



United States Department of Agriculture

Food Safety and  
Inspection Service

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Mrs. Audronė Mikalauskienė  
Acting Director  
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Lithuania

Dear Mrs. Mikalauskienė,

The United States Department of Agriculture Food Safety and Inspection Service (FSIS) conducted an onsite verification audit of Lithuania's inspection system from September 12 through 27, 2022. 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.

Sincerely,

A handwritten signature in blue ink, appearing to read "Michelle Catlin", written over a light blue circular stamp.

Michelle Catlin, PhD  
International Coordination Executive  
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED OF  
LITHUANIA

SEPTEMBER 12–27, 2022

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING  
PROCESSED BEEF AND PORK PRODUCTS  
EXPORTED TO THE UNITED STATES OF AMERICA

January 25, 2023

Food Safety and Inspection Service  
United States Department of Agriculture

## **Executive Summary**

This report describes the outcome of an onsite equivalence verification audit of Lithuania conducted by the U.S. Department of Agriculture's (USDA), Food Safety and Inspection Service (FSIS) from September 12–20, 2022. The audit concluded with an exit meeting held remotely on September 27, 2022. The purpose of the audit was to verify whether Lithuania's food safety inspection system governing 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 currently exports the following categories of beef and pork products to the United States: ready-to-eat fully cooked, not shelf stable and thermally processed, commercially sterile.

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

FSIS concluded that Lithuania's meat inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. The Central Competent Authority, State Food and Veterinary Service (SFVS), has required that establishments certified as eligible to export products to the United States implement sanitation requirements and a HACCP system designed to improve the safety of their products. In addition, the SFVS has implemented official microbiological and chemical residue testing programs that are organized and administered by the national government to verify its system. An analysis of each component did not identify any systemic findings representing an immediate threat to public health.

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## I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) conducted an onsite audit of Lithuania's food safety system from September 12–20, 2022. The audit began with an entrance meeting September 12, 2022, 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).

Representatives from SFVS accompanied the FSIS auditor throughout the entire audit. The audit concluded with an exit meeting conducted remotely via videoconference on September 27, 2022.

## II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to verify whether the food safety inspection system governing meat 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 the following categories of products to the United States:<sup>1</sup>

Process Category	Product Category	Eligible Products <sup>2</sup>
Thermally Processed - Commercially Sterile (TPCS)	Thermally Processed, Commercially Sterile	Beef and Pork - All Products Eligible
Not Heat Treated - Shelf Stable	Not Ready-to-Eat (NRTE) Otherwise Processed Meat	Pork - All Products Eligible
Not Heat Treated - Shelf Stable	Ready-to-Eat (RTE) Acidified/Fermented Meat (without cooking)	Beef and Pork - All Products Eligible
Not Heat Treated - Shelf Stable	RTE Dried Meat	Beef and Pork - All Products Eligible
Not Heat Treated - Shelf Stable	RTE Salt-Cured Meat	Beef and Pork - All Products Eligible
Heat Treated - Shelf Stable	RTE Acidified/Fermented Meat (without cooking)	Beef and Pork - All Products Eligible
Heat Treated - Shelf Stable	RTE Dried Meat	Beef and Pork - All Products Eligible
Heat Treated - Shelf Stable	RTE Salt-Cured Meat	Beef and Pork - All Products Eligible
Fully Cooked - Not Shelf Stable	RTE Fully-Cooked Meat	Beef and Pork - All Products Eligible

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<sup>1</sup> On September 15, 2022, Lithuania became eligible to export egg products to the United States. FSIS will audit Lithuania's egg products inspection system as part of the next ongoing equivalence verification audit.

<sup>2</sup> All source meat used to produce products must originate from eligible countries and establishments certified to export to the United States.

<b>Process Category</b>	<b>Product Category</b>	<b>Eligible Products<sup>2</sup></b>
Fully Cooked - Not Shelf Stable	RTE Meat Fully-Cooked Without Subsequent Exposure to the Environment	Beef and Pork - All Products Eligible
Heat Treated - Not Fully Cooked - Not Shelf Stable	NRTE Otherwise Processed Meat	Pork - All Products Eligible
Products with Secondary Inhibitors - Not Shelf Stable	NRTE Otherwise Processed Meat	Pork - All Products Eligible
Products with Secondary Inhibitors - Not Shelf Stable	RTE Salt-Cured Meat	Beef and Pork - All Products Eligible

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

Prior to the onsite equivalence verification audit, FSIS reviewed and analyzed Lithuania's Self-Reporting Tool (SRT) responses and supporting documentation, including official chemical residue and microbiological sampling plans and results. During the audit, the FSIS auditor conducted interviews, reviewed records, and made observations to verify whether Lithuania's food safety inspection system governing meat products is being implemented as documented in the country's SRT responses and supporting documentation.

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 3-year period, in addition to information obtained directly from SFVS through the SRT.

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

The FSIS auditor reviewed records related to administrative functions and oversight at SFVS headquarters, as well as government verification records from two territorial offices and three local inspection offices within the establishments. Through records review, 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 documented in the country's SRT responses and supporting documentation.

All three establishments certified to export to the United States were selected for the audit. This included two beef and pork slaughter and processing establishments and one beef and pork processing establishment. The meat products these establishments produce and export to the United States include RTE and TPCS beef and pork products.

During the establishment visits, the FSIS auditor paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that threatens food safety. The FSIS auditor assessed SFVS' ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in 9 CFR 327.2.

The FSIS auditor also visited one government chemical residue and microbiological laboratory to verify that the laboratory is capable of providing adequate technical support to the food safety inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• SFVS, Vilnius
	Territorial	2	• Utena Territorial Office, Utena • Kaunas Territorial Office, Kaunas
Laboratory		1	• National Food and Veterinary Risk Assessment Institute, microbiological unit and chemical unit, 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, UAB Krekenavos Agrofirma, Kėdainiai
Beef and pork processing establishment		1	• Establishment No. LT 68-05 EB, Orka Foods, Plungės

FSIS performed the audit to verify that Lithuania's food safety inspection system meets 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.) Section 601 et seq.);
- The Humane Methods of Slaughter Act (7 U.S.C. Sections 1901-1906); and
- The Meat Inspection Regulations (9 CFR 301 to the end).

The audit standards applied during the review of Lithuania's inspection system for processed beef and pork 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.

### **III. BACKGROUND**

From February 1, 2019, to January 31, 2022, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 160,445 pounds of beef and 1,194,920 of pork products exported by Lithuania to the United States. Of these amounts, additional types of inspection were performed on 18,582 and 168,709 pounds of beef and pork products, respectively. These additional types of inspection included product examination, condition of container examination for TPCS products, chemical residue analysis, and testing for microbiological pathogens—*Listeria monocytogenes* (*Lm*) and *Salmonella*—in RTE products. As a result of this additional testing, no beef or pork products were refused entry due to any public health concerns.

The previous FSIS audit conducted in 2019 did not identify any deficiencies that represented a threat to public health.

The most recent FSIS final audit reports for Lithuania's food safety inspection system are available on the FSIS website at: [www.fsis.usda.gov/foreign-audit-reports](http://www.fsis.usda.gov/foreign-audit-reports).

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

The first equivalence component the FSIS auditor 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 SFVS was established under the Statute of the State Food and Veterinary Service (Resolution No. 744 of June 28, 2000, modified under Resolution No. 638 of June 1, 2011). 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. The SFVS is headed by the director who is responsible for overseeing the SFVS and ensuring products destined for export to the United States are not adulterated or misbranded. The director, who is assisted by four deputy directors and an advisor, directly reports to the Minister of Agriculture. The Minister of Agriculture is responsible for the appointment of the director position.

Structurally, the SFVS is comprised of 18 divisions, 10 territorial SFVS offices (TSFVS) located across Lithuania, and 12 border inspection posts. The director of SFVS is also responsible for overseeing the national food and veterinary risk assessment institute (NFVRAI) which is Lithuania's central laboratory. Although all 18 divisions within SFVS are involved in supporting the mission of SFVS, the veterinary sanitary division (VSD) is the key department responsible for enforcing food safety regulations and implementing the inspection system at food handling businesses, including foods of animal origin. The VSD is responsible for a wide array of



inspection related functions, including coordination and implementation of sampling plans; approval of food businesses; issuance of standard operating procedures and work instructions for inspectors; coordination among the 10 TSFVS offices; and the development and delivery of training for inspectors, as well as export controls. The VSD is also the point of contact for the European Commission's (EC) Rapid Alert System for Food and Feed (RASFF).

To ensure food safety and public health, the VSD extensively collaborates with the following divisions:

- Food Division, which among others, implements the official policy on food safety and safeguards the consumer rights related to food and food businesses;
- Animal Health and Welfare Division plays major roles in surveillance and managing of contagious diseases, zoonotic diseases, animal identification and registration, animal welfare, and other related functions;
- International Affairs Division organizes and coordinates international cooperation in food safety and veterinary sectors and bilateral trade negotiations with the European Union (EU) and non-EU countries including the United States, and is responsible for developing training programs;
- Strategic Planning and Quality Management Division develops strategic plans and policies, implements its Quality Management System in accordance with International Organization for Standardization (ISO) 17020:2004. This division is also responsible for ongoing evaluation of inspection personnel competence; and
- Emergency Response Division develops a contingency action plan to combat emergencies like outbreaks of animal contagious diseases, manages recalls, monitors RASFF, and conducts risk assessments and provides recommendations to the director in food and feed sectors.

Other divisions that support SFVS in areas other than food safety include General Affairs Division; Information Systems Division; Public Procurement Division; Law Division; Border Food and Veterinary Control Division; Internal Audit Division; Personnel Division; and Finance and Budget Division. Since the previous FSIS audit in 2019, SFVS has expanded and added four more divisions to include: Animal Breeding, Internal Investigation, Public Relations, and Veterinary Medicines and Feed Divisions (VMFD). The VMFD is the main entity in planning the annual residue monitoring program.

Lithuania's meat inspection system is organized on three levels: central, territorial, and local establishment. At the central level, the SFVS headquarters is located in Vilnius where VSD oversees and coordinates with 10 TSFVS. Each TSFVS is a suboffice of SFVS that supports the mission of the SFVS in Lithuania. Each TSFVS oversees a number of territorial units (TU) which vary in number depending on geo-administrative size of any individual TSFVS. There are 33 TUs located throughout Lithuania that provide supervisory oversight to inspection staff assigned to food business operations, including three establishments certified to export to the United States. At the establishment level, the SFVS inspection personnel conduct inspection verification tasks, including sampling in accordance with the SFVS' prescribed frequency. Official veterinarians (OV) in the establishment document enforcement actions, assess the effectiveness of the establishment's corrective action plans submitted in response to identified

noncompliance, and communicate their verification results through the chain of command via the Animal Food Information System (AFIS) database. The AFIS is accessed by supervisory chain of command at the TU, TSFVS, and central level for the purpose of reviewing verification results.

As a member of the EU, Lithuania implements the requirements of the EC food hygiene regulations, which are the primary overarching laws for regulating meat inspection in the EU countries. To enforce EU inspection laws in food operation businesses, Lithuania draws its authority from Regulation (EC) No. 178/2002, which establishes the general principles and requirements of food law and defines the European Food Safety Authority (EFSA) and procedures in matters of food safety. Through its veterinary sanitary division, SFVS has developed legal acts, orders, standard operating procedures (SOP), and work instructions to implement EU regulations and FSIS import requirements.

Through document review and interviews conducted with the government officials at the SFVS headquarters, territorial offices, and local inspection offices, the FSIS auditor verified that SFVS has procedures in place to certify products intended for the United States. Upon receiving from the establishment an application to be certified as eligible to export to the United States, the OV assigned to the establishment communicates the request to the TSFVS and its respective TU which has jurisdiction over the requesting establishment. Documents reviewed by the FSIS auditor revealed that the OV reviews the application for accuracy and supporting documents followed by onsite verification prior to recommending certification. The establishment's readiness and compliance with FSIS' import requirements are verified through document review both at the territorial and central level prior to granting approval. Work Instruction 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 and Work outlines approval procedures. Once certified, SFVS informs FSIS of the new certification. SFVS also holds the authority to suspend eligibility to export if it determines the establishment is failing to comply with FSIS requirements despite warnings and documentation of noncompliance. If an establishment has not been actively exporting or would like to withdraw its eligibility voluntarily, it can do so by notification through the proper channels. The FSIS auditor's review of the certification process did not raise any issues.

The FSIS auditor reviewed the SFVS' procedure for export certification which is mainly governed by Order No. B1-26 (2017) Order on the Procedure for Export of Animal Origin Products and Feed to Third Countries, for which work instructions to the inspectors are outlined in Work Instruction KT-6-9-D1. The product certification commences when the OV receives a written request detailing the date, type, and volume of meat product intended for the United States. The OV verifies all shipment related documents which include source, product eligibility, HACCP monitoring, and verification records to ensure that the establishment's official microbiological test results are negative. If the documents are satisfactory, the senior OV at the respective TU issues and signs the health certificate. Currently, all establishments certified to export to the United States are receiving source materials from eligible establishments within Lithuania. The FSIS auditor reviewed the certification process and a recently issued certificate at one of the TSFVS overseeing a TU having supervisory jurisdiction over the establishment certified to export to the United States and did not identify any concerns.

Under the specific provisions of Order No. B1-308 (2015) Provision of Information on Unsafe Food or Potentially Unsafe Food, Food Contact Articles or Materials or Feed, the director requires food business operators to immediately notify the SFVS of any laboratory results on meat and other food products that test positive for the presence of pathogens which pose a potential risk to human health. OV's are required to assess the food safety system in response to nonconforming microbiological or chemical test results, regardless of who conducted the test and whether it was sampled by the establishment under its self-control program or the OV collected samples under the routine official sampling program. Per Resolution No. 638 (2011) Statute of the State Food and Veterinary Service, the SFVS has regulatory authority to invoke product recall and impose market bans if adulterated food products enter either domestic or foreign commerce. The SFVS has procedures in place to notify FSIS if a shipment with adulterated product has entered into the United States. Lastly, as stated above, the EU countries utilize RASFF, which is a notification system operated by the EC Commission to exchange information on identified hazards between EU Member States and covers food, food contact materials and animal feed. The FSIS auditor's review indicated there has not been any recent enforcement measures in certified establishments or recalls involving adulterated product being shipped to the United States.

Through interviews and document reviews, the FSIS auditor verified that inspection personnel assigned to certified establishments producing meat products eligible for export to the United States are public servants paid directly by the Lithuanian government. 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 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 inspection personnel assigned to certified establishments consists solely of veterinarians which include an OV and online inspectors at each slaughter establishments. OV's at the certified slaughter establishments are responsible for providing supervisory oversight to the online inspection personnel.

All veterinarians employed at SFVS are graduates of the Lithuanian University of Health Sciences and undergo a public competition to enter into government service. Once selected for public service by the SFVS, each veterinarian is required to complete specialized training developed for new employees in the inspection service. The training consists of both theoretical and practical components. The theoretical part of the training focuses on a variety of inspection related topics such as animal welfare, border veterinary control, zoonotic diseases, meat microbiology and pathobiology, food contact materials, and other allied subjects. The practical part of the training is provided upon successful completion of the theoretical part and needs to be completed before a veterinarian can be assigned independently as an OV to a certified establishment. The FSIS auditor did not identify any concerns regarding the educational credentials and training of the OV's.

In order to verify FSIS' requirement for continuous government inspection during slaughter operations, and at least once per production shift during the processing of meat intended for export to the United States, the FSIS auditor conducted interviews and reviewed documents both at the central level and at the audited establishments. 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 TU of Telšiai's TSFVS provides a full-time resident veterinarian to the processing establishment located in Plungės to ensure that the establishment meets all national, EU, and FSIS import requirements when product intended for export to the United States is being prepared. The inspection records reviewed by the FSIS auditor confirmed that SFVS ensures all shifts and any unforeseeable absences are covered by veterinarians who are stationed at each TSFVS. No concerns arose during the FSIS auditor's review regarding inspection coverage and staffing standards at the audited certified establishments.

The administrative and technical support to operate the laboratory system implemented by SFVS is consistent with the provisions in Chapter IV of Regulations (EU) 2017/625. Per requirements in Articles 37 and 38 of Regulation (EU) 2017/625, the SFVS has designated NFVRAI as the national reference laboratory for food, feed, and animal health. The NFVRAI is comprised of the institute in Vilnius as well as territorial branches in Kaunas, Klaipėda, Šiauliai, Panevėžys, and Telšiai. The institute, which is headed by the director, is comprised of 15 different units, including food microbiology, chemistry, bacteriology, molecular biology and genetically modified organisms, and serology. Four deputy directors and two chief advisors provide direct oversight to the institute's 15 functional units and five territorial branches. The current audit also included a review of food microbiology and chemistry units to assess the adequacy of the technical support the laboratory receives from the inspection system.

The SFVS requires that NFVRAI and its five territorial branches maintain accreditation according to International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025 standards. During the review of microbiology and chemical units of NFVRAI, the FSIS auditor confirmed each NFVRAI laboratory unit within the institute is accredited according to ISO 17025 standards by the Lithuanian National Accreditation Bureau (NAB). The institute is accredited for over 400 analytical methods, which include microbiological and chemical residue testing methods implemented for analyzing products intended for export to the United States. The FSIS auditor's review of the recent accreditation report by NAB indicated that the accreditation body had identified a total of 15 nonconformances. Of the 15 nonconformances, 13 were classified as minor and two were considered major. The laboratory provided training to the staff to address the major nonconformances. All proffered corrective actions were acceptable by NAB. The FSIS auditor also evaluated NFVRAI's internal audit procedures and the associated audit report for the most recent microbiology and chemistry unit audits and did not identify any concerns.

The FSIS auditor also evaluated NFVRAI's process for approving third-party laboratories for analytical testing on foods of animal origin for food microbiological and chemical residues. The NFVRAI developed a questionnaire designed to gather information on laboratory programs for calibration, testing methods, accreditation status, laboratory quality management system, and other related information. The FSIS auditor reviewed an example of a completed questionnaire submitted in 2019. Currently NFVRAI has awarded approval to three third-party laboratories. At the time of the audit, none of the approved third-party laboratories were conducting any testing on products intended for export to the United States.

To assess the competence, skills, knowledge, and ongoing training of analysts assigned to the microbiological and the chemical units of NFVRAI, the FSIS auditor reviewed the most recent proficiency reports for each unit. The FSIS auditor verified that the laboratory participates in annual proficiency testing provided by an external provider. The FSIS auditor reviewed analysts' training records, supervisory checks records, and analysts' worksheets, and determined that analysts possess the required competencies necessary to perform appropriate procedures associated with the applicable methods and protocols. The FSIS auditor 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. During the tour of both the microbiology and chemistry units, amongst others, the FSIS auditor observed the receiving department processing the sample receipt information, checking sample integrity, and transferring data into the computer which triggers a unique sample identification number that is used in analysis and reporting of results. No issues were identified as a result of the FSIS auditor's assessment of the government's oversight of the laboratories.

The FSIS auditor verified that the SFVS' meat food safety inspection system has the organizational structure to provide ultimate control, supervision, and enforcement of regulatory requirements for this component.

**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 equivalence component 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 every carcass and its parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; at least once per shift inspection during processing operations; and periodic supervisory visits to official establishments.

The SFVS implements the requirements for humane handling specified in Council Regulation (EC) No. 1/2005 on the protection of animals during transport and Council Regulation (EC) No. 1099/2009 on the welfare of animals at the time of slaughter through work instructions; KT-2-4, Official control for animal welfare at the time of killing, and KT-2-3-1-D1, Instruction on the assessment in the slaughterhouse of suitability in food of meat and other products of slaughter. The FSIS auditor observed implementation of the humane handling programs at the audited slaughter establishments. This included directly observing inspection personnel performing hands-on verification of the maintenance and conditions of the holding pens, movement of animals, and proper stunning of animals. The FSIS auditor reviewed the inspection record pertaining to humane handling verification and determined that the OV documents the results of their verification activities according to KT-2-4 and KT-2-3-1-D1. The FSIS auditor did not identify any concerns with humane handling requirements.

The requirements for ante-mortem inspection are specified in KT-2-3-1-D1 and in the Commission Implementing Regulation (EU) 2019/627. KT-2-3-1-D1 instructs the OVs to carry

out ante-mortem inspection of all livestock prior to slaughter. OV's are required to inspect livestock within 24 hours prior to slaughter to determine whether they are fit for slaughter to be used in food intended for human consumption. The FSIS auditor observed the OV's assigned to conduct ante-mortem inspection verifying documents accompanying the shipment and observing animals in motion and at rest. Animals exhibiting signs of neurological disorder or arriving in non-ambulatory conditions are condemned during ante-mortem inspection. These condemned animals are subject to BSE testing prior to disposing of carcasses in accordance with government instructions. The FSIS auditor reviewed inspection records and observed ante-mortem procedures that demonstrate proper implementation of the SFVS' requirements. No concerns arose during these reviews and observations.

KT-2-3-1-D1 outlines the procedures that OV's and online inspectors must carry out in conducting post-mortem inspection duties. These procedures are aligned with EU regulatory requirements stipulated in Article 18 of Regulation (EU) 2017/625. The FSIS auditor noted establishments slaughtering swine and cattle have either different slaughter lines for each species or slaughtering two species on alternate working days or full clean-up between species when using the same slaughter line. The auditor's assessment of line speed, slaughter volume, and number of online inspectors indicated that the correlation between these requirements was in accordance with criteria established in DR-2-1-D1 Basic Criteria for Determining the Number of State Food Veterinary Service Delegated Employees in Slaughterhouses, which have been determined to be consistent with FSIS requirements. At each establishment the auditor observed that correlation between head, carcass, and viscera are maintained, and inspectors assigned to these inspection stations have access to stop switches to be used when asynchronization occurs or for other reasons including the railing out of carcasses and parts for the OV's disposition. The auditor further noted that prior to carcasses entering the carcass chiller, a full-time inspector is stationed to conduct a final rail inspection of each carcass to catch any visible minor lesions that may have escaped trimming at the carcass inspection station. Carcasses do not receive the mark of inspection unless inspected and passed at the final rail inspection station. The FSIS auditor observed removal of the spinal cord utilizing vacuum suction equipment attached to a conduit system leading to a collection area away from the slaughter floor. Remnants of specified risk material (SRM) are collected in marked bins placed underneath the SRM removal stand. The SFVS verifies establishments' compliance with Regulation (EC) No. 999/2001 for the identification, removal, segregation, and disposal of SRMs at the slaughter floor.

The FSIS auditor reviewed the recent supervisory reviews conducted in Utena and Kaunas' TSFVS. The reviews are conducted by the senior official veterinarian stationed in the TUs within their respective TSFVS. The frequency of the supervisory reviews is based on a classification of establishments into three risk categories: high, medium, low and very low. Currently, all certified establishments fall into the high-risk category and receive a yearly supervisory visit which could change to a higher frequency if warranted. Supervisory reviews are comprised of a document review portion followed by an onsite segment in which a supervisor shadows the OV assigned to the certified establishment. The supervisor utilizes a checklist which is part of KT-2-2-1 Official Veterinary Supervision and Official Veterinary Control of Entities Handling Food of Animal Origin that covers mostly slaughter portions of inspection and assessments of the OV's performance. The auditor's verification of a recently conducted supervisory review at two audited slaughter/processing establishments did not raise any concerns. The supervisory senior

official veterinarians rely on guidelines and various checklists issued by the SFVS directorate in the document Order No. B1-726 (2019) Continuous Official Veterinary Inspection of Meat Establishments Producing Meat Products Intended for Export to the USA when conducting reviews at establishments producing RTE and TPCS products. The auditor's review of supervisory reports conducted at RTE facilities confirmed that reviews were carried out per KT-2-3-2-D1.

Pertaining to the requirements of separation of eligible product from non-eligible products, as noted earlier, the establishments that slaughter multiple species and utilize the same slaughter line conduct a full clean-up between the species or operate on separate lines when slaughtering different species simultaneously. The auditor also noted that products destined for United States export are processed and stored separately and marked with conspicuously displayed signs from non-eligible products when stored in the same cooler or freezer. To ensure that there is no comingling of eligible meat products with non-eligible meat products, the SFVS requires certified establishments to have a species testing program that is verified by OV's at least once annually for products eligible for export to the United States. The FSIS auditor concluded that certified establishments have the ability to store products intended for export to the United States separately from other products and did not identify any issues on separation of products during production or storage.

Chapter II, Article 5 of the Law on Food No. VIII-1608 mandates the requirements for labeling, which have been incorporated in Order No. B1-26 (2017) Order on the Procedure for Export of Animal Origin Products and Feed to Third Countries, requiring establishments producing products intended for export to comply with the requirements of the EU, Lithuania, and the importing country. The auditor verified random labels applied to products destined for United States export and determined that labels were in conformance with all mandatory labeling features required under FSIS regulations pertinent to labeling. The FSIS auditor further verified that OV's perform labeling verification of each lot of products intended for export to the United States.

The SFVS ensures that meat products exported to the United States are not subject to animal health restrictions by regularly visiting the APHIS' website in addition to FSIS' foreign establishment eligibility table for individual countries, which also outlines current APHIS restrictions in place for these establishments.

The FSIS auditor concluded that Lithuania's food safety inspection system continues to maintain the legal authority, a regulatory framework, and adequate verification procedures to ensure sufficient official regulatory control using statutory authority consistent with criteria established for this component.

## **VI. COMPONENT THREE: GOVERNMENT SANITATION**

The third equivalence component the FSIS auditor reviewed was Government Sanitation. The FSIS auditor verified that the CCA requires each official establishment to develop, implement, and maintain written sanitation standard operating procedures (Sanitation SOPs) to prevent direct product contamination or insanitary conditions, and to maintain requirements for sanitation performance standards (SPS) and sanitary dressing.

In addition to the overarching EU hygiene regulations for food business operations, the SFVS, under Order No. B1-795 Order on Approval of Sanitation Standard Operating Procedures, requires establishments certified to export to the United States to develop, implement, and maintain written pre-operational and operational Sanitation SOPs. Additional requirements for the establishments and work instructions for OV's are found in KT-2-3-1-D1. The verification procedures in KT-2-3-1-D1 are consistent with the regulatory requirements in 9 CFR 416. At all audited establishments, the auditor verified that the establishments have written procedures for both pre-operational and operational sanitation for their operations.

The FSIS auditor reviewed the monitoring record related to the sanitation program of the audited establishments which indicated that all food contact surfaces in slaughter/boning and in RTE production rooms are thoroughly cleaned and sanitized per the establishments' cleaning procedures. Cleaning procedures are verified by plant management followed by OV verification prior to releasing the facility for the operation. Operational sanitation is also conducted with a specified frequency per the program which is, at a minimum, once per half shift or more frequently if warranted. If the monitoring document is marked "not met," it triggers corrective actions to be taken by the responsible plant employee. At each audited establishment with associated slaughter operations, the FSIS auditor verified the establishment developed sanitary dressing procedures to ensure only carcasses that are free of contamination or extraneous material enter the carcass chiller. The auditor toured the establishment's interior and exterior premises to observe the sanitation control applied during the operation to prevent product contamination as well as to assess how establishment premises are kept clean and maintained in good repair. During the slaughter operation, the FSIS auditor verified establishments' implementation of sanitary dressing procedures to ensure only pork and beef carcasses and parts that are free of fecal matter, ingesta, and milk are eligible to receive the mark of inspection.

The FSIS auditor reviewed a sample of selected documents pertaining to government sanitation verification activities. The OV's frequently conduct pre-operational verification by direct observation and through document review and require corrective actions when nonconformances are detected. The FSIS auditor selected one establishment certified for export to the United States for pre-operational sanitation verification. The FSIS auditor shadowed the OV who reviewed the establishment's sanitation document prior to beginning his verification activity. The FSIS auditor determined the OV's inspection verification activities were in accordance with work instructions contained in KT-2-3-1-D1.

Isolated establishments' findings related to the verification of sanitation requirements identified during the previous FSIS audit in 2019 were corrected by the establishments and verified by the OV's. The current audit, however, identified in two of the three audited establishments, additional isolated findings related to sanitation requirements which have been captured in detail in Appendix A of this report.

The FSIS auditor determined that SFVS requires establishments exporting to the United States to develop, implement, and maintain sanitation programs, including requirements for SPS, Sanitation SOPs, zero tolerance, and sanitary dressing.



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

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

The FSIS auditor verified that SFVS requires all certified establishments to develop, implement, and maintain a HACCP system that identifies, prevents, and controls the food safety hazards of concern. HACCP system requirements are mandated through relevant articles of Regulations (EC) Nos. 852/2004 and 853/2004, Regulation (EU) 2017/625, and Commission Delegated Regulation (EU) 2019/624. In establishments certified for export to the United States, SFVS requires additional HACCP system requirements through Order No. B1-439, Assessment and Audit of the Hazard Analysis and Critical Control Point Systems for Entities. The requirements in the document mentioned above are consistent with FSIS' HACCP regulations described in 9 CFR 417. The work instructions KT-2-1-3-D1 instruct the OV to conduct verification inspection activities in certified establishments consistent with those described in FSIS Directive 5000.1. KT-2-1-3-D1 provides instructions to inspection personnel on how to assess an establishment's HACCP system, which must include records review, direct observation, and data analyses, as well as evaluation of sanitation programs, HACCP plans, critical control point (CCP) monitoring, corrective actions and preventive measures, and product sampling and testing programs.

The FSIS auditor's review of establishments' HACCP systems includes product description sheet, flow diagram, hazard analysis, HACCP plan, and corrective action record. The document reviewed indicated that the audited establishments conducted a hazard analysis and considered all known chemical, biological, and physical hazards associated with their processes and addressed any identified hazard that was determined to be likely to occur through a CCP with supportable critical limits (CL). Certified establishments with pork and beef slaughter processes addressed the hazard of contamination of carcasses and parts with fecal matter, ingesta, and milk with a CCP and defined the CL as zero tolerance for these contaminants. The establishment's monitoring and verification record reviewed for the zero tolerance CCP deviations indicated that establishments implemented corrective actions consistent with 9 CFR 417.3. The OV's verification of establishments' HACCP system control measures were in accordance with the instructions and frequency specified in KT-2-1-3-D1. All official verification results are documented on hard copies and entered into the AFIS database discussed previously. Supervisory reviews capture the performance of OVs related to their HACCP system verification through document review as well as shadowing OVs when they conduct onsite compliance verification.

Regarding RTE products, the FSIS auditor verified the HACCP plan for fully cooked, not shelf stable products at one stand-alone RTE meat product establishment as well as at the two slaughter establishments that were producing RTE meat products under the same process category for United States export. The RTE beef and pork products these establishments produce include both post-lethality exposed (PLE) as well as non-PLE products. The FSIS auditor noted that the hazard analysis conducted by the establishments for these processes identified all

commonly known hazards associated with these processes and any hazard identified as likely to occur were addressed through a validated CCP with a corresponding CL. The FSIS auditor further verified that establishments producing PLE RTE products addressed hazard of *Lm* associated with the RTE products in the post-lethality process step by adopting one of the *Listeria* control alternatives consistent with 9 CFR 430.4. The FSIS auditor's review of the establishment's monitoring records related to the time and temperature combination indicated that lethality applied was achieving  $\geq 6.5$  log reduction of *Salmonella* in RTE pork and beef products. The requirements to adopt one of the *Listeria* alternatives to control *Lm* in PLE RTE products is contained in SFVS' Order No. B1-726 Permanent State Veterinary Supervision Code for Meat Production Companies Exporting Meat Products to the U.S.A.

The FSIS auditor's review of official verification records revealed that procedures and frequencies applied in HACCP system verification activities were in conformance with work instruction KT-2-3-2-D1. The OVs utilize the relevant annex of the instructions in KT-2-3-2-D1 to document the outcome of verification and requires corrective actions in the event the CCP deviates, or procedures are not in compliance with the requirements. The FSIS auditor reviewed the most recent supervisory reports at all three establishments producing RTE meat products for United States export. In addition to routine supervisory reviews, each establishment eligible to export to the United States is subject to a comprehensive annual HACCP audit by the HACCP system auditor of territorial units covering all processes and associated food safety programs. The FSIS auditor reviewed the recent audit reports generated at each certified establishment. The auditor's review of this component did not raise any concerns.

The FSIS auditor determined that SFVS requires establishments exporting products to the United States to develop, implement, and maintain a HACCP system for each processing category consistent with criteria established for this component.

## **VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS**

The fifth equivalence component the FSIS auditor reviewed was Government Chemical Residue Testing Programs. The food safety 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, or muscle of carcasses for chemical residues identified by the exporting country's meat products inspection authorities or by FSIS as potential contaminants.

SFVS' authority to monitor and control chemical residues in meat products is grounded in Lithuania's Law on Veterinary Activities (1991). NFVRAI, in collaboration with the VMFD, is responsible for preparing the annual residue monitoring plan (RMP). The plan takes into consideration EU regulations pertaining to the requirements for chemical residue contamination controls as stipulated in Council Directive 96/22/EC, Commission Decision 97/747/EC, Regulation (EC) No. 178/2002, and Regulation (EU) 2017/625. The monitoring plan for residues in foods of animal origin and in livestock is governed by SFVS' Order No. B1-62 (2022) Official control sampling plan for food and food contact materials and Order No. B1-67 (2022) Monitoring plan for certain substances and residues in food of animal origin and in live animals respectively. The annual plan is distributed to the TSFVS offices, which then assign sample

distribution among targeted facilities including livestock farms and slaughter facilities. In addition to the annual plan, SFVS collects follow-up samples in response to violative results or any time there is a suspicion of noncompliance.

In designing the RMP, the critical parameters considered include comments and recommendations received from EC and EU reference laboratories on the mid- and end-of-the-year plan and previous year plan; use of veterinary medicinal products; antimicrobial resistance data including data from RASFF; scientific opinion by EFSA; and the laboratory's capacity for testing and calibration. All violations are investigated per SFVS' Orders No. B1-646 (2003) On Approval of the Rules to Monitor Substances and Residues Thereof in Animals and Animal Products and B1-359 (2004) Instructions in the event of detecting an increased level of unauthorized residues of veterinary substances in animals or animal products, which instruct inspection personnel to perform an investigation on all violative residue samples and conduct traceback to the livestock producer.

The FSIS auditor verified through interviews with OVs, that sample schedules and supplies are received from the laboratory providing the specific details as to type of matrix (which may be urine, plasma, kidney fat, muscle, liver, kidney, or fat) for every sample to be submitted.

The FSIS auditor verified that the laboratory must inform the TSFVS offices as well as headquarters of any positive results per KT-1-5-D1 Actions to be Taken in the Case of the Determination of Residues in Live Animals, Milk, Eggs and Honey. It is the TSFVS office that issues official notifications of violation to farm or farmer. The notification of violation provides instructions to the livestock owner to segregate herds implicated in violative laboratory residue finding until SFVS investigation is completed due to public health risk. Repeat violators have their registration to supply animals for slaughter or animal products revoked.

Section 7 (9-c) of KT-2-3-2-D1 describes "test and hold" requirements pending acceptable test results. The procedure states that the establishments are not to use carcasses or parts thereof for further processing or place them on the market until satisfactory results of the laboratory tests have been obtained.

The FSIS analysis and remote verification activities indicate that SFVS continues to maintain overall authority for a chemical residue testing program which is designed and implemented to prevent and control the presence of veterinary drugs and contaminants in meat products exported to the United States.

## **IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS**

The last equivalence component the FSIS auditor reviewed was Government Microbiological Testing Programs. The food safety inspection system is to implement certain sampling and testing programs to ensure that meat prepared for export to the United States is safe and wholesome. This component also addresses requirements for TPCS meat products.

The FSIS auditor verified that the SFVS requires all slaughter establishments certified to export product to the United States to collect and analyze swine and cattle carcass samples for intestinal or fecal indicator organisms in accordance with the Commission Regulation (EC) No. 2073/2005 on microbiological criteria for foodstuffs. Lithuania requires testing for Enterobacteriaceae, which FSIS has determined to be equivalent to testing for generic *Escherichia coli* (*E. coli*) for monitoring process control. The slaughter establishments conduct testing for Enterobacteriaceae in conjunction with aerobic colony count following process hygiene criteria for frequencies and other testing requirements outlined in Chapter 2 of the Commission Regulation (EC) No. 2073/2005. In addition, FSIS auditor verified that establishments were conducting pre-evisceration and post-chill sampling of swine carcasses consistent with FSIS requirements in 9 CFR 310.18, as described in KT-2-3-2-D1. The FSIS auditor verified through document review and interviews with the OV's assigned to the slaughter establishments certified to export to the United States that inspectors routinely verify establishments' process control verification procedures which include a written program, criteria for evaluating the results, and procedures to identify any emerging trends when results exceed established criteria and corrective actions are necessary. No issues were identified as a result of auditor's verification.

Per section 11 of KT-2-3-2-D1, OV's collect *Salmonella* verification samples from beef carcasses at the establishments certified to export to the United States that are slaughtering this species in accordance with Commission Regulation (EC) No. 2073/2005 on microbiological criteria for foodstuffs. Five carcasses are sampled at random at the frequency of 60 samples each year, using an abrasive sponge method. Sampling requires swabbing 4 sites covering a minimum of 100 cm<sup>2</sup> (400 cm<sup>2</sup> total) each by following methodology described in ISO/IEC 17604. The OV's take samples per SFVS' sampling procedures described above and ship samples to the NFVRAI laboratory. The certificate of analyses reviewed by the FSIS auditor indicated that the official method of analysis for *Salmonella* in carcass samples is ISO 6579-1:2017. All official test results are available to SFVS and its TSFVS offices. When SFVS identifies unsatisfactory results, establishments must implement corrective actions and propose measures to prevent recurrence. The FSIS auditor verified through interviews with government inspectors that inspection personnel verify the establishment's corrective measures when an establishment fails to meet the performance standards for *Salmonella*. The OV's are knowledgeable of SFVS' *Salmonella* sampling program and verification activity requirements following unacceptable results.

The FSIS auditor verified through interviews with OV's and document review that SFVS considers any PLE RTE pork and beef products exposed to a food contact surface (FCS) that tests positive for *Lm* through either official sampling or establishment sampling to be adulterated and ineligible for export to the United States. SFVS defines RTE products as food intended to be consumed without the need for cooking or other processing and in which the processor has effectively eliminated or reduced microorganisms of concern to an acceptable level (in the case of RTE product exported to the United States, absence of *Lm* and *Salmonella*).

Section 7 of KT-2-3-2-D1 contains instructions to OV's for verifying control of *Listeria* which are consistent with procedures in FSIS Directive 10,240.4. The FSIS auditor verified that SFVS requires establishments producing PLE RTE products to conduct verification testing of FCS and non-FCS for *Lm* or *Listeria* species. Certified establishments must also test RTE products for *Lm* and *Salmonella* as well as *E. coli* O157:H7 if product contains beef as a component or is solely

made up of beef products. The FSIS auditor verified that all the certified establishments producing RTE products intended for export to the United States have defined the scope of their production lots for the purpose of maintaining microbiological independence of production lots so that if there is a positive sample result, all affected product can be identified and excluded from export to the United States.

In addition to requiring establishment verification testing, SFVS conduct official verification sampling of RTE products, food contact surfaces, and non-food contact surfaces for *Lm*. SFVS also tests RTE products for *Salmonella*, including non-PLE products. The FSIS auditor reviewed results of establishment and SFVS verification sampling and determined that products, food contact surfaces, and the post-lethality environment are being tested at the frequencies specified in the SFVS' instructions KT-2-3-2-D1. No concerns were identified with the SFVS' sampling verification activities regarding *Lm* and *Salmonella* in RTE meat products exported to the United States.

The FSIS auditor verified that RTE beef and pork products intended for export to the United States are held until satisfactory results of the analyses are received. The review of a selected sample of official test results indicates that the government laboratory uses LST (Lithuania Standards Board) EN ISO 11290-1:2017 method for detection of *Lm* in 25 g RTE product and *Listeria* species in swabs covering 930 cm<sup>2</sup> of FCS and non-FCS in the production area of establishments that produce PLE RTE products. The FSIS auditor verified that supervisory reviews conducted by senior OV's from the territorial units routinely capture the adequacy of establishment sampling plans and analytical results during their periodic review.

The SFVS issued Order No. B1-653 (2012) Order On Approval of Recommendations, which contains recommendations for certified establishments on how to ensure the adequate heat treatment and cooling of meat products. These recommendations ensure that heat application and product stabilization processes are consistent with FSIS Compliance Guidelines for Cooking (Appendix A) and Stabilization (Appendix B) of Fully and Partially Heat-Treated RTE and NRTE Meat and Poultry Products Produced by Small and Very Small Establishments.

Lastly, the FSIS auditor verified that SFVS requires the sole certified establishment producing TPCS products to comply with the government requirements that are consistent with FSIS requirements in 9 CFR 431, and the verification procedures that are adapted from FSIS verification procedures as outlined in FSIS Directive 7530.2. Government verification procedures on these requirements are contained in the relevant section of KT-2-3-2-D1. The FSIS auditor verified that SFVS oversees the performance of establishment's verification activities, ensuring that corrective actions and preventive measures are implemented when problems are identified. The FSIS auditor verified that the establishment implemented corrective actions in response to inadequacies of the TPCS program identified by FSIS during the previous audit in 2019. During this audit, FSIS auditor did not identify any concerns with production of TPCS products.

The FSIS auditor determined that SFVS maintains the overall authority to implement its microbiological sampling and testing programs to ensure that meat products exported to the United States are unadulterated, safe, and wholesome.

## **X. CONCLUSIONS AND NEXT STEPS**

An exit meeting was held September 27, 2022, by videoconference with SFVS. FSIS concluded that Lithuania's meat inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. The SFVS has required that establishments certified as eligible to export products to the United States implement sanitation requirements and a HACCP system designed to improve the safety of their products. In addition, SFVS has implemented official microbiological and chemical residue testing programs that are organized and administered by the national government to verify its system. An analysis of each component did not identify any systemic findings representing 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 Biovela-Utenos Mesa  UAB, Utena	2. AUDIT DATE 09/14/2022	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	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57.	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Pork slaughter and processing.
Prepared Products:	

60. Observation of the Establishment
41.
- Beaded condensation was noted over products at multiple locations in a boning room and a chiller. The inspector retained the product for evaluation and proper disposition.
  - Dripping water from a condenser was observed in a packaging room; no product was stored in the area.

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION  UAB, Krekenavos Agrofirma, Kėdainiai	2. AUDIT DATE 09/16/2022	3. ESTABLISHMENT NO. LT 53-02 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	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57.	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	

60. Observation of the Establishment
39. Est. Construction/Maintenance
  - Rusty rails covered with overly dried grease were seen at multiple locations including processing rooms, chillers, and on slaughter lines.
41. Ventilation
  - Beaded condensation was observed on a conveyor belt and a surrounding structure above boning line as beef carcasses were being processed. Dripping condensation was also seen in a RTE finished product chiller as well as in the formulation room.
46. Sanitary Operations
  - The container for edible pork fat placed underneath the kill line was collecting drippage from the slaughter waste into the container. A similar practice was also noted during beef slaughter operation where beef hearts were being harvested into a container placed underneath the line carrying uninspected hides-on beef heads to the head inspection line.
  - On the swine evisceration floor, the auditor observed that head/and or other parts of carcasses were rubbing against a final wash cabinet which was not in use. The wash cabinet was removed while the audit was still in progress.
  - One bovine carcass chiller observed was packed to the extent that it obliterated inspection to all areas in the chiller. Foreshanks of many carcasses in the same chiller were rubbing against the chiller walls.
  - In the same establishment, the overcrowding of product was seen in the RTE products storage where neither the auditor nor the OV were able to access all parts of the storage cooler. The establishment corrected the problem while the auditor was still on site.

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION  Orka foods, Plungės	2. AUDIT DATE 09/20/2022	3. ESTABLISHMENT NO. LT 68-05 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	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	O
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57.	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

Establishment Operations:	Pork and Beef processing.
Prepared Products:	RTE fully cooked not self stable

60. Observation of the Establishment

There were no significant findings to report after consideration of the nature, degree, and extent of all observations.

## **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: Dr. Michelle Catlin  
International Coordination Executive  
Office of International Coordination  
Food Safety and Inspection Service  
United States Department of Agriculture  
1400 Independence Avenue S.W.  
Washington, D.C. 20250

*14-* 01-2023 No B6-(1.20.)-91

**Subject: COMMENTS REGARDING THE INFORMATION IN THE DRAFT FINAL AUDIT REPORT FOR LITHUANIA**

Dear Dr. Catlin,

Thank you for your letter dated 24 December 2022, and for provided copy of the draft final audit report. I would hereby like to present a few comments on the draft final audit report provided by the State Food and Veterinary Service (SFVS):

**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)**

*On page 10, last paragraph:*

The FSIS auditor reviewed the recent supervisory reviews conducted in Utena and Kunas' TSFVS. The reviews are conducted by the senior official veterinarian stationed in the TUs within their respective TSFVS. The frequency of the supervisory reviews is based on a classification of establishments into three risk categories: high, medium, and low. Currently, all certified establishments fall into the low-risk category and receive a yearly supervisory visit which could change to a higher frequency if warranted.

*We suggest some corrections to the text above:*

The FSIS auditor reviewed the recent supervisory reviews conducted in Utena and Kaunas' TSFVS. The reviews are conducted by the senior official veterinarian stationed in the TUs within their



respective TSFVS. The frequency of the supervisory reviews is based on a classification of establishments into three risk categories: high, medium, ~~and~~ low, *and very low*. Currently, all certified establishments fall into the ~~low~~ *high*-risk category and receive a yearly supervisory visit which could change to a higher frequency if warranted.

**Appendix A: Individual Foreign Establishment Audit Checklists**

*On page 24, point 1 ESTABLISHMENT NAME AND LOCATION:*

Biovela-Utenos Mesa EAB Utenos

*It should be corrected to:*

*Biovela-Utenos Mėsa, UAB, Utena*

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



Audronė Mikalauskienė