United States Department of Agriculture

Food Safety and
Inspection Service

1400 Independence
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Washington, D.C.
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APR 2 5 2017

Dr. Deividas Kliučinskas
Acting Director
State Food and Veterinary Service
Address: Siesikų str. 19,
07-170 Vilnius, Lithuania

Dear Dr. Kliučinskas,

The Food Safety and Inspection Service (FSIS) conducted an on-site initial equivalence verification audit of Lithuania's egg products inspection system from October 24 to November 2, 2016. Enclosed is a copy of the final audit report. The comments received from the Government of Lithuania are included as an attachment to the report.

As the next step in the review process, FSIS is evaluating the potential of the Government of Lithuania's proposed corrective actions identified during the 2016 audit. As described in FSIS policy guidance, an equivalence determination will require verification of corrective actions through direct, on-site observations when findings are associated with implementation of programs for any equivalence component. It is our intention to complete our review and schedule a verification audit in the near future.

If you have any questions, please feel free to contact Mary Stanley in the Office of International Coordination at 202-720-0287 or Mary.Stanley@fsis.usda.gov. As always, thank you for your ongoing cooperation.

Sincerely,

Jane H. Doherty

Jane H. Doherty
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN INITIAL EQUIVALENCE VERIFICATION

AUDIT CONDUCTED IN

LITHUANIA

October 24 to November 2, 2016

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

April 18, 2017

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite initial equivalence verification audit of Lithuania's egg products inspection system conducted by the Food Safety and Inspection Service (FSIS) from October 24 to November 2, 2016. The audit objective was to verify that Lithuania's egg products inspection system, as documented by the Central Competent Authority (CCA) in the Self-Reporting Tool (SRT), is implemented and effective in providing an equivalent level of public health protection as achieved in the United States, with the ability to produce egg products that are safe, wholesome, unadulterated, and accurately labeled and packaged.

The FSIS auditor focused on the following five system equivalence components: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protections Regulations (e.g., Inspection System Operation, and Product Standards and Labeling); (3) Government Sanitation; (4) Government Chemical Residue Testing Programs; and (5) Government Microbiological Testing Programs.

One egg products establishment has requested certification from the CCA to export egg products to the United States. The CCA's egg products inspection system mandated the application of the Title 9 of the United States Code of Federal Regulations (9 CFR), Part 590 - Inspection of Eggs and Egg Products, in all certified egg products establishments that intend to export egg products to the United States. During the on-site audit, the FSIS auditor identified the following findings:

Government Oversight

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

Government Sanitation

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

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

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite initial equivalence verification audit of Lithuania's egg products inspection system from October 24 to November 2, 2016. The audit began with an entrance meeting on October 24, 2016, in Vilnius, Lithuania, with the participation of representatives from the Central Competent Authority (CCA), the State Food and Veterinary Service (SFVS), and an FSIS auditor. The FSIS auditor was accompanied throughout the audit by representatives from the SFVS at the central and territorial levels.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was an initial FSIS onsite equivalence verification audit of Lithuania's egg products inspection system. The audit objective was to verify that Lithuania's egg products inspection system as documented in the Self-Reporting Tool (SRT) is implemented and effective in providing an equivalent level of public health protection as achieved in the United States, with the capability to produce and export products that are safe, wholesome, unadulterated, and accurately labeled and packaged.

The FSIS auditor conducted a review of the information provided by the SFVS in the SRT and accompanying supporting references. The FSIS auditor focused on performance within the following components: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, and Product Standards and Labeling); (3) Government Sanitation; (4) Government Chemical Residue Testing Programs; and (5) Government Microbiological Testing Programs.

The FSIS auditor reviewed administrative, management, and supervisory functions at the SFVS headquarters, one territorial office, and one local inspection office. The FSIS auditor evaluated the implementation of control systems in place, which ensures that the national system of inspection, verification, and enforcement is being implemented as intended.

The SFVS presented only one egg products establishment that has requested certification from the SFVS to export egg products to the United States. During the establishment review, the FSIS auditor evaluated the extent to which industry and government interact to control hazards, and prevent non-compliances that threaten food safety, with an emphasis on the SFVS's ability to provide oversight to ensure that egg products are processed, labeled, and packaged in accordance with requirements consistent with FSIS requirements. The requirements address importation of egg products or restriction of eggs into the United States as outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) Part 590.900, requirements for importation of egg products or restricted eggs into the United States.

Additionally, the national government laboratory, the National Food and Veterinary Risk Assessment Institute (NFVRAI) was audited to verify its ability to provide adequate technical support to the SFVS inspection system.

Competent Authority Visits		No.	Locations
Competent Authority	Central Inspection Office	1	State Food and Veterinary Service (SFVS) – CCA
	Territorial Inspection Office	1	Territorial SFVS Office (Plunge)
	Local Inspection Office	1	Local Inspection (Plunge)
Government Laboratories (Residue and Microbiological testing programs)		1	National Food and Veterinary Risk Assessment Institute (NFVRAI) (Vilnius)
Egg Products Establishment		1	Plunge

The audit was conducted under the specific provisions of the United States' laws and regulations, in particular:

- Egg Products Inspection Act (EPIA) (21 United States Code [U.S.C.] 1031, *et seq.*); and
- The Egg Products Inspection Regulations (9 CFR Part 590 to End).

III. BACKGROUND

Lithuania is not currently eligible to export egg products to the United States. USDA's Animal and Plant Health Inspection Service (APHIS) regulates the importation of animals and animal products and guards against the introduction of animal diseases not currently present or prevalent in the United States. APHIS considers Lithuania to be free of Exotic Newcastle Disease and Highly Pathogenic Avian Influenza.

In response to the SFVS' initial equivalence request for egg products, FSIS conducted a comprehensive document review and analysis to determine whether SFVS's egg products inspection system meets the equivalence requirements as set out in 9 CFR Part 590 - Inspection of Eggs and Egg Products. In the review of Lithuania's SRT submission, which was based on the equivalence criteria established for FSIS' five equivalence components, FSIS determined that the documented egg products inspection system has a level of public health protection equivalent to that of the United States inspection system.

The FSIS final audit reports for Lithuania's food safety inspection system are available on the FSIS Web site at:

http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports

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

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

The SFVS is responsible for oversight of the implementation of regulatory requirements pertaining to the production of egg products destined for export to the United Sates. The SFVS egg products inspection system is organized on three levels: central, territorial, and local. At the central level, the SFVS Director/Chief Veterinary Officer (CVO), issues guidelines, instructions, and standard operating procedures to government inspection personnel on how to perform official inspection activities; sets the frequency of periodic supervisory reviews; establishes official procedures for registration, approval, or suspension and withdrawal of certified establishments; sets the scope and methodology for carrying out sampling and testing protocols under the national chemical residue control program; and provides instructions for implementation of the microbiological sampling, testing, and inspection verification programs.

At the territorial level, 51 Territorial SFVS (TSFVS) offices are responsible for implementing the SFVS' inspection requirements within the country through the assignment of competent and qualified government inspection personnel at official egg products establishments. At the local level, government inspection personnel consist of in-plant official veterinarians (OVs), who are responsible for conducting inspection verification activities and enforcing regulatory requirements.

The FSIS auditor's review of the oversight activities carried out at the SFVS headquarters and at the Plunge territorial office verified that the SFVS has a single set of rules; legal authority and responsibility to enforce inspection regulations; and trace back capability to ensure that identified adulterated or misbranded egg products are not allowed to be exported to the United States. The SFVS' egg products inspection system mandates the application of 9 CFR Part 590 - Inspection of Eggs and Egg Products, in all certified egg products establishments that intend to export egg products to the United States.

- At the time of the audit, the FSIS auditor reported that some of the regulatory requirements cited in 9 CFR Part 590, as well as parts of the SFVS' national policies or orders as documented in the SRT had not been fully implemented as required. Therefore, the SFVS was unable to demonstrate adequate government oversight over implementation and verification of its regulatory requirements as documented in section VI, component three. The FSIS auditor's review of the Plunge's Territorial SFVS periodic supervisory review, dated October 18, 2016, indicated that the SFVS was aware of, and documented that, some of its applicable requirements for export to the United States have not been fully implemented.

In Lithuania, the European Commission (EC) regulations serve as overarching regulations and are supplemented by 9 CFR Part 590, national legislations that consist of laws, work instructions, guidelines, and standard forms that constitute the Quality Management System (QMS). The QMS provides government inspection personnel with instructions for the implementation of the inspection verification activities and enforcement of regulatory requirements in establishment(s) that intend to be certified to export to the United States.

The FSIS auditor verified that the United States' import requirements are communicated from the SFVS headquarters to TSFVS and local inspection offices via email and intranet site. The SFVS' database for Veterinary Approval Registry (VRPRAS) is a tool to document the government inspection verification activities, including information regarding the results of

periodic supervisory reviews or daily inspection verification activities, including any enforcement actions taken. This database is available on the SFVS Web site for public, administrative, and official use. The FSIS auditor observed the application of this database including entering the results of the inspection verification activities into VRPRAS at the TSFVS and the local inspection offices.

The SFVS is funded by the national budget and is responsible for hiring and assigning qualified government inspection personnel at egg products establishments. The SFVS has a written procedure for hiring government inspection personnel "Staffing of State Food and Veterinary Service" which states all OVs are required to have a Doctor of Veterinary Medicine degree from an accredited university. The FSIS auditor verified that the government inspection program personnel at the central, territorial, and local levels were all hired and paid by the national government.

The FSIS auditor reviewed government inspection personnel training records at the headquarters, territorial, and local inspection offices and verified that the SFVS has provided ongoing training for the government inspection personnel located in the Plunge territorial office and the OV responsible for conducting inspection verification activities in the establishment that seeks certification for export of egg products to the United States. The training covered such items as implementation of QMSs, conducing daily verification activities, and sampling methodology for egg products destined for export to the United States.

The appointed full time OV carries out the official veterinary control in accordance with the requirements of the SFVS' Quality System Working Procedure KT-2-3-2-D1 "Daily Official Veterinary Supervision of Animal Origin Food Handling Establishments Exporting to the USA." The audit verified that the appointed OV is employed directly by the government on a permanent basis, and is authorized to perform all aspects of egg products inspection in accordance with the SFVS requirements. The FSIS auditor's direct observations of the inspection activities and interviews with the government inspection personnel showed that the SFVS has assigned government inspection personnel who have appropriate educational credentials and training to carry out inspection tasks.

The NFVRAI provides the technical support for the inspection system and reports directly to the SFVS headquarters in Vilnius and carries out all official chemical residue and microbiological testing programs.

The FSIS auditor verified that the SFVS has the legal authority and responsibility to approve or disapprove laboratories engaged in analytical testing on regulated products. The SFVS ensures and verifies, through the NFVRAI supervisory control, that NFVRAI and territorial units meet International Organization for Standardization (ISO) 17025 standards, properly analyze product destined for export to the United States, and participate in proficiency testing schemes for food analysis. Since 2015, the NFVRAI and all of its territorial laboratories have been ISO 17025 accredited, by the National Accreditation Bureau (NAB) of the Ministry of Economy. The accreditation is valid until May 5, 2020. The SFVS' laboratory system uses an electronic database system that enables all levels of inspection personnel to review the results of the verification sampling programs. During the audit of NFVRAI laboratory, the FSIS auditor

verified that the SFVS exercises adequate control over the laboratory system and the laboratory takes measures to address deficiencies identified during internal or external audits. The external audits included: 1) NAB annual surveillance audits (last audit in May 2016), 2) the Directorate General for Health and Food Safety of EC inspection audits for conformity assessment within selected field (pesticides, contaminants, residues, etc.) in line with Regulation (EC) No. 882/2004, and 3) other external assessments (e.g., third party audits). The FSIS auditor's review of a sample of internal and external audits did not raise any concerns.

The audit verified that Lithuania's egg products inspection system is organized and administered by the national government, and that the SFVS inspection officials are assigned to enforce the laws and regulations governing production and export of egg products at the establishment proposed for the United States certification. However, at the time of the audit the FSIS auditor observed that all regulatory requirements under 9 CFR Part 590, as well as parts of their orders and other national policies as documented in the SRT were not being implemented as documented under section VI, component three . Therefore, the SFVS was unable to demonstrate adequate government oversight and verification that its orders and other national policies are being met and would ensure that egg products are not adulterated as supported by bulleted findings in this report.

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

The second of five equivalence components that the FSIS auditor reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for controls over condemned materials; controls over establishment construction, facilities, and equipment; continuous inspection; and periodic supervisory visits to official establishments.

The evaluation of this component included an interview of government inspection personnel; review of in-plant inspection generated records; and observation of the OV when conducting inspection verification activities. These daily verification activities included direct observation of the production process and review of the establishment's records including monitoring, verification, corrective actions, and sampling.

The FSIS auditor verified that the SFVS has implemented the EC's food hygiene legislations including Regulations (EC) No. 178/2002, No. 882/2004, No. 852/2004, No. 853/2004, No. 854/2004, and No. 2073/2005, through a series of statutory instruments that lay out the national framework for the inspection program related to egg products inspection. In addition, the SFVS Director's Order No. B1-1026, dated November 12, 2015, mandated additional requirements for both the establishment and the inspection personnel to implement and enforce FSIS's egg products regulatory requirements cited in 9 CFR Part 590 when the establishment is producing egg products or the inspection personnel are issuing official certificates for consignments of egg products destined for export to the United States.

The FSIS auditor's review of inspection verification records confirmed that the government inspection personnel verify that the establishment's pasteurization facilities meet the operating requirements for equipment and operations (including minimum temperature requirements and minimum holding times). The government inspection personnel also verify that the operating parameters for the heat treatment of dried egg whites (including temperature and holding time requirements) are followed in accordance with 9 CFR Part 590.

The SFVS requires shell eggs and egg products that are not suitable for human food purposes to be handled as animal by-products (ABP). The FSIS auditor verified that ABP were collected and placed in a specially marked container that was stored in a special room dedicated for this purpose. The in-plant OV conducts daily verification of the establishment's condemnation records and proper implementation of ABP handling procedures by the establishment's personnel. The establishment provides a monthly report to the SFVS headquarters that indicates the amount of the condemned materials that was sent to an ABP processing facility.

The FSIS auditor verified that the SFVS' egg products inspection system provides operating requirements for egg products facilities, equipment, and procedures for breaking eggs, freezing, drying, heat treatment, and packaging rooms in accordance with Regulations (EC) No. 853/2004- Annex III - Section X - Chapter II and No. 852/2004- Annex II-Chapters I, II and IX. In addition, the SFVS' Quality System Working Procedure KT-2-2-18-D1 provides special requirements for inspection controls over establishment construction, facilities, and equipment in accordance with related European regulations (Annexes 1, 2,3, and 5) and 9 CFR Part 590 (Annex 4).

The SFVS Director Order No B1-664, dated July 3, 2015, provides instruction to TSFVS officials for assigning a full time OV to carry out daily inspection in the egg products establishment seeking approval for export to the United States. The OV's daily verification activities are recorded as per KT-2-3-2-D1. The establishment has two processing shifts. The FSIS auditor observed a government inspector present during the first shift which consisted of preoperational inspection through packaging of finished dried egg products. The SFVS committed that the continuous inspection will cover all hours of operations and phases of processing, and covering all shifts, once the establishment is certified.

The FSIS auditor observed the territorial government inspection personnel responsible for conducting the periodic supervisory reviews. The SFVS has set a minimum frequency of one supervisory review per year for the assigned OV and the establishment according to the SFVS' risk assessment, which considers the establishment's process category, production volume, and previous inspection results. The FSIS auditor verified that during each periodic supervisory review, the government inspection personnel verify the proper implementation of the SFVS requirements. The FSIS auditor noted that the government inspection personnel conduct these reviews as planned, document their findings, and verify the implementation of the corrective actions. The government inspection personnel enter the results of the review into VRPRAS database within 5 working days of review. Examples of supervisory inspection reports that Plunge TSFVS office provided to the SFVS headquarters were made available to the FSIS auditor. The review of these records did not raise any concerns.

Currently, there is one egg products establishment in Lithuania that seeks approval to export egg products to the United States. The establishment and inspection verification records showed that the establishment is not receiving any shell eggs or egg products from other domestic or foreign egg processing establishments. The FSIS auditor verified that the establishment has a procedure in place that will separate, by time and space, any egg products that are eligible and destined for export to the United States from domestic production. In addition, the establishment will use a separate batch number that defines the labeling and product specifications for the United States market.

Lithuania's egg products inspection system includes requirements that ensure that establishment construction, facilities, and equipment are adequate; provides for periodic supervisory review of official establishments; and provides for official controls over condemned material until destroyed or removed.

VI. COMPONENT THREE: GOVERNMENT SANITATION

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

The FSIS auditor reviewed daily pre-operational and operational sanitation procedures and associated records related to the development, implementation, and maintenance of sanitation programs. The FSIS auditor also assessed the ability of government inspection personnel to verify and enforce the regulatory requirements for sanitation at the establishment level. The assessment included review of the official inspection verification records, the establishment's sanitation monitoring records, of documented corrective actions generated by the establishment, and actual sanitary conditions in the production areas.

The FSIS auditor verified that the audited establishment maintains a written sanitation program sufficient to prevent direct product contamination or adulteration, except as indicated as audit findings in this report, through routine assessment of the establishment's sanitation and hygienic practices. The FSIS auditor also confirmed that the OV conducts daily pre-operational and operational verification procedures of the implementation of the establishment's sanitation programs. The inspection verification activities consist of a combination of document reviews and hands-on inspections.

The FSIS auditor noted that the establishment's current practice did not include a process for washing, sanitizing, and drying dirty eggs. A review of the Plunge's TSFVS supervisory review, dated October 18, 2016, also indicated that the SFVS was aware, and documented that the establishment has not yet fully implemented all the SFVS' export requirements, including washing and sanitizing of shell eggs.

The FSIS auditor identified several sanitation findings where the CCA was unable to demonstrate adequate government oversight and verification that their orders and other national policies were being fully met and would ensure that egg products are not adulterated. The

following findings were identified in the audited establishment, which would not be in accordance with 9 CFR Part 590 requirements:

- Candling procedures to detect eggs with cracked shells and interior defects was not observed as being performed.
  -9 CFR 590.506 (d) requires: Candling devices of an approved type shall be provided to enable candlers to detect loss, inedible, dirty eggs, and eggs other than chicken eggs.
- Washing, sanitizing, and drying dirty eggs were not observed as being performed.
  -9 CFR 590.516 (a) requires: Immediately prior to breaking, all shell eggs shall be spray rinsed with potable water containing an approved sanitizer of not less than 100 ppm nor more than 200 ppm of available chlorine or its equivalent. Alternative procedures may be approved by the Administrator in lieu of sanitizing shell eggs washed in the plant.
- The FSIS auditor observed that some of the nest run eggs (shell eggs) loaded onto the breaking machine conveyor belt had adhering dirt and foreign material on the shell surface. The establishment's employees did not remove these eggs prior to the breaking operations.
  -9 CFR 590.510 (c) requires: Shell eggs, when presented for breaking, shall be of edible interior quality, and shall be sound and free of adhering dirt and foreign material.
- The FSIS auditor observed several large fragments of shells on the top of several cups and in the liquid egg product containers located immediately after the egg breaking machine.
  -9 CFR 590.522 (g) requires: Shell particles or other foreign materials accidentally falling into the cups or trays shall be removed with a spoon or other approved instrument.

The FSIS auditor also assessed the establishment's construction, facilities, and equipment to verify that the establishment meets the SFVS requirements and operates in a sanitary manner. The SFVS requires the proper maintenance of the establishment structures, facilities, and equipment in accordance with the requirements of Regulations (EC) No. 852/2004 and No. 853/2004. On the day of the audit, the FSIS auditor noted the following sanitation findings:

- Beaded condensate on the ceiling (egg white powder dry storage room);
- Dust on overhead structures (egg white drier room); and
- Pooling water on the floor (several processing rooms).

Although no product contamination was observed at the time, the presence of these conditions creates an insanitary condition that may result in product adulteration. Both the establishment and the government inspection personnel made commitments to take immediate actions to correct all the sanitation findings and address any potentially affected product.

The FSIS auditor verified that the CCA has procedures in place to implement sanitation requirements. These requirements include the inspection system being able to address the audit findings related to the sanitation of shell eggs used for breaking. The CCA committed to implement effective corrective actions and preventive measures to address audit findings. The FSIS onsite audit findings showed that the SFVS' verification activities were inadequate to ensure that the establishment's sanitation procedures were sufficient or effective to prevent direct contamination or adulteration of egg products.

VII. COMPONENT FOUR: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fourth of five equivalence components that the FSIS auditor reviewed was Government Chemical Residue Testing Programs. The inspection system is to present a chemical residue testing program, organized and administered by the national government, which includes sampling of chemical residues identified by the exporting country's inspection authorities or by FSIS as potential contaminants.

The NFVRAI is responsible for preparing the National Residue Control Plan (NRCP). After approval by the director of the SFVS, the NRCP is sent to the TSFVS offices. The in-plant OV is responsible for collecting samples in accordance with Annex 12 of the operating instruction of the SFVS' Quality System KT 2-3-2-D1. This includes collecting samples (500 g) of unpasteurized filtered eggs for antimicrobials, pesticides, and heavy metals with a frequency of one sample every other month.

The FSIS auditor observed that the audited egg products establishment has implemented a self-controlled monitoring program for residues and contaminants at a frequency of two samples per year. The FSIS auditor's reviews of the establishment's residue monitoring programs and official inspection residue records did not identify any issues of concern and confirmed that inspection sampling program is being implemented in compliance with the SFVS regulatory requirements.

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

VIII. COMPONENT FIVE: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last equivalence component that the FSIS auditor reviewed was Government Microbiological Testing Programs. This component covers the microbiological testing programs organized and administered by the SFVS to verify that products destined for export to the United States are safe, wholesome, not adulterated, and meet all relevant equivalence criteria.

The FSIS auditor verified that the audited establishment that intends to export egg products to the United States conducts microbiological testing in accordance with the SFVS regulatory requirements. In addition, the FSIS auditor verified that the SFVS' egg products inspection

system requires the government inspection personnel to collect official verification samples from pasteurized liquid, frozen, and dried egg products for *Salmonella* and *Listeria monocytogenes* (*Lm*) in accordance with Annex 12 of the operating instruction of the SFVS' Quality System KT 2-3-2-D1. This includes monthly official verification sampling of each egg product category for the presence of *Salmonella* and *Lm*. The SFVS requires that the OV compare, at least quarterly, the results of the official sampling with the results of the establishment self-controlled sampling for *Salmonella* and *Lm* in order to verify the effectiveness of the establishment's food safety system. The FSIS auditor's reviews of the establishments microbiological written programs and official inspection verification records did not identify any issues of concern, and confirmed that the audited establishment complied with the SFVS regulatory requirements.

The table below includes information for official verification microbiological testing and methods approved by the SFVS for egg products establishments that intend to export egg products to the United States.

Target	Matrix	Test Portion	Testing Method
Salmonella	Egg Products	Absent in 100 g	ISO 6579
Listeria	Egg Products	Absent in 25 g	ISO 11290-1

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

IX. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on November 2, 2016, in Vilnius with the SFVS. At this meeting, the FSIS auditor presented the preliminary findings from the audit. The SFVS understood and accepted the findings.

One egg products establishment has requested certification from the CCA to export egg products to the United States. The CCA's egg products inspection system mandated the application of the Title 9 of the United States Code of Federal Regulations (9 CFR), Part 590 - Inspection of Eggs and Egg Products, in all certified egg products establishments that intend to export egg products to the United States. During the on-site audit, the FSIS auditor identified the following findings:

Government Oversight

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

Government Sanitation

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

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

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklist

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Baltic Egg Production Plunge	10/27/2016	LT 68-09 EB	Lithuania
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	International Audit Staff		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

10/41/46/51: Sanitation and other requirements

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

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
International Audit Staff	

Appendix B: Foreign Country Response to Draft Final Audit Report

LIETUVOS RESPUBLIKOS
VALSTYBINĖ MAISTO IR VETERINARIJOS TARNYBA

STATE FOOD AND VETERINARY SERVICE
OF THE REPUBLIC OF LITHUANIA

To: Ms Jane H. Doherty
International Coordination Executive
Office of International Coordination
USDA/Food Safety and Inspection Service
1400 Independence Avenue,
SW. Washington DC,
United States of America

05-04-2017 No B6-(1.20.)-928

Dear Ms Doherty,

Thank you for your letter dated 9 February 2017 and the submitted draft final audit report. The report reflects the findings of the audit that took place from October 24 to November 2, 2016. I would hereby like to respond to the conclusions of the Food Safety and Inspection Service (FSIS). At the time of the audit, the FSIS auditor did not observe the full implementation of the regulatory requirements cited in 9 CFR Part 590 by CCA and identified several sanitation findings at the egg product establishment where the State Food and Veterinary Service (SFVS) was unable to demonstrate adequate government oversight regarding the implementation and verification of sanitary requirements.

In order to strengthen the official veterinary control at the egg processing plant and to ensure the rectification of the irregularities referred to in the draft audit report, the Quality System Working Procedure KT-2-2-18-D1 "Official veterinary control of egg packing and egg processing plants" was amended by Order B1-134 of SFVS Director of 15-03-2017 (Annex 1 to this letter) by laying down that the official periodic supervision (official veterinary control) at the egg processing plant exporting egg products to the USA will be carried out by the territorial SFVS 4 times a year. A model of a verification report for the activity of the supervising official veterinarian carrying out the continuous official veterinary control at the egg processing plant exporting egg product to the USA has been worked out as Annex 6 to the Quality System Working Procedure KT-2-2-18-D1 and adopted by the same Order No B1-134 of SFVS Director (Annex 2 to this letter). This report will be completed at the time of each official periodic supervision (official veterinary control) in order to assess the performance of the supervising official veterinarian.

Referring to the observation provided in your letter in relation to the non-compliance between the Quality System Working Procedure KT-2-3-2-D1 and the continuous official veterinary control, which is actually performed at the plant, we hereby confirm that continuous official veterinary

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control is ensured at the egg processing plant as the application of this kind of control is laid down by Order No B1-664 of SFVS Director of 03-07-2015 "On continuous veterinary supervision". In the translation of the aforementioned Order into the English language, wrong terminology was used, moreover, certain nonconformities appeared in the Quality System Working Procedure KT-2-3-2-D1 as the said Working Procedure was draw up as a general working procedure for meat and egg processing plants engaged in export of their production to the USA. Seeking to improve the quality management documents and to ensure the execution of the continuous official veterinary control at the egg processing plant, a separate Quality System Working Procedure KT-2-3-2-D2 "Continuous Official veterinary control of egg processing plants producing egg products intended for export to the USA" (Annex 3 to this letter) was adopted by Order No B1-189 of SFVS Director of 27-03-2017.

The following measures have been implemented at the egg processing plant to rectify the non-compliances with sanitation requirements indicated in Section VI, Part 3 of the draft audit report:

Did not fully implemented Government oversight regarding implementation and verification of sanitary requirements cited in 9 CFR Part 590	**Measures adopted at the plant to rectify the irregularities**
1. The FSIS auditor did not observe the establishment conduct candling procedures to detect eggs with cracked shells and interior defects.	The egg sorting equipment "Moba" has been adjusted: the sensor/transmitter mechanism of the sorting equipment has been replaced, therefore, adequate egg sorting process has been ensured, i. e. egg candling is carried out in the process of which eggs with interior defects and cracked or broken shell are identified and removed from the breaking process. 4 additional working places for the control of the egg sorting process and manual selection of eggs unsuitable for breaking from the transporter have been installed, which ensures 100 per cent that only eggs suitable for breaking enter the breaking process. The plant has updated the working procedure with a detailed description of the egg breaking process, i. e. in case of increase of the numbers of eggs with interior defects, cracked, broken shells or similar defects, the line is immediately stopped and the raw material is collected from the transporter, washing and disinfection is carried out. Additional training of the staff of the plant has been conducted.
2. The FSIS auditor did not observe the establishment conduct washing, sanitizing, and drying dirty eggs.	The plant made a decision that the washing and sanitising equipment will not be installed at the plant as, after the plant has implemented the requirements for classification of eggs intended for breaking in accordance with the criteria established by the USA 9 Code of Federal Regulations Part 590, paragraph 590.510, eggs without any interior or exterior defects, clean and 100 per cent suitable for breaking enter the breaking process.

	This is ensured by the proper operation of the "Moba" equipment and the additionally installed 4 working places for manual selection of eggs intended for breaking.
3. Some of the nest run eggs (shell eggs) loaded onto the breaking machine conveyor belt had adhering dirt and foreign material on the shell surface. These dirty eggs were in direct contact with each other and other eggs on the conveyor belt creating a potential for cross contamination between eggs and conveyor belt before breaking operations. The establishment's employees did not remove these eggs prior to the breaking operation.	4 additional working places for manual selection of eggs unsuitable for breaking have been installed. If dirty eggs were transferred from the sorting equipment to the conveyor belt they would be removed by the staff manually ensuring that 100 per cent clean eggs reach the breaking process. In case of increase of the number of eggs unsuitable for breaking (dirty, cracked, broken) on the conveyor belt, the line is immediately stopped, the raw material is collected from the belt, the washing and disinfection is carried out. Working procedures for the egg contamination control have been developed at the plant and training for the staff has been conducted.
4. Following breaking, an accumulation of intact shell eggs or large fragments of broken shells was observed in the egg products containers, resulting in direct product contamination	In order to preclude the presence of egg shells in the mass of liquid eggs the speed of the egg breaking machinery has been adjusted by ensuring 100 per cent quality of the egg sorting process to prevent the entering of defective and non-standard eggs into the breaking process, furthermore, in case of presence of any shell remains in the egg separation cups, they are removed manually; training has been conducted for the staff engaged in performing this procedure. The work gloves worn by the staff performing this procedure are changed and disinfected at least every 2 hours. The mechanism of the breaking machine has been enhanced in order to ensure the prevention of particles of egg shells from getting into primary containers for collecting the mass of liquid eggs, i. e. a protective sieve has been installed in the egg breaking machine "Pellbo".
5. Beaded condensate, dust on overhead structures, and pooling water on the floor were also observed. However, FSIS did not observe any direct product contamination on the day of the audit.	In order to prevent the condensate in the storage room the operation and the automatic regulation system of the ventilation system has been transformed. In order to reduce the egg powder dust in the egg powder production premises on pre-packaging equipment and the leakage, locking mechanisms for sacks have been installed, which allowed significantly reducing the dust in the egg powder production room. More frequent cleaning of structures, i. e. once per quarter to prevent the accumulation of the dust has been planned in the sanitation standard operating procedure of the plant. To prevent the pooling of water on the floor the cover of the floor has been replaced to ensure water drain. Amendments to

	the Sanitation Standard Operating Procedure have been made. Additional training for the staff responsible for washing procedures have been conducted, the control of the washing procedures has been strengthened.

The rectification of the irregularities of sanitary requirements referred to in Part 3, Section VI of the draft audit report and the implemented measures are evidenced by the plan of corrective actions provided by the egg processing plant that was ascertained by the Rectification Inspection Report No 48GPGĮ-6 of 22-03-2017 issued in the process of verification of the official veterinary control carried out by the Plungė State Food and Veterinary Service of the SFVS (Annex 4 to this letter).

The SFVS hereby assures that the newly drafted and adopted quality management documents, which are applied for carrying out the official veterinary control, ensure the compliance of the sanitary requirements at the egg processing plant with the relevant legal acts of the USA (9 CFR Part 590).

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

Sincerely yours,

Acting Director Deividas Kliučinskas

STATE FOOD AND VETERINARY SERVICE
DIRECTOR

ORDER
ON AMENDMENT OF ORDER NO. B1-96 OF DIRECTOR OF THE STATE FOOD AND VETERINARY SERVICE OF 5 FEBRUARY 2016 "ON APPROVAL OF THE QUALITY SYSTEM WORKING PROCEDURE KT-2-2-18-D1 "OFFICIAL VETERINARY CONTROL OF EGG PACKING AND EGG PROCESSING PLANTS" AND REPEALING CERTAIN ORDERS OF DIRECTOR OF THE STATE FOOD AND VETERINARY SERVICE"

No B1-134 of 15 March 2017
Vilnius

I hereby a m e n d the Quality System Operating Procedure KT-2-2-18-D1 "Official veterinary control of egg packing and egg processing plants" approved by Order No B1-96 of Director of the State Food and Veterinary Service of 5 February 2016 "On approval of the Quality System Working Procedure KT-2-2-18-D1 "Official veterinary control of egg packing and egg processing plants" and repealing certain orders of Director of the State Food and Veterinary Service":

1. I hereby amend point 4 of paragraph 1 "Execution of official veterinary control" and set it out as follows:

"4. Egg processing plants, which export egg product to the United States of America (hereinafter – the USA), must respect the requirements laid down in the USA 9 Code of Federal Regulations, Part 590 – Inspection of Eggs and Egg Products (Egg Products Inspection Act). Egg processing plants, which export egg product to the USA, must be:

4.1. within the competence classified as high risk food business operators by decision of territorial SFVSs (prior to drawing up an annual official control plan);

4.2. within the competence inspected four times a year by territorial SFVSs."

2. I hereby amend sub-point 5.3 of paragraph 1 "Execution of official veterinary control" and set it out as follows:

„5.3. at the egg processing plant, which exports egg product to the USA, – Annex 4 "Special requirements for egg processing plants, which export egg products to the USA" and Annex 6 "Inspection report on activity of a controlling official veterinarian carrying out continuous veterinary control at an egg processing plant exporting egg product to the USA".

3. I hereby add Annex 6 “Inspection report on activity of a controlling official veterinarian carrying out continuous veterinary control at an egg processing plant exporting egg product to the USA” (attached).

Acting Director Deividas Kliučinskas

Draftsperson:
Jonas Stanius,
Senior Veterinarian,
Official Veterinary Inspector
of Veterinary Sanitary Department

15-03-2017

Annex 6

STATE FOOD AND VETERINARY SERVICE

VERIFICATION REPORT FOR THE ACTIVITY OF THE SUPERVISING OFFICIAL VETERINARIAN CARRYING OUT THE CONTINUOUS OFFICIAL VETERINARY CONTROL AT THE EGG PROCESSING PLANT EXPORTING EGG PRODUCT TO THE USA

_____ No_____
(date)

_____
(place)

The Assessment Report was drawn up by the SFVS officer(s)

Assignment | | Type of inspection | |

Objective of the assessment:

To make an assessment of the continuous official veterinary control

Name of the egg product production plant

Types of egg products produced at the plant

The officially appointed veterinarian who performs the continuous official veterinary control at the egg product production plant and who attended the assessment

Last assessment was carried out on _____Report No_____
(date)

Findings

Serial No	Requirement	Yes / No / Not checked	Remarks
Part I	**Assessment of the official control of pre-operational sanitation conducted by the official veterinarian carrying out continuous official veterinary control**		

1.	Is the continuous assessment of the compliance of the plant with the sanitary requirements of the USA 9 CFR §. 590.500 made prior to starting operations as regards:		
	a) the condition of production premises		
	b) the condition of dressing rooms, toilet rooms or resting rooms		
2.	Is the continuous assessment of the compliance of equipment with USA 9 CFR §. 590.502 requirements made prior to starting operation?		
3.	Is the daily assessment of the compliance of general operating procedures with the requirements of the USA 9 CFR § 590.504 made prior to starting operation as regards:		
	a) storing, processing and handling shell eggs and raw materials;		
	b) handling and taking away ABPs.		
4.	Is the continuous assessment of the compliance of premises and equipment used for receiving and sorting shell eggs with the requirements of the USA 9 CFR § 590.506 made prior to starting operation?		
5.	Is the continuous assessment of due storage and separation of foodstuffs, chemicals and pest destruction products in compliance with the requirements of the USA 9 CFR §. 590.504 made prior to starting operation?		
6.	Is the continuous assessment of due storage of packing materials in compliance with the requirements of the USA 9 CFR § 590.504 made prior to starting operation?		
7.	Is the continuous assessment of due ensuring insect, rodent or other animal control in compliance with the requirements of the USA 9 CFR § 590.500 made prior to starting operation?		
8.	Are Salmonella surveillance reports checked and assessed daily prior to starting operation as regards the compliance with the USA 9 CFR §		

	590.504?		
9.	Is the arrangement of weekly meetings ensured?		
Part II	**Assessment of the official control of production of liquid egg products conducted by the official veterinarian carrying out continuous official veterinary control**		
10.	Is periodic control and assessment of the health status, cleanness of clothing and hands of the staff involved in production carried out during the technological process?		
11.	Is the control of the conformity of shell eggs intended for breaking and their sorting in accordance with the requirements of point c, USA 9 CFR § 590.510 ensured?		
12.	Is the periodic control of the compliance of the procedure for collection of restricted shell eggs with the requirements of the USA 9 CFR §. 590.800 carried out?		
13.	Is the periodic control of the compliance of the procedure for washing shell eggs with the requirements of the USA 9 CFR §. 590.515 carried out during the technological process?		
14.	Is the periodic control of the compliance of shell egg disinfection and drying procedures with the requirements of the USA 9 CFR §. 590.516 carried out during the technological process?		
15.	Is the periodic organoleptic assessment of shell eggs intended for breaking carried out during the technological process?		
16.	Is the periodic control of the compliance of shell egg breaking equipment and shell egg breaking procedures with the requirements of the USA 9 CFR § 590.520 and 590.522 carried out during the technological process?		
17.	Is the suspension of the shell egg breaking process and measures to eliminate contamination applied upon detection of irregularities at the time of periodic inspections during the technological process?:		
	a) separation of dirty and damaged shell eggs;		
	b) denaturation and labelling of inedible shell eggs;		
	c) washing and disinfection of		

	equipment.		
18.	Is the periodic control of the compliance of cooling and holding liquid eggs with the requirements of the USA 9 CFR § 590.530 and 590.532 carried out during the technological process?		
19.	Is the periodic control of the compliance of freezing and holding liquid eggs with the requirements of the USA 9 CFR § 590.534 and 590.536 532 carried out during the technological process?		
20.	Is the control of weighing liquid eggs ensured?		
Part III	**Assessment of the official control of production of dried egg products conducted by the official veterinarian carrying out continuous official veterinary control**		
21.	Is the control of the hygiene of special purpose clothing, hands, good food handling practice ensured?		
22.	Is the periodic organoleptic control of liquid eggs and produced egg powder carried out during the technological process?		
23.	Is the periodic control of the sanitation of the egg drying room, equipment and egg packing and its compliance with the requirements of the USA 9 CFR § 590.540 and 590.542 carried out during the technological process?		
24.	Is the introduction of additives, blending and their compliance with the USA 9 CFR § 590.548 ensured?		
25.	Is the pest, rodent and odour control and its compliance with the USA 9 CFR § 590.542 ensured?		
26.	Is the labelling and denaturation of inedible products ensured?		
27.	Is the storage and temperature control of unpasteurised liquid egg mass ensured prior to processing?		
24.	Is the control of the pasteurisation process and its compliance with the USA 9 CFR § 590.570 and 590.575 ensured?		
25.	Is the storage of packing materials and products and its compliance with the USA 9 CFR § 590.548 ensured?		
26.	Is the sanitary control of toilet rooms, dressing rooms, resting rooms and product dispatch rooms ensured?		
27.	Is the weighing control of produced products ensured?		

28.	Is the removal and taking away of waste ensured?		

Additional information

Conclusions and instructions

The Report was issued in 2 copies, which were communicated to:

1. _____ State Food and Veterinary Service
2. The officially appointed veterinarian who carries out the continuous official veterinary control at the egg production plant

The assessment was started on _____ at _____ (date, time)

The assessment was finished on _____ at ____ (date, time)

Assessed by:

_____ _____ _____
(position) (signature) (name, surname)

_____ _____ _____
(position) (signature) (name, surname)

Attended by:

_____ _____ _____
(position) (signature) (name, surname)

I have seen the Report and received a copy thereof.
The officially appointed veterinarian
carrying out continuous official veterinary control at the egg product plant

_____ _____
(name, surname) (signature)

APPROVED
by order No B1-189 of 27 March 2017 of
Director of the State Food and Veterinary
Service

QUALITY SYSTEM WORKING PROCEDURE KT-2-3-2-D2 “CONTINUOUS OFFICIAL VETERINARY CONTROL OF EGG PROCESSING PLANTS PRODUCING EGG PRODUCTS INTENDED FOR EXPORT TO THE USA“

Date	Version (No) /Amendment (No.) /revision	Full name of document author	Signature
27-03-2017	Version 1	Jonas Stanius	

QUALITY SYSTEM WORKING PROCEDURE KT-2-3-2-D2 "CONTINUOUS OFFICIAL VETERINARY CONTROL OF EGG PROCESSING PLANTS PRODUCING EGG PRODUCTS INTENDED FOR EXPORT TO THE USA"

§ 1. PURPOSE

The working procedure for continuous official veterinary control of egg processing plants producing egg products intended for export to the USA (hereinafter – Working Procedure) lays down the procedure for the continuous official veterinary control carried out by a supervising official veterinarian at an egg processing plant.

Provisions of this Working Procedure comply with requirements of regulatory legal acts seeking to:

• ensure systematic and effective official veterinary control at egg processing plants;

• ensure effective implementation of research and development experience.

The responsibility of the officially appointed veterinarian carrying out the continuous official veterinary control at egg processing plants is to ensure that the product intended for processing and produced products are in compliance with the food safety and quality requirements laid down by legislation in effect in the USA. To that end, he/she has to control and ensure:

• the compliance of production premises and equipment with hygiene and sanitation requirements;

• the implementation of sanitation standard operating procedures, control of effectiveness of cleaning and disinfection;

• the compliance of the general working procedures with requirements laid down by legislation of the USA;

• the safety and quality control of eggs intended for production of egg products;

•egg processing by ensuring technological requirements laid down by legislation of the USA;

• the sampling of products and environment and laboratory control;

• the labelling of products not intended for food and their removal;

• the safety and quality of production produced;

• timely identification of irregularities ensuring that the unsafe products are not placed on the market;

• the coordination of rectification plans with the plant;

• the provision of information and advice to specialists of the plant on new legal acts and their application in activities of the plant;

• the provision of advice in case of reconstruction of premises, launching production of new products, on export requirements in case of expanding the market.

• the conduct of weekly meetings with the management of the plant to discuss and take decisions on ensuring the food safety and quality of produced products.

§ 2. REFERENCES

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food

Safety Authority and laying down procedures in matters of food safety (OJ *2004, Special Edition*, Chapter 15, Volume 6, p. 463);

European Parliament and Council directive (EC) No 852/2004/EC of 29 April 2004 on food hygiene;

European Parliament and Council Directive (EC) No 853/2004/EC of 29 April 2004 laying down specific hygiene rules for food of animal origin;

European Parliament and Council directive (EC) No 882/2004/EC of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules;

Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria of food products (OJ 2005 L 338, p. 1)

Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ 2009 L 300, p. 1).

Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ 2013 L 347 p. 671)

COMMISSION REGULATION (EC) No 589/2008 of 23 June 2008 laying down detailed rules for implementing Council Regulation (EC) No 1234/2007 as regards marketing standards for eggs (OJ 2008 L 163, p. 6);

COMMISSION REGULATION (EC) No 543/2008 of 16 June 2008 laying down detailed rules for implementing Council Regulation (EC) No 1234/2007 as regards marketing standards for eggs (OJ 2008 L 157, p. 46)

Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ 2009 L 152, p. 11)

Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ 2006 L 364, p. 5)

Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ 2005 L 70, p. 1)

the Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ 2008 L 354, p. 16)

Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ 2011 L 304, p. 18).

Order No B1-31 of 15 January 2005 of the director of the State Food and Veterinary Service “On instructions of state veterinary supervision of food business operators”.

LST EN ISO/IEC 17020:2012 “Conformity assessment. Requirements for the operation of various types of bodies performing inspection.

KT-1-8-D1 Application of market restriction measures under the Law on Product Safety of the Republic of Lithuania.

KT-3-1 State sample collection and delivery to the laboratory.

KT-2-2-18-D1 State veterinary control of egg packaging and egg product manufacturing entities.

“Sanitation standard operating program requirements” approved by order No B1-795 of 10 October 2012 of the director of the State Food and Veterinary Service.

Part 590 of United States Code of Federal Regulations “Eggs and egg product control” (Egg Products Control Act).

FSIS Directive 5000.1 of the United States Rev. 4 Verifying an Establishment‘s Food Safety System.

FSIS Directive 5010.1 of the United States Rev. 2 Food safety related topics for discussion during weekly meetings with establishment management.

FSIS Directive 10,230.4 of the United States, Salmonella surveillance program for liquid and frozen egg products

Federal Code of Legal Acts of the United States, part 416 Sanitation.

FSIS Directive 5030.1 of the United States . Inspection methodology utilizing the public health information system (PHIS) for the verification of regulatory compliance in egg products plants.

FSIS Directive 11,000.2 of the United States. Verification activities for the use of new technology in meat and poultry establishments and egg products plants

§ 3. DEFINITIONS USED

Animal origin food business operator means a natural or legal person engaged in handling animal origin food, which holds an issued veterinary approval number of an animal origin food business operator

Supervising official veterinarian means an official veterinarian performing the function of official veterinary control in accordance with the legislation regulating veterinary activities.

§ 4. RESPONSIBILITY

The Veterinary Sanitary Department of the State Food and Veterinary Service (hereinafter – SFVS), the territorial service of the SFVS and the Internal Audit Department shall be held responsible for the control of meeting the requirements of the Working Procedure whereas the supervising official veterinarian appointed by the SFVS shall be held responsible for carrying out the actions laid down by the Working Procedure.

§ 5. CARRYING OUT THE CONTINUOUS OFFICIAL VETERINARY CONTROL

The continuous official veterinary control covers:

1. **examination,** which is carried out by observing the environment, buildings, premises, structures, equipment, staff, actions, animal origin raw materials, production and technological processes, produced products, other processes taking place at the plant.

2. **documentary check**, which is carried out at the frequency specified by the Working Procedure by checking documents and data records and, in case of a suspicion as regards the violation of the safety of a product or the procedure in effect, by randomly choosing the time for the check.

3. **physical check**, which is carried out by using measuring devices at critical control points and at control points. The measurement results are assessed based on the values and critical limits of the CCPs and CPs established under the HACCP system as well as data records in registration logs.

4. **laboratory analysis of raw materials and products**, which is carried out in accordance with Regulation No 2073/2005 of the European Parliament and of the Council on microbiological criteria for foodstuffs; FSIS Directive 10,230.4 “Salmonella surveillance program for liquid and frozen egg products”; FSIS Directive 10.300.1 “Intensified verification testing (ivt) protocol for sampling of product, food contact surfaces, and environmental surfaces for Listeria monocytogenes”; FSIS Directive 10.240.4 “Verification procedures for consumer safety inspectors for the Listeria monocytogenes regulation and Listeria monocytogenes sampling programs”; Notice to the Egg Products Industry of FSIS Director, United States Department of Agriculture of 31 October 1995 and Notice of 16 November of 1995 “Use of Shelf Life Claims on Liquid Egg Products” of FSIS Director, United States Department of Agriculture and Notice of 16 November 1995 “Use of Shelf Liquid Egg Products Correction to my November 1 Memorandum”; Notice 57-16 of the USA Department of Agriculture FSIS of 11 August 2016 to the inspection program personnel (IPP);

5. **order on holding weekly operations meetings** during which issues related to food handling irregularities and non-conformities, tendencies or observations established at the food business operator in the process of carrying out the continuous official veterinary control or arising from this control shall be discussed together with the management of the food business operator. The issues to be discussed at the meetings can be included in the agenda based on the recommendations provided in the United States FSIS Directive 5010.1 Rev. 2 “Food safety related topics for discussion during weekly meetings”, and decisions ensuring food safety and quality of production are taken.

§ 6. MAJOR PRINCIPLES OF CONTINUOUS OFFICIAL VETERINARY CONTROL

The continuous official veterinary control of animal origin food business operators engaged in production of egg products intended for the USA market is carried out by a supervising official veterinarian (hereinafter – official veterinarian) in accordance with the requirements of FSIS Directive 5000.1 Revision 4, Verifying an Establishment‘s Food Safety System and Code of Federal Regulations 9 CFR 416 Sanitation.

1. Each day, prior to launching operations at the plant, the official veterinarian has to assess the sanitary condition of the plant and fill in Part 1 of the Registration Sheet for Continuous Veterinary Control of an Egg Processing Plant provided in Annex 3 “Monitoring of pre-operational sanitation standard operating procedure” as well as the table related to the pre-operational control provided in the part of the Registration Sheet for the Continuous Official Veterinary Control of the Technological Process of a Dried Egg Product Production Plant provided in Annex 4.

During the production process, the official veterinarian shall periodically assess technological processes at the egg processing plant, which is engaged in production of liquid egg products and dried egg products intended for the USA market. The results of the inspections are recorded by filling in the column “Inspection of operations control” of the Registration Sheet for Continuous Official Veterinary Control of an Egg Processing Plant provided in Annex 3 and the table in the Registration Sheet for Continuous Official Veterinary Control of the Technological Process of a Dried Egg Product Production Plant provided in Annex 4.

§ 7. PRODUCTION SAFETY CONTROL

1. Samples for laboratory analysis are selected and transported to the accredited laboratory in accordance with the Quality Management Programme KT-3-1 “Selection of an Official Sample and its Delivery to the Laboratory” approved by Order No B1-403 of SFVS Director of 25 May 2016.

2. The official veterinarian has to check the raw materials that are brought to the processing plant to ensure that the raw materials are in compliance with the requirements laid down by legal acts of the USA and that they can be further used for the production of products intended for export to the USA.

3. Products intended for export to the USA have to comply with the requirements laid down by legal acts referred to in paragraph 2.

4. The official veterinarian, in the process of carrying out the continuous official veterinary control at an egg processing plant, must periodically assess laboratory analyses programmes of the plant, in particular, as regards *Salmonella, Listeria Monocytogenes, Enterobacteriaceae.*

5. The official veterinarian:

a. has to take monthly official samples for the detection of *Salmonella* contamination from each sort of egg products produced at the plant immediately after packaging.

b. has to take monthly official samples for the detection of *Listeria Monocytogenes* contamination from each sort of egg products produced at the plant immediately after packaging.

c. has to take an aggregate sample from yolks or the entire mass of unpasteurised, filtered eggs without additives for the detection of antimicrobial substances, pesticides and heavy metals once per quarter.

d. has to take weekly samples from one of the egg products produced at the plant (the sampling plan n – 5) for *Enterobacteriaceae* testing in accordance with requirements of point 2.3.1 , Chapter 2, Annex I to Commission Regulation (EC) No 2073/2005.

6. The State Food and Veterinary Service approves the annual official sampling plan at the egg processing plant. See the Official Sampling Plan for 2017 in Annex 5.

7. The official veterinarian keeps records of the course of the implementation of the laboratory analysis plan in the annual Registration Sheet for the Implementation of the Official Sampling Plan the form of which is provided in Annex 1.

§ 7.1. GUIDELINES FOR COLLECTING SAMPLES FROM SURFACES IN CONTACT

When samples are collected with a sponge or washings are collected with the use of a swab the sampling must be carried out in accordance with the Methodological Guidelines for Collecting Washings for Laboratory Analyses approved by Order No B1-338 of SFVS Director of 17 May 2006. Samples can be aggregated if their proper analyses can be justified scientifically. The remaining part of the sample must be stored till the aggregate results are received. If the results are unsatisfactory each sample has to be analysed to find out exactly the source of the contamination.

Samples from surfaces coming in contact with the finished product (the packaging line) must be collected from a larger area: e. g., 0.5 m x 0.5 m., 0.6 m x 1 m, etc.

Samples from the floors and the drain system should be also included into the sampling programme.

§ 8. PERFORMANCE OF THE OPERATING PROCEDURE AND REPORTING

In order to ensure the traceability of the continuous official veterinary control, the control activities have to be documented accordingly. The continuous official veterinary control has to be carried out strictly in accordance with the instruction laid down by the Operating Procedure whereas the results have to be recorded in relevant Registration Sheets. The Registration Sheets must bear the stamp and signature of the official veterinarian. The official veterinarian has to draw up a schedule for inspections in accordance with the established frequency and with the assessment of the risk and has to follow this schedule in the process of carrying out the continuous official veterinary control.

Marking:
Good, satisfactory result [+];
Poor, unsatisfactory [-];
The responsible executive has been warned [o].

If minor non-compliance with legal acts are identified during the continuous official veterinary control and they can be quickly rectified the responsible employee of the plant is warned orally. If the identified irregularities are not rectified in the fixed time or if the irregularity is of a substantial character (posing a risk to food safety and quality) a notice has to be issued for Director of the plant and Chief of the territorial SFVS (Annex 2).

Quality System Operating Procedure KT-2-3-2-D2 "Continuous official veterinary control of egg processing plants producing egg products intended for export to the USA"
Annex 1

REGISTRATION SHEET FOR THE IMPLEMENTATION OF THE OFFICIAL SAMPLING PLAN AT AN EGG PROCESSING PLANT FOR 20____

Subjects	**Analytes /Month**													**IN TOTAL**	
														number of tests	**Amount, EUR**
Egg product made in the company (during packaging)	*Salmonella spp* 100 g *L. monocytogenes 25 g*														
Liquid pasteurized egg product made in the company once per quarter, two samples, one tested immediately after delivery to the laboratory, the other on the last date of the validity term	*L. monocytogenes 25 g*														

Sample of unpasteurised filtered egg yolks or entire mass without added enhances, 500 g once per quarter.	• Antimicrobials (sulphonamides) • Pesticides • Heavy metals (arsenic) (testing according to the substance residue list for checking in the monitoring plan)														
1 sample is taken of pasteurized egg products manufactured in the company once a week, for one type of egg products	• Enterobacteriaceae Colony count per gram. Limit m=10 cfu/g M=100 cfu/g 2 from 5 samples, permissible number between m and M														
Washings from the tools and equipment surfaces in direct contact with the products (before work)	*L. monocytogenes* *Salmonella spp*														
Washings from the tools and equipment surfaces not in direct contact with the products (before the work)	*L. monocytogenes* *Salmonella spp*														
Washings from work clothes, worker hands (during work)	*Coliform bacteria*														
Total															

Quality System Operating Procedure KT-2-3-2-D2 "Continuous official veterinary control of egg processing plants producing egg products intended for export to the USA"
Annex 2

NOTICE No:

……..
(date)

To the Chief _____
(territorial SFVS)

During continuous official veterinary control of ....
(name, address of animal origin food business operator)
. …….. it was established that:
…….....……
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.....
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Conclusion:
……
……
…….....

Official veterinarian: .....
(full name, signature)

Quality System Operating Procedure KT-2-3-2-D2 "Continuous official veterinary control of egg processing plants producing egg products intended for export to the USA"
Annex 3

REGISTRATION SHEET FOR THE OFFICIAL CONTINUOUS VETERINARY CONTROL OF AN EGG PROCESSING PLANT

Name of the animal origin food business operator: _____

Veterinary approval No. _____

Inspection registration sheet for continuous official veterinary control No. _____

Date (year, month, day): _____

Processing operations

Time – egg beating from_____ to _____ pasteurisation from _____ to_____

Working hours of the official veterinarian from_____ to_____

Marking of assessment results: Mark „+" means GOOD/SATISFACTORY

Mark „– "means POOR/UNSATISFACTORY

Mark „O" means the responsible executive has been warned

PART 1

Monitoring of the pre-operational sanitation standard operating procedure		**Sheet for inspection of operations control**				
Time of control:		Time of control:				
1. Equipment used for pasteurized egg mass production washed and disinfected (piping, seals, valves, pumps)		21. Sensory test and pouring test				
2. Equipment clean and disinfected before work		22. Health condition of employees, clothing, hats, hand cleanliness				
3. Egg washing equipment and conveyors are clean		23. Beating process, sanitation requirements ensured for the beating machine.				
4. Sanitation requirements in production premises ensured		24. Organoleptic egg assessment				
5. Ensured sanitation requirements in the receipt and dispatch premises		25. Procedures only apply in cases where eggs not suitable for human consumption are found (separation of inedible eggs, equipment replacement, hand washing)				
6. Waste collection and disposal ensured		26. Separation of dirty and damaged eggs				

7. Ensured sanitary requirements in amenities and recreation rooms		27. Denaturing and marking of eggs unfit for consumption				
8. CIP piping and equipment cleaning ensured		28. Hydrogen peroxide test				
9.a. Beating and packaging room, compressors, air filters, etc. equipment conforms to specified requirements?		29. Packing room and equipment sanitary				
9. b. Duct surfaces in contact with products are without damage and clean before use.		30. Product containers are clean and filled, ensuring sanitary requirements				
10. Food storage requirements are ensured.		31. Container labelling and marking are appropriate				
11. Pest control measures are separated from the chemicals		32. Products weighing is appropriate				
12. Pest control tools and chemicals separated from food products		33. Ventilation ensured in the processing and packaging premises				
13. Packaging materials storage ensured		34. Processing rooms protected against flies and foreign odours				
14. Freezers are clean, containers arranged properly, air circulation ensured		35. Equipment cleaned and disinfected before use				
15. Disposal systems function in the recreation, reloading and waste premises		36. Sanitation in beating and processing premises				
16. Transport territory		37. Shell separators and egg mass filters operate and are cleaned				
17. Sanitation of processing premises ensured		38. Sanitation in dispatch premises, washing and equipment ensured				
18. Insect and rodent control in the company and in the territory ensured		39. Disinfection solution for eggs disinfection complies by ppm				
19. Company's Salmonella monitoring messages checked		40. Water washing temperature corresponds to the requirements for egg washing.				
20. Check the product composition and refractometry						

Other comments of the official veterinarian performing the control:

_____

CONCLUSION. The animal origin food business operator M**AY/MAY NOT** (delete as appropriate) start the food processing activities.

Official veterinarian:_____
(full name, signature)

I am familiar with the irregularities identified, corrective actions have been taken:

_____
(Full name and signature of the head of the animal origin food business operator (authorized person)

PART 2

Temperatures	Time				Time				Time				Time			
	Liquid egg	Yolks	Protein	Egg products	Liquid egg	Yolks	Protein	Egg products	Liquid egg	Yolks	Protein	Egg products	Liquid egg	Yolks	Protein	Egg products
Non-pasteurized products a. 2 hrs after breaking will be kept up to 8 hours.																
b. 2 hrs after breaking will be kept over 8 hours.																
c. Stored for removal or recycling																
a. Recorded indicator																
b. Measuring thermometer																
c. Flow diversion valve setting																
d. Yield per minute																
e. Storage time (in minutes) **Pasteurised liquid products**																
a. 2 hrs after pasteurisation will be kept up to 8 hours.																

b. 2 hrs after pasteurisation will be kept over 8 hours.																
c. stored for removal																
Fridge																
Liquid egg storage room																

PART 3

Processed eggs ..... Total (liquid product) ..... Liquid egg utilisation .....

30 batches

Ready-made product name	Output message			Final inspection (liquid or frozen)				Weight check (final product)			
	Container No	Marked container weight	Quantity	Inspection date	Container No	Temperature	Storage conditions	Container No	Weight	Container weight	Net weight
Unsuitable for consumption											

Quality System Operating Procedure KT-2-3-2-D2
"Continuous official veterinary control of egg processing plants producing egg products intended for export to the USA"
Annex 4

REGISTRATION SHEET FOR CONTINUOUS OFFICIAL VETERINARY CONTROL OF THE TECHNOLOGICAL PROCESS OF A DRIED EGG PRODUCT PRODUCTION PLANT

Name of the animal origin food business operator: _____

Veterinary approval No. _____

Control sheet for continuous official veterinary control No. _____

Date (year, month, day):_____

Processing operations: Time – egg drying from_____ to _____ pasteurisation from _____ to_____

Working hours of state veterinarian from_____ to_____

Designation of assessment results: Mark „+" means GOOD/SATISFACTORY

Mark "–" means POOR/UNSATISFACTORY

Mark „O" means Warned the responsible manager

Sanitation checklist	**Control time** →											
1. Organoleptic liquid egg and powder control?												
2. Packaging rooms, equipment, containers, liners and packaging sanitary ensured?												
3. Air filtering system and air movement satisfactory in packaging and processing rooms ?												
4. Employee health and cleanliness (spec. clothing, hand hygiene, good food handling practices)?												
5. Drying and processing facilities and equipment?												
6. Cleaning and sewerage of transport containers?												
7. Container identification, marking and weighing?												
8. Tiredness of joints, inserts unfiltered air has no access to the drying system?												
9. Injection and blending of additives?												
10. Pasteurizer and pasteurization equipment?												
11. High-pressure pumps, lines, valves, nozzles, piping CIP?												
12. Insect, rodent and odour control?												
13. Inedible product labelling, denaturation?												
14. Heat treatment facilities, spacing between products, air circulation?												

15. Other													
16. Other													
TEMPERATURES	Control time ⟶									**Indicating thermometer**			
PRODUCT										Accuracy --- ^{0}C	Thermometer Response --- Seconds		
17. UNPASTEURIZED MASS a. Approved – kept up to 8 hours.													
b. Approved – kept over 8 hours.										**Recording control**			
c. Stored prior to processing										Accuracy --- ^{0}C	Thermometer Response --- Seconds		
18. STABILISATION										**Flow diverter valve**			
19. PASTEURIZATION a. Recorder readings										Response ------ seconds	Valve is set properly? □ Yes □ No		
b. Indication thermometer										Does flow leak past forward flow seat? □ Yes □ No			
c. Flow diversion valve setting										Response to manual diversion:			
d. Flow per minute													
c. Withdrawal time													

(minutes)											
20. Pasteurized mass a. Directly for drying											
b. Will be kept up to 8 hours.											
c. Will be kept above 8 hours.											
d. Stored for processing											
e. Other											

SANITATION CHECKLIST CONTROL TIME →		DRYER SANITATION	CLEANING METHOD	CHECKED
21. Overhead line surfaces in contact with products are purged and clean before work		29. Dryer, fans and air ducts		
22. Storage of food ingredients		30. Aureus, pneumatic system, valves		
23. Insecticides and chemicals stored separately from food products		31. Strainers and flexible connectors		
24. Storage of packing materials and products		32 Sacks and bags room		
25. General sanitation in all other rooms		33. Bag replacement		
26. Amenities		34. Drier air filters, fan, air duct		
27. Other rooms, reception and dispatch		35. Disinfection or heat treatment of augers, piping, bolting, etc.		
28. Waste treatment and disposal		36. Drying system vents and exhausts holes closed after washing		
	37. Dryer heat-treated---------Time ----------^{0}C Intake ----------^{0}C Discharge			

READY-MADE PRODUCT TYPES	PRODUCTION REPORT			WEIGHING CONTROL			
	Container No	Container size	Weight	Container No	Weight	Tare	Net
Unfit for human consumption undenatured							
Unfit for human consumption denatured							
IN TOTAL							

Notes

Quality System Operating Procedure KT-2-3-2-D2 „Continuous official veterinary control of egg processing plants producing egg products intended for export to the USA"
Annex 5

OFFICIAL SAMPLING PLAN OF AN ANIMAL ORIGIN FOOD BUSINESS OPERATOR INTENDING TO EXPORT PRODUCED EGG PRODUCTS TO THE USA FOR 2017

Name of the sample, subject	Indicators	Sample size	Number of samples												Number of samples planned to be collected (according to the manufac-tured assortment)	Amount, EUR
			January	February	March	April	May	June	July	August	September	October	November	December	Total:	
KB "Baltic egg production"																

Sample of unpasteurised filtered egg yolks or entire mass without added enhances	• Antimicrobials (sulphonamides) • Pesticides • Heavy metals (arsenic) (testing according to the substance residue list for checking in the monitoring plan)	500 g		1			1			1			1		4	4x240,04	961,60
For each egg product category (during packaging)[1)]	*Salmonella spp.* 100 g	200 g	-	6	6	6	6	6	6	6	6	6	6	6	66	66 x 5,36	353,76
	L. monocytogenes 25g		-	6	6	6	6	6	6	6	6	6	6	6	66	66 x 8,40	554,40
Total products																**132**	**908,16**
Washings from instruments and equipment in contact with products (before work, sponge sampling method), 5 samples per week	*Salmonella spp.* *L. monocytogenes*	Sampling plan (1-5)	- -	10 10	10 10	10 10	10 10	10 10	10 10	10 10	10 10	10 10	10 10	10 10	110 110	110 x10,43 110 x3,77	1147,30 414,70
Washings from the surfaces not in contact with products (before work, sponge sampling method), 5 samples per week	*Salmonella spp.* *L. monocytogenes*	Sampling plan (1-5)	- -	10 10	10 10	10 10	10 10	10 10	10 10	10 10	10 10	10 10	10 10	10 10	110 110	110 x10,43 110 x3,77	1147,30 414,70
Washings from work clothes, worker hands (before work, sponge sampling method) 5	Coliform bacteria		-	8	10	10	10	10	10	10	10	10	10	10	108	108 x0,87	93,96

samples per week																	
Total washings																**548**	**3217,96**
In accordance with Commission regulation (EC) No 2073/2005, Annex I chapter 2, section 2.3.1, from the egg products packaged in the company, once a week, from one product batch (by selecting a different type of product)	Enterobacteriaceae	200 g Sampling plan (1-5)	-	10	20	20	20	20	20	20	20	20	20	20	210	210 x0,87	**182,70**
Total				70	82	82	82	82	82	82	82	82	82	82	890	**890**	**4308,82**

[1)] egg product samples for salmonella tests must be taken depending on the number of manufacturing processes per month. For example, if the company only makes pasteurized yolk mass, the number of samples per month is one. If the company makes pasteurized yolks and white's masses (two separate categories), the number of samples per month is two, i.e. one sample for each product category.

Sampling personnel must mark the sample reports with a reference "For Export to the U.S."

Kokybės sistemos programos KT-2-1
„Bendrieji reikalavimai vykdant ūkio subjektų veiklos priežiūrą“
2 priedas

PLUNGĖS VALSTYBINĖ MAISTO IR VETERINARIJOS TARNYBA

ŪKIO SUBJEKTO TRŪKUMŲ ŠALINIMO PATIKRINIMO AKTAS

2017 m. kovo 22 d.	Nr.	48GPGĮ- 6
(data)		

Plungė
(vieta)

Patikrinimo aktą surašęs pareigūnas (-ai)

Viršininkas-valstybinis veterinarijos inspektorius Virginijus Gailius
Vyriausiasis veterinarijos gydytojas-inspektorius Vytautas Mazrimas

Pavedimas	T12-104, 2017-03-20; 48MV1-91, 2017-03-21	Patikrinimo rūšis	Neplaninis

Patikrinimo tikslas

KB “Baltic egg production” (toliau - Įmonė) tikrinama dėl JAV FSIS (Food Safety and Inspection Service) audito ataskaitoje 2017-02-03 nurodytų trūkumų pašalinimo.

Ūkio subjektas

KB „Baltic egg production“, veterinarinio patvirtinimo numeris LT 68-09 EB, Birutės skg. 5, Macenių k., Plungės r. sav., tel.: 8 448 73170, faks: 8 448 71674, el.p.: info@vici.lt., subjektas priskirtas padidintos rizikos grupei.

Ekonominės veiklos rūšys

Pagrindinė	46.33 Kiaušinių ir kiaušinių produktų didmeninė prekyba, veiklos rūšis LEP, PP (skystųjų kiaušinių gamyba, produktų perdirbimas)

Patikrinime dalyvavęs (-ę) tikrinamo ūkio subjekto įgaliotasis (-ieji) darbuotojas (-ai)

Kokybės vadovė Ingrida Rupeikienė,
Įmonės nuolatinę priežiūrą atliekanti vyriausioji veterinarijos gydytoja Sandra Šeputytė

Vartotojų skundai

Skundų negauta

Paskutinis patikrinimas atliktas 2016-10-18 aktas Nr. 48GPGĮ-29
(data)

Trūkumu šalinimas

Įmonė, atsižvelgusi į JAV audito ataskaitą, 2017-02-24 Plungės VMVT pateikė Trūkumų šalinimo planą su nurodytomis priemonėmis ir terminais nustatytiems pažeidimams pašalinti.

Ūkio subjekto patalpų/veiklos pakeitimai/atnaujinimai

Nebuvo

Nustatyta

JAV audito ataskaitoje nurodyti pažeidimai: 1. Kiaušinių tikrinimo procesas neužtikrino, kad kiaušiniai su pažeistu lukštu ar nešvarūs, yra atskiriamai ir išimami iš srauto; 2. Ant padavimo transporterio patenka tiek švarūs, tiek ir pažeisti kiaušiniai, kuriais uzžteršiamas transporteris bei žaliava; 3. Daužymo metu, dalis lukšto pateko į pirmines sukaupimo talpas (voneles) - tiesioginė kryžminė produkto tarša; 4. Audito metu buvo pastebėtas susidaręs kondensatas miltelių sandėliavimo patalpoje, dulkės ant sijų - miltelių fasavimo patalpoje, ne visose patalpose grindys buvo sausos; 5. Nebuvo atliekamas nešvarių kiaušinių plovimas, dezinfekavimas ir džiovinimas

Eil. Nr.	Reikalavimas	Atitiktis Taip/Ne/ Netikrinta	Pastabos
	Paskutinio patikrinimo metu nustatyti teisės aktų pažeidimai pašalinti:	Taip	Pagal įmonės 2017-03-17 prašymą Nr. 6, patikrinimas atliktas dėl Trūkumų šalinimo plane numatytų priemonių įgyvendinimo. Tikrinti visi kiaušinių gaminių gamybos procesai - nuo žaliavos rūšiavimo iki galutinio produkto. Įmonė pašalino trūkumus, įgyvendintos šios priemonės:
1.	Kiaušinių tikrinimo procesas neužtikrino, kad kiaušiniai su pažeistu lukštu ar nešvarūs, yra atskiriamai ir išimami iš srauto		1. Pagal Mobos gamintojo rekomendacijas pašalintas įrenginio gedimas - jutiklio defektas - 2017-01-27. Atlikti įrenginio reguliavimo darbai užregistruoti "Įrengimų profilaktinių techninių apžiūrų ir remonto darbų registracijos žurnale Nr. 63". Prie kiaušinių padavimo transporterio įrengtos dvi darbo vietos (I-as žaliavos atrinkimo / kontrolės taškas) išrūšiuotų kiaušinių papildomam tikrinimui, atrenkant nešvarius ir pažeistu lukštu kiaušinius. Šią procedūrą atliekantys darbuotojai (visų trijų kontrolės taškų) supažindinti ir apmokyti su reikalavimais žaliavai. Darbo vietoje iškabintos instrukcijos su reikalavimais žaliavai. Esant nenumatytam atvejui, padidėjus nešvarių, skilusių kiaušinių kiekiui, nedelsiant stabdoma linija, nuo transporterio surenkama žaliava, atliekamas plovimas ir dezinfekavimas.
2.	Ant padavimo transporterio patenka tiek švarūs, tiek ir		2. Įrengus I-ą žaliavos atrinkimo / kontrolės tašką (žr. 1-ą eilutę) ant transporterio patenka tik švarūs, nepažeisti kiaušiniai. Tačiau siekiant užtikrinti 100% švarių kiaušinių patekimą į daužymą įrengti II-as ir III-ias žaliavos atrinkimo

	pažeisti kiaušiniai, kuriais užteršiamas transporteris bei žaliava		/ kontrolės taškai, tuo išvengiama transporterio užteršimo. Procedūros, reguliuojančios švarių kiaušinių padavimą daužymui, aprašytos RVASVT sistemos programose.
3.	Daužymo metu, dalis lukšto pateko į pirmines sukaupimo talpas (voneles) - tiesioginė kryžminė produkto tarša		3. Eilutėse Nr. 1 ir Nr. 2 nurodytomis priemonėmis užtikrinus švarių kiaušinių padavimą daužymui, išvengiama produkto kryžminės taršos. Daužymo metu, kiaušinių lukšto dalys, patekusios į atskyrimo lėkštutes, pašalinamos rankiniu būdu (lėkštutė apverčiama). Įrenginyje "Pelbo", po rankinio atrinkimo vieta ir atskyrimo lėkštučių išvertimo vieta įrengti specialūs sietai, sulaikantys kiaušinių lukšto dalis. Į pirmines sukaupimo talpas (voneles), patenka tik švarus kiaušinių turinys (trynys, baltymas, bendra kiaušinių masė). Procedūras atliekantys darbuotojai supažindinti ir apmokyti su kiaušinių daužymo reikalavimais.
4.	Audito metu buvo pastebėtas susidaręs kondensatas miltelių sandėliavimo patalpoje, dulkės ant sijų - miltelių fasavimo patalpoje, ne visose patalpose grindys buvo sausos		4. Sandėliavimo ir kitose patalpose kondensato nerasta. Ši neatitiktis pašalinta, nustačius nuolat veikiantį vėdinimo sistemos darbo režimą. Buvę grindų nelygumai ištaisyti, vanduo nebesusilaiko, po plovimo papildomai sausinama nubraukėju. Visose patalpose grindys sausos. Papildomai 2017-02-27 atlikti darbuotojų, atsakingų už plovimo procedūras, mokymai, sugriežtinta plovimo kontrolė. Miltelių gamybos ir fasavimo patalpose įrengus maišų fiksatorius žymiai sumažintas dulkėtumas. Tačiau dėl sudėtingų (pavojingų) darbų aukštai esančias, sunkiai pasiekiamas sijas ir konstrukcijas valo speciali aukštalipių komanda. Patvirtintas 2017 m. planas, numatantis šiuos valymo darbus atlikti kiekvieną metų ketvirtį. Paskutinis valymas atliktas 2017-01-12, sekantis valymas - š. m. balandžio 4-14 dienomis. Prieinamos konstrukcijos valomos kiekvieną dieną pagal sanitarijos programą.
5.	Nebuvo atliekamas nešvarių kiaušinių plovimas, dezinfekavimas ir džiovinimas		5. Įmonė priėmė sprendimą, kad kiaušinių plovimo ir dezinfekavimo įranga nebus diegiama, nes įgyvendino kiaušinių, skirtų daužymui, rūšiavimo reikalavimus pagal JAV 9 Federalinių taisyklių kodekso 590 dalies 590.510 paragrafe nustatytus kriterijus. Užtikrinamas 100 % švarių, be vidaus ir išorės defektų kiaušinių patekimas į daužymą. Tai garantuoja kiaušinių rūšiavimo įrangos Moba tinkamas darbas ir papildomai įrengti žaliavos atrinkimo / kontrolės taškai (I, II, III taškai). Įmonėje, savikontrolės tikslais, yra patvirtinta ir vykdoma kiaušinių produktų laboratorinė kontrolė. Be to, įmonės nuolatinę valstybinę veterinarinę kontrolę atlieka Plungės valstybinė maisto ir veterinarijos tarnyba, kuri vykdo

			valstybinių mėginių ėmimą pagal patvirtintą planą KB "Baltic egg production".

Papildoma informacija

Tikrinimo metu padarytos nuotraukos, su jomis ūkio subjektas supažindintas.

Išvados ir nurodymai

Subjektas įgyvendino trūkumų šalinimo plane numatytas priemones. Įmonė užtikrina, kad kiaušinių produktų, skirtų JAV rinkai, gamybai būtų naudojama švari, nepažeista kiaušinių žaliava.

Imti mėginiai

produkto kodas, pavadinimas	skaičius	produkto kodas, pavadinimas	skaičius	produkto kodas, pavadinimas	skaičius	produkto kodas, pavadinimas	skaičius
Mėginiai neimti							

Pridedami papildomi dokumentai

1. 2017-02-24 raštas Nr. 5 "Dėl trūkumų, nustatytų JAV audito metu, šalinimo" , 5 lapai;
2. 2017-03-17 Dėl atsiliepimo į JAV auditoriaus pateiktas išvadas, 4 lapai;
3. 2017-01-17 elektroninis laiškas, 1 lapas;
4. Įrengimų profilaktinių techninių apžiūrų ir remonto darbų registracijos žurnale Nr. 63, 2 lapai;
5. JAV rinkai skirtos žaliavos reikalavimai ir RVASVT programos atnaujinimas, 3 lapai;
6. JAV rinkai skirtos žaliavos daužymas, 1 lapas;
7. Procedūra "Kiaušinių padavimo į daužymą patalpos bei įrenginių plovimas ir dezinfekavimas Nr. BP02-INC-03-L01", 10 lapų;
8. Rankų plovimo ir vienkartinių pirštinių naudojimo instrukcija, 2 lapai;
9. Grindų sausinimas po plovimo, 1 lapas;
10. Sijų valymo ir dezinfekavimo planas 2017m., 1 lapas;
11. Nuotraukos.

Surašyti akto 2 egzemplioriai ir perduoti:

1. VMVT Plungės VMVT - 1 egz.;
2. KB "Baltic egg production" - 1 egz.

Tikrinimas pradėtas 2017-03-22, 08:30 (diena, valanda)

Tikrinimas baigtas 2017-03-23, 14:00 (diena, valanda)

Tikrino:

Viršininkas-valstybinis veterinarijos inspektorius	Virginijus Gailius
Vyriausiasis veterinarijos gydytojas-inspektorius	Vytautas Mazrimas

Dalyvavo:

Kokybės vadovė	Ingrida Rupeikienė
Vyriausioji veterinarijos gydytoja	Sandra Šeputytė

Su aktu susipažinau ir vieną egzempliorių gavau
Ūkio subjekto
(juridinio asmens arba jo struktūrinio padalinio) vadovas (įgaliotas darbuotojas)/ fizinis asmuo (dirbantis pagal verslo liudijimą)

(parašas)

DIREKTORĖ
KRISTINA GAPŠIENĖ
(vardas ir pavardė)

VG AGRO HOLDING

Kooperatinė bendrovė „Baltic egg production“
Birutės skg. 5, Macenių k., LT-90100, Plungės r. sav.
Įmonės kodas 302602880, PVM mokėtojo kodas LT 100006690018
NORDEA BANK AB, SWIFT : NDEALT2X, IBAN : LT582140030002725952
www.viciunaigroup.eu

Priedas prie rašto 2017-02-24 Nr.5

TRŪKUMŲ, NUSTATYTŲ JAV AUDITO METU, ŠALINIMO PLANAS

Eil. nr.	Audito metu nustatyti trūkumai	Normatyvinis dokumentas (JAV)	Trūkumų atsiradimo priežastis	Korekcinių veiksmų aprašymas	Trūkumų įgyvendinimo data, atsakingi asmenys
1	Kiaušinių tikrinimo procesas neužtikrinimo, kad kiaušiniai su pažeistu lukštu ar nešvarūs, yra atskiriami ir išimami iš srauto	9 CFR 590.506 - Candling and transfer-room facilities and equipment. (d)	Dėl kiaušinių rūšiavimo įrenginio „Moba“ daviklio-jutiklio gedimo sutriko kiaušinių rūšiavimas. Dėl šio gedimo buvo neužtikrintas tinkamas kiaušinių rūšiavimas.	1. Įmonės techninis personalas identifikavo neatitikimą, kreipėsi į įrangos „Moba“ gamintoją; 2. „Moba“ gamintojas pateikė įmonei rekomendacijas dėl gedimo pašalinimo; 3. Įmonės techninis personalas pašalino daviklio-jutiklio gedimą; 4. Atliktas kontrolinis kiaušinių atrinkimo tikrinimas. Įrenginiu „Moba“ atlikus kiaušinių rūšiavimą, papildomai netinkami daužymo procesui kiaušiniai atrenkami rankiniu būdu. Įrengtos 2 darbo vietos prie kiaušinių padavimo transporterio ir 4 prie kiaušinių padavimo į daužymo įrenginį. Paruoštos darbo instrukcijos, atlikti darbuotojų mokymai.	2017-01-27 Andrius Orentas 2017-01-27 Andrius Orentas 2017-01-27 Andrius Orentas 2017-02-27 Ingrida Rupeikienė, Laima Šliožienė

2	Ant padavimo transporterio patenka tiek švarūs, tiek ir pažeisti kiaušiniai, kuriais užteršiamas transporteris bei žaliava	9 CFR 590.510 - Classifications of shell eggs used in the processing of egg products. (c)	Šios neatitikties priežastis tęstinė, sutampa su nurodytomis priežastimis lentelės 1 eilutėje. Prie linijos dirbantys asmenys, dėl padidėjusio nešvarių kiaušinių srauto, nespėdavo jų pašalinti. Darbuotojai nebuvo pakankamai apmokyti ir nesugebėjo tinkamai užtikrinti kiaušinių atrinkimo.	1. Koregavimo veiksmai atlikti kaip nurodyta lentelės 1 eilutėje; 2. Įrengtos papildomos darbo vietos rankiniam kiaušinių atrinkimui, garantuojant 100 proc. švarių kiaušinių patekimą į daužymą; 3. Esant netinkamų (nešvarių, skilusių, dužusių) kiaušinių kiekio padidėjimui, nedelsiant stabdoma linija, nurenkama žaliava, atliekamas plovimas ir dezinfekavimas. Atlikti pakeitimai RVASVT sistemos programose; 4. Atnaujintos darbo instrukcijos, atlikti darbuotojų mokymai.	2017-02-27 Sonata Žilvienė 2017-02-27 Sonata Žilvienė 2017-02-27 Ingrida Rupeikienė
3	Daužymo metu, dalis lukšto pateko į pirmines sukaupimo talpas (voneles) – tiesioginė kryžminė produkto tarša	9 CFR 590.522 - Breaking room operations. (g)	Kiaušinių daužymo įrenginyje „Pellbo“ neįrengtas lukšto sulaikymo sietas. Dalis kiaušinių lukštų patenka į atskyrimo lėkštutę.	1. Įrenginyje „Pelbo“ po atskyrimo lėkštutėmis, prieš pirmines sukaupimo talpas, įrengtas apsauginis sietas (akučių dydis 3-6 mm); 2. Lukšto likučiai patekę į atskyrimo lėkštutes, išimami rankiniu būdu. Atlikti darbuotojų mokymai. 3. Darbo pirštinės keičiamos, dezinfekuojamos kas 2 val. arba pagal poreikį	2017-02-20 Giedrius Mažeika 2017-02-27 Ingrida Rupeikienė 2017-02-27 Laura Pelenytė

4	Audito metu buvo pastebėtas susidaręs kondensatas miltelių sandėliavimo patalpoje, dulkės ant sijų – miltelių fasavimo patalpoje, ne visose patalpose grindys buvo sausos	9 CFR 590.500 - Plant requirements.	Netinkamas vėdinimo sistemos darbo režimas (periodiškai įsijungia / išsijungia). Dėl grindų nelygumų susidaręs vandens perteklius nebuvo tinkamai nusausintas. Sunkiai pasiekiamų konstrukcijų valymą gali atlikti tik speciali (aukštalipių) komanda. Todėl buvo nustatytas jų valymo periodiškumas kas šeši mėnesiai	1. Nustatytas nuolat veikiantis vėdinimo sistemos darbo režimas. Už sistemos priežiūrą atsakinga išorinė kompanija. 2. Buvę grindų nelygumai ištaisyti, po plovimo grindys sausinamos (nubraukėju), procesas kontroliuojamas. Atlikti darbuotojų mokymai , atnaujintos darbo instrukcijos. 3. Sunkiai pasiekiamų konstrukcijų valymas atliekamas kartą per 3 mėnesius, patalpos ir įranga valoma atsakingų darbuotojų kiekvieną darbo dieną. 4. Siekiant sumažinti dulkėtumą, ant fasavimo įrangos sumontuoti maišo fiksatoriai.	2016-11-02 Giedrius Mažeika 2016-11-08 Laura Pelenytė 2016-11-08 Laura Pelenytė 2016-11-14 Giedrius Mažeika
5	Nebuvo atliekamas nešvarių kiaušinių plovimas, dezinfekavimas ir džiovinimas	9 CFR 590.516 - Sanitizing and drying of shell eggs prior to breaking. (a)	Įmonėje nėra įrenginių, kurie atliktų kiaušinių plovimą, dezinfekavimą ir džiovinimą.	Įmonei įgyvendinus priemones, kuriomis įgyvendinti kiaušinių rūšiavimo reikalavimai pagal JAV 9 Federalinių taisyklių kodekso 590 dalies 590.510 paragrafe nustatytą tvarką ir kurie užtikrina švarių, kokybiškų ir saugių kiaušinių (100 proc.) patekimą į daužymą, kiaušinių plovimo ir dezinfekavimo įranga nebus diegiama. Siekiant įvertinti proceso efektyvumą, įmonėje bus patvirtinta ir vykdoma nuolatinė	2017-02-27 Ingrida Rupeikienė

				skystų kiaušinių laboratorinė kontrolė pagal savikontrolės programą, jos valstybinę kontrolę ir valstybinių skystų kiaušinių gaminių mėginių ėmimą užtikrins VMVT Plungės valstybinė maisto ir veterinarijos tarnyba	

Direktorė Kristina Lapytė