



United States Department of Agriculture

JUN 01 2022

Food Safety and
Inspection Service

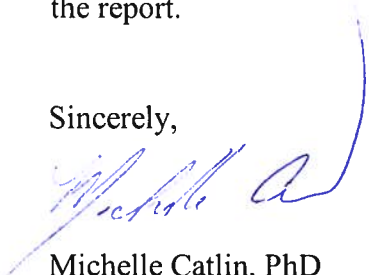
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Ms. Hrönn Ólína Jörundsdóttir
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Icelandic Food and Veterinary Authority, MAST
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Dear Ms. Jörundsdóttir,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted a remote verification audit of Iceland's inspection system November 9–December 14, 2021. 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.

Sincerely,



Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF A REMOTE AUDIT CONDUCTED OF
ICELAND

NOVEMBER 9–DECEMBER 14, 2021

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING
RAW LAMB, GOAT, AND MUTTON PRODUCTS
EXPORTED TO THE UNITED STATES OF AMERICA

May 26, 2022

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of a remote ongoing equivalence verification audit of Iceland conducted by the U.S. Department of Agriculture Food Safety and Inspection Service (FSIS) from November 9 to December 14, 2021. Due to the global COVID-19 pandemic, the audit was conducted remotely using video conferences to conduct interviews and records review. The purpose of the audit was to determine whether Iceland's food safety inspection system governing raw lamb, goat, and mutton products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Iceland currently exports raw intact lamb products to the United States.

The audit focused on six system equivalence components: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditor concluded that Iceland's raw lamb, goat, and mutton products inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. The Icelandic Food and Veterinary Authority (MAST), as the Central Competent Authority (CCA) has required that establishments certified as eligible to export products to the United States implement sanitation and HACCP requirements to ensure the safety of their products. In addition, MAST has implemented requirements for a chemical residue testing program that is organized and administered by the national government to verify its system and establishment a microbiological testing program for generic *E. coli*. An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditor identified the following finding:

GOVERNMENT OVERSIGHT (e.g., ORGANIZATION and ADMINISTRATION)

- MAST failed to provide the District Veterinary Officer (DVO) of one district adequate training when promoting the individual to the position. The new DVO was unaware of individual reports that were required monthly during slaughter operation.

During the audit exit meeting, MAST officials committed to address the preliminary finding as presented. FSIS will evaluate the adequacy of MAST's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) conducted a remote audit of Iceland's food safety system from November 9 to December 14, 2021. The audit began with an entrance meeting held via videoconference on November 9, 2021, with representatives from the Central Competent Authority (CCA)—Icelandic Food and Veterinary Authority (MAST). Representatives from MAST participated throughout the entire audit.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit that was conducted remotely. The audit objective was to determine whether the food safety inspection system governing raw lamb, goat, and mutton products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Iceland is eligible to export the following categories of products to the United States:

Process Category	Product Category	Eligible Products ¹
Raw - Non Intact	Raw Ground, Comminuted, or Otherwise Non-Intact Meat-Other (Sheep, Goat)	Lamb and Mutton - All Products Eligible except Mechanically Separated and Advanced Meat Recovery Product
Raw - Intact	Raw Intact Meat-Other (Sheep, Goat)	Lamb and Mutton - All Products Eligible

The USDA's Animal and Plant Health Inspection Service (APHIS) recognizes Iceland as free of foot-and-mouth disease.

Prior to the remote equivalence verification audit, FSIS reviewed and analyzed Iceland's Self-Reporting Tool (SRT) responses and supporting documentation. During the audit, the FSIS auditor conducted interviews and reviewed records to determine whether Iceland's food safety inspection system governing raw lamb, goat, and mutton products is being implemented as documented in the country's SRT responses and supporting documentation.

FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, point-of-entry (POE) reinspection and testing results, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS over a three-year period, in addition to information obtained directly from MAST through the SRT.

Determinations concerning program effectiveness focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight (e.g.,

¹ All source meat used to produce products must originate from eligible countries and establishments certified to export to the United States.

Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditor reviewed records related to administrative functions and oversight from MAST's headquarters, government verification records from two regional offices, and verification records from two local inspection offices within the establishments. The remote audit involved meetings with government personnel and laboratory staff. FSIS scheduled up to three meetings each week over a six-week period. FSIS did not conduct virtual establishment visits as part of this audit. Through records review, the FSIS auditor evaluated the implementation of control systems that ensure the national system of inspection, verification, and enforcement is being implemented as documented in the SRT and supporting documentation.

The two establishments currently certified by MAST to export to the United States were selected for the remote audit. The products these establishments produce and export to the United States include raw lamb, goat, and mutton.

This remote audit focused on a review of records associated with official government verification activities conducted at the selected establishments. It did not include review of establishments' conditions or records. The FSIS auditor assessed MAST's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in Title 9 of the Code of Federal Regulations (CFR) 327.2.

The FSIS auditor also remotely audited one private microbiological laboratory to verify that the laboratory can provide adequate technical support to the food safety inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	<ul style="list-style-type: none"> Icelandic Food and Veterinary Authority (MAST), Selfoss
	District	2	<ul style="list-style-type: none"> Northwest District Office, Hvammstangi South District Office, Selfoss
Laboratory		1	<ul style="list-style-type: none"> Sýni Laboratory Service (private, microbiological, Reykjavik
Lamb slaughter and raw processing establishments		2	<ul style="list-style-type: none"> Establishment #A022, Sláturhús KVH, Hvammstangi Establishment #A081, Sláturfélag Suðurlands, Selfoss

FSIS performed the audit to verify that the food safety inspection system meets requirements equivalent to those under the specific provisions of United States laws and regulations, in particular:

- The Federal Meat Inspection Act (21 United States Code [U.S.C.] Section 601 et seq.);

- The Humane Methods of Livestock Slaughter Act (7 U.S.C. Sections 1901-1906); and
- The Meat Inspection Regulations (9 CFR Parts 301 to the end).

The audit standards applied during the review of Iceland's inspection system for raw lamb, goat, and mutton products included: (1) all applicable legislation originally determined by FSIS as equivalent as part of the initial review process, and (2) any subsequent equivalence determinations that have been made by FSIS under provisions of the World Trade Organization's Agreement on the Application of Sanitary and Phytosanitary Measures.

III. BACKGROUND

From March 1, 2018 to February 28, 2021, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 605,411 pounds of lamb products exported by Iceland to the United States. Additional types of inspection were performed on 42,874 pounds of lamb products. These additional types of inspection included physical examination and chemical residue analysis. There were no rejections of lamb products as a result of this additional testing.

The prior FSIS audit in 2018 identified the following findings:

Summary of Findings from the 2018 FSIS Audit of Iceland	
Component 1: Government Oversight (e.g., Organization and Administration)	
<ul style="list-style-type: none"> • MAST allowed government inspection personnel to issue an export certificate for product intended for export to the United States before test results were known for samples taken in the MAST's chemical residue program. 	
Component 2: Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling)	
<ul style="list-style-type: none"> • MAST provided inadequate oversight of official veterinarians (OV) at establishments that are certified to export to the United States. The FSIS auditors identified the following: <ul style="list-style-type: none"> ○ In one of two audited establishments, OVs were not conducting pre-operational sanitation verification activities in the fabrication and packaging room. ○ In one of two audited establishments, government inspection personnel were conducting zero-tolerance verification tasks at the final carcass inspection station prior to where the establishment was conducting their zero-tolerance monitoring. ○ In one of two audited establishments, OVs were not consistently documenting that sanitation and HACCP verification tasks were completed on the official inspection Daily Control in Slaughterhouses checklist, as required by the CCA guidelines. 	
Component 6: Government Microbiological Testing Programs	
<ul style="list-style-type: none"> • MAST provided inadequate oversight of Iceland's government laboratory. The laboratory did not follow procedures for monitoring testing media; for example, the laboratory's only sheep species identification test kit had expired in August 2017. 	

The FSIS auditor verified that the corrective actions for the previously reported findings were implemented and effective in resolving the findings.

The FSIS final audit reports for Iceland's food safety inspection system are available on the FSIS website at: www.fsis.usda.gov/foreign-audit-reports.

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

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

Icelandic Act No. 167/2007 established MAST's authority to enforce inspection laws, including enforcement of the Icelandic Act No. 93/1995 (Food Law). Article 30 of Act No. 93/1995 gives MAST the authority and the ability to require corrective actions in certified establishments and to take additional enforcement measures. In addition, Article 138 of Regulation European Union (EU) 2017/625, requires competent authorities to take action to ensure that the operator corrects noncompliances. This regulation gives MAST the authority and responsibility to enforce the laws governing meat inspection, require corrective actions in certified establishments, and to take additional enforcement measures as appropriate.

There have been no major changes in MAST's organizational structure since the prior audit in 2018. MAST is governed by a director general who oversees the work of the Office for Animal and Health Welfare and the Office of Consumer Protection. The chief veterinary officer (CVO), located at the MAST headquarters office in Selfoss, leads the Office for Animal Health and Welfare and oversees the six District Offices. Each District Office is supervised by a District Veterinary Officer (DVO) who is responsible for coordinating fieldwork and providing supervision to the official veterinarians (OV) assigned to carry out official inspection activities at certified slaughter establishments. The lead OVs are responsible for daily inspection verification activities and for supervising the post-mortem inspection work carried out by OVs, as MAST has phased out auxiliary veterinarians since the prior FSIS audit in 2018. Within the Office of Consumer Protection, there is a Food Control Team (FCT) that collaborates with the CVO of meat inspection and DVOs to conduct supervisory reviews at establishments certified to export to the United States.

The FSIS auditor confirmed through records review that the inspection system is organized and administrated by the national government of Iceland. The FSIS auditor confirmed that MAST continues to maintain the overall responsibility for setting policy, implementing legislation, and managing official controls in relation to food safety. Iceland is one of the contracting parties to the European Economic Area and has implemented the EU legislation on veterinary matters, foodstuffs, feed, and other food chain related issues.

The FSIS auditor verified that MAST has the authority and responsibility to ensure that adulterated or misbranded product is not exported to the United States. Article 1 of Icelandic Act No. 96/1997, gives MAST the legal authority to conduct inspection activities to ensure that

products are wholesome, evaluated and classified by type and quality, and not adulterated or misbranded. This law establishes requirements on the raising and health of animals for slaughter, slaughtering, processing, health inspection, and quality grading of slaughter products and the basis for ensuring that meat and offal is wholesome and not adulterated.

Articles 8 and 11 of the Icelandic Act No. 93/1995 provide the regulatory definitions of adulterated and misbranded product, respectively. Article 1 of Icelandic Act No. 96/1997, gives MAST the legal authority to conduct inspection activities to ensure that products are wholesome, evaluated and classified by type and quality, and not adulterated or misbranded. To ensure product is not adulterated and correctly labeled, government inspection personnel perform routine verification activities continuously during slaughter operations and at least once per production shift during the processing of raw lamb products in all the establishments certified to export to the United States. The FSIS auditor verified that MAST has the authority and responsibility to ensure that adulterated or misbranded product is not exported to the United States. The FSIS auditor also verified that labels and marks of inspection are approved by MAST.

Icelandic Act No. 93/1995, Article 13 requires food processors to trace product through all stages of production and distribution. MAST has the authority to recall adulterated product and the ability to seize and dispose of product if deemed necessary. When MAST determines that there is reasonable risk that product has or will cause a risk to human health, it informs the public about the nature of the risk. In making this determination, MAST measures the nature, severity, and extent of the risks. If adulterated product has been shipped to the United States, MAST notifies FSIS and the EU 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 FSIS auditor verified through FSIS POE data that no adulterated or misbranded products have been exported to the United States since the prior audit in 2018.

The FSIS auditor reviewed the procedures for certification of establishments for eligibility to export to the United States. MAST certifies and decertifies establishments according to provisions in Icelandic No. 103/2010, Icelandic No. 104/2010, Icelandic No. 105/2010, and Icelandic No. 135/2010. The process for certifying an establishment for export to the United States begins with an electronic application from the establishment to MAST. The establishment must submit documentation related to the specific requirements for export to the United States, in addition to Icelandic requirements. When the establishment claims that it meets the United States' requirements, MAST will audit the establishment to verify that the establishment meets the United States' requirements. If all requirements are met, MAST updates the list of eligible establishments and then submits the list to FSIS. No new establishments have been certified to export to the United States since the previous audit in 2018. Icelandic Act No. 96/1997, Article 6 prescribes that MAST reviews certified establishments annually to determine ongoing compliance with all applicable laws and regulations.

The FSIS auditor verified that government inspection personnel maintain export certificates and an accountable item inventory of all issued certificates in a secure environment. A review of export certificates and accompanying documents associated with lots of product previously exported to the United States demonstrated that the certificate is accompanied by the document

of loading from the appropriate DVO, pictures of the product's container and seal, packing list, information concerning shipment number whether by ship or aircraft, and all relevant laboratory results. The FSIS auditor's review of records indicated that government inspection personnel routinely confirm acceptable test results of official chemical residue sampling and establishment microbiological sampling prior to certifying product for export to the United States.

The FSIS auditor confirmed that the system ensures only eligible source materials are used to produce products intended for export to the United States. Iceland does not import raw materials to further process product for export to the United States. The DVO must complete the checklist titled Internal Control in Relation to Export and Produced in Certified Slaughter Establishments in Iceland to certify that products exported from Iceland are of Icelandic origin. OVs use the Daily Control in Slaughterhouse checklist to ensure product meets requirements for export to the United States.

The FSIS auditor confirmed that the same set of laws, regulations, and policies are applied consistently to all establishments certified to export raw lamb products to the United States. This is achieved through the implementation of procedures described in the Daily Supervision of Sheep, Pigs, and Large Animals manual and the General Handbook Inspection Food of Animal Origin. If the establishment is not following the required procedures, then MAST will take enforcement actions that may include instructions for improvement, revocation of certification, and suspension of the issuance of export certificates. The FSIS auditor determined through review of government inspection records that regulatory verification and inspection activities were consistently implemented at all audited establishments, and MAST enforces the rules of their food safety inspection system to identify and document noncompliance and verify the adequacy of corrective actions and preventive measures. Inspection verification procedures are recorded in the Daily Control in Slaughterhouses checklist.

In certified establishments, the OVs under supervision of the DVOs, verify compliance with sanitation standard operating procedures (Sanitation SOPs) and HACCP requirements and record the results on the Daily Control in Slaughterhouses checklist. This checklist also notes whether the product was produced for export to the United States. The export certificates are issued, signed, and stamped at the Office of Import and Export at MAST headquarters. All exported products are certified by MAST by an Official Certificate of Origin Health in accordance with importing country requirements.

The FSIS auditor verified that government inspection occurs continuously during slaughter operations, and at least once per production shift during the processing of raw lamb products intended for export to the United States. MAST implements Icelandic Regulation No. 105/2010 that requires a government inspector to perform post-mortem inspection of every carcass and components during the slaughter of livestock. The OV assigns three inspectors for post-mortem inspection at these establishments (one viscera inspector, and two carcass inspectors). Government inspection personnel record who performed post-mortem inspection on the Daily Control in Slaughterhouses checklist. There is also one off-line inspector, who is an OV, who supervises the government inspection personnel conducting post-mortem inspection, in addition to conducting ante-mortem inspection of all livestock presented for slaughter and official inspection Sanitation SOP and HACCP verification tasks, checking cooler temperatures,

performing zero-tolerance, and other offline inspection duties at each establishment. The OV's are also responsible for daily pre-operational inspection duties during sheep slaughter operations for products intended for export to the U.S. MAST maintains direct authority over all inspection activities and the personnel who conduct them. The OV's are present in the certified establishments during operating hours. MAST has established procedures to ensure sufficient staffing in the event that absences of government inspection personnel occur.

The FSIS auditor confirmed that MAST is responsible for hiring, training, and paying the wages of the government inspection personnel. Icelandic Regulation No. 567/2012 details the funding of MAST through inspection fees levied on the certified establishments, and by the Icelandic government budget, which allocates funds to pay the government inspection personnel. The national government pays the salaries of government inspection personnel directly. In addition, Icelandic Regulation No. 234/2010 outlines the fee schedule levied on certified establishments. MAST sends invoices to all certified establishments receiving official inspection. Additionally, MAST requires OV's to declare the absence of conflicts of interest to ensure that government inspection personnel act in the public's interest. The FSIS auditor verified through a review of employment records, monthly payroll documents, certificates, and identification documents of government inspection personnel assigned to establishments certified to export meat products to the United States that MAST government employees are paid directly by the Icelandic government.

The FSIS auditor confirmed that OV's have the appropriate educational credentials and training to carry out their inspection tasks. MAST follows the standard in Directive 2005/36/EC to determine what constitutes professional qualifications to be recognized as a veterinarian. MAST follows Icelandic Law No. 70/1996, Article 6 that requires all Icelandic government employees meet a basic educational requirement. In Iceland, all government inspection personnel are required to be veterinarians. During the hiring process, MAST ensures that OV's have a veterinary degree by requiring a copy of their license to practice veterinary medicine and requires them to be licensed to work as a veterinarian. The FSIS auditor reviewed documentation for a select number of OV's assigned to establishments certified to export to the United States to verify that they had the required veterinary degrees.

The FSIS auditor confirmed through records review that MAST has implemented and conducted initial and ongoing training programs intended to ensure that government inspection personnel are aware of FSIS import regulations and Iceland's regulations for lamb products to be exported to the United States. MAST holds training for new government inspection personnel before the beginning of lamb slaughter season. New government inspection personnel are trained on administrative procedures and perform on the job training by shadowing experienced government inspection personnel. The OV determines when the new employee is performing post-mortem inspection appropriately. The FSIS auditor reviewed the recent training records that documented MAST provided training to government inspection personnel, which included requirements for Sanitation SOPs, HACCP, review of generic *Escherichia coli* (*E. coli*) establishment sampling results, residue sampling collection, and FSIS import requirements. The FSIS auditor confirmed through records review that ongoing training materials, including program updates on inspection-related issues and procedures, and training participation records were maintained. MAST has implemented a system used to assess the technical competence and

performance of individual OV's in conducting official inspection activities at establishments that export to the United States. MAST sets performance standards with OV's and conducts a performance evaluation annually for each OV at the certified establishments. The FSIS auditor identified the following finding:

- MAST failed to provide the DVO of one district adequate training when promoting the individual to the position. The new DVO was unaware of individual reports that were required monthly during slaughter operation.

MAST maintains a communication system to convey FSIS import requirements throughout its inspection system. The FSIS auditor verified through documents that MAST conducts an informational meeting for OV's and DVO's that are working at certified establishments before lamb slaughtering season every year to update them on FSIS import requirements. The DVO's receive updates at regular meetings and the CVO reports changes of requirements, controls, regulations, and guidelines with emphasis to DVO's. In addition, MAST maintains an electronic communication system used to disseminate new legislation, including MAST instructions to the DVO's via e-mail, who then disseminate the information to government inspection personnel.

MAST maintains administrative and technical support for its laboratory system by implementing Regulation (EU) 2017/625, which requires laboratories that carry out sample analysis for the CCA of Member States to operate in accordance with International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025, General Requirements for the Competence of Testing and Calibration Laboratories. Icelandic Act 24/2006 Article 3 gives the Icelandic Board for Technical Accreditation (ISAC) the authority for accreditation on behalf of the Icelandic government. The criteria used by MAST for designating official laboratories are under Icelandic Regulation No. 106/2010. MAST has contracted two Icelandic laboratories, Matis and Sýni, to accept, register, and ship official chemical residue samples to two foreign laboratories for screening and confirmation tests.

The foreign laboratories, Livsmedelsverket Biologiavdelningen and Eurofins Food and Feed Testing, both located in Sweden, and Wageningen Food Safety Research located in the Netherlands are contracted by MAST to analyze official chemical residue samples. Per Icelandic Act No. 24/2006 on Laboratory Accreditation, Article 1, the Icelandic Board for Technical Accreditation (ISAC), Iceland's accreditation body, assesses the competence of all laboratories that support the National Residue Control Program (NRCP). For foreign laboratories, ISAC has an agreement with the Swedish Board for Accreditation and Conformity Assessment (SWEDAC) and the Danish Accreditation Fund (DANAK), accreditation bodies in Sweden and the Netherlands, respectively, to perform assessments on its behalf.

Every year MAST reviews and renews the agreement with the foreign laboratories and maintains the official listing on its website. The FSIS auditor reviewed the ISO/IEC 17025 accreditation certificates and scopes of accreditation provided by MAST for Livsmedelsverket Biologiavdelningen, Eurofins Food and Feed Testing, Wageningen Food Safety Research, and Matis and Sýni laboratories and confirmed the laboratories were in good standing with the accrediting bodies. Further, Icelandic Regulation No. 106/2010 requires that laboratories report results directly to the MAST. In the case of a positive sample, the laboratory immediately

notifies MAST via e-mail; the CVO of meat inspection and DVO evaluate the results and determine if enforcement actions are necessary per Icelandic Regulation No. 30/2012. The FSIS auditor confirmed through records review that all sample results from foreign laboratories were reported to MAST in a timely manner.

The FSIS auditor conducted a review of the Sýni Laboratory Service. The FSIS auditor interviewed laboratory personnel on residue sample receipt and handling, including checking sample integrity and security, registration of the sample per the laboratory quality assurance system, assigning the identification and storage of samples, and the packaging of samples for shipment in accordance with the laboratory's standard operating procedure. The FSIS auditor reviewed the MAST contract with Sýni Laboratory Service and verified that the private laboratory handling the samples received and notified MAST of the collection and shipment to foreign laboratories in a timely manner. The FSIS auditor did not have any concerns from these interviews and document reviews.

The FSIS auditor verified that Iceland's government organized and administers the country's food safety inspection system. MAST officials enforce laws and regulations governing production of raw intact lamb products at establishments certified to export to the United States. However, MAST failed to provide adequate training when promoting an individual to a DVO position. MAST committed to address this finding as presented. FSIS will evaluate the adequacy of MAST's proposed corrective actions and verify their implementation during the next scheduled verification audit.

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

The second equivalence component the FSIS auditor reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of each and every carcass and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; at least once per shift inspection during processing operations; and periodic supervisory visits to official establishments.

MAST has adopted Regulation (EC) No. 1099/2009 to meet the requirement of humane handling and slaughter of animals. MAST implements provisions in Regulation (EC) No. 1099/2009 through Icelandic Regulation No. 911/2012, which contain specific humane handling requirements. The Daily Supervision of the Slaughter of Sheep, Pigs, and Large Animals manual contains verification procedures and instructions on how OV's should verify compliance and enforce requirements for humane handling and humane slaughter of livestock in accordance with Icelandic Regulation No. 911/2012. According to the Daily Supervision of the Slaughter of Sheep, Pigs and Large Animals manual, OV's are also required to verify the condition of transport vehicles and holding pens and record such conditions. In addition, the OV's verify that the establishment must ensure that the slaughtered animals are unconscious within the prescribed time limits and the animals are bled at least 30 seconds. OV's document the results of daily

inspection verification activities for humane handling and humane slaughter of livestock on the Daily Control in Slaughterhouses checklist.

The FSIS auditor confirmed that all livestock presented for slaughter receive ante-mortem examination in accordance with Regulation (EU) 2017/625, Icelandic Act No. 96/1997, Article 11, and Icelandic Regulation No. 461/2003. The Daily Supervision of the Slaughter of Sheep, Pigs, and Large Animals manual and MAST's Control Guide for Slaughterhouses Section 4.2 contains guidance and procedures on how OV's should perform ante-mortem inspection in certified slaughter establishments. Records reviewed by the FSIS auditor indicated that at least one OV conducts ante-mortem inspection of all animals prior to slaughter. OV's review the incoming documents of each truck including registration and owner identification documents for traceability of the animal to its source, statements on the health of the animal, animal welfare controls report, and reports of the detection of any animal diseases. The FSIS auditor confirmed through interviews that the OV performs ante-mortem inspection of all animals at rest and in motion in designated holding areas before slaughter in order to determine whether the animals are fit for slaughter, and the OV's document ante-mortem inspection in accordance with the MAST requirements. The FSIS auditor, through records reviews and interviews of government inspection personnel, confirmed that humane handling and slaughter of livestock are conducted in accordance with Iceland's requirements.

MAST implements the requirements specified in Regulation (EC) No. 853/2004 through Icelandic Regulation No. 461/2003, which requires that post-mortem inspection shall be performed immediately after slaughter and include inspection of the carcasses and organs and marking of internal organs to maintain consistent identity with the head and carcass. Daily Supervision of the Slaughter of Sheep, Pigs and Large Animals manual and the Control Guide for Slaughterhouses contain guidance and procedures on how government inspection personnel should perform post-mortem inspection in certified slaughter establishments. Government inspection personnel document the results of daily post-mortem inspection activities on the Daily Control in Slaughterhouses checklist. MAST provided inspection documentation to demonstrate that each slaughter establishment is staffed with a sufficient number of government inspectors to conduct post-mortem inspection activities in accordance with Regulation (EU) 2017/625. The FSIS auditor confirmed through interviews that inspectors are present during all slaughter operations and post-mortem inspection is conducted on every carcass by online OV's during all hours of slaughter consistent with FSIS requirements. This included reviews by the FSIS auditor of supervisory records to verify the implementation of inspection requirements regarding proper presentation, identification, and post-mortem examination. These reviews of documents include MAST verification on the proper techniques related to the visual inspection and palpation of relevant portions of the animal described within the MAST Daily Supervision of the Slaughter of Sheep, Pigs, and Large Animals manual performed by the OV and disposition of affected carcasses and parts.

The control of animal by-products, including condemned materials, is accomplished through the application of Regulation (EC) No. 1069/2009 and Regulation (EU) No. 142/2011, which are implemented through Icelandic Regulation No. 674/2017. MAST's Daily Supervision of the Slaughter of Sheep, Pigs, and Large Animals manual provides procedures for the verification of the condemnation of animal by-products by government inspection personnel. MAST provided

inspection documentation to demonstrate that condemned and inedible materials are appropriately identified in accordance with the categories described therein, segregated in specially marked or otherwise secure containers, and burned by the establishment's risk material incinerator that is licensed by Iceland's Environment Agency. The FSIS auditor verified that OV's document this daily on the Veterinary Checklist as required.

The FSIS auditor confirmed that complete separation by time and space is maintained between product certified for export to the United States and domestic product. The OV's in certified establishments control products from non-certified establishments ensuring they are not received and processed in certified establishments. The FSIS auditor confirmed through records review that the audited establishments processed only meat from lambs that were slaughtered on-premises and did not receive any raw materials from outside sources.

MAST references Icelandic Act No. 97/1997, Article 5 that requires that product exported to foreign markets must be slaughtered in certified slaughterhouses. The FSIS auditor confirmed that Iceland does not import raw materials from other countries to further process product for United States export. The only products exported use source material derived from sheep that are born and raised in Iceland. The OV verifies that each shipment of source meat originated only from establishments certified to export to the United States and ensures the product meets FSIS import requirements. MAST's 2021 official sampling plan and 2020 results show that species verification testing is performed for product intended for export to the United States. Samples are collected once every month during the lamb slaughtering season for species testing. The FSIS review of results did not identify any concerns.

MAST ensures that meat exports are not subject to animal health restrictions by consulting the relevant sections of the APHIS website, and only those products confirmed by MAST as meeting both FSIS and APHIS requirements can be certified for export to the United States. There are no current APHIS restrictions in place for Iceland.

The FSIS auditor confirmed that the Office of Consumer Protection's FCT collaborates with the DVOs conducting supervisory reviews at establishments authorized to export to the United States at least once per calendar month during the lamb slaughter season (August - October). Supervisory reviews are conducted in accordance with the Daily Inspections Manual through direct observations and records review of government inspection verification activity and verification records by the FCT and DVOs.

The CVO of meat inspection supervises the OV's. The supervisors perform direct verification evaluations of the certified slaughter and processing establishments at least once per calendar month during the lamb slaughter season to verify their compliance with requirements (including HACCP, Sanitation SOPs, facilities and equipment, animal welfare, and traceability). The supervisors also evaluate the performance of government inspection personnel which include reviews of the following inspections activities: ante- and post-mortem inspection techniques; control of condemned product; security of stamps, seals, and other security items; chemical residue program controls; species verification sampling; and verification of the establishments' microbiological testing program for generic *E. coli*. Supervisory reviews are documented in the IsLeyfur database, which 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 gathered in the database provides analysis and trends on inspection verification, noncompliances, corrective actions, and other issues, allowing MAST to monitor government inspection personnel activities.

The FSIS auditor reviewed periodic supervisory reports conducted by representatives of FCT and DVOs for establishments selected for this remote audit. All findings are documented in IsLeyfur. If findings result in noncompliance, the process ensures documentation on noncompliance records instructing the establishment to correct the finding(s). The OV's are responsible for verification of corrective actions resulting from the supervisory reviews. The FCT is responsible for conducting follow-up verification of the corrective actions proposed by the establishment during the next supervisory review. The FCT is also responsible for confirming that the OV's verified those corrective actions in order to evaluate the effectiveness and implementation of the establishment's action plan. The FSIS auditor reviewed the supervisory review reports and inspection-related records and concluded that MAST demonstrated that they were consistent in their evaluation of the adequacy of the establishments' food safety system and the capability of government inspection personnel to conduct inspection activities at certified establishments. The FSIS auditor also verified that the annual evaluations of OV's were conducted by the DVO and documented on the evaluation checklist Surveillance Vets in Sheep Slaughterhouses as required by MAST.

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

VI. COMPONENT THREE: GOVERNMENT SANITATION

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

MAST requires that each official establishment operate in such a manner as to prevent insanitary conditions, focus attention on those aspects of sanitation that pose a risk of causing direct product contamination, take action to prevent product contamination when insanitary conditions or contaminated products are found, correct insanitary conditions, and properly dispose of contaminated product. Through the adoption of Regulation (EC) No. 852/2004 requiring general hygiene rules applying to all foodstuffs and Regulation (EC) No. 853/2004 requiring specific hygiene rules for products of animal origin, MAST requires that establishments operate in a sanitary manner, and has specific requirements to maintain sanitary standards. Iceland adopted Sanitation SOP requirements consistent with 9 CFR 416.11-416.16.

The FSIS auditor confirmed through interviews with government inspection personnel and inspection record reviews that MAST ensured that each certified establishment operates in a sanitary manner. The onsite OV's verify that the establishment implements sanitary dressing

procedures throughout the slaughter process daily. MAST provides guidance to government inspection personnel on official control procedures for slaughter hygiene verification and for ongoing assessment of the establishment's compliance with food hygiene requirements from acceptance of animals for slaughter through carcass dressing and chilling.

The government inspection personnel follow the guidelines in the Inspection Manual for Daily Work Activities in Slaughterhouses for Sheep, Pig, and other Large Species and in the Control Manual for Health in Slaughterhouses and Meat Packing Plants, Section 11. These documents specify that government inspection personnel perform verification activities to verify if Sanitation SOP requirements are met. Verification results are recorded on the Daily Control in Slaughterhouses checklist. The government inspection personnel at the final rail position inspect each lamb carcass to ensure that it has no visible fecal material, ingesta, and milk contamination, and to ensure that the carcasses are trimmed. The carcasses are then reinspected by government inspection personnel before entering the cooler. Government inspection personnel further verify the establishment's ability to implement corrective actions and its compliance with MAST requirements in Icelandic Act No. 93/1995, Article 10, slaughter hygiene verification at final inspection. Icelandic Act No. 93/1995, Article 30, prescribes MAST's authority to take effective enforcement actions.

MAST follows Regulation (EC) Nos. 852/2004 and 853/2004 and guidelines in the Inspection Manual for Daily Work Activities in Slaughterhouses for Sheep, Pig, and other Large Species and in the Control Manual for Health in Slaughterhouses and Meat Packing Plants to maintain official controls over establishment construction, facilities, and equipment. The layout, design, and construction of the establishment facilities must permit adequate maintenance to prevent conditions that can lead to insanitary conditions. Equipment and utensils must be maintained in a sanitary manner. Regulation (EC) No. 853/2004 Chapter II, Section I, Annex III stipulates specific requirements for food business operators to ensure that the construction, layout, and equipment of slaughterhouses prevent the contamination or adulteration of meat.

The FSIS auditor confirmed through the review of inspection records that the government inspection personnel are verifying pre-operational and operational Sanitation SOP requirements in accordance with MAST's requirements. The FSIS auditor also reviewed noncompliance reports generated by government inspection personnel where deficiencies were identified during pre-operational and operational verification activities. The FSIS auditor also verified that OVs closed the noncompliance reports only after verifying the adequacy and effectiveness of the establishment's corrective actions to ensure that sanitary conditions were restored, and product was protected from contamination. The FSIS auditor's review of this documentation determined that government inspection personnel adequately described noncompliance and verified the effectiveness of the establishment's corrective actions. In addition, at least once per month during the lamb slaughter season, the DVOs perform evaluations of the establishments certified to export to the United States. This evaluation includes sanitation SOP program verification.

The FSIS auditor determined that MAST requires establishments certified to export to the United States to develop, implement, and maintain sanitation programs to ensure that the establishment's construction, facilities, equipment, and sanitary dressing prevent the contamination or adulteration of meat products destined for export to the United States. MAST's

food safety inspection system continues to maintain sanitary regulatory requirements that meet the core requirements for this component.

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

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

Through the Icelandic Regulations No. 103/2010 and No. 105/2010, MAST requires establishments certified to export to the United States to develop, implement, and maintain a HACCP plan. The HACCP plan is to identify food safety hazards and institute controls to prevent the hazards or control the hazards within identified operational parameters adhering to the prescriptive requirements set forth in Regulation (EC) No. 852/2004, Article 5 and consistent with 9 CFR Part 417. MAST further references Regulation (EC) No. 853/2004, Annex III that mandates that “the carcasses must not contain visible fecal contamination. Any visible contamination must be removed without delay by trimming or alternative means having an equivalent effect.” To implement Regulation (EC) No. 853/2004, Annex III, MAST requires certified establishments to develop and implement a Critical Control Point for controlling fecal matter, ingesta, and milk (i.e., zero-tolerance) during lamb slaughter, to prevent visible fecal contamination and ensure food safety hazards are controlled effectively.

The OV's are responsible for performing verification activities that include the review of the establishment's written HACCP plans and their contents, review of establishment-generated HACCP monitoring and verification records, and direct observation verification of those procedures by the establishment to assess the adequacy of establishments' implementation of HACCP plans.

MAST inspection manual and control plans, requires that the OV's conduct daily verification activities of the HACCP plan. These verification activities include direct observation verification of the implementation of monitoring and recordkeeping procedures by the establishment to assess the adequacy of implementation of HACCP as prescribed in the establishment's HACCP plan and in accordance with the aforementioned documents. OV's are to use a Daily Inspection Verification Schedule form to direct them to conduct specific HACCP plan verification tasks. OV's document daily inspection verification activity results, including findings and verification of actions taken, on the Daily Control in Slaughterhouses checklist and the Daily Inspection of Slaughterhouses checklist. Additionally, during supervisory reviews, MAST's FCT and the DVO verify whether the certified establishment's HACCP plan is adequate and assess compliance of the plan with all requirements in the aforementioned documents. The FCT and DVO also assess inspection tasks and procedures performed by the OV at these establishments at least once a month.

The FSIS auditor conducted interviews of government inspection personnel and reviewed OV HACCP verification records, supervisory reviews, and noncompliances for each audited establishment. The FSIS auditor confirmed through records review that government inspection

personnel conducted verification of HACCP plans consistent with procedures in FSIS Directive 5000.1, Verifying an Establishment's Food Safety System, as required by MAST. The government inspection personnel verification procedure encompasses the evaluation of written HACCP programs and verification of HACCP prerequisites and plan monitoring, corrective actions, and recordkeeping. Government inspection personnel consistently documented verification activity and verified the adequacy of the establishments' corrective actions. The establishments' corrective actions in response to deviations from critical limits, identified by the establishment or the government inspectors, were consistent with all four parts of FSIS corrective action requirements described in 9 CFR 417.3(a), which have been adopted by Iceland. The FSIS auditor verified that at least once per month during the lamb slaughter season, the FCT verified the adequacy of the HACCP system as described in the inspection manual, Control Manual for Health in Slaughterhouses and Meat Packing Plants.

The FSIS auditor determined that MAST requires operators of establishments certified to export to the United States to develop, implement, and maintain HACCP programs. The FSIS auditor concluded that MAST's food safety inspection system continues to meet the core requirements for this component.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth equivalence component the FSIS auditor reviewed was Government Chemical Residue Testing Programs. The food safety inspection system is to present a chemical residue testing program organized and administered by the national government, which includes random sampling of internal organs, fat, or muscle of carcasses for chemical residues identified by the exporting country's meat products inspection authorities or by FSIS as potential contaminants.

Prior to the remote audit, FSIS reviewed Iceland's 2021 National Residue Control Program (NRCP), associated methods of analysis, and additional SRT responses outlining the structure of Iceland's chemical residue testing program.

MAST ensures the implementation and maintenance of a national chemical residue control program that prevents and controls all specific compounds of concern both domestically and in exports to the United States by implementing the provisions of Regulation (EU) 2017/625 into their national residue control program. This regulation prescribes requirements for Member States to establish residue monitoring plans, sampling frequency, and the substances included in testing.

The FSIS auditor confirmed that MAST continues to maintain the legal authority to regulate, plan, and execute activities of the inspection system that are aimed at preventing and controlling the presence of residues of veterinary drugs and chemical contaminants in the tissues of lamb slaughtered for human consumption in accordance with provisions in the Icelandic Act No. 93/1995. MAST additionally has the legal authority for surveillance of chemical residues and to prevent/control/enforce the entry, commercialization, and outlet of products of animal origin that have chemical residues in excess of the maximum levels allowed by national and international standards.

The NRCP is designed and conducted in accordance with the Icelandic Act No. 93/1995 and is further derived from the following 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; and Icelandic Regulation No. 265/2010 on setting maximum levels for certain contaminants in foodstuffs.

The CVO of meat inspection and the senior officer for contaminants in foods administer the national residue program. The program covers use of banned and controlled drugs; heavy metals; pesticides; and pollutants (e.g., polychlorinated biphenyls, dioxins, insecticides). The NRCP includes random sampling and testing of internal organs, muscle, and fat of carcasses for targeted residues; implementing risk analysis in chemical residue areas that FSIS regulates; and monitoring lamb meat for chemical residues identified by the exporting country's meat inspection authorities or by FSIS as potential contaminants.

Iceland's NRCP provides instructions to its inspection system on method of sampling (strategy and criteria of sampling choice); type and quantity of samples; directions for performed examinations; course of action in case of detection of prohibited substances or excess of maximum permitted residue limits of chemical residues; biological residues and medicinal products; and method of documentation of the action taken. Iceland's NRCP specifies type and size of samples, sampling strategy, location, species, tissues, target compounds, and maximum residue limit. Depending on the target compounds, the type of samples consists of muscles, liver, kidney, fat, or urine. In addition, the NRCP lists the official laboratory and methods to be used for analysis of samples.

Icelandic Regulation No. 30/2012, Article 11 through 13, describes the procedures that MAST is to implement after confirming a positive result to determine if there was illegal administration of specific compounds of concern. These procedures include the following: gathering information identifying the animal and farm of origin; investigating the farm of origin to determine the reason for the presence of residues; and, if the treatment is illegal, trace the origin of the materials or products in the production, processing, storage, transport, handling, distribution, and marketing. MAST bans livestock originating from certain farms or processing centers. In the case of repeated violations, MAST increases the number of samples taken for a six-month period and withholds product until the sample results come back negative. If the results come back positive, the product is declared unfit for human consumption.

The FSIS auditor's verification of this component occurred at multiple levels of the inspection system. It included interviews with the CVO of meat inspection; senior officer for contaminants in foods, FCT, and DVOs of two district offices. The FSIS auditor reviewed documents including certificates of analysis and reviewed residue sampling result records to confirm that the type and size of samples, sampling method, method of analysis, and location of sample collection of the targeted compounds were consistent with the information included in the MAST's SRT submission.

During the interviews with government officials, the FSIS auditor confirmed through records review that MAST implements policies and procedures to address situations when product has been released into commerce but chemical residue results are violative. In those cases, MAST

notifies certified establishments, FSIS, and the RASFF. Additionally, MAST's routine chemical residue testing program requires the selected carcass and products thereof be held or controlled and not exported until receipt of non-violative sample results. The OV ensures this by marking each sampled carcass with a tag or a special label indicating that it is not to be exported to the United States prior to receipt of laboratory results.

The FSIS auditor confirmed through records review implementation of the NRCP for the two audited slaughter establishments. The official monitoring is conducted according to the NRCP, which is defined every year. The plan lists the residue group, the number of samples for the group, and the matrix for each month. The OVs are responsible for the collection of samples at slaughterhouses. The OVs who collect residue samples at the lamb slaughter establishments have received sufficient training that includes such subjects as sampling methodology, identification of animals, traceability, and sample security.

Icelandic Regulation No. 30/2012, Article 10 describes MAST's requirements and controls for sample collection, including procedures used to ensure sample integrity and chain of custody which included collecting and documenting information such as: name and address of owner, address and site of sampling; breed and age of animal; sample type and amount; and specific animal identification sufficient for traceback.

The FSIS auditor confirmed that government inspection personnel are following guidance in the NRCP SOP, Instructions for Residue Sampling. The auditor also confirmed that once samples are collected, the OV completes the laboratory submission form and a copy is packaged with the sample, which the OV secures with a security seal to maintain integrity. The sample is then transported by official courier to the sample registration and preparation laboratories contracted by MAST. Residue results are communicated to the MAST headquarters, DVOs, OVs, and the establishment through e-mail. In the case of a positive sample, the laboratory immediately notifies MAST via e-mail; the CVO of meat inspection and DVO evaluate the results and determine if enforcement actions are necessary per Icelandic Regulation No. 30/2012. The FSIS auditor's review of all 2021 sample results received as of November 2021 showed no violations.

The remote audit activities indicate that MAST continues to maintain the legal authority to regulate, plan, and execute activities of the inspection system that are aimed at preventing and controlling the presence of residues of veterinary drugs and chemical contaminants in lamb products destined for human consumption and for export to the United States.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth equivalence component the FSIS auditor reviewed was Government Microbiological Testing Programs. The food safety inspection system is to implement certain sampling and testing programs to ensure that raw lamb products prepared for export to the United States are safe and wholesome.

MAST ensures the implementation and maintenance of its meat food safety inspection system microbiological sampling program by verifying that all certified establishments exporting to the

United States comply with the requirements in Icelandic Regulation No. 650/2001 in order to verify process control during sheep slaughter and carcass dressing. MAST requires the use of generic *E. coli* as an indicator organism to ensure that process control systems are sufficient to prevent fecal contamination. Generic *E. coli* sampling is an establishment responsibility, not part of an official government sampling program.

Icelandic Regulation No. 650/2001, Article 2, requires all certified establishments to have a written sampling program addressing *E. coli* to include the following: written instructions regarding sampling; labeling of samples; sampling method; sample handling; interpretation of results; and corrective actions if permissible levels are exceeded. Certified establishments conduct daily sampling for generic *E. coli* at a frequency of 1 per every 300 chilled sheep carcasses or at least once a week if slaughter is below the limit. Carcass samples are collected after at least 12 hours of chilling and analyses should start within 24 hours of sample collection. The samples are analyzed at a private laboratory approved by the CVO. Iceland's requirements are consistent with FSIS regulatory requirements cited in 9 CFR 310.25(a) for generic *E. coli* with a focus on lamb slaughter as the only species eligible for export to the United States. Icelandic Regulation No. 650/2001, Article 15, requires certified establishments to take corrective actions if permissible levels are exceeded. The OV and DVO then conduct follow-up verification of corrective actions implemented.

The FSIS auditor verified the microbiological sampling and testing programs of the two audited slaughter establishments through interviews with government officials and document reviews of government inspection personnel. The FSIS auditor confirmed that OVs conduct daily verification activities of the establishments' generic *E. coli* testing programs in chilled lamb carcasses and record the results on the Daily Control in Slaughterhouses checklist. The CVO of meat inspection and the DVOs (during monthly supervisory reviews) verify that slaughter establishments comply with MAST's regulatory requirements regarding generic *E. coli* testing of lamb carcasses and record results on the Control of *E. coli* in Slaughterhouses checklist. The inspection activity includes verifying that each establishment uses appropriate sampling methodology and technique; the frequency of sampling is appropriate; the laboratory uses an appropriate method for analysis; records of analytical results are maintained and correctly evaluated; and appropriate corrective actions are taken if the upper control limits are exceeded. Control charts shared by MAST with the FSIS auditor indicated that results were properly recorded. The FSIS auditor's review of inspection records identified no concerns.

The FSIS auditor concluded that Iceland's food safety inspection system continues to maintain the legal authority to regulate, plan, and execute verification activities of the microbiological sampling program and that MAST continues to meet the core equivalence requirements for this component. There have not been any POE violations related to this component since the previous FSIS audit in 2018.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held December 14, 2021, by videoconference with MAST. At this meeting, the FSIS auditor presented preliminary findings from the audit. An analysis of the findings

within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditor identified the following findings:

GOVERNMENT OVERSIGHT (e.g., ORGANIZATION and ADMINISTRATION)

- MAST failed to provide the DVO of one district adequate training when promoting the individual to the position. The new DVO was unaware of individual reports that were required monthly during slaughter operation.

During the audit exit meeting, MAST committed to address the preliminary finding as presented. FSIS will evaluate the adequacy of MAST's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

Appendix: Foreign Country Response to the Draft Final Audit Report

In an email dated May 25, 2022, MAST provided the following response to FSIS:

A response to findings in; Iceland - Draft Final Report of a Remote Audit Conducted

The FSIS auditor identified the following finding: GOVERNMENT OVERSIGHT (e.g., ORGANIZATION and ADMINISTRATION) • MAST failed to provide the District Veterinary Officer (DVO) of one district adequate training when promoting the individual to the position. The new DVO was unaware of individual reports that were required monthly during slaughter operation

Reaction of Mast:

Mast has a well working procedure on training of new employees, running for some years where all areas of official competent authority assignments are covered. There are only 4 DVO's in Iceland now. Unfortunately there has not been an official training program for temporary DVO's that step in, in a sick leave.

In the mentioned district where there was a finding in the mentioned remote audit conducted late year 2021, the DVO had been on sick leave since 1.september 2021 which was prolonged until january where the person retired. So the temporary DVO had to step in fast and for much longer then was expected in the beginning and did not receive adequate training. Now, after the remote audit the temp. DVO and the OV in the district are well aware of the requirements for exporting meat. There has not yet been hired a new DVO in the district.

To prevent repetition of a similar incident Matvælastofnun has implemented a procedure for training plan, since february 2022 for official veterinarians that have to step in and cover a DVO – position for a period longer than 4 weeks, called “Afleysing í starfi Héraðsdýralæknis” (Temporary DVO). This training plan is managed by a digital system called CCQ and training of DVO's is now under the responsibility of a new position “Director of office of food and feed control”, who ensures that correct training takes place. “Afleysing í starfi Héraðsdýralæknis”-training includes theoretical training in special markets, export to third countrys as introduced in the attachment with the same name. The attachments shows a checklist that is available on-line in the training-database CCQ and will be signed there.

Also there has been introduced a procedure to prepare long-time illness leaves for an employee and a procedure for welcoming back an employee from long time illness leave.

This procedure should prevent a similar incidence to occur.

Málaflokkar sem þarf að kynna fyrir tímabundið ráðnum héraðsdýralæknum til lengri tíma

Nafn starfsmanns:				
Hóf störf:		Dagsetning þjálfunar:	Staðsetning:	
Dagur (day)	Þjálfunaratríði: (training items)	Lengd (duration)	Hver þjálfar (trainer)	Kvittun f. Þjálfun (signature)
	Slaughterhoses			
1	EU Regulation – Specific rules for the performance of official controls on production of meat	1 hour	VO for meat	
1	Veterinary standards and hygienic procedures at abattoir and abp - handling	1 hour	VO for meat, senior VO for abp	
1	Regular audits in slaughterhouse and inspection manual		VO for meat	
1	Quarantine zones if sheep slaughterhouse	0,5 hour	Senior VO for Epidemiology	
1	Sampling in slaughterhouses	0,5 hour	Official veterinarian	
1	Special markets, third countrys	0,5 hour	VO for meat	
1	Daily-reports, non-compliance reports etc.	45 min	VO for meat	
1	Loading documents	0,5 hour	VO for import and export	
		7 hours		
	Mast Quality systems			
2	Introduction of Mast quality system, LEMA and databases, (ONE systems, Ísleyfur, CCQ)	2 hours	Quality Manager, Project manager and another DVO	
2	Staff management and team working	1 hours	Another DVO	
	Animal welfare			
2	Animal welfare during transport	0,5 hours	Senior V.O.for Welfare and the the one for welf. slaughter Animals	
2	Animal welfare in general and during slaughter	0,5 hours	same	
	Animal diseases			
2	Animal health and disease status, monitoring and sampling	0,5 hours	Senior VO for Epidemiology	
2	Medicin registrations, residues, veterinary practices	0,5	Senior Veterinary	

			Officer of Residues	
		5 hours		

Við lok þjálfunar skal eyðublaðinu skilað útfylltu til sviðsstjóra og afriti til mannauðsstjóra.

Þjálfun skráð í þjálfunarskrá

Dagsetning

Skráð af

Law and Regulations

Gæðaskjöl

önnur gögn

Lög 93/1995

Lög 25/1993

EB 2019/627

EB 2917/625

EB 853/2004

EB 852/2004

EB 2073/2005

EB 1099/2009

1250/2019 dýrasjúkdómar

651/2001 riða

527/2017 flutningsvelferð

A temporary DVO shall always be able to get an assistance from another experienced DVO and be in direct contact

After training the temp. DVO has to document a proceeding self-education on another form.