



United States Department of Agriculture

Food Safety and
Inspection Service

JUL 17 2018

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Washington, D.C.
20250

Mr. Darius Remeika
Director
State Food and Veterinary Service
07-170 Vilnius, Lithuania

Dear Mr. Remeika,

The FSIS onsite audit conducted from March 12 through March 23, 2018, supports that Lithuania's inspection system continues to remain equivalent to that of the United States. Enclosed is a copy of the final audit report. The comments received from the Government of Lithuania are included as an attachment to the report.

For any questions regarding the FSIS audit report, please contact the Office of International Coordination, by electronic mail at InternationalCoordination@fsis.usda.gov.

Sincerely,

A handwritten signature in black ink that reads "Janell Kause". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

Janell Kause
Acting International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN THE
REPUBLIC OF LITHUANIA

MARCH 12-23, 2018

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING
MEAT

EXPORTED TO THE UNITED STATES OF AMERICA

July 10, 2018

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit conducted by the Food Safety and Inspection Service from March 12-23, 2018. The purpose of the audit was to determine whether the Republic of Lithuania's (Lithuania) food safety system governing raw and processed beef and pork products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Lithuania is currently eligible to export in following categories of products: raw pork, thermally processed-commercially sterile, and fully cooked-not shelf stable ready-to-eat meat products to the United States. Currently, Lithuania only exports thermally processed-commercially sterile beef and pork, and fully cooked-not shelf stable ready-to-eat beef and pork products to the United States.

The 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 Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditor concluded that the Lithuania's food safety system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements associated with the slaughter and processing of beef and pork products intended for export to the United States. The Central Component Authority (CCA) routinely verifies implementation of sanitation procedures and establishment HACCP systems to ensure adequate control of beef and pork food safety hazards. In addition, the CCA has implemented official government microbiological and chemical residue testing programs to verify the effectiveness of its food safety inspection system on an ongoing basis. An analysis of each equivalence component did not identify any deficiencies that represent an immediate threat to public health.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite equivalence verification audit of the Republic of Lithuania's (Lithuania) food safety system governing raw and processed beef and pork products from March 12-23, 2018. The audit began with an entrance meeting held on March 12, 2018, in Vilnius, Lithuania, during which the FSIS auditor discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – State Food and Veterinary Service (SFVS).

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to determine whether the food safety system governing raw and processed beef and pork products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Lithuania is eligible to export raw pork, and thermally processed-commercially sterile and fully cooked-not shelf stable ready-to-eat (RTE) meat products to the United States.

The USDA's Animal and Plant Health Inspection Service (APHIS) recognizes that pork imported from Lithuania is subject to the African swine fever requirements specified in Title 9 of the United States Code of Federal Regulations (9 CFR) §94.8, the classical swine fever requirements specified in 9 CFR §94.31, the swine vesicular disease requirements specified in 9 CFR §94.13, and the foot-and-mouth disease and rinderpest requirements specified in 9 CFR §94.11. Beef imported from Lithuania is subject to the foot-and-mouth disease and rinderpest requirements specified in 9 CFR §94.11, and the bovine spongiform encephalopathy (BSE) requirements specified in 9 CFR §94.18 and/or 9 CFR §94.19.

In preparation of the ongoing equivalence verification audit, FSIS applied a risk-based procedure that included an analysis of country performance within the six equivalence components, exported product types and volumes, frequency of prior audit-related site visits, point-of-entry (POE) testing results, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS since Lithuania became eligible to export on October 30, 2015, in addition to information obtained directly from the CCA through the self-reporting tool (SRT).

The FSIS auditor was accompanied throughout the entire audit by representatives from the CCA, territorial offices, and local inspection offices. Determinations concerning program effectiveness focused on performance within the following six components upon which 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 Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditor reviewed administrative functions at the CCA headquarters, one regional office, six local inspection offices, and one government chemical residue and microbiological laboratory. The FSIS auditor evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

The FSIS auditor visited six establishments from a total of eight establishments certified by Lithuania to export to the United States. The six establishments included three beef and pork slaughter and processing establishments, two beef and pork processing establishments, and one cold storage facility. During the establishment visits, the FSIS auditor paid particular attention to the extent in which industry and government interacted to control hazards and prevent noncompliance that threaten food safety. The FSIS auditor examined the CCA’s ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign inspection systems outlined in 9 CFR §327.2.

Additionally, the FSIS auditor visited one government laboratory that conducts microbiology and chemical residue testing to verify its ability to provide adequate technical support to the inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	<ul style="list-style-type: none"> State Food and Veterinary Service (SFVS), Vilnius
	Territorial	1	<ul style="list-style-type: none"> Kaunas SFVS Territorial Office, Kaunas
Laboratories		1	<ul style="list-style-type: none"> National Food and Veterinary Risk Assessment Institute, government microbiological and chemical residue testing, Vilnius
Beef and pork slaughter and processing establishments		3	<ul style="list-style-type: none"> Establishment LT5304EB, Krekenavos Agrofirma, Kedainiu Establishment LT5504EB, Pajūrio mėsinė, Klaipėdos Establishment LT17EB, Utenos mėsa, Utena
Beef and pork processing establishments		2	<ul style="list-style-type: none"> Establishment LT8202EB, Biovela mėsos perdirbimo padalinys, Utena Establishment LT8824EB, Klaipėdos mėsinė, Silgaliai
Cold storage facilities		1	<ul style="list-style-type: none"> Establishment LT1930EB, Liūtukas ir Ko, Kaunas

FSIS performed the audit to verify that Lithuania’s food safety system remains equivalent to FSIS’s system regarding 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 Livestock Slaughter Act (7 U.S.C. 1901-1906); and
- The Federal Meat Inspection Regulations for Imported Products (9 CFR §327).

The audit standards applied during the review of Lithuania's food safety system for meat 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 (SPS Agreement). This also 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. 1/2005;
- Regulation (EC) No. 2073/2005;
- Regulation (EC) No. 1069/2009;
- Regulation (EC) No. 1099/2009;
- Regulation (EC) No. 142/2011;
- EC Directive No. 93/119/EC;
- EC Directive No. 96/22/EC; and
- EC Directive No. 96/23/EC.

III. BACKGROUND

Lithuania currently exports thermally processed-commercially sterile and fully cooked-not shelf stable RTE beef and pork products to the United States. From October 30, 2015 through November 1, 2017, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 246,584 pounds of thermally processed-commercially sterile and fully cooked-not shelf stable RTE products exported by Lithuania to the United States. Of that amount, additional types of inspection were performed on 38,256 pounds, including testing for chemical residues and microbiological pathogens (*Listeria monocytogenes* and *Salmonella*) for which no products were rejected for issues related to public health.

The evaluation of all six equivalence components included a review and analysis of documentation previously submitted by the CCA as support for the responses provided in the SRT. The FSIS onsite equivalence verification audit included record reviews, interviews, and observations made by the FSIS auditor.

The FSIS final audit reports for Lithuania's food safety system are available on the FSIS Web site at: <http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports>.

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (E.G., ORGANIZATION AND ADMINISTRATION)

The first of six equivalence components that the FSIS auditor reviewed was Government Oversight. FSIS import regulations require the foreign 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 at least once per shift at processing establishments and on the line during all slaughter operations.

The CCA of Lithuania is the SFVS, which is administered by the national government. The *Statute Of The State Food And Veterinary Service* gives the SFVS authority to enforce laws and regulations governing the safe production of beef and pork products. Lithuania's Minister of Agriculture appoints the Chief State Veterinary Inspector (Director) to lead the SFVS. The Director is responsible for overseeing the SFVS and ensuring products destined for export to the United States are not adulterated or misbranded. The Director leads the SFVS with four subordinate deputies that oversee 14 departments and one sub department. This includes 52 territorial SFVS (TSFVS) offices dispersed throughout the country, 12 border inspection posts and the National Food and Veterinary Risk Assessment Institute (NFVRAI) that represents Lithuania's central laboratory.

The departments within the SFVS ensure implementation of effective controls for veterinary hygiene and food handling at all stages from food, crops, and animals to the food supply for consumers. The SFVS's inspection system has three levels of government oversight: central, territorial, and establishment. At the central level, the SFVS headquarters is located in Vilnius and provides oversight over territorial offices and establishments. At the territorial level, five of the 52 offices have direct oversight and supervisory responsibilities for the establishments certified by Lithuania to export beef and pork to the United States. At the establishment level, the SFVS inspection personnel conduct inspection verification tasks, including sampling in accordance with the SFVS's prescribed frequency; document enforcement actions; assess the effectiveness of the establishment's corrective action plans submitted in response to identified noncompliance; and communicate inspection personnel's verification task results through the chain of command.

The FSIS auditor's review of the oversight activities carried out at the SFVS headquarters, TSFVS office, and establishments' government offices demonstrate that the SFVS: has a single set of rules; has legal authority and responsibility to enforce inspection regulations; and enforces requirements that ensure adulterated or misbranded products are not exported to the United States. The EC legislation serves as overarching regulations and is supplemented by national legislation that consists of laws, work instructions, guidelines, and standard forms that constitute the Quality Management System (QMS). The QMS provides inspection program personnel with instructions on how to perform inspection activities and ensures that an adequate level of coordination exists between the SFVS headquarters and the TSFVS offices.

The Director of the SFVS issues guidelines, instructions, and standard operating procedures to inspection personnel on how to perform official inspection tasks. The SFVS disseminates information related to the regulatory and administrative affairs via e-mail or an intranet site. For changes to United States import requirements, the SFVS utilizes the GovDelivery Communication Cloud and analysis of published FSIS documents. The FSIS auditor verified that the United States' import requirements are communicated from the SFVS headquarters to TSFVS and local inspection offices via e-mail and intranet site without any concerns.

SFVS has a definition for the adulteration of products that may not be placed on the market. Specifically, the SFVS verifies that food intended for sale into commerce is adequately labeled, conforms to safety, quality, and other mandatory requirements. The SFVS defines adulterated product under the *Republic of Lithuania Law on Food Safety, 4 April 2000, No. VIII-1608* document.

The SFVS also has the responsibility to take enforcement actions in accordance with QMS procedures. The FSIS auditor reviewed enforcement procedures at the SFVS headquarters. This included a review of the flow of information from laboratories, TSVS offices, and establishments that could trigger enforcement. No enforcement actions were taken since the previous audit by the SFVS that included production of products intended for export to the United States. Interviews with the SFVS did not raise any concerns with the ability to identify potential issues that may rise to the level of enforcement. The FSIS auditor also reviewed how the SFVS verifies the corrective actions outlined by establishments in response to issues of noncompliance. The process includes a review by the TSVS director prior to closing out the noncompliance at the establishments. The FSIS auditor's review of the corrective action verification process did not raise any concerns.

The FSIS auditor verified that all government inspection personnel assigned to the establishments certified by Lithuania to export to the United States are employees of the SFVS. These employees are paid directly by the SFVS, which is funded by Lithuania. The FSIS auditor verified this through a review of employment and training records of employees assigned to establishments certified by Lithuania to export to the United States.

The FSIS auditor reviewed initial employment and ongoing training records at the SFVS headquarters and establishments. The SFVS has a written procedure for hiring government inspection personnel entitled *Staffing of State Food and Veterinary Service*, which states all government inspectors, who are referred to as Official Veterinarians (OVs), are required to have a Doctor of Veterinary Medicine degree from an accredited university. All SFVS employees are trained in accordance with the requirements laid down in *Regulation (EC) No. 882/2004* on official controls performed to ensure the verification of compliance with feed and food law and animal health and welfare rules. The SFVS's government inspection personnel receive extensive training prior to assignment to an establishment. The SFVS designs an annual and ongoing training plan each year with approval from the Director. At least once per year the SFVS organizes training on changes to United States import requirements. This training includes an evaluation test with the new United States import requirements. During the audit, no concerns arose with the initial employment requirements, initial training, or ongoing training of employees.

The SFVS's *Order No. B1-50* of 24 January 2005 outlines the staffing requirements for slaughter establishments. These establishments are staffed according to the following criteria: slaughterhouse capacity, working hours, slaughter equipment, speed and layout of slaughter line, organization of ante- and post-mortem inspection, handling of documents, amounts of certificates issued to third countries, and number of laboratory analyses. The staffing includes a supervisory OV and subordinate OV inspectors.

All establishments, both slaughter and processing, that are certified by Lithuania to export to the United States are required to have continuous daily inspection throughout the entire shift. The SFVS provides relief inspectors which are OV's, if needed, when regular inspectors are absent. The FSIS auditor reviewed inspection records and directly observed OV's performing inspection activities daily throughout the entire shifts without any noted concerns.

The FSIS auditor noted that traceability requirements for food business operators, including establishments certified to export to the United States, are laid out by *Article 18 of Regulation (EC) No. 178/2002*. The SFVS requires the territorial and establishment offices to conduct verification activities for traceability (trace back and recall) as outlined in QMS procedure KT-2-1-4 *Food or Feed Traceability Control*. The FSIS auditor confirmed, through interviews, that the inspection personnel review and verify the implementation of these requirements at the establishments in accordance with the SFVS's requirements without any concerns.

The SFVS has procedures in place to notify the United States in the event of recalls involving product exported to the United States. Additionally, the European Union (EU) countries utilize the Rapid Alert System for Food and Feed. This system facilitates a rapid response to food safety authorities for emerging health threats within the EU. The FSIS auditor noted that the SFVS has a system in place for investigations of establishments involved in the recall of meat products. These investigations include requiring the establishments recalling products to support the recall of all affected products.

Beef and pork products intended for export to the United States must be produced from animals that are slaughtered in Lithuanian or EU slaughterhouses that are certified to export to the United States. The SFVS is responsible for ensuring compliance and control on imported livestock and other animals, animal products and raw materials. At each establishment certified by Lithuania to export to the United States, OV's ensure all products approved for export contain only raw material from Lithuanian or EU member states establishments certified to export products to the United States. The SFVS procedures outline the provisions for when establishments source raw materials from outside of Lithuania. This ensures raw materials from these countries originate from establishments certified to export to the United States. The FSIS auditor reviewed receiving procedures and records at the establishments and did not identify any issues regarding source materials received at processing establishments. Furthermore, the FSIS auditor verified that all animals utilized for slaughter originate from Lithuanian farms.

The FSIS auditor verified the initial certification process for establishments wishing to start exporting beef and pork products to the United States. Prior to becoming initially certified, establishments must demonstrate compliance with requirements to include a sanitation program, Sanitation Standard Operating Procedures (Sanitation SOPs), HACCP system, laboratory analysis program, animal welfare controls, product recall/traceability, all applicable EU requirements, Lithuanian laws/requirements, and specific requirements of third countries such as the United States. The Internal Audit Department will perform an audit at the requesting establishment to verify compliance with export requirements. Establishments determined to be compliant will be added to the list as eligible to export to the United States. The FSIS auditor did not find any concerns with the initial establishment certification process.

The FSIS auditor verified that the SFVS has the authority to delist establishments certified by Lithuania as eligible to export to the United States that fail to meet regulatory requirements or cannot resolve issues of noncompliance. The FSIS auditor verified, through interviews and records review, that the SFVS implements periodic audits of the establishments currently certified by Lithuania. A negative outcome of the periodic audit could trigger delistment, meaning the certified establishment will no longer be recognized and listed eligible to export meat products to the United States. No concerns arose regarding review of the SFVS's delistment process.

The FSIS auditor verified that NFVRAI provides scientific and technical assistance in the field of food safety and veterinary medicine, as well as performing functions of the national reference laboratory and carrying out laboratory tests in the areas of food and feed safety, quality and animal health. NFVRAI is a subordinate body of the SFVS. The FSIS auditor verified through interviews, emails, and presentation of Web sites that technical support is provided to government veterinarians and establishments through e-mails and the use of intranet Web sites.

The SFVS has the legal authority and responsibility to approve or disapprove laboratories engaged in analytical testing on regulated products. NFVRAI is designated as a National Reference Laboratory (NRL) for food safety testing. The central laboratory of the SFVS is the NFVRAI facility in Vilnius, which is utilized for all the SFVS analysis of beef and pork product samples intended for export to the United States. Lithuania's laboratory system uses an electronic database system that enables all levels of the SFVS to review and manage data and results of the sampling programs. The FSIS auditor verified through records review that the SFVS exercises adequate control over the laboratory system and takes measures to address deficiencies identified during internal and third party audits of the laboratory system.

The SFVS ensures and verifies through supervisory control that NFVRAI and territorial units meet and are certified to the International Organization for Standardization (ISO) 17025 standards, properly analyze product destined for export to the United States, and participate in proficiency testing schemes for food analysis. All the SFVS laboratories are accredited according to ISO 17025 requirements by the Lithuanian National Accreditation Bureau (NAB).

The FSIS auditor verified that the laboratory QMS carries out annual proficiency testing. The laboratory maintained training and equipment calibration records supporting that each technician had been qualified for their assigned duties. The FSIS auditor also verified that the SFVS's reviews of intra-lab and inter-lab proficiency testing ensure that each analyst possesses the required competencies necessary to conduct the analyses. Furthermore, the FSIS auditor observed OVs collect official government samples and laboratory personnel perform appropriate procedures associated with the applicable method and protocol.

The audit determined that Lithuania's government organizes and administers the country's food safety system, and that the SFVS inspection officials enforce laws and regulations governing production and export of beef and pork products at the establishments certified by Lithuania to export to the United States.

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 that the FSIS auditor 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 carcasses and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; periodic supervisory visits to official establishments; and requirements for thermally processed/commercially sterile products.

The FSIS auditor verified that in-plant inspection personnel are required to conduct ante-mortem inspection in accordance with the SFVS's requirements. The OV conducts ante-mortem inspection within 24 hours of slaughter by observing all animals at rest and in motion from both sides in designated holding pens. Animals are examined to determine if they are fit for slaughter to be used to produce human food. OVs document daily the ante-mortem inspection results.

The FSIS auditor observed that the audited slaughter establishments provided a holding pen designated for observation and further examination of suspect animals. Additionally, the OVs ensure any APHIS requirements are followed by reviewing the incoming registration and owner's identification documents. When livestock is delivered to slaughterhouses, the OVs ensure origin of animals meets the all requirements.

The SFVS provides instructions describing disease conditions warranting condemnation of animals at ante-mortem inspection. The OVs identify and condemn any animal that shows signs of central nervous system disorders, including non-ambulatory cattle, during the ante-mortem inspection. The SFVS mandates that inspection personnel collect required tissue samples from any animal with signs of neurological disorders, document their ante-mortem observations on suspect animals, and dispose of the entire carcass of these animals in accordance with the SFVS's requirements. Furthermore, the SFVS samples all bovine 48 months or older to be tested for BSE and Transmissible Spongiform Encephalopathies (TSE), this includes implementing test and hold procedures. The FSIS auditor reviewed inspection records and observed execution of ante-mortem procedures that demonstrate proper implementation of the SFVS's requirements. No concerns arose as a result of these reviews and observations.

The FSIS auditor also observed implementation of the humane handling programs at the audited slaughter establishments. This included directly observing inspection personnel perform hands-on verification of the maintenance and conditions of the holding pens, movement of animals, and proper stunning of animals. Additionally, the FSIS auditor reviewed the inspection-generated humane handling verification records documenting the results of their verification activities. The FSIS auditor did not identify any areas of concern with humane handling requirements during the direct observations and review of records.

The FSIS auditor verified that government inspection personnel are performing on-line post-mortem inspection on all carcasses and parts, including the head and viscera, to ensure that

carcasses and parts are free from pathological conditions or any contamination before applying the mark of inspection. Additionally, the FSIS auditor noted that the government requires reinspection to be completed by OV's for any carcasses and parts railed out during the slaughter process.

The FSIS auditor verified that government inspection personnel perform post-mortem inspection at the time of slaughter in accordance with the SFVS's requirements. Inspection personnel are required to document post-mortem inspection results, including any retained or condemned carcasses. The FSIS auditor directly observed the implementation of the SFVS's requirements by inspection personnel during post-mortem inspection presentation, identification, examination, and disposition of carcasses and parts. The FSIS auditor also directly observed the performance of government inspection personnel performing on-line post-mortem inspection of each and every carcass and part to assess whether the proper incision, observation, and palpation of required organs and lymph nodes is conducted in accordance with the SFVS's requirements.

The SFVS limits the establishment's line speed of pork slaughter to 120 head per hour and beef slaughter to 35 head per hour. Direct observation of the line speeds and records reviewed during the audit demonstrated line speeds did not exceed the allowed limits and that the SFVS has the appropriate number of OV's during slaughter operations.

The FSIS auditor observed the establishments have the ability to store products intended for export to the United States separately from other products. This included both slaughter and processing establishments. It was verified through interviews with the SFVS that products intended for export to the United States are produced first, at the start of production or separated by production lots. This allows for separation of products intended for export to the United States from other products. The FSIS auditor did not identify any issues with the ability of the SFVS to ensure separation of products during production or storage, based on the interviews with SFVS and the establishment personnel.

The SFVS ensures that beef products are free of infectious materials associated with BSE and TSE. The control is carried out in accordance with the requirements of *Annex V of Regulation (EC) No. 999/2001* and the *Council of 22 May 2001* which outlines the rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies.

Lithuania has designated specified risk materials (SRMs) in bovine as: (i) the skull excluding the mandible and including the brain and eyes, and the spinal cord of animals aged over 12 months; (ii) the vertebral column excluding the vertebrae of the tail, the spinous and transverse processes of the cervical, thoracic and lumbar vertebrae and the median sacral crest and wings of the sacrum, but including the dorsal root ganglia, of animals aged over 30 months; and (iii) the tonsils, the last four meters of the small intestine, the caecum and the mesentery of animals of all ages.

The FSIS auditor directly observed the implementation of SRM removal and disposal during the slaughter operation. The SFVS verifies establishments' compliance with *Regulation (EC) No. 999/2001* for the identification, removal, segregation, and disposal of SRMs. The SFVS's procedures outline the inspection and verification activities for SRM controls. The FSIS auditor

reviewed government verification records and the establishments' monitoring records concerning control and disposal of SRMs. The FSIS auditor also observed that the establishments use dedicated equipment for removal of SRMs and ensures the safeguarding of inedible materials. No issues identified regarding the implementation of SRM controls at the establishment during the audit.

The FSIS auditor reviewed the TSFVS supervisory audits of establishments to include HACCP, inspection audits, and supervisory reviews. The frequency of the TSFVS supervisory audits is based on a classification of establishments into three categories of risk: high, medium, and low. Establishments certified by Lithuania for export to a foreign country are usually classified into a high-risk group, which means a minimum of two supervisory reviews and HACCP audits once per year. The FSIS auditor verified through review of audits and interviews with the SFVS that during each periodic TSFVS supervisory review, the government inspection personnel verify the proper implementation of the SFVS requirements.

At the establishments, the OV supervisory inspector conducts audits on the subordinate OV inspectors on an ongoing basis. Examples of supervisory inspection reports that the TSFVS office provided to the SFVS headquarters were made available to the FSIS auditor. The review of these records did not raise any concerns. The FSIS auditor noted that the government inspection personnel conduct these reviews as planned, document their findings, and verify the implementation of the actions taken as a result of the audits.

The SFVS requires the establishments to segregate and store inedible products in a separate area from edible products. In addition, containers used for collecting inedible products must be marked and distinguished from other containers. The FSIS auditor noted that the inspection personnel have the authority and responsibility to detain, denature, and destroy inedible products in accordance with the SFVS's requirements. The FSIS auditor reviewed both inspection- and establishment- generated records and observed the disposal process of condemned and inedible materials at the audited establishments and found no concerns.

The FSIS auditor verified that the SFVS has verification activities in place for the establishments producing thermally processed-commercially sterile beef and pork products. Establishments are required to meet FSIS canning regulations and may have additional support for the canning process through a HACCP plan. The canning establishment that produces products certified by Lithuania for export to the United States utilizes a HACCP system, in addition to meeting FSIS canning regulations, with a validated HACCP plan for the canning process. The SFVS OV walked the FSIS auditor through the canning process identifying the verification activities that the SFVS conducts at the canning establishment. The walkthrough included a review of records, the processing schedule, and the incubation process.

At least annually, the TSFVS conducts a HACCP audit of the canning establishment to include audits of the canning process. The FSIS auditor noted that the establishment or the SFVS tests each lot of canned product for commercial sterility when exporting to the United States. The FSIS auditor did not identify any areas of concern with the SFVS's verification activities of the thermally processed-commercially sterile canning process.

Lithuania's food safety system continues to maintain the legal authority and a documented regulatory framework that is consistent with the requirements for this component.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components that the FSIS auditor reviewed was Government Sanitation. The FSIS auditor verified that the SFVS requires each official establishment to develop, implement, and maintain written standard operating procedures to prevent direct product contamination and insanitary conditions.

The FSIS auditor reviewed the legislation, regulations, official instructions, procedures, and guidelines of Lithuania. The FSIS auditor verified that the SFVS uses its legal authority to require that establishments certified by Lithuania to export to the United States develop, implement, and maintain sanitation programs to prevent direct contamination of product and the creation of insanitary conditions. The FSIS auditor verified that the SFVS has adopted requirements consistent with 9 CFR §416.1 to §416.5, and in accordance with EU sanitary regulations.

The SFVS requires establishments certified by Lithuania to export to the United States to develop, implement, and maintain daily pre-operational and operational Sanitation SOPs sufficient to prevent the direct contamination or adulteration of beef and pork products. *Order No. B1-795 (2012)* prescribes that establishments develop, implement, and maintain Sanitation SOPs that include pre-operational and operational procedures, monitoring procedures at established frequencies, and appropriate corrective actions. *Order No. B1-726 (2016)* instructs inspection personnel to verify daily the sanitary and hygienic conditions of the premises and equipment.

The FSIS auditor reviewed records related to the design and implementation of sanitation programs in the audited establishments. The FSIS auditor verified the implementation of pre-operational inspection verification was adequate by observing government inspection personnel conducting pre-operational sanitation verification of slaughter and processing areas. The government inspection personnel's hands-on verification procedures started after the establishment had conducted its pre-operational sanitation and determined that the establishment was ready for the government inspector's pre-operational sanitation verification inspection. Inspection personnel conduct and document pre-operational sanitation verification activities daily and in accordance with the SFVS's established procedures.

The FSIS auditor verified through interviews that government inspection personnel met SFVS stated frequency of procedures by performing monthly verification tasks of each establishment's building exterior and premises, which includes the floor, walls, windows, ceiling and roof finish, doors, ventilation, lighting, general sanitation (good housekeeping), equipment, and pest control. The SFVS has the power to take formal enforcement action to direct the establishments to rectify both hygiene and structural/maintenance deficiencies.

The FSIS auditor observed government inspection to verify the establishment's operational sanitation procedures and compared their overall sanitary conditions to the inspection

documentation. Observations included inspection personnel activities directly observing establishments operations and reviewing the establishment's operational sanitation records. The FSIS auditor noted that the SFVS requires the establishments certified to export to the United States to develop and implement sanitary dressing procedures of livestock at the slaughter establishments. As a result, the audited slaughter establishments have implemented daily sanitary dressing procedures to prevent potential carcass contamination for each step throughout the process. These included sanitary procedures to prevent carcass contamination during hide removal; direct contact between carcasses; and carcass contamination with gastrointestinal contents during evisceration. The FSIS auditor interviewed the government inspectors and directly observed sanitary dressing of carcasses without identifying any issues.

FSIS concluded that Lithuania's food safety system requires all establishments certified to export to the United States develop, implement, and maintain Sanitation SOPs to prevent the creation of insanitary conditions and contamination of products. The audit found that the SFVS inspection system has incorporated and implemented Sanitation SOP verification activities.

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

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

The FSIS auditor verified that the SFVS requires establishments to develop, implement, and maintain a HACCP system outlined in *Regulation (EC) No. 852/2004*. At the SFVS headquarters and the TSFVS offices, the FSIS auditor verified that Lithuania has legislative requirements for establishments that produce, process, and distribute beef and pork products to develop, implement, and maintain an effective HACCP system. This includes a flow diagram, hazard analysis, HACCP plan for hazards identified as likely to occur, monitoring and verification activities, corrective action, reassessment, validation, and recordkeeping requirements supporting the implementation of the HACCP system.

The FSIS auditor verified that the inspection system carries out routine reviews of establishments' HACCP systems designed to identify, evaluate, and prevent food safety hazards in accordance with *Regulation (EC) No. 882/2004*. Reviews of the HACCP systems include regular daily inspection verification activities and audits from each TSFVS office as outlined in *QMS KT-2-1-3-D1*. The SFVS bases the inspection procedures and audit frequency on risk assessment done at least annually.

At the SFVS Headquarters and TSFVS offices, the FSIS auditor verified that Lithuania has legislative statutes that requires establishments that produce, process, and distribute meat products to develop, implement, and maintain an effective HACCP system. This requirement is based on *Chapter II, Article 5 of Regulation (EC) 852/2004*, and Standard Operating Procedure of the QMS KT-2-1-3-D1, *Assessment and audit of systems based on Hazard Analysis and Critical Control Points in food or feed handling entities*. FSIS verified that the inspection system

carries out routine reviews of establishments' HACCP systems designed to identify, evaluate, and prevent food safety hazards in accordance with *Regulation (EC) No. 882/2004*.

The FSIS auditor reviewed the hazard analysis and HACCP plans for RTE products during the audit. The review included directly observing the implementation of critical limit monitoring activities by the establishment. HACCP reviews included ensuring the appropriate hazards are identified in the hazard analysis. Records reviews included the documentation showing the monitoring of critical limits and verification activities associated with RTE products. The FSIS auditor also reviewed the establishment's validation documents that including the appropriate pathogen reduction such as *Salmonella* and control of outgrowth for spore forming pathogens.

Government inspectors at the establishment perform HACCP procedures as outlined in *QMS procedure KT- 2-1-3-D1*. The FSIS auditor visited five establishments to determine whether the SFVS maintained adequate government oversight for the implementation of HACCP requirements. In addition, the FSIS auditor assessed the adequacy of HACCP program verification activities conducted by inspection personnel and establishment employees at the audited establishments. The FSIS auditor review of Lithuania's RTE HACCP system verification activities did not raise any concerns.

The FSIS auditor noted that the three audited slaughter establishments implement monitoring of carcasses for zero tolerance as a CCP for the presence of fecal matter, ingesta, and milk. The FSIS review of the establishment's monitoring and corrective actions records in response to the few observed deviations from the zero tolerance critical limit showed that the establishments took appropriate corrective actions, therefore addressing all four parts of the corrective action regulation. The FSIS auditor also reviewed the inspection verification records and observed the in-plant inspection personnel's hands-on verification activities for the zero tolerance CCP.

The FSIS auditor noted that inspection personnel conduct daily verification of the CCPs through records review and direct observation in accordance with the SFVS's requirements. The zero tolerance CCP monitoring and verification location for both the establishment's employees and in-plant inspection personnel is at the final rail, before entering the cooler for chilling. No issues were identified during the audit with the SFVS verification procedures for the zero tolerance CCP.

FSIS concluded that the Lithuanian food safety system requires all establishments certified to export to the United States to develop and implement HACCP systems. The audit concluded that the SFVS has incorporated and implements HACCP verification procedures into the inspection system.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth of six equivalence components that the FSIS auditor reviewed was Government Chemical Residue Testing Programs. The inspection system 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 inspection authorities or by FSIS as potential contaminants.

The FSIS auditor verified that the SFVS maintains the legislative authority and implements a national residue control program through the *Law on Veterinary Activities (1991)*. The *Law on Pharmaceutical Activities (1991)* requires that medicines and medicinal substances used for medical and veterinary purposes in Lithuania must be approved and registered by the Ministry of Agriculture. The Ministry of Agriculture will revoke licenses of those who engage in misuse of pharmaceutical activities.

NFVRAI is responsible for developing the annual National Residue Monitoring Plan (NRMP). Government inspection personnel collect and ship residue samples to the laboratories for analysis. The plan is based on *EC Directive No. 96/23/EC*. The document notes applicable laws and procedures for implementing the plan. The SFVS tests the following matrices: urine, plasma, kidney fat, muscle, liver, kidney, and fat in swine and bovines. NFVRAI used guidelines in *EC Directive No. 96/23/EC* to calculate the minimum number of samples to be taken based upon the amount of products of animal origin produced the previous year (January-December). The SFVS ensures that analytical methodologies are appropriate for screening and confirmation.

During the evaluation of ante-mortem inspection at all of the slaughter establishments, the FSIS auditor observed that government inspectors verify that all lots of animals are accompanied by documentation that discloses their origin and includes a signed declaration that attests that owners have adhered to veterinary pharmaceutical withdrawal periods. A review of the government residue sampling records maintained at inspection offices indicated that the 2018 sampling program was being adhered to as scheduled.

Order No. B1-646 (2003) and B1-359 (2004) instruct inspection personnel to perform an investigation on all positive residue samples and trace back animals to the supplier. Inspection personnel are to identify all affected animals and animal products associated with a positive residue sample and ensure that slaughtered animal carcasses and beef and pork products are sent for rendering. Positive suppliers are to receive increased screen sampling for 12 months. Inspection personnel at slaughterhouses are to collect suspect samples from suspicious animals and ensure that these animals are separated during slaughter. Sampled carcasses and parts thereafter will put on hold pending receipt of laboratory results. Violators who do not adhere to the laws may be penalized for liability and have administrative actions enforced. Repeat offenders shall lose their registration to supply animals and animal products for use as human food. The FSIS auditor verified the in-plant OVs are familiar with the requirements for positive drug residue results.

The FSIS auditor noted that The SFVS does not require that carcasses sampled under routine monitoring conducted by the SFVS to be detained pending test results, but a noncompliant result will trigger follow-up investigation by the SFVS. The FSIS auditor observed that the three audited slaughter establishments have procedures in place to hold products before receiving any test results for drug residues.

The FSIS auditor visited the NFVRAI chemical residue laboratory, which is an ISO 17025 accredited government laboratory. NAB provides accreditation in line with *Regulation (EC) No. 765/2008*. This laboratory serves as the National Reference Laboratory providing analytical services under the NRMP and participates in proficiency testing organized by the European Union Reference Laboratories in accordance with *Regulation (EC) No. 882/2004*. The FSIS auditor interviewed the quality management personnel who conduct the internal audits of this laboratory. The internal audit scope included sample handling, sampling frequency, timely analysis, data reporting, analytical methodologies, equipment operation, intra-laboratory check samples, and quality assurance programs, including standards books and corrective actions. The FSIS auditor's review of the internal audit reports and corresponding follow-up reports found no concerns with the SFVS's implementation of its chemical residue testing program.

The SFVS conducts residue testing at the NFVRAI laboratory. In the event subcontracting is necessary, NFVRAI must utilize a laboratory that is ISO 17025 certified or meets the same standards. NFVRAI quality system procedures describe all requirements needed to ensure the subcontractor's competence for each test method utilized. When possible, NAB performs an audit in the relevant field of the subcontractor's laboratory work. If an audit is not possible, the subcontractor must supply information through a questionnaire. The subcontractor's response must provide information about the accreditation body, accreditation status, validation, participation in proficiency testing programs for NFVRAI subcontracting tests and other required information. The FSIS auditor did not identify concerns with the subcontractor approval process.

Prior to the onsite visit, FSIS's residue experts thoroughly reviewed the 2016 NRMP, 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 Lithuania's food safety system was determined equivalent and became eligible to export beef and pork products to the United States.

The result of the onsite audit activities demonstrate that Lithuania continues to maintain the legal authority to regulate, plan, and execute activities of the food safety system that are aimed at preventing and controlling the presence of residues of veterinary drugs and chemical contaminants in beef and pork products destined for export to the United States.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last equivalence component that the FSIS auditor reviewed was Government Microbiological Testing Programs. The system is to implement certain sampling and testing programs to ensure that beef and pork products produced for export to the United States are safe and wholesome.

Lithuania has adopted *Enterobacteriaceae* in lieu of generic *E. coli* for carcass testing, which FSIS has determined is acceptable for EU member states eligible to export to the United States. Sampling and testing is the responsibility of the establishments. The SFVS OVs assigned to the slaughter establishment are responsible for verification that establishments' sampling and testing

is adequate. The FSIS auditor verified through interviews of government inspectors that the SFVS inspection program includes procedures to verify the implementation of *Enterobacteriaceae* sampling programs. The OVs possessed the appropriate knowledge of the SFVS verification activities including the upper and lower control limits, as well as the corrective actions for exceeding the upper limit.

The SFVS collects *Salmonella* verification samples from beef and pork slaughter establishments in accordance with *Regulation (EC) No. 2073/2005* on microbiological criteria for foodstuffs. OVs take samples following the SFVS's sampling procedures and the samples are then tested at a NFVRAI laboratory. When the SFVS identifies unsatisfactory results, establishments must implement corrective actions to prevent reoccurrence. The FSIS auditor observed that the in-plant inspection personnel's *Salmonella* sample collection methodology was in accordance with the SFVS's requirements. The FSIS auditor verified through interviews with government inspectors that the SFVS provides instructions to its inspection personnel to verify the establishment's corrective measures when the establishment does not meet the performance standards. The OVs possessed knowledge of the SFVS *Salmonella* sampling program and verification activity requirements for unacceptable results.

The FSIS auditor verified through interviews with government inspectors that the SFVS considers any RTE beef and pork products or beef and pork products that are exposed to a food contact surface that tested positive (through either government verification sampling or establishment sampling) for *Listeria monocytogenes (Lm)* to be adulterated and ineligible for export to the United States. The SFVS defines RTE products as food intended by the producer or the manufacturer for direct human consumption without the need for cooking or other processing and has effectively eliminated or reduced microorganisms of concern to an acceptable level.

The FSIS auditor verified that the SFVS requires establishments producing RTE products to conduct verification testing of products, food contact surfaces, and the post-lethality environment (non-food contact surfaces) for the presence on *Lm*. In addition to the required establishment verification testing, SFVS requires government testing of products, food contact surfaces, and the post-lethality environment. The SFVS requires *Salmonella* testing in RTE products in addition to testing for *Lm* in all products including products without post-lethality exposure. The FSIS auditor reviewed testing plans and test results and determined that the SFVS and establishments are testing products, food contact surfaces, and the post-lethality environment at the stated frequencies. No concerns were identified with the SFVS's verification activities regarding *Lm* and *Salmonella*.

The FSIS auditor verified that RTE beef and pork products intended for export to the United States are held before the reception of results and export is allowed only after satisfactory results of the analyses performed are received. If an unsatisfactory result of the analysis is received, samples are not retested and the only the first result of the laboratory analysis is considered. The FSIS auditor directly observed how establishments and the SFVS holds products before receiving test results. No concerns arose with the requirements to hold products pending test results at the establishments.

There are no requirements for routine microbiological testing for thermally processed-commercially sterile products. However, the inspection system demonstrated its capability to maintain a microbiological program that would ensure that canned products produced for export to the United States are safe, wholesome, and not contaminated with *Clostridium botulinum* spores or toxins. The establishments are required to follow the FSIS canning regulations and assess the nature and cause of abnormal containers according to their HACCP system and are to provide acceptable final disposition of the affected production. The inspection system ensures that only safe and stable product is exported to the United States. The FSIS auditor verified that the SFVS oversees the performance of establishment verification activities, ensuring that corrective and preventive measures are implemented when problems are identified. Additionally, the establishment tests each lot of canned product for commercial sterility when exporting to the United States.

The FSIS auditor visited the NFVRAI microbiology laboratory, which is an ISO 17025 accredited government laboratory. The FSIS auditor reviewed the inspection records associated with the official verification sampling and laboratory testing programs for beef and pork products. The FSIS auditor focused on the verification of analysts' qualifications, sample receiving, sample handling, timely analysis, analytical methodologies, and recording results, and reporting of results. The FSIS auditor's review of the laboratory records found that the sampling plans for microbiological analysis were in place, and the analyses were performed using FSIS or equivalent methods that had been validated. The FSIS auditor's review of a sample of past internal and external audit reports revealed that all laboratory audit findings were corrected and verified through follow-up audits.

There have not been any POE violations related to this component since Lithuania was added to the Code of Federal Regulations as eligible to export beef and pork products to the United States effective October 30, 2015. The SFVS's food safety system has a microbiological testing program that is organized and administered by the national government. In addition, the SFVS implements sampling and testing programs to ensure that meat products produced for export to the United States are safe and wholesome.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on March 23, 2018, in Vilnius, Lithuania with the SFVS. The FSIS auditor concluded that Lithuania's food safety system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. The SFVS routinely verifies implementation of sanitation procedures and establishment HACCP systems to ensure adequate control of beef and pork food safety hazards. In addition, the SFVS implemented official government microbiological and chemical residue testing programs to verify the effectiveness of its food safety inspection system on an ongoing basis. An analysis of each equivalence component did not identify any deficiencies that represent an immediate threat to public health.

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 UAB Biovela Mesos Perdirbimo Patalinys	2. AUDIT DATE 03/13/2018	3. ESTABLISHMENT NO. LT 82-02 EB	4. NAME OF COUNTRY Lithuania
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

41 - Observed condensation in droplet form on bottom of refer in RTE cooler and raw processing area. No product contamination observed. Government inspection notified the establishment immediately. Action were taken by the establishment to restore sanitary conditions.

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT03/13/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Utenos Mesa	2. AUDIT DATE 03/14/2018	3. ESTABLISHMENT NO. LT 17 EB	4. NAME OF COUNTRY Lithuania
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	0
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

03/14/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION UAB Liutukas ir Ko	2. AUDIT DATE 03/15/2018	3. ESTABLISHMENT NO. LT 19-30 EB	4. NAME OF COUNTRY Lithuania
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP	O	33. Scheduled Sample	O
8. Records documenting implementation.	O	34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.	O	35. Residue	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	O	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.	O	37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	O	38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	O	39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .	O	41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	O	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.	O	43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.	O	44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.	O	46. Sanitary Operations	
19. Verification and validation of HACCP plan.	O	47. Employee Hygiene	
20. Corrective action written in HACCP plan.	O	48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.	O	Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	O	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O	54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

03/15/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION UAB Pajurio Mesine	2. AUDIT DATE 03/19/2018	3. ESTABLISHMENT NO. LT 55-04 EB	4. NAME OF COUNTRY Lithuania
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	0
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

03/19/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION UAB Klaipedos Mesine .	2. AUDIT DATE 03/20/2018	3. ESTABLISHMENT NO. LT 88-24 EB	4. NAME OF COUNTRY Lithuania
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	0
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	0
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

03/20/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION AB Krekenavos Agrofirma	2. AUDIT DATE 03/21/2018	3. ESTABLISHMENT NO. LT 53-04 EB	4. NAME OF COUNTRY Lithuania
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	0
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

03/21/2018

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: Mr. Todd Furey
Acting International Coordination Executive
Office of International Coordination
USDA/Food Safety and Inspection Service
1400 Independence Avenue,
SW. Washington DC,
United States of America

05-07-2018 No BC-(1.20.)-1799

Subject: **IMPLEMENTATION OF CORRECTIVE MEASURES**

Dear Mr. Furey,

Thank you for your letter dated 23 May 2018 and the submitted draft final audit report. The report reflects the findings of the audit conducted in the Republic of Lithuania on March 12–23, 2018. I would hereby like to respond to the conclusions of the Food Safety and Inspection Service (FSIS). The following measures have been implemented at the meat processing plant to rectify the non-compliance with sanitation requirements:

Non-compliances identified during audit	Measures adopted at the plant to rectify the non-compliances
The establishment LT 82-02 UAB Biovela Mėsos Perdirbimo Patalinys did not fully implement requirements cited in 9 CFR Section 416.2 (d): Ventilation adequate to control odors, vapors, and condensation to the extent necessary to prevent adulteration of product and the creation of insanitary conditions must be provided	On 23 March 2018, a plan of preventive measures for the establishment LT 82-02 UAB Biovela Mėsos Perdirbimo Patalinys was adopted to increase the efficiency of the ventilation and to eliminate the presence of condensation in the RTE cooler and raw sausages processing area. The plan was agreed with Utena State Food and Veterinary Service of the SFVS. The following measures have been implemented according to the plan:

	<ol style="list-style-type: none">1. The work cycle of the refrigeration unit has been modified, i. e. the stirring of the air subject to cooling (operation of ventilators) is performed continuously, the frequency of the defrosting cycle has been increased. To reduce the incoming moisture the control of closing the door and staff movement has been strengthened.2. The freezing cameras are filled up with meat products only after primary cooling up to 30–35⁰C with the application of the “empty-full” principle in the process of filling up the cameras.3. In accordance with the adopted plan of preventive measures of the plant, a person responsible for carrying out the control of the presence of condensation in the RTE cooler and raw sausages processing area on fixed days was appointed.4. To remove condensation in case of contingency situations special places for keeping tools for the removal of the condensation have been installed in rooms, persons responsible for the control of condensation, its timely and safe removal have been appointed.
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After the measures provided in the plan of preventive measures of the plant had been implemented, Utena State Food and Veterinary Service of the SFVS conducted inspections at the time of which the veterinarian who is engaged in the continuous official control at the plant has not identified any cases of presence of odors, vapors, and condensation in the RTE cooler and raw sausages processing area since April 13, 2018. Results of the official controls confirm that the measures implemented and applied at the plant LT 82-02 EB, UAB Biovela Mėsos Perdirbimo Patalyns ensure the efficiency of the ventilation enabling the prevention of the presence of odors, vapors, and condensation.

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.

Yours sincerely,

Acting Director



Mantas Staškevičius