, or total time required to pasteurize a single lot that would enable verification of the documented temperature and holding times.
  - The FSIS auditors could not confirm that all product comprising a lot achieved the temperature and holding time requirements and therefore concluded that the CCA's verification procedures failed to ensure that the CCA's requirements were met.

- The establishment could not produce the current calibration certificate for one flow rate probe used during the pasteurization process. The accuracy of the flow meter and probes is essential to ensure pasteurization requirements are met and to ensure process control.

- Multiple blood spots were observed on the yolks of multiple eggs with no actions taken by the official government veterinarians or establishment personnel to remove the blood spots or reject the affected egg products. The CCA's requirements in *KT-2-2-18-D1* and *KT-2-3-2-D2* specifically cite the FSIS requirements that require the removal of blood spots (9 CFR 590.510(c)(3) and 590.522(g)). FSIS does not consider filtration as an acceptable means of removing blood spots.

- The establishment was not monitoring and documenting product temperature during heat treatment of dried whites. The CCA's requirements in *KT-2-2-18-D1* and *KT-2-3-2-D2* specifically cite 9 CFR 590.575, *Heat Treatment of Dried Whites*, that requires the heating of product to minimum temperature and time parameters. The recordkeeping requirements include documentation of product temperatures. However, the FSIS auditors determined that the CCA failed to identify that the establishment is not monitoring and documenting product temperature during heat treatment of dried whites.

- Blocks of yeast used in the fermentation of egg products were stored in a refrigerator but lacked any labeling indicating the actual product contents. In addition, one package had been opened and the wrapper left open exposing product to the refrigerator environment without protecting the contents. This is not consistent with the CCA's own requirements in *KT-2-2-18-D1* and *KT-2-3-2-D2* that cite 9 CFR 590.435, *Wholesomeness and Approval of Materials*.

The FSIS analysis and on-site verification activities indicated that the CCA's meat and egg products inspection system has the legal authority and a documented regulatory framework to implement the CCA's regulatory requirements for this component. However, FSIS identified findings related to the inadequacy of the SFVS' verification procedures for egg products inspection.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components the FSIS auditors reviewed was Government Sanitation. The FSIS auditors verified that the CCA requires each official meat establishment to develop, implement, and maintain written sanitation SOPs to prevent direct product contamination or insanitary conditions and to maintain sanitary operations in egg products establishments.

The CCA requires meat establishments certified to export to the United States to develop, implement, and maintain written pre-operational and operational sanitation SOPs per *Order B1-795, Sanitation Standard Operating Procedures*. The FSIS auditors reviewed the records generated by the in-plant inspection personnel and the establishments to verify that noncompliant findings are identified, corrected, and verified by the inspection personnel. The FSIS auditors verified that the OVs are performing daily verification activities of establishments' pre-operational and operational sanitation, in addition to Sanitation Performance Standards verification and are adhering to verification procedures listed in *KT-2-2-1, State Veterinary Supervision and State Veterinary Control of Animal Food Business Operators*. OVs are also responsible for verifying 9 CFR Part 416 requirements as per instructions laid out in *KT-2-3-2-D1, Continuous Official Veterinary Control of Meat Production Establishments Producing Meat Products Intended for Export to the USA*. Through a review of records and observations during the audit, the FSIS auditors verified that the OVs are verifying sanitation SOP requirements and reviewing corrective actions in response to deficiencies in sanitation on a daily basis.

The CCA's egg inspection system requires that establishments certified to export to the United States comply with requirements consistent with the sanitation and facility requirements in 9 CFR 590.500 through 590.547. The SFVS ensures that certified egg establishment construction, facilities, and equipment prevent the contamination or adulteration of egg products. The CCA provides inspection personnel with instructions for verifying sanitation requirements in *KT-2-3-2-D2*, *Continuous Official Veterinary Inspection of Egg Processing Plants Producing Egg Products Intended for Export to the United States*, Annex 5, and *KT-2-2-18-D1*, *Official Veterinary Control of Egg Packing and Egg Product Manufacturing Establishments, Annex 4*. The FSIS auditors observed the OV perform pre-operational sanitation verification and evaluated sanitary conditions and practices during operations. No concerns were identified.

The FSIS auditors' observations and record reviews, including the establishment's sanitation monitoring and corrective action records, as well as those of inspection personnel documenting in-plant inspection verification results or periodic supervisory reviews, did not raise any concerns. Except for isolated sanitation findings listed in Appendix A, the CCA's meat and egg products inspection system maintains sanitary regulatory requirements that meet the core requirements for this component.

VII. COMPONENT FOUR: GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM

The fourth of six equivalence components the FSIS auditors reviewed was Government HACCP System. The food safety inspection system for meat is to require that each official establishment develop, implement, and maintain a HACCP system.

The FSIS auditors verified that the CCA requires meat establishments to develop, implement and maintain a HACCP system consistent with EC and United States requirements. SFVS ensures that HACCP requirements are meeting EC requirements per Regulation (EC) No. 852/2004 and FSIS requirements in accordance with the procedure, *KT-2-3-2-D1, Continuous Official Veterinary Control of Meat Producing Establishments Producing Meat Intended for Export to the USA*, which also provides an overview of official inspection verification activities. The FSIS auditors verified that SFVS has the authority and ability to take enforcement measures in the event that a certified establishment fails to implement its HACCP system.

The OVs conduct daily verification activities for HACCP requirements through direct observation and hands-on activities as well as review of records. The OVs are responsible for verification of the flow chart, hazard analysis, HACCP plan, and all other HACCP requirements. The OVs also verify that all HACCP requirements are met prior to signing export certificates for export of meat products to the United States. The FSIS auditors verified through review of inspection records that official inspection personnel conduct daily HACCP verification activities. The FSIS auditors observed the implementation of HACCP systems, and also reviewed the programs and records maintained by inspection personnel at the audited establishments.

Each meat establishment visited had developed a flow chart and conducted hazard analyses for expected hazards. For specific hazards that are reasonably likely to occur, the establishments have instituted critical control points (CCPs) described in HACCP plans. The FSIS auditors verified that the OVs are observing the establishments' sanitary dressing procedures on a daily basis in addition to performing zero tolerance verification for fecal material, milk, and ingesta contamination through a review of associated records and demonstration by the OVs of such tasks. However, the following finding was identified during a review of HACCP records of both meat establishments audited:

- The CCA does not ensure HACCP records include the time of monitoring CCPs. The establishments' zero tolerance monitoring records failed to document the actual times monitoring occurred.

The FSIS auditors determined that the CCA requires operators of meat establishments certified as eligible to export to the United States to develop, implement, and maintain HACCP systems. However, the audit finding listed above demonstrates that the CCA's inspection system did not effectively verify the implementation of HACCP systems.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth of six equivalence components the FSIS auditors reviewed was Government Chemical Residue Testing Programs. The food safety inspection system for meat is to present a chemical residue testing program, organized and administered by the national government, which includes random sampling of internal organs, fat, and muscle of carcasses for chemical residues identified by the exporting country's meat inspection authorities or by FSIS as potential contaminants.

Prior to the on-site visit, FSIS' residue experts thoroughly reviewed Lithuania's 2019 Residue Monitoring Program, associated methods of analysis, and additional SRT responses outlining the structure of Lithuania's chemical residue testing program. There have not been any POE violations related to this component since the last FSIS audit.

The NFVRAI is responsible for preparing the draft annual residue monitoring plan according to the *Rules for Monitoring of Substances and Residues of Substances in Animals and Animal Products* that implements the requirements of Council Directive No. 96/23/EC. The annual plan is distributed to the territorial SFVS offices, which then assign samples to locations including establishments certified to export to the United States. In addition to the annual plan, the CCA provides for the collection of samples in response to follow-up from positive results or any time there is a suspicion of noncompliance.

The FSIS auditors verified that the OVs are collecting samples for residue testing and are adhering to the 2019 sampling plan. At the audited meat establishments, the FSIS auditors verified that the OVs are identifying, during ante-mortem and post-mortem examination, suspect animals or carcasses warranting residue testing as described in the country's official government residue control program. The OVs place products destined for the United States on hold pending residue tests and keep them under their control during testing at establishments certified to export to the United States. Results are communicated from the laboratory to the SFVS headquarters and territorial offices, which are then communicated to the OVs assigned to the establishments. Once results are received at the territorial SFVS office, they are entered into the DMS and further distributed to appropriate recipients. Territorial offices provide instructions to OVs on the disposition of the product in the event of a positive sample, and both positive and negative results are communicated to the establishment by the OV. The FSIS auditors verified that there have not been any residue violations for 2019 at the audited meat establishments.

The audit of the NFVRAI in Vilnius included interviews with the laboratory management, document reviews, and observations of the laboratory. The NFVRAI utilizes multi-residue methods for the detection of 117 analytes for veterinary drugs in meat and eggs. The FSIS auditors verified that the audited laboratory ensured traceability throughout sample receipt, analysis, and reporting. The methods of analysis are implemented as described in Lithuania's residue control plan.

The CCA's meat inspection system has regulatory requirements for a chemical residue testing program that is organized and administered by the national government. No concerns with the chemical residue laboratory were identified during the audit.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth of six equivalence components the FSIS auditors reviewed was Government Microbiological Testing Programs. The food safety inspection system is to implement certain sampling and testing programs to ensure that meat and egg products prepared for export to the United States are safe and wholesome.

SFVS requires that establishments sample and test for *Enterobacteriaceae* according to the requirements of Regulation (EC) No. 2073/2005. The FSIS auditors verified that OVs are reviewing establishments' testing programs for *Enterobacteriaceae* on a weekly basis during meetings with establishment personnel to discuss the effectiveness of food safety controls. At the audited establishments, indicator organism sampling was being conducted in accordance with Regulation (EC) No. 2073/2005. Establishments are utilizing statistical process control for evaluating test results and OVs are verifying that the establishments certified to export to the United States restore process control and corrective actions are taken when the performance criteria are exceeded.

The FSIS auditors observed OVs carrying out *Salmonella* sampling at the audited meat establishments and verified that sample collection procedures as described in Regulation (EC) No. 2073/2005 and *KT-3-1, Official Sampling and Delivery of Samples to the Lab*. Test results are reviewed by OVs once received, in addition to once a week during weekly meetings with establishments, and for every shipment of product to the United States.

The FSIS auditors verified that both the CCA and territorial offices receive laboratory results for official samples tested for *Lm*, *E. coli* O157:H7, and *Salmonella* in RTE meat products, *Lm* and *Salmonella* in egg products, and *Lm* and *Salmonella* on food contact surfaces and environmental surfaces, directly from the laboratory in a timely manner. The results are then assessed, and the CCA and territorial offices provide oversight to ensure that government inspection personnel take appropriate actions in the event of positive test results. The territorial offices subsequently communicate the results to the OV, who will then inform the establishment and verify corrective actions and product disposition. The FSIS auditors reviewed the 2019 results to date and verified that OVs conduct sampling according to the annual sampling plan at the audited establishments and in accordance with sampling guidelines in *Order B1-338, Approving the Methodological Guidelines for the Collection of Washings for Laboratory Testing*.

The FSIS auditors verified that establishments are addressing lethality for RTE meat products through cooking CCPs and are sampling product for *Salmonella* and *Lm*, and food contact and environmental surfaces for *Lm* at the frequencies appropriate for the alternative used for each product. Lithuania has implemented requirements consistent with 9 CFR Part 430 within *KT-2-3-2-D1, Continuous Official Veterinary Control of Meat Production Establishments Producing Meat Products Intended for Export to the USA*, which the OVs are responsible for verifying when establishments are producing RTE product for export to the United States. The FSIS auditors verified that OVs are reviewing test results from the establishment on a weekly basis, in addition to verifying test results for each shipment of product destined for the United States. The FSIS auditors verified that production lots are defined by establishments producing RTE products and lots are separated by cleaning and sanitizing. The FSIS auditors verified that when

corrective actions are taken by the establishment in response to positive results for *Salmonella* or *Lm*, OVs are responsible for verifying the corrective actions. Additionally, the FSIS auditors verified that the OVs are reviewing the establishments sampling results on a weekly basis and no concerns were identified.

Order B1-299 requires egg products establishments intending to export to the United States to perform microbiological testing for *Lm* and *Salmonella* on every lot of finished product. Further, the order makes clear that each lot must test negative for *Lm* and *Salmonella* prior to export to the United States. Samples must be collected according to the FSIS Egg Product Sampling document and instructions consistent with FSIS Directive 10,230.4, *Salmonella Surveillance Program for Liquid and Frozen Egg Products*. Lastly, the FSIS auditors verified that establishments are meeting the CCA's requirement to select five separate samples from each batch of egg products and the laboratory analysis must be performed on 25-gram aliquots for *Lm* and 100-gram aliquots for *Salmonella*.

The FSIS auditors observed establishment sampling of dried egg whites and verified the methodology is consistent with the SFVS *Egg Product Sampling Guide for Establishments Approved for Export to the USA*. The FSIS auditors reviewed establishment sampling records and confirmed that all establishment samples were analyzed at the NFVRAI Klaipėda laboratory using the same methods as official verification sampling. The laboratory results confirmed that each of the five samples comprising each sampled lot are analyzed separately. The OV reviews and verifies all establishment test results as noted by the OV signature on each laboratory result report. In the event product tests positive for either *Lm* or *Salmonella*, the Senior VI from the territorial or regional SFVS office immediately initiates an on-site investigation and the CCA performs additional verification sampling to ensure effectiveness of establishment corrective actions. No products testing positive are allowed to be exported to the United States. No concerns were identified regarding implementation of establishment sampling programs.

The CCA ensures through sampling and other verification activities that all lots of pasteurized egg products are not contaminated with microbiological pathogens, including *Lm* and *Salmonella.* The CCA performs official verification testing for *Lm* and *Salmonella* once per month for each category of egg products according to *KT-2-3-2-D2*, Annex 9. Samples are collected by the OV assigned to the establishment or a Senior VI from the territorial or regional office. The FSIS auditors observed the OV perform sampling on dried yellow product during the audit. The FSIS auditors reviewed official sample results and verified that the CCA is following the sampling and analytical procedures as described. No concerns were identified.

Official samples are analyzed at the NFVRAI Klaipėda laboratory. The analytical methodology for detecting *Lm* in 25 grams or milliliters is ISO 11290-1:2017. The analytical methodology for detecting *Salmonella* in 100 grams or milliliters is ISO 6579-1:2017. Both methods are accepted by FSIS as equivalent to the FSIS methodologies for testing processed egg products. The FSIS auditors reviewed laboratory results reports and no concerns were identified.

The audit included one processing establishment producing TPCS products, which is the only establishment certified as eligible for this process category for export to the United States. The FSIS auditors reviewed the written program and associated records for TPCS products. OVs are

to assess how establishments ensure TPCS requirements are met in accordance with 9 CFR 318.300 – 318.311, and FSIS Directive 7530.2, *Verification Activities in Canning Operations that Choose to Follow the Canning Regulations*, per *KT-2-3-2-D1, Continuous Official Veterinary Control of Meat Production Establishments Producing Meat Products Intended for Export to the USA.* However, the FSIS auditors identified the following finding related to SFVS verification of TPCS requirements:

- The CCA does not ensure support is maintained for the TPCS process, as evidenced by the failure of the sole establishment eligible to export TPCS product to the United States to maintain heat penetration or heat distribution data for the validation of their thermal process.

There have not been any POE violations related to this component since the last FSIS audit. While the CCA maintains many of the technical elements to operate its inspection system, the failure to implement verification of TPCS requirements does not meet FSIS' requirements for this component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on July 24, 2019, in Vilnius, Lithuania, with SFVS. At this meeting, the FSIS auditors presented the preliminary findings from the audit.

GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)

- The CCA was unable to demonstrate adequate government oversight regarding implementation and verification of its egg products requirements as evidenced by the Government Statutory Authority and Food Safety and Other Consumer Protection Regulations component findings described below.

GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (e.g., INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)

- The FSIS auditors observed the following at the sole egg products establishment the CCA intends to certify as eligible for export to the United States:
    - The CCA personnel could not explain how the egg products pasteurization records presented during the audit supported that pasteurization requirements were met.
    - The establishment could not produce a current calibration certificate for one flow rate probe used during the pasteurization process at the time of the audit.
    - Multiple blood spots were observed on the yolks of multiple eggs with no actions taken by the official government personnel or establishment to remove the blood spots or reject the affected egg products.
    - The establishment was not monitoring and documenting product temperature during heat treatment of dried whites.

- Blocks of yeast used in the fermentation of egg products were stored in a refrigerator but lacked any labeling indicating the actual product contents.

GOVERNMENT HACCP SYSTEM

- The CCA does not ensure HACCP records include the time of monitoring CCPs.

GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

- The CCA does not ensure support is maintained for the TPCS process, as evidenced by the failure of the sole establishment eligible to export TPCS product to the United States to maintain heat penetration or heat distribution data for the validation of their thermal process.

During the audit exit meeting, the CCA committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklists

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Biovela Utenos Mesa, UAB Pramones g. 4 LT-28216 Utena, Lithuania	07/16-17/2019	LT 17 EB	Lithuania
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	X
19. Verification and validation of HACCP plan.	X
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	X
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57.	
58.	
59.	

60. Observation of the Establishment

18. The establishment failed to document times that CCP monitoring was conducted for zero tolerance.

19. The establishment lacked supporting documentation to support an adequate thermal process.

20. The establishment failed to HACCP plan failed to identify and eliminate the cause of a deviation for exceeding the limits of indicator organism test results, therefore did not address all four parts of the corrective actions.

41. The establishment was not maintain adequate ventilation, as evidenced by liquid condensate and frozen condensate that were observed in covered raw product transit areas. No product adulteration was observed.

45. During pre-operational sanitation verification, the FSIS auditor observed a shank cutter with frayed and peeling electrical cord covering resulting in the potential for direct product contamination.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	07/17/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
UAB Liutukas ir Ko Aloves g. 15 LT-46344 Kaunas, Lithuania	07/17/2019	LT 19-30 EB	Lithuania
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	O
8. Records documenting implementation.	O
9. Signed and dated SSOP, by on-site or overall authority.	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	O
11. Maintenance and evaluation of the effectiveness of SSOP's.	O
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	O
13. Daily records document item 10, 11 and 12 above.	O
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	O
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	O
16. Records documenting implementation and monitoring of the HACCP plan.	O
17. The HACCP plan is signed and dated by the responsible establishment individual.	O
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	O
19. Verification and validation of HACCP plan.	O
20. Corrective action written in HACCP plan.	O
21. Reassessed adequacy of the HACCP plan.	O
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	O
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	O
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	O
37. Import	
38. Establishment Grounds and Pest Control	O
39. Establishment Construction/Maintenance	O
40. Light	O
41. Ventilation	O
42. Plumbing and Sewage	O
43. Water Supply	O
44. Dressing Rooms/Lavatories	O
45. Equipment and Utensils	O
46. Sanitary Operations	O
47. Employee Hygiene	O
48. Condemned Product Control	O
Part F - Inspection Requirements	
49. Government Staffing	O
50. Daily Inspection Coverage	O
51. Periodic Supervisory Reviews	O
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57.	
58.	
59.	

60. Observation of the Establishment

The CCA has certified the establishment as a cold storage facility. However, on the date of the audit it was confirmed that the establishment is not certified for any process categories and does not store products from any other certified establishments. No export certification is conducted from this establishment.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	07/17/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
AB Krekenavos Agrofirma Mantviloniai LT-57346 Kedainiai, Lithuania	07/18/2019	LT 53-04 EB	Lithuania
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	X
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57.	
58.	
59.	

60. Observation of the Establishment

10. A steam vacuum tube hose observed contacting the ground and subsequently contacting the heads of pork carcasses. The affected carcasses were subsequently trimmed and were not used for export to the United States. Corrective actions were immediately taken by the establishment to hang the tube and prevent the situation from occurring.

18. The establishment failed to document which CCP monitoring was conducted for zero tolerance.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	07/17/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Baltic Egg Production Plunge, Lithuania	07/19/2019	LT 68-09 EB	Lithuania
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	O
8. Records documenting implementation.	O
9. Signed and dated SSOP, by on-site or overall authority.	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	O
11. Maintenance and evaluation of the effectiveness of SSOP's.	O
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	O
13. Daily records document item 10, 11 and 12 above.	O
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	O
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	O
16. Records documenting implementation and monitoring of the HACCP plan.	O
17. The HACCP plan is signed and dated by the responsible establishment individual.	O
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	O
19. Verification and validation of HACCP plan.	O
20. Corrective action written in HACCP plan.	O
21. Reassessed adequacy of the HACCP plan.	O
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	O
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	X
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Egg Products Requirements	X
58.	
59.	

60. Observation of the Establishment

The following non-compliances were not identified by Lithuania 's inspection officials during the establishment review:

25. Blocks of yeast used in the fermentation of egg products were stored in a refrigerator but lacked any labeling indicating the actual product contents.

39. The seals around the entry doors of two out of three egg products freezing rooms were worn and frayed resulting in the build-up of ice around the internal and external surfaces surrounding the doors and on the floor of the freezers.

57. The establishment's egg products pasteurization records did not include data such as flow rate, total volume of the pasteurized lot, volume of the holding tubes, or total time required to pasteurize a lot and therefore failed to demonstrate that the lethality requirements were met.

The establishment could not produce current calibration certificates for one flow rate probe in use at the time of the audit.

The establishment was not taking action to remove blood spots from yolks or reject the eggs following breaking.

The establishment is not monitoring and documenting product temperature during heat treatment of dried whites.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	07/19/2019

Appendix B: Foreign Country Response to the Draft Final Audit Report

LIETUVOS RESPUBLIKOS
VALSTYBINĖ MAISTO IR VETERINARIJOS TARNYBA

STATE FOOD AND VETERINARY SERVICE
OF THE REPUBLIC OF LITHUANIA

To: Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination
USDA/Food Safety and Inspection Service
1400 Independence Avenue, SW
Washington DC,
United States of America

20-12-2019 No 3G-(420)-3661

Subject: **IMPLEMENTATION OF CORRECTIVE MEASURES**

Dear Dr. Catlin,

Thank you for your letter dated 24 October 2019 and the submitted draft final audit report. The report reflects the findings of the audit that took place from July 15 to July 24, 2019. I would hereby like to respond to the conclusions of the Food Safety and Inspection Service (FSIS). At the time of the audit, FSIS auditors provided findings of an audit and recommendations on their elimination.

The following measures have been implemented at the meat processing, egg product establishments and by CCA to rectify the non-compliance with sanitation requirements and government oversight:

Non-compliances identified during audit	**Measures adopted by CCA and at the plant to rectify the non-compliances**
The CCA personnel could not explain how the egg products pasteurization records presented during the audit supported that pasteurization requirements were met.	In order to eliminate identified findings and to ensure the rectification of the irregularities referred to in the draft audit report SFVS made changes to the quality system working procedure KT-2-3-2-D2 "Continuous official veterinary inspection of egg processing plants producing egg products intended for export to the USA". Procedure was supplemented with additional points implementing calculation methods and formulas allowing OV to verify whether the factory is in compliance with the time / temperature requirements for pasteurisation of the product being manufactured. The OV, after the evaluation of the

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	temperature of the pasteurisation device and the holding time of the pasteurized liquid egg product, concludes on the pasteurisation process assurance and the product safety. Each batch of liquid egg products intended for the US market must undergo the verification of the pasteurisation process. During the meeting which took place after the conclusion of an audit, Official Veterinarians from Telšiai and Plungė who perform regular and periodic control on egg product establishment were introduced with FSIS audit findings. Also by Order B4-249 of SFVS Director of 7 August 2019 was conducted training on the subject of egg product plant operations with the material from FSIS egg product training program and on subject of changes in the quality system working procedure KT-2-3-2-D2 *"Continuous official veterinary inspection of egg processing plants producing egg products intended for export to the USA"* was given to the official veterinarians responsible for supervision of egg product establishment. CCA has also foreseen to organize external training in 2020 that would be held by laboratory of Kaunas university of technologies. During the training SFVS personnel responsible for supervision of egg product establishments will be provided additional information on pasteurization process. Due to establishments' inability to provide auditors with pasteurization records which would include all necessary data that would meet FSIS requirements at the time of the audit, SFVS obliged establishment to ensure that all required data would be available at any given time. Right now the records show data on flow rate, total volume of the pasteurized lot, volume of the holding tubes, total time of pasteurization, a lot number and additional data can be provided if necessary.
The establishment could not produce a current calibration certificate for one flow rate probe used during the pasteurization process at the time of the audit.	Paragraph 8.2 of quality system working procedure KT-2-3-2-D2 *"Continuous official veterinary inspection of egg processing plants producing egg products intended for export to the USA"* was supplemented with additional question allowing official veterinarian to continuously verify if the egg pasteurisation equipment of an appropriate and approved design, maintains a continuous and automatic record of the pasteurisation process data (9 CFR 590.570 (a), or has an in-house equipment maintenance program or controls the frequency of calibration of the pasteurisation equipment to record temperature and flow rate, or are the recording devices

	paragraph 8.2 of quality system working procedure KT-2-3-2-D2 is obliged to check HACCP records – make a Pre-Shipment review of establishment, checking the records of internal temperature of the lots ensuring that temperature and holding time requirements were met and only then is allowed to sign the export certificate. The egg processing establishment is planning to undergo reconstruction which will take place from December 27th 2019 till April 1st 2020 during which new pasteurization equipment will be installed. The establishment is obliged to prepare and implement validation program for the control of internal temperature of every lot of dried egg whites in accordance with US requirements. Implementation is planned until May 2020.
Blocks of yeast used in the fermentation of egg products were stored in a refrigerator but lacked any labelling indicating the actual product contents.	In accordance with supplemented quality system working procedure KT-2-3-2-D2 OV verifies that the ingredients/substances added in the processing of egg products are clean, approved for their intended use, at the correct concentration or percentage, and fit for human food (9 CFR 590.504(j)) and (9 CFR 590.435) This control shall be performed continuously on a daily basis as part of the monitoring of the preoperative sanitation program and the result of the inspection shall be recorded in this Procedure (Annex 3, paragraph 10). Establishment was obliged to label every package of yeast indicating original name, product manufacturer, shelf life, lot number and weight.
The CCA does not ensure support is maintained for the TPCS process, as evidenced by the failure of the sole establishment eligible to export TPCS product to the United States to maintain heat penetration or heat distribution data for the validation of their thermal process.	Considering observations made during audit at meat product establishments and according to requirements of 9 CFR 417.4 SFVS has supplemented quality system working procedure KT-2-3-2-D1 "Continuous official veterinary inspection of meat establishments producing meat products intended for export to the USA" indicating that at least once a year and / or before introducing new product, exploitation of new production lines, after replacement of equipment, after occurrence of an incident, if there is an indication that the food safety of manufactured products in any way is getting worse, meat product establishment is obliged to prove / validate (with validation protocols) that there is enough data to support HACCP system as written in establishment's HACCP plan. In order to verify if establishment's HACCP system is valid (has scientific prove or validation has been carried out in accordance with validation procedures) OV checks all provided documents. If OV decides that establishment's validation does not meet US

	calibrated to a set frequency. Due to egg product establishments inability to explain how dates written on calibration certificates provided during the time of an audit prove that the certificates are valid, SFVS obliged establishment to add additional statement to their equipment control program for calibration of flow meters and probes that would indicate routine equipment calibration frequency. Calibration has to be performed at least once a year at the Metrology Service. Establishment has purchased additional flow meter to have a replacement when one of the flow meters is being calibrated.
Multiple blood spots were observed on the yolks of multiple eggs with no actions taken by the official government veterinarians or establishment personnel to remove the blood spots or reject the affected egg products.	Referring to observation on removal of the blood spots, SFVS updated the quality system working procedure KT-2-3-2-D2 "Continuous official veterinary inspection of egg processing plants producing egg products intended for export to the USA" by adding additional questions to verification checklist allowing OV to ensure that blood spots are being removed in an acceptable manner in accordance to 9 CFR 590.510(c)(3). This requirement is ensured through the continuous control of egg breaking, carried out by the OV in accordance with Annex 3 of this procedure. Continues verification for adequate removal of eggs with blood spots shall be carried out throughout the whole egg breaking process. If the OV determines that the removal of eggs with blood spots is not guaranteed, the OV shall suspend the breaking process, until adequate corrective actions will be taken by responsible personnel. Establishment taking audit finding into account installed mechanized manually controlled inedible egg rejection system, allowing employees of egg product establishment to remove eggs with blood spots that were not rejected by egg sorting machine. Additional training for the staff of the breaking room, informing on the changes in plant operating procedures, was carried out.
The establishment was not monitoring and documenting product temperature during heat treatment of dried whites.	Quality system working procedure KT-2-3-2-D2 now also indicates that in order to ensure that dried egg whites intended for the export to the United States of America meet US requirements, every single lot of dried egg whites has to be verified by OV ensuring pasteurization effectiveness indicated by thermologgers records that are checked in accordance to Annex 3 of aforementioned quality system working procedure. In order to sign an export certificate of dried egg whites intended for US market OV in addition to other requirements according to point 13 of

	requirements or does not have sufficient evidence of validation, OV must document the non-compliance, inform SFVS and the company's responsible personnel and request additional process validation to be performed. The company must provide the competent authority and the OV with all documentation related to the validation process for assessment. After the validation evaluation and in the absence of comments, OV signs on the approval protocol. CCA has also foreseen to organize external training in 2020 that would be held by laboratory of Kaunas university of technologies. During the training SFVS personnel responsible for supervision of meat product establishments will be provided additional information on sterilization process. The establishment has performed validation of TPCS process, SFVS in accordance with updated quality system working procedure KT-2-3-2-D1 has evaluated documents provided and deemed that the validation meets US requirements for sterilization process.
The CCA does not ensure HACCP records include the time of monitoring CCPs.	Quality system working procedure KT-2-3-2-D1 was supplemented to indicate that OV must check if meat processing establishments sign their HACCP records and indicate date and time of monitoring as required by 9 CFR 417.4(a)(3). After verification OV signs HACCP records indicating date and time of verification. Templates for recording of CCP of "Zero contamination" forms was updated by adding time area and training regarding updated procedures for the recording of CCP of "Zero contamination" was conducted for responsible personnel by both meat product establishments.

The SFVS hereby assures that the newly drafted and adopted quality management documents, which are applied for carrying out the official veterinary control, ensure the compliance of the sanitary requirements and government oversight at the egg processing plant and meat product establishments with the relevant legal acts of the USA.

Please do not hesitate to contact Ms Giedrė Čiuberkytė, Head of International Affairs Department of the State Food and Veterinary Service, by phone: +370 5 249 1648 or e-mail: giedre.ciuberkyte@vmvt.lt, for any information you may need.

Sincerely yours,

Director Darius Remeika

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