



United States Department of Agriculture

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Food Safety and  
Inspection Service

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OCT 7 2014

Dr. Jonas Milius, Chief Veterinary Officer  
Director of the State Food and Veterinary Service  
Republic of Lithuania  
Siesiku Str. 19, LT - 07170 Vilnius -10  
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Dear Dr. Milius:

The Food Safety and Inspection Service (FSIS) conducted an initial equivalence follow-up audit of Lithuania's meat inspection system in the period from September 16 - 24, 2013. Lithuania's comments to the FSIS draft final audit report has been attached to the audit report. Please find attached a copy of the final audit report. The final report will be posted on the FSIS web site.

If you have any questions regarding the FSIS audit or you need additional information, please contact me at telephone number 202-720-0082, facsimile number 202-720-7990, or by e-mail at [internationalequivalence@fsis.usda.gov](mailto:internationalequivalence@fsis.usda.gov).

Sincerely,

A handwritten signature in blue ink that reads "Keller".

Andreas Keller  
Director, International Equivalence Staff  
Office of Policy and Program Development

FINAL REPORT OF AN INITIAL EQUIVALENCE FOLLOW-UP AUDIT

CONDUCTED IN

LITHUANIA

September 16 - 24, 2013

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING  
THE PRODUCTION OF MEAT PRODUCTS INTENDED FOR EXPORT  
TO THE UNITED STATES OF AMERICA

Food Safety and Inspection Service  
United States Department of Agriculture

## **Executive Summary**

This report describes the outcome of an initial equivalence follow-up audit of Lithuania's meat inspection system conducted by the Food Safety and Inspection Service (FSIS) from September 16 to 24, 2013. The objective of the audit was to verify whether Lithuania employs meat system equivalent to that of the United States (U.S.), with the ability to produce meat products that are safe, wholesome, unadulterated, and properly labeled. This audit was necessary to assess the effectiveness of the implementation of the corrective action plan proffered by Lithuania in response to the findings related to the previous FSIS initial equivalence on-site audit conducted from September 10 to 26, 2012.

This follow-up audit focused on the ability of the State Food and Veterinary Service (SFVS), the Central Competent Authority (CCA), to implement effective inspection and control programs related to the production and export of meat products to the U.S. The auditor focused on the following six equivalence components: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Point Systems, (5) Chemical Residue Programs, and (6) Microbiological Testing Programs. The auditor also verified the adequacy and effectiveness of the corrective actions measures implemented by the CCA to address the findings of the previous audit which was conducted in 2012.

The CCA addressed all the findings related to the previous FSIS initial equivalence on-site audit by developing a comprehensive corrective action plan. FSIS evaluated Lithuania's results from this plan and concluded that the corrective actions, as documented, satisfactorily addressed the previous initial equivalence audit findings. The auditor verified during this audit that the SFVS had effectively implemented the proffered corrective action plan, and that Lithuania met the equivalence criteria for all six components.

The auditor identified the need for improvement in two areas within the inspection system. First, inspection personnel need to verify that the establishment's HACCP system is ensuring that all portions of carcasses are free of visible contamination with fecal material, milk, or ingesta. Establishment and inspection personnel should not just focus on those portions of product that are intended for export to the U.S. Second, the auditor identified a need for the inspection system to establish stronger controls over the movement of personnel and materials in establishments that produce Ready-to-Eat (RTE) product. Attentive response to FSIS's observations will prevent cross-contamination of raw meat products during slaughter and of RTE product in the post-lethality environment. FSIS's observations were made to highlight areas of potential improvement and to document the CCA's commitment to meeting the requirements that must be met to export meat and meat products to the U.S.

In response to the observations that FSIS made during the follow-up audit, the CCA's proposed actions included measures to ensure immediate adjustments to the establishments' HACCP systems and sanitation programs, introduction of correlation sessions for supervisory personnel to reinforce their understanding of food safety tasks related to requirements for export to the U.S., and preventive maintenance policies and plans intended to enhance performance of the food safety and verification activities through introduction of on-going training programs for the inspection program personnel. The CCA implemented its corrective action plan and provided supporting documents during and after the exit meeting. The FSIS auditor was able to verify that SFVS has adequately implemented its corrective action plan and addressed the two observations with an immediate action and preventive measures.

Based on the analysis of the corrective actions taken by the SFVS in response to the findings of the initial equivalence audit conducted in 2012 and the results of the current follow-up audit, FSIS has determined that the CCA has adequately addressed all identified issues of concern and is able to meet FSIS equivalence criteria and requirements related to all six components. There is no need to conduct an additional follow-up audit.

FSIS's evaluation of all data collected before, during, and after the on-site audit supports that the Lithuanian meat regulatory system achieves the level of protection required by the U.S.'s meat inspection system. Therefore, FSIS will move forward with proposing a regulation to list Lithuania as a country eligible to export meat and meat products to the U.S.

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## ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

BSE	Bovine Spongiform Encephalopathy
CCA	Central Competent Authority
CFR	Code of Federal Regulations
CVO	Chief Veterinary Officer
EC	European Commission
EU	European Union
EU-RLs	European Union Reference Laboratories
<i>E. coli</i>	<i>Escherichia coli</i>
FSIS	Food Safety and Inspection Service
IES	International Equivalence Staff
<i>Lm</i>	<i>Listeria monocytogenes</i>
MLA	Minimum Level of Applicability
NFVRAI	National Food and Veterinary Risk Assessment Institute
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point
QMS	Quality Management System
RTE	Ready-to-Eat
<i>Salmonella</i>	<i>Salmonella</i> species
SFVS	State Food and Veterinary Service
SRMs	Specified Risk Materials
SPS	Sanitation Performance Standards
SSOP	Sanitation Standard Operating Procedures
STEC	Shiga Toxin–Producing <i>Escherichia coli</i>
TSFVS	Territorial State Food and Veterinary Service
QMS	Quality Management System
VI	Veterinary Inspector

## **1. INTRODUCTION**

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an initial equivalence on-site follow-up audit of Lithuania's meat inspection system from September 16 to September 24, 2013. This follow-up audit was conducted to complement the initial equivalence audit conducted in 2012 and to reassess the inspection system after the implementation of corrective actions in response to the findings of the previous audit. The follow-up audit began with an entrance meeting on September 16, 2013, in Vilnius, Lithuania, with the participation of representatives from the Central Competent Authority (CCA), the State Food and Veterinary Service (SFVS), and the Embassy of the United States in Lithuania. The FSIS auditor was accompanied throughout the audit by representatives from the SFVS at the central and territorial levels.

## **2. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY**

The objective of the initial equivalence follow-up audit was to verify the adequacy of the control exercised by the CCA over the implementation of the corrective action plan proffered in response to the findings of FSIS audit conducted from September 10 to 26, 2012. The audit also was designed to determine whether the food safety system governing meat inspection is equivalent to that of the United States' inspection system. Before conducting the audit, the auditor reviewed the proffered corrective action plan and supporting documents provided by the CCA in response to the previous audit findings. These documents included descriptions of the new control measures and procedures adopted by Lithuania's meat inspection system.

The audit focused on the CCA's performance in addressing six equivalence components: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Point Systems (HACCP), (5) Chemical Residue Programs, and (6) Microbiological Testing Programs. Because some of the findings FSIS made during its 2012 audit pertained to microbiological testing and the government's oversight of the laboratory system, these findings are addressed in this report under both the government oversight and microbiological testing program equivalence components.

The administrative functions of sampling and testing were assessed through a review of records at the CCA's headquarter office in Vilnius and two territorial inspection offices. Further assessments were conducted through observations and document review at the central laboratory, one regional laboratory, and three local inspection offices located within three different slaughter and processing establishments. During the review of the CCA offices at the Headquarters and territory levels, the FSIS auditor evaluated the implementation of the management control systems established to ensure that the national inspection system and verification and enforcement strategies are implemented as intended. The review of the administrative functions of the local inspection offices was conducted as part of the establishment reviews.

FSIS reviewed the inspection operations at three slaughter and processing establishments to determine whether the CCA is able to provide effective government oversight and consistent inspection measures across different regions to meet FSIS equivalence's criteria. The selected establishments, which are located within two different territorial SFVS offices, were identified by the SFVS as establishments intended to be certified to export meat and meat products derived

from bovine and swine to the U.S. The selected establishments produce raw and RTE products within the processing categories intended for export to the U.S.

In order to determine the effectiveness of the coordination between the different components of the CCA, the auditor looked closely at the CCA's ability to provide oversight through supervisory reviews conducted in accordance with the requirements of 9 CFR 327.2. In addition, the auditor paid particular attention to the extent to which industry and government interact to control public health hazards and meet the equivalence standards and other FSIS import requirements.

Furthermore, the FSIS auditor conducted a review of two official laboratories that perform microbiological and residue testing. The review was intended to verify that the testing that the laboratories perform is equivalent to FSIS's testing programs. The auditor reviewed the National Food and Veterinary Risk Assessment Institute (NFVRAI) in Vilnius and one Kaunas territorial laboratory. The review of NFVRAI, which functions as a reference laboratory, focused mainly on microbiological testing programs but also included verification of the residue control programs. The review of Kaunas Territorial Laboratory focused on the microbiological testing programs.

### Audit Scope Summary

Competent Authority Visits		No	Locations
Competent Authority	Central	1	<ul style="list-style-type: none"> <li>State Food and Veterinary Service (SFVS) - CCA Headquarters office (Vilnius).</li> </ul>
	Territorial offices	2	<ul style="list-style-type: none"> <li>Utena Territorial SFVS Office</li> <li>Šilalė Territorial SFVS Office</li> </ul>
	Local offices ( <i>In-plant Level</i> )	3	Reviews were conducted as part of the establishment reviews at Utena, Vilnius, and Šilalė.
Government Laboratories ( <i>Microbiological testing programs and Residue testing programs</i> )		3	<ul style="list-style-type: none"> <li>National Food and Veterinary Risk Assessment Institute (NFVRAI) (Vilnius)</li> <li>NFVRAI Territorial Laboratory (Kaunas)</li> </ul>
Establishments <ul style="list-style-type: none"> <li>Meat Slaughter and processing</li> <li>Meat Processing</li> </ul> <p style="text-align: center;">Total</p>		<p style="text-align: center;">1</p> <p style="text-align: center;"><u>2</u></p> <p style="text-align: center;">3</p>	<ul style="list-style-type: none"> <li>Est. LT 17 EB UAB "Utenos mėsa" Pramonės str. 4, Utena (<i>Slaughter-Bovine/Swine, Processing Raw, RTE</i>)</li> <li>Est. LT 87-16 EB UAB "Grimeda" Džiaugėnų k., Šilalės r. (<i>Thermal processing commercial sterile-canning</i>)</li> <li>Est. LT 41-23 EB, UAB "Biovela" Dūkštų vil., Vilniaus r. (<i>Processing fermented RTE products</i>)</li> </ul>

### 3. LEGAL BASIS FOR THE AUDIT AND AUDIT STANDARDS

This initial equivalence follow-up audit was conducted under the following U.S. laws and regulations:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.)
- The Federal Meat Inspection Regulations (9 CFR parts 301 to end)
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901-1906)

The audit standards included all applicable regulations and procedures tentatively determined to be equivalent by FSIS during the initial document review process. The legislation and regulations reviewed included:

- European Commission (EC) Regulations: (EC) No 852/2004; 853/2004; 854/2004; 882/2004; 178/2002; 2073/2005; and Council Directive 96/22/EC and 96/23/EC;
- Lithuania's national legislation concerning food safety: Law of Product Safety; Law on Veterinary Activities; Law on Food; Law on Pharmaceutical Activities; Law on Pharmaceuticals; Animal Health and Animal Welfare Rules; Law on Labor Protection; Law on Safeguarding the Rights of Consumers; Law on Advertising and labeling; and the Resolution of the Government of the Republic of Lithuania on the approval of the Statute of State Food and Veterinary Service;
- U.S. regulations and control measures adopted by Lithuania. The SFVS Director Order No B1-529 delineated legislative commitment homologous to the standards addressing the lethality and stabilization requirements for cooked products as described in 9 CFR 318.17; and the SFVS Director Order No B6-508 delineated legislative commitment homologous to the control programs for *Lm* in Ready-to-Eat (RTE) products as described in 9 CFR 430.

#### 4. BACKGROUND

Lithuania is a member of the European Union (EU) and is not eligible to export meat, poultry, or egg products to the U.S. At the time of the audit, the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) considered Lithuania to be free of African Swine Fever (ASF), Swine Vesicular Disease (SVD), Rinderpest and Foot-and-Mouth Disease (FMD). APHIS, however, placed Lithuania in a special category because of Lithuania's common land border with countries that have not been identified to be free of the above-identified animal diseases, and because Lithuania's trade practices are less restrictive than those acceptable to the U.S. These trade practices could result in a meat supply that is supplemented by imported fresh, chilled, or frozen meat from ruminants or swine from neighboring countries. APHIS considered Lithuania to be free of Bovine Spongiform Encephalopathy (BSE). Therefore, if granted equivalence, without any changes to the animal disease status, Lithuania will be eligible to export raw meat products, including meat products derived from beef to the U.S. Lithuania will be required to address APHIS's animal disease restriction through certification and other measures that meet regulatory requirements described in 9 CFR 327.4. Since Lithuania's disease status may change during the equivalence process, FSIS will follow-up with APHIS and consider how any change in the animal disease status may impact the country's eligibility to export certain types of products to the U.S.

In Response to Lithuania's application for initial equivalence for meat and meat products, FSIS conducted a document review and analysis to determine whether Lithuania's meat inspection system meets the equivalence requirements as set out in 9 CFR 327.2. The review, which was based on the equivalence criteria established for FSIS's six equivalence components, did not identify any major deficiencies within the design of the inspection system. Therefore, FSIS concluded that Lithuania's laws, regulations, control programs, and procedures cumulatively achieve the level of public health protection required by FSIS. The decision to proceed with the initial equivalence follow-up audit of the inspection system was made to verify that the CCA is able to effectively implement the laws, regulations, and control programs found to be equivalent during the initial review process.

The previous [report of FSIS initial equivalence on-site audit of Lithuania's meat inspection system](#) conducted from September 10 to September 26, 2012 and posted on FSIS website

concluded that the CCA was able to meet the requirements of component (5) Chemical Residue Testing Programs although FSIS identified that the residue control program as implemented did not ensure that the analytical method used by the Klaipeda territorial laboratory to analyze meat samples for pesticide residue can reach the Minimum Level of Applicability (MLA) applied by FSIS for the same kind of analysis. The 2012 audit found, however, that the CCA did not meet the requirements for component (3) Sanitation because modification to its inspection requirements deviated from the information provided during FSIS's document review. The modification resulted in omission of mandate for establishments seeking certification to develop and implement written SSOPs. All establishments visited during the audit were implementing SSOPs in accordance with the old version of the Lithuanian regulatory requirements.

Furthermore, FSIS's initial equivalence audit of September 2012 concluded: 1) The SFVS did not maintain specific procedures underpinning the determination whether an establishment is eligible for export to the U.S; 2) The supervisory reviews did not adequately focus on the competence of the inspection program personnel, and did not emphasize on pathogen control programs, post-mortem inspection, and proper labeling of inedible product receptacles; 3) The SFVS did not verify that establishments' SSOP and HACCP corrective actions included measures to prevent recurrence, and in many instances, the SFVS did not ensure proper documentation of the establishments' monitoring or verification records; and 4) Deficiencies were identified at audited laboratories related to testing for *E. coli* O157:H7 and other Shiga Toxin-Producing *Escherichia coli* (STECs), including method validation, sample size, and incubation practices.

The CCA provided corrective action plan that adequately addressed all FSIS previous audit findings. The proffered corrective action included new regulations, procedures, implementation measures, and verification activities that ensure uniformity in conducting the official inspection activities. Consequently, FSIS decided to conduct a follow-up audit to assess the effectiveness of the implemented corrective action measures. This follow-up audit focused mainly on verifying the implementation of the corrective action taken to address previous audit findings rather than the aspects of the inspection system that were determined to be meeting FSIS's equivalence criteria.

## **5. GOVERNMENT OVERSIGHT**

The first of the six components reviewed by the FSIS auditor was Government Oversight. This component addresses the requirement for the inspection system to be organized and administered by the national government and employ standards equivalent to those of the federal system of meat inspection in the U.S. The evaluation and verification of these requirements were carried out through interviews of government officials and reviews of inspection records and indicated that the SFVS met the requirements for this component.

The State Food and Veterinary Service (SFVS) is Lithuania's CCA that administers meat inspection regulations. The director of the SFVS is the Chief Veterinary Officer (CVO) who is accountable to the Government of the Republic of Lithuania and the Minister of Agriculture. Lithuania's CCA consists of SFVS headquarters in Vilnius, 51 Territorial SFVS (TSFVS) offices dispersed throughout the country, and supporting laboratory system. TSFVS are responsible for implementing the inspection activities through the assignment of inspection personnel at

regulated establishments. The results of the inspection activities are reported to both levels of SFVS. The evidence gathered during FSIS audits demonstrates that SFVS has ultimate control and supervision over the official activities of all program employees or licensees.

FSIS' reviews of the oversight activities carried out at the HQ and at territorial offices indicated that the CCA has a single set of rules; the CCA has legal authority and responsibility to enforce inspection regulations; and the CCA enforces requirements that ensure adulterated or misbranded products not be exported to the U.S. 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 instruction for the implementation of the inspection activities and ensures that an adequate level of coordination 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; sets the frequency of supervisory reviews; establishes procedures for registration, approval, conditional approval, or suspension and withdrawal of regulated establishments; sets the scope and method of carrying out sampling and testing under the national residue control plan; and provides instructions for execution of the microbiological testing and verification programs. The CCA disseminates information related to the regulatory and administrative affairs electronically by e-mail or on intranet site. FSIS auditor verified that issuances related to the inspection procedures were implemented in accordance with the applicable standards which include the U.S.'s requirements.

The SFVS has the legal authority and responsibility to certify and de-certify any of the registered establishments for export to any third country, including the U.S. During the previous FSIS audit, FSIS determined that SFVS did not possess specific underpinning procedures to determine eligibility requirements and certify or decertify establishments based on their ability to fully comply with all of the requirements applied to official establishments in the U.S and otherwise meet the requirements of 9 CFR 327.2(a). In response to the previous audit finding, the SFVS issued and implemented a new procedure for certification of establishments seeking eligibility to export meat products to the U.S. The review process is conducted in accordance with SFVS Director Order No B1-684. During this audit, FSIS verified that SFVS has communicated the certification requirements to all levels of the inspection system and to regulated establishments that requested certification for export of meat products to the U.S. Under the procedure, as implemented, the CCA verifies that official establishments meet necessary requirements to become eligible to export product to the U.S. The written SFVS procedure explains the phases of the process and the types of enforcement actions, including delisting, taken in response to non-compliance encountered during periodic review process. During the audit, FSIS auditor reviewed the establishments' and the inspection program records related to the processing of the establishments application for certification. This review included non-compliances identified during official review of the establishment operation as well as corrective actions taken to address findings and meet regulatory and Lithuania's export requirements for the U.S.

FSIS verified that SFVS takes enforcement action in response to an establishment's failure to comply with the regulatory requirements or an establishment's inability to take necessary measures that prevent contamination or adulteration of products. The enforcement procedure is

based on Regulation (EC) 882/2004, QMS procedure for restrictive measures for placing foodstuffs on the market, the Resolution of the Government of the Republic of Lithuania No 744 on “the approval of the Statute of State Food and Veterinary Service,” and Procedure for issuing veterinary documents as described in Chapter VI, points 41 and 42 of the SFVS Director Order No B1-288. The FSIS review of the composite noncompliance reports, periodic supervisory reviews documentation, and documented enforcement actions indicated that the CCA has measures that ensure consistent enforcement of regulations.

The FSIS audits of Lithuania’s meat inspection system showed that the CCA has adequate administrative and technical support to operate its inspection system. The National Food and Veterinary Risk Assessment Institute (NFVRAI), which provides the technical support for the inspection system, consists of the central laboratory and five territorial laboratories located in Klaipeda, Panevėžys, Šiauliai, Kaunas, and Telšiai. The laboratory system reports directly to the SFVS Headquarters and carries out all official chemical residue and microbiological testing programs. FSIS auditor verified that SFVS has the legal authority and responsibility to approve or disapprove laboratories engaged in analytical testing on regulated products in accordance with Article 12 of Regulation (EC) No 882/2004, and Resolution of the Government of the Republic of Lithuania on “the approval of the Statute of State Food and Veterinary Service.” The CCA ensures and verifies, through the NFVRAI supervisory control, that certified laboratories and territorial units meet EN ISO/IEC 17025 standards, properly analyze product destined for the U.S., and participate in proficiency testing schemes for food analysis with overall successful results. Lithuania’s laboratory system uses an electronic database system that enables all levels of SFVS to review and manage data and results of the sampling programs. During the audit, the FSIS auditor verified, through records review, that the CCA exercises adequate control over the laboratory system and takes measures to address deficiencies identified during internal and third party audits of the laboratory system.

This follow-up audit verified that SFVS implements measures to ensure that meat products meet the specific product equivalence standards such as lethality requirements and stabilization performance standards for certain meat products; retained water in raw meat products; product standard of identity; identification and separation of inedible materials such as lungs and thyroid gland; and removal of the Specified Risk Materials (SRMs) in accordance with the SFVS Director Order No B1-252 “Amendment of the SFVS Director Order No B1-189 on approval of the requirements on handling animal byproducts in animal food handling businesses.” Furthermore, establishments are required to ensure that food intended for human consumption that is placed on the market or is likely to be placed on the market, is adequately labeled or identified to facilitate its traceability through relevant documentation or information collected in accordance with the regulatory requirements established under Article 18 for Regulation (EC) No 178/2002. The identification and labeling requirements include, at least, the source of food, animal byproduct, or ingredients in a manner that support the conduction of effective investigation and traceability.

The FSIS auditor visited SFVS headquarters in Vilnius and two territorial SFVS offices to assess the CCA’s ability to effectively communicate the inspection requirements to the inspection program personnel. The implementation of these requirements was assessed at three slaughter and processing establishments through interviews of program supervisors, review of the

establishments' and inspection records and observation of the inspection and verification procedure conducted by the inspection personnel. The review of the ante-mortem inspection and the humane handling of animals were carried out as prescribed by Article 5 of Regulation (EC) No 854/2004, Law on Veterinary Activities, Animal Welfare and Protection Act, and Lithuania's Standard operating procedure of the Quality Management System QMS KT-2-1 "General requirements to perform inspections" and KT-2-2-1 "Control program for meat and meat product handling enterprises." The inspection procedures as carried out by an official veterinarian or by a veterinary inspector, under direct supervision of official veterinarian, were properly documented in official inspection forms. The SFVS uses QMS procedure KT-2-1-3-D1 to address handling of non-ambulatory disabled cattle, which ensures that meat products derived from non-ambulatory disabled cattle, will not be destined for the U.S. FSIS auditor verified that post-mortem inspection is conducted by official veterinarians, and documented in paper records in accordance with Article 5 of Regulation (EC) No 854/2004, Law on Veterinary Activities; the Order of the SFVS Director No B1-252 titled "Amendment of the SFVS Director Order No B1-189 on the approval of the requirements on handling animal byproducts in animal food handling businesses"; and QMS, KT-2-1 "General requirements to perform inspections."

During the previous FSIS audit, it was determined that inspection program personnel: 1) incised and examined only the left side submaxillary lymph node on swine heads; 2) did not routinely ensure that bovine kidneys were removed from their capsule to ensure proper visual examination and palpation of these organs; and 3) did not ensure that regulated establishments use receptacles bearing conspicuous or distinctive marking to identify its permitted uses. In response to FSIS audit findings, the SFVS Director issued Order No B4-65, "Official veterinary supervision in pig and cattle slaughterhouses," and organized a three-day training session that included a theoretical part and a practical part in a slaughterhouse. The training program, which was delivered by an international training group, delivered training for 25 official inspectors on post-mortem inspection procedure. Furthermore, the SFVS scheduled and completed another training session in the third quarter of 2013, and both training sessions serve as an on-going annual training for the inspector program personnel performing post mortem inspection in the slaughterhouses. The annual ongoing training program is conducted in collaboration with the Lithuanian University of Health Sciences.

During this audit, the FSIS auditor reviewed the inspection personnel's training records at the headquarters, territorial, and local inspection offices. The training records are used to ensure the assignment of competent qualified inspectors at certified establishments and to increase the effectiveness of the CCA's ongoing plan to continuously analyze and implement the staffing requirements at certified establishments. FSIS reviewed Lithuania's corrective action plan related to the competency of the inspection staff and concluded that the SFVS had satisfactorily addressed the audit findings. The CCA demonstrated that it has the ability to provide specialized, ongoing training to its inspection personnel assigned to official certified establishments in specific U.S. import requirements. The auditor's direct observations of the inspection activities and interviews with the inspection personnel, conducted during this audit, showed that the inspection system has competent, qualified inspectors assigned to official establishments that will export products to the U.S.

Additionally, FSIS previous audit indicated that the supervisory reviews did not focus adequately on the competency of the inspection program personnel and did not emphasize pathogen control programs and enforcement of the inspection program requirements. In response to the audit finding, the CCA amended QMS procedure KT-2-3-2-D1 “Daily Veterinary Supervision of Animal Food Handling Businesses which Export their Produce to USA.” The amendment obligates official veterinarians to conduct quarterly supervisory reviews to verify proper implementation of the testing programs for *Salmonella* and STECs in raw product, *Salmonella* and *Lm* in RTE products, and *E. coli* O157:H7 in semi-dry or fermented meat products containing bovine tissue when applicable. FSIS’s review conducted during this audit included observation of the performance of the inspection personnel and their ability to implement inspection activities including specific U.S. requirements, interviews of supervisors, and review of supervisory records. The auditor’s review during this audit found that periodic supervisory reviews were conducted according to the specified frequency on all inspection personnel. Furthermore, the supervisory reviews placed emphasis on the competency of the inspection program personnel and identified potential training needs of the inspection personnel. The results of the supervisory review were found to be consistent with the knowledge of the inspection personnel.

FSIS’s assessment of the CCA’s ability to implement the corrective action related to effective supervisory reviews being conducted. The auditor found that the SFVS had satisfactorily addressed the audit findings. It was evident to the auditor that Lithuania’s inspection system is attaining more consistency in applying regulatory requirements throughout the meat inspection system and ensuring the competency of the inspection program personnel. FSIS’s follow-up audit found that the SFVS has ultimate control and effective supervision over the official activities of inspection program employees and provides for periodic supervisory review that focuses on the competency of the inspection program personnel and places special emphasis on the control of biological pathogens.

FSIS review of the periodic internal control audit reports and other oversight reports that were prepared before this audit was conducted revealed that the SFVS provided direct and continuous inspection of the meat slaughter and processing establishment. The FSIS auditor verified that the SFVS takes measures to ensure proper separation of domestic product from products intended for export and verified that the inspection system has a procedure in place to verify that the final product meets the requirements of the importing countries.

FSIS auditor verified that the SFVS maintains ultimate control over regulated establishments in accordance with standard operating procedure of the QMS KT-2-2-1 “Program for control of meat and meat processing establishments,” and points 1-16 of Annex 3 of the Standard Operating Procedure of the QMS KT-2-1-D1 “Official veterinary supervision and official veterinary control of entities handling food of animal origin.” Each day, an assigned official veterinarian assesses the overall sanitary and hygiene condition of the premises and equipment. According to SFVS instructions, inspection program personnel use Form KT-2-2-1 “Program of control of meat and meat products handling companies” to document the daily inspection and verification activities.

During this audit, FSIS auditor reviewed the inspection records, interviewed supervisory personnel, and determined that inspection program personnel receive, review, and understand applicable inspection program procedures. Inspection personnel assigned at visited establishments were found to be knowledgeable about relevant EC regulations, national legislation addressing implementation, and export requirements such as removal of SRMs.

FSIS auditor observations and reviews of inspection program records during the audit indicated that the CCA has administrative controls to support its inspection system and was consistently enforcing applicable regulations and properly addressing findings identified during the previous audits. Therefore, FSIS determined that SFVS meets the equivalence criteria for the Government Oversight component.

## **6. STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS**

The second of the six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. This component pertains to the legal authority and the regulatory framework used by the CCA to impose control measures equivalent to FSIS's requirements related to ante-mortem inspection, humane handling of livestock, post-mortem inspection of carcasses and parts, requirements concerning condemned materials, requirements concerning establishments construction, facilities, and equipment, daily inspection, and periodic supervisory visits to official establishments to ensure implementation of equivalent measure to those governing the meat inspection system as organized and maintained in the U.S.

This audit verified that the SFVS has the legal authority and the regulatory framework to impose regulatory requirements related to humane handling, ante-mortem, and post-mortem inspection, control over the establishment construction and processes, measures to ensure that supervisory reviews emphasize the oversight related to competence of the inspection program personnel related to essential inspection components and to the establishments' control of pathogens such as *Lm* and *Salmonella* in RTE product, and testing for *E. coli* O157:H7 and other STECs in raw non-intact beef products. SFVS holds the product if inspectors have a reason to believe that food is unsafe or adulterated. The measures employed by SFVS were found to be equivalent to those governing the U.S. meat inspection system and thus meet the equivalence criteria for the Statutory Authority and Food Safety Regulations component.

During the previous audit, FSIS found that the CCA has erroneously dropped a legislative article that authorizes the CCA to require establishments to develop and maintain SSOPs as a condition for gaining certification to export meat products to the U.S. In response to the audit finding, the CCA issued SFVS Director Order No B1-795, "Requirements of sanitation standard operating procedure," to reestablish the regulatory requirement. FSIS auditor verified that SFVS has communicated the SFVS Director Order No. B1-795 to all inspection program personnel, took effective measures to ensure continuous compliance with the regulatory requirements, and instituted measures to ensure that the veterinary supervisors and the Internal Audit Department of SFVS has added this requirement into the audit plan for establishments seeking certification for export of meat products to the U.S. Furthermore, FSIS verified that the inspection system has established official procedures to verify that each establishment has an effective sanitation program that meets the requirements of Regulation (EC) No 852/2004, Chapter I, Article 1; Regulation (EC) No. 853/2004 Article 4; Lithuania's Hygiene Norm HN-15"Hygiene of

Foodstuffs”; and the SFVS Director Order No B1-795 which reinstated the establishments’ responsibility to develop and implement SSOPs.

The inspection system enforcement program is described in QMS procedure KT-1-2 “Manual of Administrative Sanctions under the Administrative Code”, and Application Procedure of Restrictive Measures to Place Foodstuffs on the Market, and other applicable regulations. The enforcement program includes action such as suspension and withdrawal of inspection that might be taken when the establishments fail to prevent product contamination or take adequate corrective actions. The SFVS has authority to take measures to restrict marketing of product, if the safety of the products could not be verified, or when there is reason to believe that a production lot of meat product presents a serious and immediate risk to consumers’ health.

FSIS verified that the SFVS has reinstated and implemented the legislation that authorizes the CCA to require establishments to develop and maintain SSOPs, as a condition for gaining certification to export meat products to the U.S. The review and analysis of all relevant regulations and procedures resulted in a conclusion that the SFVS meets the requirements for this component.

## **7. SANITATION**

The third of the six equivalence components that the FSIS auditor reviewed was Sanitation. This component requires that the inspection system provide for measures to address the sanitation operation requirements, the sanitary handling of products, as well as the development and implementation of sanitation standard operating procedures (SSOPs). Lithuania’s meat inspection system requires that each official establishment meet all the sanitation requirements. The review and analysis of the relevant regulations, verification procedures, inspection records, and other relevant documents indicated that SFVS is equivalent to the FSIS for this component.

FSIS assessed the inspection system’s ability to meet the requirement of this component at SFVS headquarters in Vilnius, two TSFVS offices, and three slaughter and processing establishments. The FSIS auditor reviewed the regulation, and instructions issued to ensure proper implementation of the requirements, and assessed the CCA’s ability to communicate these requirements throughout the inspection system to ensure proper implementation of the official control and verification procedures and the execution of an effective sanitation program.

The FSIS auditor assessed the CCA’s ability to implement the regulatory requirements for the sanitation system at the establishment level. The review included review of the inspection records, the establishment’s sanitation monitoring records, documented corrective actions, training programs for establishment employees, and assessment of the actual sanitary conditions in the production areas. The FSIS auditor verified that each official establishment is operating in a manner that prevents creation of insanitary conditions and is maintaining a written SSOP to prevent direct product contamination or adulteration. The Sanitation Control Procedure document (PR-12) outlines the operational regulations and procedures that have to be implemented in official establishments. These procedures include a register of Premise Cleaning Control (PR-111-F-01) and Premise Cleaning and Disinfection Scheme (PR-112-F-04). In addition, there are written procedures that address the cleaning and disinfection process and the maintenance and improvement of sanitary conditions through assessment of establishment’s

hygienic practice and condition of premises. All visited establishments were found to be maintaining daily records that document the implementation and monitoring of the SSOPs and taking measures to prevent product contamination and adulteration.

The inspection program personnel were found to be conducting verification activities that consist of a combination of document review and organoleptic inspections. The inspection verification activities are supported by Lithuania's Work Instruction KT-2-1-3-D1, "Assessment and audit of hazard analysis and critical control points system of food or feed handling entity;" KT-2-2-1, "Control programme for meat and meat product handling enterprises;" and the standard operating procedure of the QMS KT-2-1, "General requirements for supervision of activities of businesses". One area of improvement identified by the FSIS auditor in this audit concerned the design of one of the audited facilities where vehicle or personnel traffic from a raw-product area of the plant may enter an area where exposed finished products are handled or stored. In response to auditor's observation, the CCA immediately updated its policy and coordinated with the establishment's management improvements to the traffic flow. The establishment's action were using different color clothes for worker in the raw and RTE areas, constructing of a separation wall between the raw and RTE areas, and installing a video camera to monitor the traffic flow. In addition, the CCA amended QMS order KT-2-1, "General requirements to perform inspections." Paragraph 5.3.2 drew particular attention to the risk of cross contamination, and an assessment is made to determine whether the premises are arranged to restrict employee's movement between the raw and processing areas of the facility. FSIS verified that the amended instruction was communicated electronically to the field personnel and used as a subject of correlation sessions for the inspection program personnel as one of the means used to establish consistency in conducting official inspection and verification activities.

In conclusion, the FSIS auditor verified that the CCA had implemented corrective action plan related to all previous audit findings for this component. The CCA has taken measures to ensure that certified establishments implement effective SSOPs and other sanitation procedures that prevent direct contamination and adulteration of meat products destined for the U.S. The measures employed by SFVS were found to be equivalent to those governing the U.S. meat inspection system. Therefore, it was determined that Lithuania's meat inspection system meets the equivalence criteria for the Sanitation component.

## **8. HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEM**

The fourth of the six equivalence components that the FSIS auditor reviewed was HACCP. This component addresses the inspection system's ability to ensure that each official establishment develops, implements, and maintains an effective HACCP system. FSIS assessment indicated that Lithuania's SFVS met the requirements for this component.

The assessment of the CCA's ability to effectively communicate the requirements of HACCP throughout the inspection system was conducted at SFVS headquarters and two TSFVS offices, and the review of the measures taken to ensure proper implementation of the applicable requirements was conducted at three establishments intended to export meat products to the U.S. At the SFVS Headquarters and TSFVS offices, the FSIS auditor verified that Lithuania has legislative commitment 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. SFVS’s official reviews, assessments, and internal control audits were based on a risk assessment module, which takes into account the establishment’s compliance history and the volume and the type of product. The assessment and audits of the establishments’ HACCP system were conducted based on the standard operating procedure in 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.” In accordance with Title VII, Articles 54 and 55 of the Regulation (EC) No. 882/2004 and Article 14 of Regulation (EC) No 178/2002, the TSFVS offices are authorized to initiate enforcement action when audited establishments fail to take appropriate corrective actions. The enforcement procedures include measures to: (1) restrict or prohibit product from being placed on the market, imported, or exported; (2) monitor and, if necessary, recall and destroy food product that may pose threat to the public health; (3) suspend the operation or close all or part of the establishment for an appropriate period of time.

FSIS’s previous audit concluded that the SFVS did not ensure that establishments’ HACCP corrective actions included preventive measures, and in many instances, the SFVS did not ensure proper documentation of the establishments’ monitoring or verification records. Specifically, the inspection personnel, assigned to establishments seeking certification to export meat products to the U.S. did not verify that: 1) the establishments’ written HACCP plans, and records of corrective actions taken in response to deviation from the established critical limits, include preventive measures; 2) the establishment’s recordkeeping for monitoring and verification of the established CCP always document the times when the specific events occurred and the initials of the responsible employee in accordance with the regulatory requirements as described in article 5 of Regulation (EC) 852/2004 and in Lithuania’s QMS procedure KT-2-1-3-D1; and 3) the establishment’s verification activities follow the prescribed frequency and type in their HACCP plans. In response to FSIS’s previous audit finding, the CCA amended the QMS procedure KT-2-1-3-D1 to provide detailed instructions to the inspection personnel on how to perform their inspection procedure and carried out a training program to enhance their abilities to conduct more effective verification activities. Additionally, the CCA instructed the Internal Audit Department of SFVS to verify during internal audits that inspection personnel abide by the updated requirements. The FSIS auditor verified that SFVS has disseminated updated procedure to levels of the inspection system and conducted supervisory reviews and internal audits to ensure that the new measures were implemented effectively.

During the visit to the three official establishments intending to export meat products to the U.S., the FSIS auditor assessed the CCA’s ability to conduct daily HACCP verification activities, verified that the CCA addressed the previous audit findings, and verified that inspection program personnel follow the updated QMS procedure when verifying the establishments’ execution of their HACCP systems. The FSIS auditor observed the plants’ operations, reviewed the establishments’ HACCP records, and the official inspection records maintained by local SFVS offices. The official records included, but were not limited to, records of daily verification of the inspections tasks, schedule and results of the official microbiological sampling programs, routine

assessment of the establishment's operations, and records of the previous supervisory reviews. The FSIS auditor's observations and documents review indicated that the inspection program personnel have improved their ability to perform verification activities designed to ensure that establishments are monitoring and verifying their CCPs in accordance with their written HACCP plans, properly documenting their monitoring and verification activities, and documenting the preventive measures they have put in place in response to HACCP system deviations and meet regulatory requirements as described in article 5 of Regulation (EC) 852/2004 and Lithuania's QMS procedure KT-2-1-3-D1.

FSIS auditor noticed that the inspection program personnel have improved their decision making process and have initiated enforcement action when appropriate in accordance with the amended QMS procedure KT-2-1-3-D1. However, the FSIS auditor pointed out that improvement in verification of the establishments' compliance with the zero tolerance for fecal material, ingesta, and milk on carcasses and parts was needed. In one establishment, the HACCP plan designed address this issue did not include locations to monitor and verify these requirements with respect to head and cheek meat. Further discussions with the CCA in-plant personnel revealed that this was an intentional omission, as these portions were not intended for export to the U.S. However, the CCA ultimately updated its requirements for export to the U.S. to indicate that monitoring should extend to all portions the carcass, regardless of the intended export.

During this audit, FSIS verified that these updated requirements are reflected in amendment to QMS KT-2-3-1-D1, "Official Veterinary Supervision and Evaluation of Meat and Other Slaughter Products on Suitability in Food in Slaughterhouses," in paragraph 5, "Inspection personnel must verify that carcasses, organs, and other parts are not contaminated with feces, milk, ingesta, or other contaminants," FSIS verified that the establishment made a change in its slaughter flow-chart, adding a point for monitoring animal parts. The CCA organized training for the inspection personnel on new control measures to verify that livestock carcasses and parts are free of visible contamination with fecal material, milk, or ingesta. Additionally, FSIS verified that the SFVS organized a meeting with the chiefs of territorial SFVS offices to discuss the updated procedure and ensure consistent implementation of the updated control measures and other inspection verification activities throughout the inspection system

The SFVS implements a product traceback system. The system requires that each establishment identify its suppliers, intended consumer, and the actual recipients of each batch of product and develop and maintain an establishment recall plan. The product traceback system was implemented within Lithuania's inspection system in accordance with the standard operating procedures KT-2-1-4 on "Traceability control of food and feed," and KT-1-3-D2, "Actions upon detection of infringements of requirements for quality and labeling of foodstuffs." The SFVS assesses the effectiveness of the establishment's traceability system daily and annually. SFVS demonstrated the effectiveness of the traceability by following random samples of product back to their origin and forward to the distribution center. The daily verification activity of the tractability is conducted as part of completing a HACCP checklist, while the annual assessment of the traceability system is conducted as part of the annual assessment of the HACCP system. The CCA has a system in place to verify and enforce regulatory requirements related to HACCP. The CCA has demonstrated the use of control measures for HACCP systems that are equivalent to the measures used by FSIS. Therefore, FSIS concludes that Lithuania's inspection system

meets the equivalence criteria for the Hazard Analysis and Critical Control Point System component.

## **9. CHEMICAL RESIDUE PROGRAMS**

The fifth of the six equivalence components the FSIS auditor reviewed was Chemical Residues. The inspection system is required to have a chemical residue control program that is organized and administered by the national government. The residue control program is expected to include random sampling of muscle, internal organs and fat of carcasses for chemical residues identified, by either the exporting country's meat inspection authorities or FSIS as potential contaminants. The program must include an effective enforcement action that addresses handling and disposition of contaminated product and measures to deter repeat violators. The SFVS met the requirements for this component.

To assess Lithuania's ability to meet the equivalence requirement of this component, the FSIS audit team conducted reviews of the SFVS headquarters in Vilnius and the National Food and Veterinary Risk Assessment Institute (NFVRAI) in Vilnius. The FSIS auditor interviewed the CCA officials, and reviewed the testing methods, enforcement strategies, and communication tools used with laboratory system.

In accordance with Article 4 Council Directive No. 96/23/EC, Lithuania is required to draft and submit a National Residue Control Plan (NRCP) for the EC approval. The SFVS is responsible for coordinating the preparation and implementation of the plan. The NFVRAI is responsible for drafting the NRCP. The draft plan is presented to the Veterinary Sanitary Department (VSD) and approved by order of the Director of the SFVS. The FSIS auditor verified that Lithuania's residue control program is designed and conducted by SFVS. The sampling for residue monitoring is performed by authorized inspectors from the TSFVS, and auditing of the territorial services is carried out by the internal audit department. The NFVRAI laboratory analyzes residue samples, supervises the quality of analyses made in the territorial laboratories, administrates proficiency tests, and organizes trainings and analytical seminars. In order to ensure public safety through the application of uniform and accurate detection and quantification methods, NFVRAI routinely participates in proficiency tests organized by the European Union Reference Laboratories (EU-RLs). In the planning of the NRCP, the NFVRAI takes account of its animal population, production data, capacity of the laboratory, and the results of the previous year's residue testing. The NFVRAI allocates a proportional number of samples in the NRCP to each TSFV. The TSFVS, in turn, distributes the samples between regulated establishments. Additionally, the SFVS manages national random and targeted testing programs for chemical residues. Reports of the implementation plan are sent quarterly, by TSFVS, to the VSFD. The overall design of the testing programs, and the operational processes that includes sample collection, shipping to laboratories, management, analysis of data, and initiation of trace-back activities are managed by the SFVS.

During the previous FSIS audit conducted in 2012, the analytical method used by the Klaipeda Territorial NFVRAI laboratory, to analyze meat samples for pesticide residue, could not reach the minimum level of applicability (MLA) as applied by FSIS for the same kind of analysis. MLA for pesticides is defined in [Title 40 CFR Part 180](#), tolerances and exemptions for pesticide chemical residues in food. In response to the FSIS auditor finding, the SFVS decided to conduct

the pesticide residue testing at the NFVRAI laboratory in Vilnius only and to discontinue the conducting of this type of testing in Klaipeda until adequate measures are taken to ensure the laboratory has the ability to meet the MLA. This audit verified that Residue Monitoring Plan approved by the SFVS Director Order of 27 December 2012 requires that testing for pesticide residues in meat be conducted at the NFVRAI laboratory in Vilnius only. Furthermore, the auditor verified that the CCA exerts adequate control over the implementation of laboratory quality systems. The CCA has communicated the SFVS Director Order to all levels of the inspection system to ensure that residue samples will be requested and sent to the NFVRAI laboratory that is capable of conducting the analysis of the samples and meet the required MLA for the specific tested compound.

During the visit of the NFVRAI laboratory in Vilnius, the auditor assessed how the CCA ensures that certified laboratories meet the basic EN ISO/IEC 17025:2005 standard and properly analyze product destined for the U.S. The FSIS auditor verified that implementation of the residue program follows the sample frequency and handling, timely analysis, date reporting, analytical methodologies, tissue matrices, equipment operation and printouts, detection levels, percent recoveries, intra-laboratories check samples, and quality assurance programs, including standards books and corrective actions, in Lithuania's annual residue plan. The auditor interviewed supervisors and analysts who are assigned duties associated with the analysis of product destined to the U.S. and reviewed records related to the analyst training, calibration, equipment maintenance, intra-laboratory performance checks, Standard Operating Procedures (SOP), laboratory test methods, reporting of test results, periodic internal audit reports, and corrective actions. The records reviewed included copies of the accreditation protocols for chemical testing for the NFVRAI. The review established that the management and the staff were familiar with the testing requirements for products destined for the U.S. The FSIS auditor received copies of the accreditation protocols for chemical testing for the NFVRAI. Based on the foregoing, the auditor concluded that laboratory personnel were qualified, adequately trained, and capable of conducting analytical methods, and that the residue laboratories demonstrated the ability to produce timely and accurate data.

In conclusion, FSIS analysis of all the audit observations, records, and findings indicated that the CCA effectively implemented a national residue control program for its meat inspection system. The laboratory analyst used to support the inspection system conducts analysis in accordance with the SOP and follows the standards of ISO/IEC 17025:2005 related to general requirements for the competence of testing and calibration laboratories. Therefore, FSIS determined that Lithuania's meat inspection system meets the equivalence criteria for the Chemical Residue Programs component.

## **10. MICROBIOLOGICAL TESTING PROGRAMS**

The sixth, and last, equivalence component that FSIS auditor reviewed was the Microbiological Testing Program employed by the CCA. This component pertains to regulatory requirements that the inspection system have a microbiological testing program that is organized and administered by the national government. The sampling and testing program must ensure that meat products intended for export to the U.S. are safe, wholesome, and unadulterated. In particular, the microbiological testing programs should include:

- Provisions for the establishments' sampling and testing program for generic *E. coli* or indicator organism. The testing results are to be used to verify the establishments' slaughter processing and dressing controls.
- Provisions for the *Salmonella* sampling and testing program in raw product, which includes *Salmonella* performance standards. The inspection system should achieve pathogen reduction by ensuring that all slaughter and ground product establishments meet the *Salmonella* Performance Standards.
- Provisions for *E. coli* O157:H7 sampling and testing program and for all other six adulterant non-O157 STECs in raw non-intact beef products or components intended for raw, non-intact product.
- Provisions and control measures to prevent adulteration of both non post-lethality exposed ready-to-eat (RTE) products, and post-lethality exposed RTE products by *Lm* and *Salmonella* spp. The control measures are expected to include verification activities for sampling and testing for *Lm*, *Listeria* spp. or *Listeria*-like organisms in the post-lethality exposed RTE products, product contact and environmental surface samples, and *Salmonella* in the ready-to-eat (RTE) products, and *E. coli* O157:H7 and other STECs in RTE beef products, at a frequency that ensures that the establishments' control measures are effective in controlling these pathogens.

The SFVS implements microbiological testing programs that meet FSIS requirements.

The FSIS auditor assessed Lithuania's ability to meet the equivalence requirements for this component by conducting reviews of the SFVS headquarters in Vilnius, the National Food and Veterinary Risk Assessment Institute (NFVRAI) in Vilnius, and NFVRAI territorial laboratory in Kaunas. At SFVS offices, the FSIS auditor reviewed the microbiological sampling regulatory requirements and procedures, testing reports, and internal audit reports of official laboratories. At NFVRAI laboratories, the FSIS auditor reviewed records, interviewed technical analysts and supervisors, and reviewed the central and territorial laboratories testing methods, enforcement strategies, and communication tools. At the establishment level, the FSIS auditor reviewed the instructions for collection of samples and inspection testing records maintained at local inspection offices. The FSIS auditor observed sample collection by the inspection personnel, reviewed the results of the microbiological sampling conducted before the audit, and verified that the inspection personnel were following the established sampling protocol, which includes testing frequency, sample collection, and the delivery of samples to laboratories.

During the previous audit, FSIS found that the SFVS did not ensure collection of *Salmonella* verification sampling from bovine carcasses at all certified establishments and did not provide justification for using 25g test-portion to detect *E. coli* O157:H7 in RTE products instead of 325g in lieu of conducting baseline study. The NFVRAI laboratory, which provides the technical support to the microbiological testing programs, was following a Standard Operating Procedure (SOP) that: 1) includes modification of the analysis method for detection of *E. coli* O157:H7 that affect the primary enrichment media used and the incubation time in a manner that adversely affects the performance and the validation of the BAX screening assay; 2) does not provide for incubation of both the swab and the hydration liquid to determine the presence of *Lm* in the environmental sample which may reduce the opportunity for detecting the presence of *Lm* in environmental samples; 3) does not provide for the use of both positive and negative controls for batches of analyses for each pathogen being tested; and 4) does not require issuance of analysis

reports that distinguish results of product samples intended for domestic use from those destined for the U.S. In response to those audit findings, SFVS decided to implement corrective actions that included:

- Amendment of the QMS procedure KT-2-3-1-D1 to instruct official veterinarians to collect 50 official samples annually from bovine carcasses to detect *Salmonella* in process hygiene.
- Issuance of SFVS Director Order No B1-683 “On extra microbiological tests in relation with export of animal food to the United States of America”. The order instructed inspection and laboratory personnel to collect and use of 325g test-portions to detect *E. coli* O157:H7 in RTE beef products rather than 25g.
- Removal of all modification made to BAX System Real-Time RCR Assay for *E. coli* O157:H7 and instruction for analysts to follow the letter of the BAX System protocol.
- Revision of the SOP for *Lm* environmental sampling to increase sensibility of the method by incubating both the swab and the hydration liquid for detection of *Lm* in environmental samples.
- Revision of the Quality control plan No. 42 of SOP 5.4.4.M.17:2012 “*E. coli* O157:H7 detection by BAX system Q7” and add quality control measure to include use of positive and negative controls whenever group of samples intended for the export to USA is analyzed.
- Changes to the format of the analysis report to include clear identification of samples of product destined for the U.S.

The FSIS auditor verified during this follow-up audit that SFVS has implemented amended QMS procedure KT-2-3-1-D1 that instructs official veterinarians to collect fifty (50) official samples annually from bovine carcasses to detect *Salmonella* as a measure of process control. The amended procedure was communicated throughout all levels of inspection system. SFVS Internal Audit Department has incorporated the new measures into its audit plan for control of *Salmonella* sampling from bovine carcasses to ensure that the testing program is performed consistently by inspection program personnel. All *Salmonella* sample sets are analyzed using ISO 6579 and provide for a maximum of two unacceptable positive samples in the set. The sampling plan for minced and mechanically separated ground products requires the collection of a 5-sample set and does not allow any positive results within the set. The inspection system assesses the effectiveness of the establishments’ process controls in reducing or controlling pathogenic microorganisms on or in raw meat products. The establishments are required to take corrective action if the maximum allowed number of positive samples is exceeded in the testing. Lithuania participates in the EC program for reduction of *Salmonella* in slaughter establishments and provides for a sampling and testing program for *Salmonella* in raw meat products. The testing program, which includes performance standards, is conducted in accordance with Regulation (EC) No. 2073/2005. The FSIS auditor verified that the SFVS takes measures to ensure that inspection program personnel collect *Salmonella* samples from all classes of meat products. The microbiological testing program is conducted in accordance with the SFVS Director Order B1-74, dated Jan. 27, 2012, part 2, and the QMS KT-3-1, “Sample taking and delivery of the samples of goods under the control of State Food and Veterinary Service to the National Food and Veterinary Risk Assessment Institute or to the National Public Healthcare Laboratory.” The criteria used to design the test scheme were changed to reflect the testing requirements for the U.S. and to include consideration of the number of animals killed annually.

This audit verified that the SFVS has implemented the corrective action related to the use of 325g test-portion for detection of *E. coli* O157:H7 in RTE products as described in Annex III of the SFVS's amended QMS procedure KT-2-3-2-D1, "Daily Veterinary Supervision of Animal Food Handling Businesses which Export their Produce to USA." The amended QMS procedure was disseminated to all levels of the inspection system to include NFVRAI laboratory. The Internal Audit Department of SFVS has employed measures to ensure compliance with the requirements for *E. coli* O157:H7 sampling and analysis.

The review of Lithuania's microbiological testing program found that Lithuania has the technical capability to conduct the testing program once the country becomes eligible to export meat products to the U.S. The SFVS issued instruction for inspection program personnel on how to conduct testing for *E. coli* O157:H7 in non-intact raw beef products. The SFVS Director Order "Additional microbiological testing associated with exports of food of animal origin to the U.S" requires that all certified establishments test non-intact beef products for *E. coli* O157: H7 using a 325 g sample size. Product lots that test positive for *E. coli* O157: H7 will be considered adulterated. The SFVS in Vilnius and territorial officers are required to ensure that meat shipments have tested negative before signing the export certificates for product destined for the U.S. The testing program will be conducted in accordance with SFVS Director Order B1-74, part 2, and the QMS KT-3-1. The office of internal audit will routinely verify the proper implementation of the regulatory requirement.

The FSIS auditor verified that NFVRAI laboratory is no longer using "SOP 5.4.4.M.17- Detection of *E. coli* O157:H7 in foodstuffs by BAX Q7 system." NFVRAI laboratories use BAX System Real-Time RCR Assay for *E. coli* O157:H7. The method used does not include any modifications to the primary enrichment media or the incubation temperature and time. Additionally, the FSIS auditor verified that the SFVS has continued to work with the EU-RLs in developing and validating appropriate methods for analysis of all other STECs. The implantation of the testing program for non-intact raw beef products includes testing for *E. coli* O157:H7 and the other six STECs. The SFVS requires all TSVS offices ensure that meat shipments have tested negative before signing the export certificates for meat product destined for the U.S.

The FSIS auditor verified that the SFVS provides for inspection procedure and verification measures to ensure that establishments certified to export to the U.S. employ control measures to prevent adulteration of both non post-lethality exposed Ready-To-Eat (RTE) products and post-lethality exposed RTE products by *Lm*, *Salmonella*, and *E. coli* O157:H7. The employed control measures are based on Lithuania's hygiene norm HN 26:2006, "Microbiological criteria of foodstuffs;" Work Instruction KT-2-2-1-D4, "Verification of special conditions of meat products;" Work Instruction KT-2-3-2-D1, "Daily Veterinary Supervision of Animal Food Handling Businesses which Export their Produce to USA;" and the "Order on the Safety Requirements for Food of Animal Origin." SFVS Work Instruction KT-2-3-2-D1 has specifically referenced FSIS Directives 10300.1, 10240.4 and 10240.5 which include procedures for verifying compliance with *Lm* control regulations and Risk-based *Lm* (RLm) sampling programs. The testing programs for RTE products include specific provisions for government sampling of product, government verification of establishment sampling, and the verification of control measures in every establishment certified for export to the U.S. certified establishments. The establishments are to take corrective action in response to positive *Lm* findings in official or

companion samples. The FSIS auditor verified that each visited establishment had an annual microbiological sampling program that includes sampling of product and product contact surfaces, as well as environmental samples. The samples are collected and delivered to the laboratory in accordance with the requirements of standard QMS procedure KT-3-1 on “sample taking and delivery to the laboratory.” The QMS KT-3-1 procedure describes the protocol for collection of official samples for analysis by NFVRAI laboratory.

The FSIS auditor verified that NFVRAI has issued instruction to ensure proper implementation of the Standard Operating Procedure (SOP) 5.4.4.B.39, “Detection of *Listeria spp.* in environmental samples, clinical and pathological material,” to enhance the environmental sampling techniques and increase the sensitivity of the method. The amended procedure provides for sample preparation that incubates both the swab and the hydration liquid which enhances the opportunity for detecting *Lm* in environmental samples.

The FSIS auditor verified that the revised NFVRAI laboratory report format will indicate whether the meat sample belongs to a product destined for the U.S. The inspection program personnel will be able to verify that consignments of meat products tested negative for pathogens of concern before they sign the export certificate for products destined to the U.S.

At the establishment level, the FSIS auditor verified that the inspection personnel were able to follow the inspection system’s sampling protocols, which include testing frequency, sample collection, and the delivery of samples to laboratories. SFVS considers RTE products that test positive for *Lm* and RTE products that come into contact with food contact surfaces that have tested positive for *Lm* to be adulterated and takes appropriate enforcement action in accordance with the guidelines to prevent contamination of *Lm* that were issued by the SFVS, Director Order No B1-537. Furthermore, the SFVS mandates that the companies wishing to export meat and meat products to the U.S. must meet all the requirements for export, the Performance Standards for the Production of Processed Meat Products, and the performance standards for lethality for all ready-to-eat products, which require a 6.5 log<sub>10</sub> reduction of *Salmonella* throughout finished meat products and a 7.0 log<sub>10</sub> reduction of *Salmonella* throughout finished products that contain poultry. Ready-to-eat fermented products that contain beef are required to have 5 log<sub>10</sub> reduction of *E. coli* O157:H7 throughout the product. For thermally-processed, commercially-sterile products, the performance standards for stabilization require no growth of *Clostridium botulinum* and no more than 1 log<sub>10</sub> growth of *Clostridium perfringens* throughout all RTE products.

The FSIS auditor verified that the NFVRAI laboratory is implementing its amended Quality Control Measures to ensure that both positive and negative controls are applied for the detection of all pathogens in relation to the samples tested for lots destined for the US. The use of quality control measures is specified in quality control plans according to NFVRAI Quality System procedure QSP 5.9.3, “Assuring the quality of test results,” and NFVRAI quality system procedure QSP 5.4.4, “Preparation of Standard Operating Procedures.” The SOP has a chapter “Quality Assurance” which describes measures of quality assurance (e.g., reagent blanks, marked and empty samples, positive and negative controls, and other measures). Even though the export of meat products to the U.S. has not yet started, the FSIS auditor reviewed the operation of the Kaunas territorial laboratory as a sample of Lithuania’s territorial laboratories. The review was intended to verify that the laboratory system possesses the technical

capacity to conduct accurate testing of product destined for the U.S. The FSIS auditor interviewed laboratory personnel and supervisors, reviewed relevant records including analyst qualifications, sampling protocols, testing methods, test reporting, enforcement strategies, and communication tools. The review indicated that the laboratory system employs qualified staff who participate in routine professional training and periodic proficiency tests. The laboratory system uses an electronic database to manage data and report results of laboratory analyses carried out in the NFVRAI, and in the territorial NFVRAI laboratories.

FSIS auditor verified that laboratories involved in the official microbiological analysis are accredited and approved by the SFVS. All NFVRAI laboratories participate in proficiency tests organized by the EU-RLs with satisfactory results. The NFVRAI executes its supervisory role over the territorial laboratory in Kaunas through periodic supervisory visits and proficiency tests conducted several times every year. The proficiency tests that are regularly organized cover different microbiological criteria including *Salmonella*, *E. coli* O157:H7 and *Listeria* and use different matrices, including meat products. Lithuania's microbiological testing laboratories are accredited by the German accreditation body Deutsche Akkreditierungsstelle GmbH (DAkkS), in accordance with ISO 17025, the laboratory system is well-equipped to provide technical support to the meat inspection system, and the laboratory management is familiar with microbiological testing requirements for export of Lithuania's meat products to the U.S.

The CCA has regulatory requirements including sampling and enforcement strategies for the microbiological testing programs. The CCA was found to be capable of designing, coordinating, and reporting microbiological testing programs and their respective results, employing performance standards, and taking appropriate enforcement actions in response to unacceptable microbiological results in meat products. In conclusion, Lithuania's inspection system met all the requirements for maintaining an equivalent microbiological sampling program.

## **11. EXIT MEETING**

An exit meeting was held on September 24, 2013 at SFVS headquarters in Vilnius. The participants of the meeting included both levels of CCA, NFVRAI laboratories, and U.S.D.A.'s Foreign Agricultural Service (FAS). During this meeting, FSIS presented and discussed the follow-up audit results and observations. The CCA outlined strategies and policies intended to enhance performance of the food safety and inspection tasks and to better understand FSIS requirements for importing meat products to the U.S.

## **12. CONCLUSIONS AND NEED FOR FURTHER ACTIONS**

This follow-up audit verified that Lithuania's CCA has appropriately implemented the corrective action plan proffered in response to the findings of FSIS audit conducted from September 10 to 26, 2012, and SFVS exercised adequate control over the execution of inspection programs. The audit did not identify systemic findings that would impact Lithuania's meat inspection system ability to meet the equivalence criteria and other FSIS import requirements. The auditor documented two observations at the establishment level that point to areas of desired improvement to ensure a smooth transition to meeting the eligibility requirements for export to the U.S. once equivalence status is granted. The observations are related to the expertise of inspection program personnel in verifying the establishments' implementation of effective SSOP

and HACCP plans. One observation is related to the monitoring the flow of product in RTE facilities. The establishment and monitoring of sanitary handling procedures to address traffic patterns and product flow between rooms and processes are basic principles upon which the Pathogen Reduction (PR), Hazard Analysis Critical Control Point systems (HACCP) and Sanitation Operating Procedures (SOP's) are based. The second observation is related to extent to which the establishment should monitor, under its HACCP plan, all portions of carcasses for the zero tolerance for visible contamination with fecal material, milk, or ingesta, rather than just those portions that were intended for U.S. export. The auditor did not observe any direct product contamination or adulteration as a result of these observations.

The SFVS initiated immediate action by updating its export requirements and requiring modification to the establishments' SSOP and HACCP systems to address FSIS observations. Furthermore, SFVS outlined strategies and policies intended to enhance performance of the food safety and verification activities and to better understand FSIS requirements for importing meat products to the U.S. The strategy included the introduction of correlation sessions for supervisory personnel on U.S. requirements and on-going training programs for inspection program personnel as well as measures taken by the internal audit department to ensure consistency within the inspection system in conducting monitoring and verification activities.

The SFVS has demonstrated its ability to implement an equivalent system without actual export of meat product to the U.S. Considering the relevance and timeliness of training provided to inspection personnel at this point and the time that elapses between completion of the on-site audit and publication of the final rule, Lithuania's CCA intends to implement strategies to continue to train SFVS employees and reinforce their understanding of how to perform food safety duties and determine noncompliance with the regulatory requirements. Furthermore, SFVS intends to implement new policies and develop comprehensive training for their meat industry personnel on how to better understand the requirements for meat export to the U.S.

FSIS evaluation of Lithuania's proffered corrective actions and presented implementation records and determined that all audit findings and observations were properly addressed, and that there is no need for an additional follow-up audit. FSIS's audit verified that there is reason to believe that Lithuania's food safety system governing meat inspection is equivalent to that of the U.S. with the capability to produce and export products that are safe, wholesome, unadulterated, and properly labeled. Therefore, FSIS will make recommendation to move forward with proposed rulemaking process for system equivalence.

Faiz Agarib, DVM, Senior Equivalence Officer, IES, OPPD



### **13. ATTACHMENTS TO THE AUDIT REPORT**

Lithuania's response to the FSIS draft final audit report.



**LIETUVOS RESPUBLIKOS  
VALSTYBINĖ MAISTO IR VETERINARIJOS TARNYBA  
STATE FOOD AND VETERINARY SERVICE REPUBLIC OF LITHUANIA**

To: Dr Andreas Keller  
USDA, FSIS, OIA  
Director, International Equivalence Staff  
Office of Policy and Program Development  
Food Safety and Inspection Service  
1400 Independence Avenue S.W.  
Washington, D.C. 20250

06-10-2014 No *B6-(1.20)-2507*  
Your ref: 03-10-2014

**Subject: AUTHORISATION PROCEDURE FOR EXPORT OF MEAT PRODUCTS  
FROM LITHUANIA TO THE UNITED STATES – RESPONSE TO THE DRAFT FINAL  
FOLLOW-UP AUDIT REPORT**

Dear Dr Keller,

The State Food and Veterinary Service of the Republic of Lithuania presents its compliments to the Food Safety and Inspection Service of the United States Department of Agriculture and has no comments to the presented Draft Final Report of an Initial Equivalence Follow-Up Audit Conducted in Lithuania on September 16 - 24, 2013 Evaluating the Food Safety Systems Governing the Production of Meat Products Intended for Export to the United States of America.

Please do not hesitate to contact Ms Giedrė Čiuberkytė, Head of International Affairs Department of the State Food and Veterinary Service, phone: +370 5 249 1648, e-mail: [gciuberkyte@vet.lt](mailto:gciuberkyte@vet.lt), for any information you may need.

Sincerely yours,

Director

Dr Jonas Milius

## 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 Utena Mesa Pramones g. 4 Utena	2. AUDIT DATE 9/18/2013	3. ESTABLISHMENT NO. 17 EB	4. NAME OF COUNTRY Lithuania
	5. NAME OF AUDITOR(S) Faiz Agarib, DVM		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.	X	49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
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	X
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

## 60. Observation of the Establishment

**Est. 17 EB Utenos mesa (Slaughter -Bovine /Swine; Processing-Raw-not ground; Canning), Utena Territorial Office**

## 22/51/ HACCP:

- The establishment's HACCP plan is designed to monitor and verify the requirements of zero tolerance for visible contamination of livestock carcasses with fecal material, milk, or ingesta at or immediately after the final rail. However, the established CCP did not include locations for monitoring and verification of the zero tolerance requirements on beef parts which are diverted to a side-processing station that ends before the final rail station. Head meat, cheek meat, and weasand meat is frequently used in ground beef products. If the meat from these parts is contaminated, it represents a way of importing pathogens, including *E. coli* O157:H7, into ground beef. Since the establishment is required to have documents to support selected monitoring procedures, inspection program personnel should verify that the establishment implants effective monitoring and verification procedures in the design of its HACCP system in accordance with Article 5 of Regulation (EC) 853, and Lithuania Standard Operating Procedure KT-2-1-3-D1 [9 CFR part 417.5 and 417.8].

61. NAME OF AUDITOR

Faiz Agarib, DVM

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Biovela Dukstu K. Vilniaus r.	2. AUDIT DATE 9/19/2013	3. ESTABLISHMENT NO. 41-23 EB	4. NAME OF COUNTRY Lithuania
	5. NAME OF AUDITOR(S) Faiz Agarib, DVM		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.	X	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. 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	
<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	X
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

**Est. 41-23 EB Biovela (Processing Raw-ground and RTE), Vilnius Territorial Office**

**10/56 SSOP:**

- During the official verification of the establishment’s pre-operational sanitation, the FSIS auditor observed minute pieces of meat and biological residues from the previous day's production in the bottom on the mixing and formulation tank. The SFVS assigned inspection program employee recognized the insanitary finding, took control action and documented the findings in her records. The finding was corrected by the establishment personnel and verified for adequacy by the inspection before the start of the operation. A review of the pre-operational inspection forms revealed that the IIC conducts the pre-operational inspection verification on a daily basis and have identified, recorded, and verified non-compliances as per Lithuanian’s SOP KT-2-1-3-D1. [9 CFR 416.13, 9CFR 416.1]. This constitutes an *audit observation* that demonstrates the inspection system ability to perform the daily verification activities of the establishment’s sanitation program.

**46/56 Sanitation operation**

- During the official verification of the establishment’s pre-operational sanitation, the FSIS auditor observed the wheels of two carts, used to transport product between process rooms and storage areas, to be soiled with biological residues. The SFVS assigned inspection program employee recognized the insanitary finding before FSIS and took official control of the two carts. The two carts were released later after the corrective action was taken by the establishment personnel and verified by the inspector in accordance with Article 5 of Regulation (EC) 852 and Lithuanian’s SOP KT-2-1-3-D1 [9CFR 416.4 (b) (d)]. This constitutes an *audit observation* that demonstrates the ability of the inspection to perform the daily verification activities of the establishment’s sanitation program.

61. NAME OF AUDITOR  
Faiz Agarib, DVM

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION  Grimeda" Džiaugėnų k. Šilalės r. Tauragės apskritis Šilalė	2. AUDIT DATE 9/20/2013	3. ESTABLISHMENT NO. 87-16 EB	4. NAME OF COUNTRY Lithuania
	5. NAME OF AUDITOR(S)  Faiz Agarib, DVM		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.	X	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. Enforcement	X
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. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58. RTE control program	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

## 60. Observation of the Establishment

**Est. 87-16 EB Grimeda” Džiaugėnų k. (Processing RTE “Fermented and thermally treated”), Šilalė Territorial Office****11/51/58 Sanitation /control of Lm in the post-lethality environment**

- The establishment’s written sanitation program did not include control measures to ensure that Ready-to-Eat (RTE) product will not be subjected to contamination in the post-lethality environment. The facility design and product flow paths do not provide for control that prevents raw product and finished products cross over. Vehicle or personnel traffic from a raw-product area of the plant may enter an area where exposed finished products are handled or stored. The absence of such control may result in contamination or cross-contamination of the finished RTE product, in the post-lethality area of the establishment, with *Listeria monocytogenes*. The establishment is expected to take precautions to protect the finished products in the post-lethality environment. The implementation of such control measure is essential since the establishment has elected to use alternative 3, sanitation procedures only, to control *Lm* in the post-lethality processing environment. The inspection program personnel are expected to verify regulated establishments have effective measure to prevent product adulteration by the pathogens of concern in accordance with Article 5 of Regulation (EC) 852, instruction of the SFVS No. B1-508 of 26 June 2012 on “Safety Requirements of Animal Food“of 27 July 2012, and Lithuanian’s SOP KT-2-1-3-D1 [9CFR416.14, 16(a), and 416.17 and 430.4(b)].

61. NAME OF AUDITOR

Faiz Agarib, DVM

62. AUDITOR SIGNATURE AND DATE