



United States Department of Agriculture

Food Safety and
Inspection Service

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Washington, D.C.
20250

Jón Gíslason
Director General
Icelandic Food and Veterinary Authority, MAST
Austurvegur 64
800 Selfoss, Iceland

Dear Mr. Gíslason,

The September 20-29, 2016 onsite audit conducted by USDA's Food Safety and Inspection Service (FSIS) supports that Iceland's inspection system continues to remain equivalent to that of the United States. Enclosed is a copy of the final audit report. The comments received from the Government of Iceland are included as an attachment to the report.

For any questions regarding the FSIS audit report, please contact Mary Stanley in the Office of International Coordination at mary.stanley@fsis.usda.gov. Thank you for your ongoing commitment to food safety and close cooperation with our Agency.

Sincerely,

A handwritten signature in black ink that reads "Jane H. Doherty". The signature is written in a cursive, flowing style.

Jane H. Doherty
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

ICELAND

SEPTEMBER 20 - 29, 2016

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

MEAT PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

February 22, 2017

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from September 20 - 29, 2016. The purpose of the audit was to determine whether Iceland's food safety system governing meat remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and accurately labeled and packaged. Iceland currently exports the following categories of lamb products: intact raw bone-in and boneless products and edible offal.

The audit focused on six system equivalence components: Government Oversight (e.g., Organization and Administration); Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); Government Sanitation; Government Hazard Analysis and Critical Control Points (HACCP) System; Government Chemical Residue Testing Programs; and Government Microbiological Testing Programs.

The FSIS auditor identified the following two findings:

Government Oversight: The Central Competent Authority (CCA) had not implemented corrective actions to remedy the 2014 audit finding regarding the lack of procedures to assess and document technical competence of government inspection personnel at the in-plant inspection levels of the organization.

Government Sanitation: In one of two certified establishments audited, the FSIS auditor identified concerns of cross contamination/insanitary conditions that could lead to contamination of edible meat products.

The FSIS audit did not identify any significant findings representing an immediate threat to public health for eligible lamb products that Iceland is currently exporting to the United States. The CCA acted immediately to correct the above non-compliances and provided assurances that corrective measures would be implemented. FSIS will evaluate the adequacy of the CCA's proposed corrective actions, which are attached.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite equivalence verification audit of Iceland's meat food safety inspection system from September 20 – 29, 2016. The audit began with an entrance meeting held on September 20, 2016, in Selfoss, Iceland with the participation of representatives from the Central Competent Authority (CCA) – the Icelandic Food and Veterinary Authority (Icelandic name: Matvælastofnun –MAST) and the FSIS auditor.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to ensure that Iceland's meat food safety inspection system maintains equivalence to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and accurately labeled and packaged.

To meet this objective, FSIS applied a risk-based procedure, which included an analysis of country performance within six equivalence components, currently exported product types and volumes to the United States, frequency of prior audit-related site visits, point-of-entry (POE) testing results, and specific oversight activities and testing capacities of government offices and laboratories. The review process included an analysis of data collected by FSIS over a three-year timeframe, in addition to information obtained directly from the CCA through FSIS Self-Reporting Tool (SRT). The FSIS auditor further verified implementation of corrective actions by the MAST in response to the FSIS audit in 2014.

The FSIS auditor was accompanied throughout the audit by representatives from the MAST. Determinations concerning program effectiveness focused on performance within the following six components upon which system equivalence is based: Government Oversight (e.g., Organization and Administration); Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); Government Sanitation; Government Hazard Analysis and Critical Control Points (HACCP) System; Government Chemical Residue Testing Programs; and Government Microbiological Testing Programs.

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

Iceland currently has two certified establishments and FSIS audited both. For the purposes of this report, a certified establishment is one certified by the MAST as eligible to export equivalent commodities to the United States. During the establishment visits, the FSIS auditor paid particular attention to the extent to which industry and government interact to control hazards and prevent non-compliances that threaten food safety.

Additionally, the FSIS auditor focused on the CCA’s ability to provide oversight through supervisory reviews conducted in accordance with the FSIS equivalence requirements for foreign inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) § 327.2, the FSIS regulations addressing equivalence determinations for foreign meat inspection systems.

Additionally, FSIS audited one private microbiological laboratory (Syni Laboratory Service in Reykjavik), and two government laboratories (i.e., the Institute for Experimental Pathology located at Keldur and the Matís Laboratory in Reykjavik) to verify the CCA’s ability to provide adequate technical support to the inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	MAST/Selfoss
	District	2	<ul style="list-style-type: none"> • South district office/ Selfoss • Northwest district office/ Hvammstangi
Laboratories		3	<ul style="list-style-type: none"> • Syni Laboratory Service in Reykjavik - Private • Institute for Experimental Pathology at Keldur - Government • Matís Laboratory in Reykjavik - Government
Lamb Slaughter and Processing Establishments		2	<ul style="list-style-type: none"> • Selfoss • Hvammstangi

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

- The Federal Meat Inspection Act (21 United States Code [U.S.C.] 601, et seq.); The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901, et seq.); and
- The Food Safety and Inspection Service Regulations for Imported Meat (9 CFR Part 327).

The audit standards applied during the review of Iceland’s inspection system for meat included: (1) All applicable legislation originally determined by FSIS as equivalent as part of the initial review process, and (2) any subsequent equivalence determinations that have been made by FSIS under provisions of the World Trade Organization’s Sanitary/Phytosanitary Agreement.

III. BACKGROUND

Iceland is eligible to export Sheep/lamb and goat raw and processed products to the United States. Iceland currently exports the following categories of lamb products to the United States: intact raw bone-in and boneless products, and edible offal. The only lamb products exported from Iceland are of Icelandic origin. No goat products have been exported to the United States since October 1, 2013. Iceland does not import raw materials from other eligible countries to further process for export to the United States.

From October 1, 2013 to December 31, 2015, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 1,219,472 pounds of lamb products

exported by Iceland to the United States. FSIS also performed reinspection on 496,269 pounds at United States point-of-entry (POE) locations for additional types of inspection (TOI), of which a total of 1,543 pounds were rejected because of food safety issues (e.g., ingesta), and 1,111 pounds were refused entry for issues not involving food safety concerns (transportation damage and labeling).

FSIS last audited Iceland in 2014 and reported that Iceland's meat inspection system had no systemic findings, however, there were isolated deficiencies pertaining to the lack of procedures to assess and document technical competence of official government inspection personnel at the in-plant inspection levels, and enforcement of sanitation performance standards (SPS) to ensure sanitary operations are maintained. The CCA proffered corrective actions that were acceptable to FSIS to address the 2014 audit findings. The FSIS final audit reports for Iceland's food safety system are available on the FSIS Web site at:

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

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

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

The evaluation of this component included a review of the documentation submitted by the CCA as support for the responses and corrective actions provided in the SRT. The evaluation also included onsite record reviews, interviews, and observations made by the FSIS auditor at government offices, laboratories, and certified establishments.

The FSIS audit of the CCA headquarters included an examination of its oversight activities, including the verification of certified establishments conducted by the MAST. In addition, the FSIS auditor examined enforcement activities, verification activity reports, and training records for official personnel by interviewing government departmental personnel and reviewing documentation.

The MAST is Iceland's CCA for food and feed safety, animal health, and animal welfare and it is part of the Department of Food and Agriculture of the Ministry of Industries and Innovation. The Ministry of Industries and Innovation (MOII) covers all business sectors and economic activity. The MAST has the authority to enforce inspection laws established in Icelandic Law No. 167/2007, passed by the Icelandic Parliament on December 14, 2007. The MAST has the legal authority and the responsibility to write,

implement, and enforce the meat food safety inspection system. In addition, the MAST issues all directives and guidelines concerning meat export to other countries, certifies or decertifies slaughter establishments for export, and is responsible for the translation, distribution, and implementation of all relevant United States import requirements in certified establishments.

The MAST system ensures all the FSIS requirements (including new legislation, regulations, guidelines, etc.) are properly transposed and distributed to government inspection personnel. Since the last FSIS audit of Iceland in 2014, there have been major changes in the organizational structure at the MAST. The chain of command has not changed, but responsibilities of offices have changed to harmonize tasks and responsibilities, providing a clarification of roles within the MAST.

The current MAST structure that the FSIS auditor observed is headed by a Director General who is responsible for governing the organization, setting its working policies, and monitoring its financial operations. The Director General oversees the Chief Veterinary Officer (CVO), the District Veterinary Officers (DVO), and other Directors (Administration, Consumer Protection, Animal Health and Welfare, Legal Strategy and Coordination, Import and Export, and Agricultural Affairs). The MAST consists of the following offices:

- The Office for Administration is responsible for the overall coordination of the offices, the budget, and human resources;
- The Office for Consumer Protection is responsible for regular controls based on risk classification of the businesses and establishing inspection teams;
- The Office for Animal Health and Welfare is responsible for daily controls in slaughterhouses and oversees the district offices. Previously, slaughterhouses and all food related issues were divided between the Office for Animal Health and Welfare and the Office of Food Safety and Consumer Affairs. The CVO is the head of the Office for Animal Health and Welfare;
- The Office for Legal Strategy and Coordination is responsible for overall coordination and analysis of official controls;
- The Office for Import and Export is responsible for all border controls and issues export certificates; and
- The Office of Agricultural Affairs is responsible for databases related to agriculture and handles payment of state subsidies to farmers.

Iceland is divided into six veterinary districts: Southwest District, Western District, Northwest District, Northeast District, Eastern District, and South District. Each district is coordinated by the DVO, who are responsible for fieldwork related to food safety and animal health since their local offices are in their assigned districts. The certified establishments are located at the district office at Selfoss (South District), and the district office in Hvammstangi (Northwest District). DVO provide supervision to Official Veterinarians (OV) assigned to carry out official inspection activities at the approved slaughterhouses. OVs are responsible for supervising the post-mortem inspection work carried out by official veterinary inspectors and official non-veterinary personnel. With

the reorganization, the MAST is in the process of replacing official non-veterinary personnel with official veterinary inspectors for all inspection tasks.

The FSIS auditor verified the MAST ensures that all government inspection personnel assigned to certified establishments are official employees paid by the national government. The MAST is responsible for the hiring, training, and payment of government inspection personnel. All certified slaughter and processing establishments have a staff of at least two full-time veterinarians. During the lamb slaughter season, the full time staff assigned to work at these establishments is not enough to provide inspection coverage. Implementation of the new system is scheduled to be in place for next season (lamb slaughter is seasonal in Iceland, beginning in August and ending in late October).

To provide adequate staffing during the lamb slaughter season, the MAST hires additional veterinarians and inspectors on a temporary basis. The MAST follows Icelandic Law No. 66/1998 to determine what constitutes professional qualifications to be recognized as a veterinarian. Veterinarians are also required to hold current EU veterinary certification credentials. Inspectors' abilities are initially evaluated based on the job experience and qualifications.

The MAST provides initial and ongoing training to government inspection personnel assigned to certified establishments. When entering into duty, newly hired government inspection personnel receive new employee training by the MAST on administrative procedures related to their status as government employees. The new hires receive on the job training by working with an experienced OV, and by being under direct supervision of the DVO. Directors of all district offices prepare plans and requirements for training and continuing education for their staff.

During verification of the corrective actions from the 2014 audit, the FSIS auditor found that the MAST has not developed and implemented a standardized procedure to assess, document, and provide feedback on technical competence of government inspection personnel. Although, the MAST has started to prepare a corrective action plan, it has not been fully implemented.

Currently, supervisory checks are performed every 3 months, which includes oversight of government inspection personnel performance at certified establishments. Reports (e.g., regulatory inspection, follow-up approval inspection, different fees for inspection activities, and hours on site) are entered into the IsLeyfur database. IsLeyfur is a single database for all official controls for food of animal origin, feed, and all primary producers. The database contains all relevant information on each certified establishment. Information being gathered in the database will provide trend analysis on controls conducted, non-compliances, actions taken, and other issues allowing the MAST to monitor inspection personnel directly.

The FSIS auditor verified that the MAST continues to use documented periodic supervisory reviews of certified establishments. Reports are reviewed at the MAST

headquarters in Selfoss and at both audited establishments. The supervisory reviews are conducted using a standard form, “Mánaðarskoðun sauðfjársláturhús” (translation: Monthly Inspection of Sheep Slaughterhouse), which is a checklist that is completed on a monthly basis by either the Chief of Meat Inspection and Dairies or, in his absence, by his designee. The checklist requires the individual completing it to observe items such as sanitary conditions in various areas of the establishment’s physical facilities as well as whether official personnel are carrying out required inspection activities.

Actions that are not corrected immediately by the certified establishment are addressed during the next supervisory visit. The FSIS auditor performed verification through onsite certified establishment visits and performing a review of records at district and certified establishment levels.

The MAST is responsible for certifying and decertifying establishments and maintaining the official list of certified establishments determined to be eligible to export equivalent commodities to the United States. New facilities interested in becoming certified must submit their request to the MAST headquarters. The MAST ensures the establishment has developed all required programs, including generic *E. coli* testing, species verification sampling, Sanitation Standard Operating Procedures (SSOPs), and HACCP system.

The MAST has the legal authority and responsibility to ensure the FSIS regulatory requirements are uniformly implemented at certified establishments. There is a requirement for inspection at all times when product for export to the United States is being produced. The OV’s are present in the certified establishments during operating hours. Both OV and inspectors can perform post-mortem inspection, but only OV can perform final disposition.

The daily supervision of veterinary controls in slaughterhouses is under Icelandic Regulation No. 105/2010. Daily inspection is defined in work procedures and a newly updated inspection manual, *the Inspection Manual for Sheep, Cattle, and Pigs*. The DVO performs monthly inspections to ensure Icelandic national requirements are fulfilled and current FSIS requirements are met if the establishment is eligible to export to the United States.

The MAST does not operate official laboratories or have contracts with private laboratories. The MAST, on an as needed basis for certified establishments, uses private laboratories. At the present time, the MAST believes there is no need for a contract, since private laboratories are only used if the MAST has no other options. The MAST is responsible for monitoring residues in live animals and animal products. The FSIS auditor verified that Iceland is sending government collected samples to a contracted laboratory (i.e., Switzerland) for screening and confirmation testing. The laboratories Iceland is using must be accredited to International Organization for Standardization (ISO) 17025 and are routinely audited to verify that they are meeting ISO 17025. The criteria used by MAST for designating official laboratories are under Icelandic Regulation No. 106/2010. The MAST maintains the official listing on its Website.

The FSIS auditor determined that the MAST implements its meat food safety inspection system as documented in the SRT and its controls are effective. However, the FSIS auditor found that the MAST had not developed and implemented corrective actions to remedy the 2014 audit finding that no procedures had been developed to assess and document technical competence of official government inspection personnel at the in-plant inspection levels of the organization. The FSIS auditor observed that the MAST is assessing and verifying the competence of government inspection personnel at least every 3 months and maintaining documentation of their assessments; however, the MAST does not possess written procedures on assessing the competence of government inspection personnel.

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

The second of six equivalence components that the FSIS auditor reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of carcasses and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; and daily inspection.

The FSIS auditor verified that the MAST maintains regulatory authority as outlined in official legislation, regulations, ordinances, and other regulatory instructions issued in accordance with the Icelandic Law No. 167/2007, including:

- *Food and Foodstuffs* (Icelandic Law No. 93/1995);
- *Communicable Diseases* (Icelandic Law No. 19/1997);
- *Veterinarians and Animal Health Services* (Icelandic Law No. 66/1998);
- *Governing Animal Diseases and Preventive Measures Against Them* (Icelandic Law No. 25/1993);
- *Raising and Health of Slaughter Animals, Slaughtering, Processing, Health Inspection and Quality Grading of Slaughter Products* (Icelandic Law No. 96/1997);
- *The Animal Protection* (Icelandic Law No. 15/1994);
- *Institute for Experimental Pathology of the University of Iceland at Keldur* (Icelandic Law No. 67/1990);
- *Importation of Animals* (Icelandic Law No. 54/1990);
- *Animal Husbandry* (Icelandic Law No. 103/2002);
- *Sampling for Generic E. coli in sheep intended for export to the United States* (Icelandic Law No. 650/2001); and
- *Animal Welfare* (Icelandic Law No. 55/2013).

These documents outline the sanitation policies and sanitary measures to protect public and animal health in live animals and animal products, and HACCP requirements. The

MAST has had no regulatory changes associated with the export of meat products to the United States.

The FSIS auditor verified that the MAST maintains continuous government inspection in the certified establishments during slaughter of meat intended to be exported to the United States. Inspection officials complete a standard form, GAT-019.2, *Daily control in slaughterhouses*, for every day of production, when product for the United States is produced. Copies of standardized inspection records are available at the MAST, except for daily inspection records, which are retained at the OV's offices at the certified establishments.

The government inspection personnel monitor, verify, and enforce the associated SSOP, HACCP, economic/wholesomeness, generic *E. coli* testing, SPS, other inspection requirements, and humane handling of livestock. The OV investigates and analyzes relevant records of the farm animals and considers the information in the ante-mortem and post-mortem inspection. They also collect the official certificates and statements accompanying the animals.

The FSIS auditor verified that each certified establishment has an OV in charge of coordinating and verifying ante-mortem inspection. The in-plant OV conducts ante-mortem inspection on the day of slaughter by reviewing the incoming documents including: registration and identification documents for traceability of the animal to its source; statements on health of the animal; assurances that no producer has been identified more than two times as a residue violator; and any reports of the detection of animal or zoonotic diseases. The in-plant OV observed all animals at rest and in motion to determine whether they are fit for slaughter. Each certified establishment had a designated observation pen for further examination of suspect animals.

The FSIS auditor also verified that the MAST implements, in each certified establishment, humane handling/slaughter/stunning of animals as documented in their food safety inspection system. The MAST maintains written requirements to provide for the humane treatment of livestock at slaughter in accordance with Icelandic Regulation No. 911/2012. The FSIS auditor observed that all animals had access to water in all holding pens, and were provided with feed and water if held overnight. During the 2016 audit, in each certified establishment, the FSIS auditor verified that humane handling, slaughter, and stunning of lambs was being performed properly. No incidents of improper stunning were observed.

The FSIS auditor verified post-mortem inspection activities through onsite record reviews, interviews, and observations of inspectors conducting post-mortem inspection. Government inspection personnel are trained in performing post-mortem inspection activities. Icelandic Regulation No. 105/2010 requires the OV to conduct post-mortem visual and other additional examinations, including palpation or incisions of carcasses and offal, of slaughtered animals destined for human consumption. The FSIS auditor verified that the proper presentation, identification, examination, and disposition of carcasses and parts are being implemented. The FSIS auditor also verified that audited

establishments are providing official inspection personnel with the appropriate facilities to conduct post-mortem inspection (i.e., inspection station, adequate lighting, etc.). The auditor observed the performance of examination of carcasses and viscera at each certified establishment and verified government inspection personnel were implementing the MAST government inspection procedures as written.

The FSIS auditor verified that the MAST maintains control over the destruction of condemned material. The establishments maintain receptacles that are specifically designated for inedible or condemned product.

Based on FSIS' onsite document reviews, interviews, and the audit observations, Iceland's meat inspection system continues to maintain the legal authority and a regulatory framework to implement requirements governing meat inspection.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of the six equivalence components that the FSIS auditor reviewed was Government Sanitation. To be considered equivalent to FSIS' program, the CCA is to provide general requirements for sanitation, sanitary handling of products, and development and implementation of SSOPs.

The FSIS auditor's verification of this component was based on SRT responses, review of records at government offices in the certified establishments, interviews conducted with inspection and supervisory staff, and onsite observations at the two lamb slaughter and processing establishments audited.

The MAST has the ability to verify that the certified establishments maintain sanitary conditions, ensure sanitary operations are maintained to protect meat products from adulteration during processing, handling, storage, loading, and unloading at and during transportation from certified establishments. Both certified establishments maintained and implemented SSOP's addressing sanitation to verify effectiveness of their sanitation programs. The MAST personnel monitor certified establishments to ensure they comply with sanitation requirements.

The FSIS auditor reviewed sanitation plans and records associated with the design and implementation of sanitation programs at the two audited certified establishments. The certified establishments maintained sanitation records sufficient to document the implementation and monitoring of the SSOPs and any associated corrective actions. Results of the in-plant government inspection pre-operational and operational verification activities are entered into the official MAST standard form, GAT-019.2, *Daily control in slaughterhouses*. If the OV determines that there is a noncompliant practice, the OV records the observation in the MAST standard form EBL 066.2, *Krafa um urbaetur*, Non-compliance report. This form requires the certified establishment to respond to the government inspector's observation and to provide corrective actions addressing the non-compliant practice. The FSIS auditor observed that the records reflected the actual sanitary conditions of the certified establishments.

The FSIS auditor observed pre-operational sanitation at one certified establishment by shadowing and observing the OV conduct pre-operational sanitation verification inspection. The in-plant government inspection pre-operational verification activities began after certified establishment personnel conducted their pre-operational sanitation tasks and determined that the facility was ready for in-plant inspector pre-operational verification activities. The in-plant government inspection personnel then conducted the pre-operational verification tasks in accordance with the MAST established procedures, which include direct observation of sanitary conditions of facilities and equipment and verification of the certified establishments' pre-operational sanitation records.

The FSIS auditor also observed in-plant inspection verification of operational sanitation procedures at both audited establishments. These verification activities include direct observation of operations and review of the establishments' associated records.

During observation of operational sanitation, in one of two establishments audited, the FSIS auditor identified concerns of cross contamination/insanitary conditions that could lead to contamination of edible meat products.

- The FSIS auditor observed that a carcass moving on the rail from the chiller area to the cutting area, which is on a lower floor, occasionally hits the end of the rail-stop prior to being moved to the cutting area. The rail-stop is covered with plastic that is torn and stained from repeated contact. The SSOP in place did not address daily cleaning of the rail-stop. The OV took immediate enforcement action and the certified establishment corrected the issue promptly. At the audit exit conference, the MAST provided the FSIS auditor with evidence that the establishment SSOP non-compliance had been corrected and an SSOP was developed to address the non-compliance.

The FSIS auditor verified that findings identified during the 2014 audit related to the enforcement of SPS in one of the audited certified establishments had been corrected. In that certified establishment, government inspection personnel were precluded from observing conditions in one of the freezer rooms used to store product within the facility because boxed product was stored in such a manner that prevented examination of storage conditions within most of the freezer. The MAST verified corrective actions taken by the certified establishment, which included redesigning the freezer and improving the pathway leading from the freezer door, to permit boxed product to be stored in a way that allows examination of storage conditions in the freezer. This allowed government inspection personnel to be able to examine the boxed products stored in this room. The FSIS auditor verified that the MAST and the establishment have adequately addressed the reported finding.

The FSIS auditor verified that the MAST meat inspection system requires all certified establishments implement sanitation programs to prevent insanitary conditions and to prevent direct product contamination. Government inspection personnel conducting verification on the implementation adequacy of sanitation programs assess the risks

posed by conditions that could cause direct product contamination, and when a non-compliance is identified, they require the establishment to implement corrective actions.

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

The fourth of six equivalence components that the FSIS auditor reviewed was Government HACCP Systems. The inspection system is to require that each official establishment develop, implement, and maintain a HACCP plan. The evaluation of this component included a review and analysis of the information provided by the MAST in the SRT and observations during the onsite verification audit.

Iceland's meat inspection system follows Icelandic Regulations 103/2010 and 105/2010 to ensure HACCP regulatory requirements are prescribed and found equivalent to 9 CFR Part 417 for establishments eligible to export product to the United States. The MAST ensures that HACCP based procedures are satisfactory in all certified establishments and inspections are performed according to the inspection manual and control plans. Inspection personnel routinely verify that all potential hazards associated with a given process are identified within the establishment's hazard analysis; and verify that all decisions made within the establishment's hazard analysis are supported with documentation on file.

The FSIS auditor verified the design and implementation of HACCP programs by reviewing the regulations, official instructions, and guidelines at the two audited establishments. All audited establishments had developed, implemented, and maintained a HACCP plan for products eligible to be certified for United States export to ensure that the requirements equivalent to 9 CFR 417.1-417.7 are met. As part of evaluating the system's design, the FSIS auditor was able to verify that the HACCP system complied with the following required elements:

- A flowchart and hazard analysis that matched the actual production processes in the establishment;
- The hazard analysis accurately considers food safety hazards relating to the product and its intended uses and determines whether the identified hazard is reasonably likely to occur;
- Critical Control Points (CCPs) for hazards reasonably likely to occur in the process were identified;
- The hazard analysis adequately supports any decision that a food safety hazard is not likely to occur in the process; and
- The HACCP system is reassessed annually, and any time changes occur that could affect the hazard analysis or HACCP plan.

The FSIS auditor reviewed zero tolerance (e.g., feces, ingesta, and milk) CCP records and noted both establishments were conducting 100 percent monitoring. The FSIS auditor also verified the physical CCP locations by observing inspection personnel conducting HACCP hands-on verification activities; the physical CCP monitoring location for

government verification is before the final wash. In one of the audited establishments, the FSIS auditor observed the establishment employee conducting HACCP hands-on verification activities at this CCP location, making a direct examination of carcasses. The FSIS auditor also reviewed official inspection records for zero tolerance verification checks with the OV. The inspection personnel and the FSIS auditor observed no deviation from the critical limits on the day of the audit.

The FSIS auditor verified that in-plant inspection personnel at certified establishments conduct daily verification of HACCP plans, and enter the results on form GAT-019.2. The in-plant inspection personnel verification of HACCP plans includes verification of CCPs for all production shifts. HACCP systems at certified establishments comply with the foundational elements of a flowchart and hazard analysis that match the actual production processes in the establishments.

The FSIS auditor verified that the MAST requires certified establishments to develop, implement, and maintain HACCP programs for each processing category. The FSIS auditor's verification further indicates that the CCA continues to demonstrate the ability to effectively implement and verify its regulatory requirement for products that Iceland is currently eligible to export to the United States.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUES TESTING PROGRAMS

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

The MAST has a chemical residue control program that includes random sampling and testing of internal organs and fats for targeted residues; implements risk analysis in chemical residue areas that FSIS regulates; and monitors lamb meat for chemical residues identified by the exporting country's meat inspection authorities as potential contaminants. The MAST, through the Icelandic Food Law, has the legal authority for surveillance and to prevent/control/enforce, the entry, commercialization, and outlet of products of animal origin and with chemical residues that exceed the maximum levels of residues accepted nationally and internationally. The Chief of Meat Inspection and the senior officer for contaminants in foods administer the residue program. The program covers use of banned and controlled (regulated) drugs, heavy metals, pesticides, and pollutants (i.e., polychlorinated biphenyls, dioxins, insecticides).

The legal basis for the Icelandic National Residue Control Plan (NRCP) derives from the following Icelandic regulations:

- Icelandic Regulation No. 30/2012, on the control of residues in animal products;

- Icelandic Regulation No. 653/2001 on maximum residue limits in meat, eggs and milk;
- Icelandic Regulation No. 265/2010 on setting maximum levels for certain contaminants in foodstuffs;
- Icelandic Regulation No. 768/2010 on medicinal products; and
- Icelandic Regulation No. 539/2000 on prescribing veterinarians.

The MAST is responsible for monitoring residues in live animals and animal products. The NRCP is based on yearly historic totals of animal production along with usage patterns of veterinary medicinal products sold and distributed in Iceland. The NRCP annual sampling plan makes the OV responsible for the collection of samples at slaughterhouses. According to the NRCP, depending upon the compound being monitored, the OVs are instructed to collect muscle, organ, fat, or urine samples. Once samples are collected, they are sealed and transported by official courier to the sample registration and preparation facilities leased by the MAST at Keldur laboratory, the Institute for Experimental Pathology for the University of Iceland, where the MAST personnel record them. The samples are then prepared and packaged by the MAST official for submission to an accredited laboratory for analysis.

The MAST does not operate official laboratories; therefore, analysis of samples for some residues is contracted to two government laboratories: the Institute for Experimental Pathology for the University of Iceland, and the Matís laboratory, both located in Reykjavik. Because some residue samples cannot be analyzed in these two laboratories, the MAST officials sort and send residue samples to foreign laboratories for analysis. Iceland's accreditation body, the Icelandic Board for Technical Accreditation (ISAC), a division of the Icelandic Patent Office, assesses the competence of all laboratories that support the NRCP according to Icelandic Law No. 24/2006 on Lab Accreditation. The assessment is carried out by SWEDAC (the Swedish Accreditation Body) on behalf of ISAC according to an agreement between the accreditation bodies. ISAC and SWEDAC are members of the European co-operation for Accreditation (EA).

The FSIS auditor conducted an onsite audit of the two government laboratories, Keldur and Matís. The review of the internal procedures and onsite observations verified that sampling procedures, analytical procedures, quality assurance procedures, calibration and temperature recording, and intra-laboratory check samples for these laboratories are being implemented and documented in records as written in their documented food safety inspection system. The MAST ensures sample collection requirements and controls are in place to guarantee the sample integrity, reliability, and chain of custody.

The FSIS auditor interviewed personnel at the Matís laboratory to assess their technical competency, training, and knowledge of the analytical methods used on the samples to detect chemical residues. The document review also included an evaluation of management system documents, and internal audit reports. The review of proficiency testing records revealed that all results were acceptable. During the visit to the facility, the FSIS auditors observed the laboratory personnel at the sample receipt area who were receiving samples, checking sample integrity and security, assigning the identification,

and storing the samples in accordance with the laboratory's procedure. No concerns arose as a result of the laboratory audit.

During interviews with the MAST, district, and certified establishment government inspection officials, it was determined that the MAST does have a policy or procedure to address if a product was released into commerce and results were violative. The MAST would notify certified establishments, FSIS, and the Rapid Alert System for Food and Feed (RASFF), a tool used by the EU to react promptly when risks to public health are detected in the food chain.

The MAST carries out effective regulatory activities to prevent contamination of food products concerning chemical residues. Based on the evaluation of information contained in the SRT and pre-audit analysis of supporting documents, in conjunction with the information gathered during the onsite audit, the FSIS auditor's review found no concerns with the CCA's chemical residue control program. Iceland's meat inspection system has regulatory requirements for a chemical residue control program that is organized and administered by the national government.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

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

The evaluation of this component included a review and analysis of the MAST's Icelandic Regulation No. 650/2001, "*Sampling and testing of E. coli in sheep in slaughterhouses authorized to export to the United States of America,*" previously submitted by the MAST as support for the responses provided in the SRT. The regulation describes the official inspection methodology for generic *E. coli*.

The MAST conducts verification activities that monitor an establishment's generic *E. coli* testing program in chilled lamb carcasses. The testing program complies with FSIS equivalence criteria and as mandated under Icelandic Regulation No. 650/2001 that describes the requirement for conducting generic *E. coli* testing for lamb and lamb products that are exported to the United States.

The FSIS auditor verified that testing for generic *E. coli* is conducted in the lamb slaughter establishments by establishment employees and the OV verifies sample results are within the established limits. The FSIS auditor verified that both the establishment and inspection personnel are familiar with the upper and lower control limits, as well as the correct actions to be taken when the upper limits are exceeded. The FSIS auditor also verified that contracts are established between private laboratories and slaughterhouses that the MAST inspects. During onsite establishment audits, the FSIS auditor verified, through record reviews that process control was being maintained at these establishments.

Considering the very low test results (typically at the lower limits of detection) observed while reviewing the establishment records, the FSIS auditor was able to determine that process control was being maintained at these establishments. No concerns arose as a result of verification of the MAST's *E. coli* testing program.

The FSIS auditor conducted an onsite audit of a government-approved private microbiological testing laboratory, Syni Laboratory Service, to verify their ability to provide adequate microbiological testing support to the MAST's meat inspection system. The FSIS auditor verified the SWEDAC Accreditation Certificate and Scope of Accreditation issued, meeting the criteria of the ISO 17025. The review of the internal procedures and onsite observations verified that training records, sampling procedures, analytical procedures, quality assurance procedures, calibration and temperature recording, and intra-laboratory check samples for this laboratory are being properly implemented and documented in records. The FSIS auditor observed a minor issue involving the disposal of expired media during the laboratory tour. The Syni Laboratory Service quality control program manager documented the non-compliance and demonstrated the corrective actions and preventive measures, showing how their quality assurance procedures work. The FSIS auditor verified the Syni Laboratory Service was performing proper analysis and possessed the technical capability to test product destined for the United States.

The analysis and onsite verification activities indicate that the MAST meat inspection system has a microbiological testing program organized and administered by the national government. Analytical testing conducted by FSIS at United States POE has not reported any microbiological violations. Observations were made about sample collection requirements and controls that ensure the sample integrity, reliability, and chain of custody at the Syni laboratory. There were no concerns identified.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on September 29, 2016, in Reykjavik with the MAST. At this meeting, the FSIS auditor presented the preliminary findings from the audit. The MAST understood and accepted the findings. The FSIS auditor identified the following two findings:

Government Oversight: The CCA had not implemented corrective actions to remedy the 2014 audit finding regarding the lack of procedures to assess and document technical competence of government inspection personnel at the in-plant inspection levels of the organization.

Government Sanitation: In one of two establishments audited, the FSIS auditor identified concerns of cross contamination/insanitary conditions that could lead to contamination of edible meat products.

The FSIS audit did not identify any significant findings representing an immediate threat to public health for those products that Iceland is currently eligible to export to the United

States. The CCA acted immediately to correct non-compliances identified during the audit and provided assurances that long-term corrective measures would be implemented. The FSIS will evaluate the adequacy of the CCA's proposed corrective actions, which are attached.

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 Sláturfélag Suðurlands Fosnesi 800 Selfoss	2. AUDIT DATE 09/21/2016	3. ESTABLISHMENT NO. A081	4. NAME OF COUNTRY Iceland
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment Sláturfélag Suðurlands A081 09/21/2016

No non-compliances identified

In this establishment, corrective actions based on the 2014 audit were implemented to allow Government program employees to observe conditions in one of the freezer rooms used to store product within the facility, because of improvement to the pathway leading from the freezer door permitted boxed product to be stored in such a manner that it allowed examination of storage conditions in the rest of the freezer. This allows an official employee to be able to examine the boxed products stored in this room.

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

Enter Date Here 09/21/2016

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Slátturhús KVH ehf Norðurbraut 24 530 Hvammstangi	2. AUDIT DATE 09/23/2016	3. ESTABLISHMENT NO. A022	4. NAME OF COUNTRY Iceland
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment Sláturhús KVH ehf Est. A022 09/23/2016

Observed non-compliances:

10. Carcasses moving from chiller area to cutting area (a lower floor) on rail. Occasionally, a carcass hits the end of the rail-stop prior to being moved to the cutting area. The rail-stop is covered with plastic; the plastic is torn and stained from repeated contact over time. The Sanitation SSOP in place did not address daily changing/cleaning of plastic on the rail-stop.

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

Enter Date Here 09/23/2016

Appendix B: Foreign Country Response to Draft Final Audit Report

Food Safety and Inspection Service
United States Department of Agriculture
1400 Independence Ave. SW
Washington, D.C. 20250

Selfoss, 21 February 2017
Ref: 1605303

Subject: Iceland's response to FSIS draft final report of an audit in Iceland in 2016.

Two findings were identified in the draft final report of the audit evaluation the food safety systems in Iceland governing the meat products exported to the United States of America.

Part IV. Component one - Government Oversight

The Central Competent Authority (CCA) had not implemented corrective actions to remedy the 2014 audit finding regarding the lack of procedures to assess and document technical competence of government inspection personnel at the inplant inspection levels of the organization.

Response:

Iceland has, as explained in the exit meeting, started work on its online computer system and data base to put in place actions that enable MAST to review daily data from each slaughterhouse and compare this data between establishments. The data stems from the daily reports filled out by the official veterinarian (OV) at the establishment. At the same time MAST also receives data from the disease registration systems in the establishments. In this way MAST can partially evaluate the performance of the OV in the respective establishment.

A monthly report form will continue to be used once a month in slaughterhouses eligible to export to USA. MAST has started to compare this old report form to new performance evaluation forms, and is hoping to come forward with an updated form to test in the slaughter season 2017 (September - October).

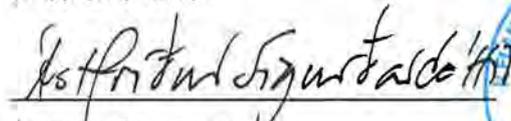
Part VI. Component three - Government Sanitation

In one of two certified establishments audited, concerns of cross contamination/insanitary conditions were identified that could lead to contamination of edible meat products.

This was addressed on the spot and corrected. MAST auditor will follow up on this in coming season 2017.

The FSIS audit did not identify any significant findings representing an immediate threat to public health for eligible lamb products that Iceland is currently exporting to the United States. The CCA acted immediately to correct the above non-compliances and provided assurances that corrective measures would be implemented.

Respectfully
on behalf of MAST



Ástfríður Sigurðardóttir
Office of legal affairs and coordination

