



United States Department of Agriculture

Food Safety and
Inspection Service

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Mr. Jón Gíslason
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APR 13 2015

Dear Mr. Gíslason,

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Iceland's meat inspection system from September 29 through October 10, 2014. 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.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 720-8609, by facsimile at (202) 720-0676, or electronic mail at international.audit@fsis.usda.gov

Sincerely,

Dr. Shaukat H. Syed
Director
International Audit Staff
Office of Investigation, Enforcement, and Audit

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

Iceland

September 29 – October 10, 2014

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

April 13, 2015

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from September 29 – October 10, 2014, to determine whether Iceland’s food safety system governing the production of meat continues to be equivalent to that of the United States, with the ability to produce products that are safe, wholesome, and correctly labeled and packaged.

The previous FSIS audit of Iceland’s meat inspection occurred from September 12 – 27, 2007. During the course of the 2007 audit, FSIS identified a facility sanitation performance standards (SPS) issue related to insufficient lighting to conduct proper ante-mortem inspection in the lamb holding pens.

During the current audit, FSIS verified that corrective actions were implemented to remedy the 2007 audit SPS finding. In addition, the current audit also included one special emphasis area in which FSIS verified that species separation measures are adequate in slaughterhouses that export to the United States. The FSIS audit results confirm that the Icelandic inspection system continues to maintain equivalence.

The 2014 audit results indicate that Iceland’s food safety inspection system is performing at an “average” level meeting the core criteria for all six equivalence components. FSIS identified some operational (or procedural) weaknesses related to government oversight and its verification of sanitation. However, none of these weaknesses were significant enough as to raise a question about Iceland’s on-going equivalence.

An exit meeting was held on October 10, 2014 in Reykjavik with the Icelandic Food and Veterinary Authority (Icelandic name: *Matvælastofnun* – MAST). The preliminary findings from the audit were presented by the FSIS auditor. FSIS will evaluate any information provided by Iceland including the submittal of the Central Competent Authority (CCA) proposed corrective actions in response to the audit observations to assess the effectiveness of the corrective actions. FSIS requests that the CCA provide a detailed response for the observations within 60 calendar days of receipt of this report.

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I. INTRODUCTION

FSIS of the United States Department of Agriculture (USDA) conducted an on-site equivalence verification audit of Iceland's meat inspection system from September 29 to October 10, 2014. The audit began with an entrance meeting held on September 30, 2014 in Selfoss with the participation of representatives from the CCA MAST and the FSIS auditor.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine on-going equivalence verification audit. The audit objective was to verify that Iceland's meat inspection system continues to be equivalent to that of the United States, with the capacity to produce products that are safe, wholesome, and correctly labeled and packaged.

During the audit, areas of special emphasis included:

- Corrective actions proffered and implemented by the CCA in response to previous FSIS audit in 2007.
- Information recently provided by MAST concerning control of species separation measures in slaughter/processing establishments.

FSIS used a risk-based approach to determine the audit scope which included an analysis of country performance within six equivalence components, production types and volumes, frequency of prior audit-related site visits, Port-of-Entry (POE) testing results, and specific oversight activities and testing capacities of government offices and laboratories. The review process included data collected by FSIS over a three-year timeframe, in addition to information obtained directly from the CCA through a self-reporting process, outlining the current structure of the country's inspection system and identifying any significant changes that have occurred since the last audit.

The FSIS auditor was accompanied throughout the entire audit by representatives from the CCA and representatives from the state and local inspection offices. Determinations concerning program effectiveness focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, (4) HACCP Systems, (5) Chemical Residues Control Program, and (6) Microbiological Testing Programs.

Administrative functions were reviewed at CCA headquarters and at two local inspection offices, during which the auditor evaluated the implementation of those management control systems in place that ensure that the national system of inspection, verification, and enforcement was being implemented as intended.

Both of the slaughter and processing establishments certified to export raw intact lamb products to the United States were audited. During the establishment visits, particular attention was paid to the extent to which industry and government interact to control hazards and prevent non-compliances that threaten food safety, with an emphasis on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with 9 Code of Federal Regulations (CFR) 327.2 to ascertain equivalency.

Additionally, three laboratories were audited to verify their ability to provide adequate technical support to the inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	CCA (MAST) – Selfoss
	District	2	<ul style="list-style-type: none"> • South • Northwest
Laboratories		3	<ul style="list-style-type: none"> • One private microbiology lab in Reykjavik • Two government laboratories in Reykjavik
Establishments		2	<ul style="list-style-type: none"> • Two sheep slaughter and processing establishments

III. LEGAL BASIS FOR THE AUDIT AND AUDIT STANDARDS

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. Title 7), and
- The Federal Meat Inspection Regulations for Imported Products (9 CFR Part 327).

The audit standards applied during the review of Iceland’s meat inspection system included (1) all applicable legislation 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 Sanitary/Phytosanitary Agreement.

Currently, Iceland has equivalence determinations in place for the following:

- Sheep and equines can be slaughtered in the same slaughterhouse,
- The national residue control program,
- The generic *Escherichia. coli* (*E. coli*) testing program for sheep and lamb, and
- Removal of sheep and lamb heads from the carcass prior to veterinary disposition.

IV. BACKGROUND

Iceland is eligible to export lamb, goat, beef, and pork products to the United States, although no goat, beef, or pork products have been received at any United States POE. From October 1, 2012, to April 30, 2014, FSIS’s import inspectors performed re-inspection for labeling and certification on 594,542 pounds of lamb products exported by Iceland to the United States. FSIS also performed re-inspection for additional types of inspection (TOI)¹ on 250,701 pounds at POE, and a total of 1,795 pounds were refused

¹ Additional information regarding types of inspection (TOI) and FSIS’ POE re-inspection process can be found in [FSIS PHIS Directive 9900.2, IMPORT REINSPECTION OF MEAT, POULTRY, AND EGG PRODUCTS](#)

because of non-food safety issues (e.g., transportation damage). Iceland exports to the United States intact raw bone-in and boneless lamb meat products, edible offal, and boneless manufacturing trimmings.

FSIS conducted a follow-up examination of the CCA's corrective action in response to the previous audit, which took place from September 12 – 27, 2007. During the 2007 audit, FSIS identified deficiencies related to SPS because of insufficient lighting to conduct proper ante-mortem inspection in the lamb holding pens. FSIS verified that implemented corrective actions addressing this deficiency were effective.

V. GOVERNMENT OVERSIGHT

The first of the six equivalence components that the FSIS auditor reviewed was Government Oversight. FSIS import eligibility requirements state that the foreign inspection system must be designed and administered by the national government of the foreign country with standards equivalent to the United States.

The evaluation of this component includes a review and analysis of documentation previously submitted by the CCA as support for the responses and corrective actions provided in the Self-Reporting Tool (SRT) as well as on-site record reviews, interviews, and observations made by the FSIS auditor at government offices and audited establishments.

Several changes have occurred since the 2007 audit. The CCA, MAST, 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 sectors of ordinary business and economic activity. MoII opened on 1 September 2012 following the merger between the Ministry of Fisheries and Agriculture, the Ministry of Industry, Energy and Tourism, and part of the Ministry of Economic Affairs. Since January 1, 2008, MAST has been deemed Iceland's CCA for food and feed safety, animal health, and animal welfare. MAST operates six district offices and is responsible for operation of eight border inspection posts (BIP), which control imports from non-European Economic Area (EEA) countries.

MAST's primary roles include:

- Food safety/control of primary production of products of animal origin including fish products, as well as, import and export control of all foodstuffs,
 - Meat classification services,
 - Controls regarding animal health and animal welfare,
 - Disease control and prevention (zoonosis and contingency plans),
 - Consumer affairs and education,
 - Administration of organic production of agricultural products, and
 - Supervision of domestic food control by the Independent Municipal Environmental and Public Health Offices (Local Competent Authorities – LCAs).
-

MAST is headed by a Director General, who governs the organization, sets its working policies and is responsible for financial operations. The Director General also oversees the work of the Chief Veterinary Officer (CVO), the District Veterinary Officers (DVOs), other Directors (Administration, Legal Affairs, Food Safety, and Consumer Affairs), and the Import/Export head of office. MAST's work is divided between two offices: 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, whereas a Director heads the Office of Food Safety and Consumer Affairs. The country is divided into six veterinary districts: Southwest Regional, Western, Northwest, Northeast, Eastern, and South. Fieldwork related to food safety and animal health is coordinated by the DVO. DVO's have local offices in the district they are assigned to cover. DVO's provide supervision to Official Veterinarians (OVs) assigned to carry out official inspection activities at approved slaughterhouses. OVs are responsible for supervising the post-mortem inspection work carried out by Auxiliaries. Auxiliaries are official non-veterinary personnel who have received training to distinguish and segregate normal from abnormal tissues for veterinary disposition. All official personnel are employed and paid by MAST. MAST ensures uniform implementation of regulatory requirements and is responsible for oversight of the official activities of inspection personnel at establishments eligible to export to the United States.

New facilities interested in becoming certified as eligible to export to the United States must submit their request to the CCA headquarters. The Chief of Meat Inspection and Dairies visits the facility along with the DVO to make the determination as to whether or not the facility has developed all required programs such as Generic *E. coli* testing, Sanitation Standard Operating Procedures (SSOP), and HACCP

The CCA's authority to enforce inspection laws was established in Act Number 167/2007, passed by the Icelandic Parliament on December 14, 2007. The CCA has the legal authority and the responsibility to write, implement, and enforce requirements equivalent to those governing the system of meat inspection organized and maintained in the United States. To achieve these objectives, in accordance with the requirements outlined in 9 CFR 327.2, the CCA conducts periodic supervisory visits to each establishment.

The auditor conducted a review of inspection system documents at the Headquarters (HQ) office, two District Offices, and inspection offices in the two audited establishments. Document reviews focused primarily on food safety hazards. The FSIS auditor reviewed non-compliance reports (NRs) that were generated by in-plant inspection personnel at both audited establishments. FSIS noted that the inspection personnel had identified and documented deficiencies in NRs. The inspection personnel closed the NRs after verifying the adequacy and effectiveness of the establishment's corrective actions and preventive measures. The auditor determined that the inspection personnel have adequately described non-compliances and verified the effectiveness of the establishment's corrective actions. The FSIS auditor also reviewed the last two months of written periodic supervisory reviews to assess the enforcement capability of the inspection personnel and the adequacy of establishment's corrective actions. The supervisory reviews reports are consistent with the FSIS auditor's observation in the audited establishments. No non-compliance trends related to SSOP, HACCP, SPS, or slaughter activities were observed.

The FSIS auditor verified that documented periodic supervisory reviews are performed in both establishments eligible for export to the United States. The Chief of Meat Inspection and Dairies (CMID), with the Office of Food Safety and Consumer Affairs, and the DVOs are responsible for conducting the supervisory reviews at establishments authorized to export to the United States. The supervisors perform direct verification evaluations of the United States-certified slaughter and processing establishments at least once per calendar month during the lamb slaughter season. In addition to establishment compliance (including HACCP, SSOPs, facilities and equipment, animal welfare, and traceability), the procedure includes a general evaluation of in-plant inspection personnel controls, including ante- and post-mortem inspection techniques, documentation, SSOP- and HACCP-program verification, control of condemned product, security of stamps, seals, and other security items, microbiological and residue program controls, species verification sampling, and verification of the establishments generic *E. coli* testing program. A copy of the completed supervisory report is shared with both the OV and the establishment operator.

The FSIS auditor verified through discussions and documentation that the CCA exercises its legal authority to require United States-eligible establishments to develop, implement, and maintain sanitation programs that are sufficient to prevent direct product contamination or insanitary conditions. Both audited establishments had developed, implemented, and maintained Good Manufacturing Practices (GMP) prerequisite programs that support their food safety system. CCA personnel have access to and review GMP records as part of their daily inspection control activities.

The auditor verified, through document review at the CCA and both audited establishments, that inspection personnel assigned to United States-eligible establishments are employees of the national government. Inspection personnel at all levels audited (HQ, District, establishment) are employed by the national government. All US-eligible 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. To provide adequate staffing during the lamb slaughter season, MAST hires additional veterinarians and auxiliaries on a temporary basis. As part of the hiring process, veterinarians hired on a temporary basis by MAST are required to submit a copy of their *Curriculum Vitae* (CV) and copies of their veterinary education diplomas. MAST follows guidance provided by the European Union (EU) in Directive 2005/36/ EC of 7 September 2005 to determine what constitutes professional qualifications to be recognized as a veterinarian. Veterinarians are also required to hold current EU veterinary certification credentials. Auxiliaries' abilities are initially evaluated based on the job experience and qualifications listed on their CV.

Once hired, employees, both full time and temporary, receive new employee training by MAST on administrative procedures related to being government employees. New employees receive on-the-job training by working next to an experienced employee until the OV can determine that the employee is performing the assigned post-mortem inspection tasks appropriately. A formal training and development program addressing the technical knowledge needs of OVs or Auxiliaries in regards to their assigned inspection duties has not been developed by MAST. MAST tries to retain the same staff on a year-to-year basis. Some of the temporary OVs and Auxiliaries observed during the

course of this audit had returned to work in the same establishment for the last eight lamb slaughter seasons.

FSIS determined that the CCA hires competent and qualified personnel. The CCA also provides initial task-specific training to ensure that safe, wholesome, and accurately labeled lamb and lamb products are produced in United States-certified establishments.

Chapter 10.1 of MAST's September 2014 *Inspection Manual for Daily Work Activities in slaughterhouses for sheep, pig, and other large species* tells official personnel working at United States- certified establishments that, in order for lamb products to become eligible for export to the United States, the following special requirements have to be met:

In processing plants licensed to produce lamb for export to the United States of America (USA), the local inspection controls need to ensure that the following USA requirements are met (9 CFR, 416 and 417):

- a. Pre-operational and Operational Sanitation.
- b. HACCP.
- c. For post-mortem exam, kidney must be released from its capsule.
- d. Lighting where post mortem is performed should be at least 540 lux (50 ft. candles).
- e. Measures to prevent the mixing of horsemeat with lamb meat intended for the United States market.
- f. Species verification testing.
- g. Sampling and testing for generic *E. coli* on sheep intended for the United States market.
- h. Pre-shipment Review requirement.
- i. Veterinary supervision and support staff will be identified in a manner that will make it clear that they are part of official supervision/inspection.

The on-site audit findings revealed that although the CCA has a procedure to assess and document technical competence of its official personnel at the central level of the organization, a procedure to assess and document technical competence of official personnel at the in-plant inspection levels of the organization has not been developed. The procedure in use to assess the technical competence of in-plant inspection officials does not require the supervisor to conduct a periodic review to elaborate on how the regulatory knowledge and inspection skills (i.e., ante-mortem, post-mortem, and handling in connection with slaughtering) of individual in-plant personnel were assessed.

The records of supervisory reviews provided by the CCA and examined during the course of the audit did not document the method used to determine how regulatory knowledge and inspection skills of official in-plant personnel are determined to be adequate, nor the type of feedback provided to individuals whose inspection skills were found to be inadequate. Interviews by FSIS with MAST and the DVOs confirmed that there is no standardized method by which to assess, document, and provide feedback to in-plant inspection officials. If during the course of a supervisory visit the determination is reached that in-plant officials are not performing inspection tasks adequately, the

supervisory report does not document the measures taken to address the observed performance deficiency.

FSIS did verify, however, that documented periodic supervisory reviews are performed as required by 9 CFR 327.2(a) (2) (iv) (A) in an equivalent manner. These reports are reviewed at the MAST HQ in Selfoss and at both audited establishments. In all locations, 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. In the event the individual completing the checklist observes deviations, these are to be described on the form. Immediate corrective actions in response to deviations are also recorded on the form. Actions that are not corrected immediately are followed up on during the next supervisory visit.

FSIS’ on-site verification methodology included observations, document reviews, and interviews with in-plant veterinary officials and supervisors helped confirm that the CCA monitors, verifies, and enforces the implementation of SSOP, HACCP, and SPS regulatory requirements in both of the audited establishments. Based on FSIS’ on-site document reviews, interviews, and the audit observation that a procedure to assess and document technical competence of official personnel at the in-plant inspection levels of the organization has not been developed, FSIS concludes that the CCA continues to maintain equivalence and is operating at an “adequate” level for this component.

VI. STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS

The second of the six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. There are no regulatory changes associated with the slaughter of lamb in the United States since the last audit that would have required changes by the CCA.

The inspection system must be organized and administered by the national government of the foreign country. The system must 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; daily inspection; periodic supervisory visits to official establishments; and requirements for thermally processed/commercially sterile products.

Icelandic Parliament Act No 167/2007 resulted in the creation of MAST, now responsible for enforcing the following Icelandic food safety related legislation:

- Act number 93/1995 on *Food and Foodstuffs*;
- Act number 19/1997 on *Communicable Diseases*;
- Act number 66/1998 on *Veterinarians and Animal Health Services*;
- Act number 25/1993 *Governing Animal Diseases and Preventive Measures Against Them*;

- Act number 96/1997 on the *Raising and Health of Slaughter Animals, Slaughtering, Processing, Health Inspection and Quality Grading of Slaughter Products*;
- The *Animal Protection Act*, number 15/1994;
- Act number 67/1990 on the *Institute for Experimental Pathology of the University of Iceland at Keldur*;
- Act number 54/1990 on *Importation of Animals*;
- Act number 103/2002 on *Animal Husbandry*; Regulation no. 650/2001 on *Sampling for Generic E. coli in sheep intended for export to the United States*; and
- Act number 55/2013 on *Animal Welfare*.

The CCA issues, distributes, and makes available on its website (<http://mast.is/>) inspection- related publications, guidelines, and instructions to its inspection personnel.

The FSIS auditor verified that in-plant OV conduct ante-mortem inspection on the day of slaughter by observing all animals at rest and in motion from both sides in designated holding pens in order to determine whether the animals are fit for slaughter, and by reviewing in-coming documents including:

- Statements from the producer regarding the health of the sheep,
- Statements from the producer indicating that withdrawal times and transportation restrictions were followed,
- Assurance that no animals from producers having been identified more than two times as residue violators are presented for slaughter,
- Animal identification, collected from each animal as they enter the stunning area,
- Mandatory reporting of the detection of animal or zoonotic diseases , and
- Pen cards.

Each audited establishment has a designated observation pen for further official veterinary examination of suspect animals. The FSIS auditor observed and verified that all animals have access to water in all holding pens (including the pens used for suspect animals); and that if animals are held overnight, feed and water are provided. The FSIS auditor further verified through on-site record review, interviews, and observations that the CCA's requirements concerning ante-mortem inspection are followed in all audited slaughter establishments. The FSIS auditor was also able to verify that humane handling/slaughter of livestock requirements contained in Iceland's Regulation 1099/2009 are being met and enforced by the CCA when non-compliances are detected in all audited slaughter establishments. In one slaughterhouse, while visiting the stunning area, the CCA observed that lambs were not stunned properly. The OV and the DVO immediately notified the establishment operator, who used the available backup equipment to stun the affected animals. The incident was documented by the OV in a standard form, *Krafa um urbaetur* (translation: Demand for improvements). Delivery of the form to the establishment is MAST's official notification that an official from MAST observed a deviation. A FSIS review of available documents revealed that the incident

was a one-time event. FSIS assessed post-mortem inspection examinations through on-site record review, interviews, and observations of inspection activities in both audited slaughter establishments. The FSIS auditor observed and verified that proper presentation, identification, examination, and disposition of carcasses and parts are being implemented. Both in-plant veterinary and non-veterinary inspectors are adequately trained in performing their on-line post-mortem inspection duties. The FSIS auditor observed the performance of official inspection personnel examining the viscera and carcasses and determined that the inspection personnel were performing well. Regulation number 854/2004 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.

9 CFR 327.2 prescribes the certification language that must be included in a foreign official meat establishment certificate. In Iceland, export certificates are issued, signed, and stamped by the CCA's central Office of Import and Export, located in Reykjavik. The process to obtain an export certificate to export meat begins at the exporting facility, with the exporter completing a standard form, "*Útflutningur á dýraafurðum öðrum en mjólk*" (translation: Exports of animal products other than milk), which is turned in to the OV. The OV reviews the application and, upon determining that product listed on the application form meets requirements of the exporting country, signs and makes a copy of the form, and returns the original to the export applicant. The applicant then submits the form to the Office of Import and Export, located in Reykjavik, to request that an Official Meat-Inspection Certificate for fresh meat and meat byproducts be issued for the load. FSIS noted that the application form used as part of the process of obtaining export certificates for exporting animal products other than milk did not include a certification statement indicating that products being certified for export met United States requirements.

Based on FSIS' on-site document reviews, interviews, and the audit observations in conjunction with the SRT review and document analysis of the CCA's control measures, FSIS concludes that the CCA continues to maintain equivalence and is operating at an "average" level for this component.

VII. SANITATION

The third of the six equivalence components that the FSIS auditor reviewed was Sanitation. To be considered equivalent to FSIS' program, the CCA must provide general requirements for sanitation, sanitary handling of products, and SSOP. The CCA has compiled specific sanitation requirements related to United States export in Chapter 10.1 of MAST's September 2014 "*Inspection Manual for Daily Work Activities in slaughterhouses for sheep, pig, and other large species*".

The FSIS auditor reviewed sanitation plans and records related to the design and implementation of sanitation programs at all of the audited establishments. In one of the audited establishments, the FSIS auditor verified the actual pre-operational inspection by shadowing and observing the OV conducting pre-operational sanitation verification of slaughter and processing areas. The in-plant inspection personnel's hands-on verification procedures began after the establishment personnel conducted their pre-operational

sanitation and determined that the facility was ready for in-plant inspector pre-operational sanitation verification activities. The in-plant inspection personnel conduct this activity in accordance with the CCA's established procedures, which include direct observation of sanitary conditions of facilities and equipment and verification of the establishments' pre-operational sanitation records. Results of the pre-operational verification activity are entered into an official MAST standard form, GAT-019.2, *Daily control in slaughterhouses*. If the OV determines that there is a noncompliance, the observation is recorded by the OV in the previously referenced MAST standard form, [*Krafa um urbaetur*](#). The form requires the establishment to respond to the observation and to provide corrective actions addressing the noncompliance. The manner in which the OV performed the pre-operational inspection verification procedure was equivalent to the manner in which the procedure is performed under the Federal system of inspection in the United States.

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. Standard form, GAT-019.2, *Daily control in slaughterhouses*, is used to record operational sanitation observations. Operational sanitation noncompliances are addressed by issuing the previously referenced standard form, [*Krafa um urbaetur*](#). The manner in which the OV performed the operational inspection verification procedure was equivalent to the manner in which the procedure is performed under the Federal system of inspection in the United States.

Findings related to the enforcement of sanitation performance standards (SPS) were identified in one of the audited establishments.

- In that establishment, Government program employees were precluded from observing conditions in one of the freezer rooms used to store product within the facility because, with the exception of a pathway leading from the freezer door, boxed product was stored in such a manner that it prevented examination of storage conditions in the rest of the freezer. The only way an official employee would have been able to examine the boxed products stored in this room would have been by climbing on the stacks of boxed product. In the same establishment, an adjacent freezer was examined, where the auditor observed wrapped carcasses and boxed product stored in the same room as two pallets of boxed ovine lungs wrapped in blue plastic film that were marked "INEDIBLE." The CCA indicated that this was an acceptable practice because the pallets upon which the boxed inedible products were placed upon were wrapped in a double layer of plastic film, the product was clearly labeled as "INEDIBLE," and the products did not create an insanitary condition in the freezer.

The OV, DVO, and MAST HQ representative accompanying the auditor demonstrated an overall ability to verify that the establishments maintain sanitary conditions, although there is need for improvement concerning the enforcement of sanitation performance standards in ensuring that sanitary operations are maintained to protect products from adulteration during processing, handling, storage, loading, and unloading at and during transportation from official establishments.

Based on FSIS' on-site document reviews, interviews, and the audit observations in conjunction with the SRT review and document analysis of the CCA's control measures, FSIS concludes that the CCA continues to maintain equivalence and is operating at an "average" level for this component.

VIII. HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

The fourth of the six equivalence components that the FSIS auditor reviewed was HACCP. The inspection system must require that each official establishment develop, implement, and maintain a HACCP plan.

The FSIS auditor verified through record review and observation that the in-plant inspection personnel at certified establishments conducted daily verification of HACCP plans, for which verification results are entered on Form GAT-019.2. The in-plant inspection personnel verification of HACCP plans includes verification of CCPs for all production shifts.

At both slaughter establishments audited, the FSIS auditor conducted a review of the zero tolerance (feces, ingesta, and milk) Critical Control Point (CCP) records generated during the year. In addition, the FSIS auditor reviewed the zero tolerance verification records (Form GAT-019.2) generated by the in-plant inspector at these locations. All establishments audited were conducting 100% monitoring of carcasses for this CCP. Furthermore, the FSIS auditor confirmed that the physical CCP monitoring location for government verification was before the final wash in all establishments audited.

The FSIS auditor evaluated the HACCP systems at both of the audited facilities, including the development and implementation of the system. As part of evaluating the design of the system, the auditor was able to verify that the HACCP system complied with the following foundational elements: a flowchart and hazard analysis that matched the actual production processes in the establishment; in the hazard analysis the establishment accurately considered food safety hazards that relate to the product and its intended uses and determined whether the identified hazard is reasonably likely to occur; CCPs for hazards reasonably likely to occur in the process where identified; the hazard analysis adequately supported any decision that a food safety hazard is not likely to occur in the process; and the HACCP system was reassessed annually and any time changes occur that could affect the hazard analysis or HACCP plan.

Based on FSIS' on-site document reviews, interviews, and the audit observations in conjunction with the SRT review and document analysis of the CCA's control measures, FSIS concludes that the CCA continues to maintain equivalence and is operating at an "average" level for this component.

IX. CHEMICAL RESIDUE CONTROL PROGRAMS

The FSIS auditor reviewed Chemical Residue Control Programs as the fifth of the six equivalence components. The FSIS criteria for this component include the design and implementation of a program managed by the CCA that carries out effective regulatory activities to prevent chemical residue contamination of food products. To be considered equivalent to FSIS' residue control program, the CCA's program needs to include

random sampling of muscle, internal organs and fat of carcasses for chemical residues identified by the exporting countries and FSIS as potential contaminants. In addition, the CCA needs to identify the laws, regulations, or other decrees that serve as the legal authority for the implementation of the program; provide a description of its residue sampling and testing plan and the process used to design the plan; describe the actual operation of its residue plan and actions taken to deal with unsafe residues as they occur; and provide oversight of laboratory capabilities and analytical methodologies to ensure the validity and reliability of test data.

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

- Regulation no. 30/2012, on the control of residues in animal products (types 96/23 EC, 2006/104, 98/179, 89/153, 97/747);
- Regulation no. 653/2001 of MRLs in meat, eggs and milk (EC type 2377/90);
- Regulation no. 265/2010 on the entry into force of Regulation (EC) no. 1881/2006 setting maximum levels for certain contaminants in foodstuffs (EC concluded 1126/2007, 629/2008);
- Regulation no. 768/2010 on the entry into the European Union regulations on Evaluation (IX) (EC 140/2007 type); and
- Regulation no. 539/2000 on prescribing veterinarians (EC type 81/851).

Iceland joined the European Free Trade Association (EFTA) in 1970 and has been a party to the Agreement on the EEA since its entry into force in 1994. Participating in the single market for over 15 years through the EEA, Iceland has adopted a significant part of EU law. The EFTA Surveillance Authority (ESA) regularly monitors Iceland's performance under the EEA Agreement. Iceland presented its application for membership to the EU on July 17, 2009. As part of the process of becoming an EU member, Iceland adopts and enforces European Community (EC) regulations.

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 OV's responsible for the collection of samples at slaughterhouses. According to the NRCP, depending upon the compound being monitored, OV's are instructed to collect muscle, organs, 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 MAST at the Institute for Experimental Pathology located at Keldur where MAST personnel log them in. The samples are then prepared and packaged by a MAST official for submission to an accredited laboratory for analysis. MAST does not operate official laboratories. Analysis of samples for some residues is contracted to two government laboratories: the Institute for Experimental Pathology for the University of Iceland (*Tilraunastöð HÍ í meinafræði*) and the Matis laboratory (*Matis ohf.*), both located in Reykjavik. Because there are residue samples that cannot be analyzed in their national laboratories, Iceland also submits some of their NRCP samples to foreign laboratories. Iceland's accreditation body 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 Act No. 24/2006 on Accreditation. The assessment is carried out by SWEDAC (the Swedish Accreditation Body) on behalf of ISAC according to an agreement between the two accreditation bodies. ISAC and SWEDAC are members of the European co-operation for Accreditation (EA). FSIS is in receipt of Iceland's results of the Icelandic monitoring program for residues in food for 2013 and the monitoring plan for 2014. During visits to establishments, laboratories, and government offices, the interviews held with inspection officials indicated that they were familiar with the requirements of the NRCP.

Based on FSIS' on-site document reviews, interviews, and the audit observations in conjunction with the SRT review and document analysis of the CCA's control measures, FSIS concludes that the CCA continues to maintain equivalence and is operating at an "average" level for this component.

X. MICROBIOLOGICAL TESTING PROGRAMS

The last of the six equivalence components that the FSIS auditor reviewed was Microbiological Testing Programs. This component pertains to the microbiological testing programs organized and administered by the CCA to verify that products destined for export to the United States are safe, wholesome, and meet all equivalence criteria.

The evaluation of this component included a review and analysis of the CCA's 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 CCA as support for the responses provided in the SRT. The regulation describes the official inspection methodology for generic *E. coli*.

The CCA 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 is outlined in Icelandic Regulation 650/2001. While on-site at two establishments, the FSIS auditor verified that the responsible individuals have the knowledge and skills to implement this type of testing on an on-going basis. Similarly, 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. Both of the audited establishments evaluate the status of process control with respect to fecal contamination by charting and looking at the results of the most recent 13 tests in a "moving window" approach. By doing so, as each new test result is obtained, the verification criteria are applied anew to evaluate the status of process control with respect to fecal contamination. At one of the audited establishments, one instance of loss of process control was documented in the on-site documents reviewed for this year, with the establishment addressing the issue by conducting a review of process control, discovering the cause, and implementing measures to prevent recurrence. Measures implemented by the establishment in response to the loss of process control to prevent recurrence included employee training as well as a temporary modification to the HACCP plan that increased the verification frequency of the zero tolerance CCP until process control was again demonstrated.

Based on FSIS' on-site document reviews, interviews, and the audit observations in conjunction with the SRT review and document analysis of the CCA's control measures,

FSIS concludes that the CCA continues to maintain equivalence and is operating at an “average” level for this component.

XI. CONCLUSIONS

The 2014 audit results indicate that the Iceland’s food safety inspection system is performing at an “average” level meeting the core criteria for all six equivalence components. FSIS identified some operational (or procedural) weaknesses related to government oversight and sanitation. However, none of these findings were significant enough as to raise a question about Iceland’s on-going equivalence.

An exit meeting was held on October 10, 2014, in Reykjavik with MAST. The preliminary findings from the audit were presented by the FSIS auditor. FSIS will evaluate any information provided by Iceland including the submission of the CCA’s proposed corrective actions in response to the audit findings. FSIS requests that the CCA provide a detailed response for the identified weaknesses within 60 calendar days of receipt of this report.

XII. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Checklists

Foreign Country Response to Draft Final Audit Report

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Sláturfélag Suðurlands Fossnesi 800 Selfoss	2. AUDIT DATE 10/03/14	3. ESTABLISHMENT NO. A081	4. NAME OF COUNTRY Iceland
	5. NAME OF AUDITOR(S) Juan F. Rodriguez, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
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 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	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		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	X
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	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment A081, Sláturfélag Suðurlands

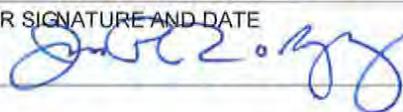
46. Government program employees were precluded from observing conditions in one of the freezer rooms used to store product within the facility because, with the exception of a pathway leading from the freezer door, boxed product was stored in such a manner that it prevented examination of storage conditions in the rest of the freezer. The only way an official employee would have been able to examine the boxed products stored in this room would have been by climbing on the stacks of boxed product. In this same freezer room, boxes of equine meat and meat products were observed stored next to boxes of lamb meat and meat products. An adjacent freezer was examined, where the auditor observed wrapped carcasses and boxed product stored in the same room as two pallets of boxed ovine lungs wrapped in blue plastic film that were marked "INEDIBLE". The CCA indicated that this was an acceptable practice because the inedible products were boxed and wrapped in plastic.

52. While observing the effectiveness of stunning at this facility, both the auditor and the CCA noticed that slight corneal reflexes were present on animals that had been electrically stunned. After the CCA notified the establishment of the observation, the facility used its secondary stunning equipment (captive bolt) to stun the animals that were improperly stunned. The facility was able to correct the improper stunning issue by making adjustments to the electrical stunning equipment. A FSIS review of available documents revealed that the incident was a one-time event.

61. NAME OF AUDITOR

Juan F. Rodriguez, DVM

62. AUDITOR SIGNATURE AND DATE

 10/03/14

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 10/07/14	3. ESTABLISHMENT NO. A022	4. NAME OF COUNTRY Iceland
	5. NAME OF AUDITOR(S) Juan F. Rodriguez, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

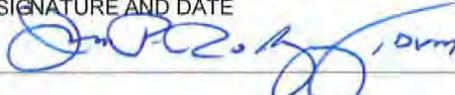
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8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation 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 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	X
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	X
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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	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment A022, Slátturhús KVH ehf

36. A section of the rail on which carcasses are moved from the cooler room into the cutting room was observed to have rust on one side of the rail. The length of the area which had rust on it was approximately 20" in length. No product was affected by the deficiency. The deficiency was immediately corrected by plant management.

61. NAME OF AUDITOR
Juan F. Rodriguez. DVM

62. AUDITOR SIGNATURE AND DATE

 , DVM 10/07/14

Rodriguez, Juan - FSIS

From: Kjartan Hreinsson <Kjartan.Hreinsson@mast.is>
Sent: Friday, April 10, 2015 9:22 AM
To: Rodriguez, Juan - FSIS
Subject: Re: Comments to FSIS Draft Final Audit Report of Iceland's Meat Inspection System

Mr. Juan Rodriguez FSIS.

The Icelandic Food and Veterinary Authority (MAST) has reviewed the report and do not have any contradictory comments to the findings in the report. MAST will however take notice of these findings and improve on things that can be addressed both on central and establishment level, some have already been corrected (freezer store), but other are on the agenda for next season.

Með kveðju, / Best regards,

Kjartan Hreinsson

Dýralæknir heilbrigðiseftirlits / Chief of Meat Inspection and Dairies

Matvælaöryggis- og neytendamálasvið / Office of Food Safety and Consumer Affairs



Matvælastofnun / Icelandic Food And Veterinary Authority

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