



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

MAR 8 2007

Dr. Halldor Runolfsson
Chief Veterinary Officer
Agricultural Authority of Iceland,
Austurvegi 64
800 Selfoss, Iceland

Dear Dr. Runolfsson:

This letter transmits the final report of the Food Safety and Inspection Service's system audit of Iceland's meat inspection system conducted October 5 through 16, 2006. The government of Iceland chose not to submit comments for this final report.

If you have any questions regarding the audit or need additional information, please contact me by telephone at 202-720-3781, by fax at 202-690-4040, or by e-mail at sally.white@fsis.usda.gov.

Sincerely,

Sally White
Director
International Equivalence Staff
Office of International Affairs

Enclosure

FINAL

FEB 26 2007

**FINAL REPORT OF AN AUDIT CARRIED OUT IN ICELAND
COVERING ICELAND'S MEAT INSPECTION SYSTEM**

OCTOBER 5 THROUGH OCTOBER 16, 2006

**Food Safety and Inspection Service
United States Department of Agriculture**

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

AAI	Agricultural Authority of Iceland
CCA	Central Competent Authority [Agricultural Authority of Iceland]
CVO	Chief Veterinary Officer
CCP	Critical Control Point
DO	District Office
DV	District Veterinarian
<i>E. coli</i>	<i>Escherichia coli</i>
FSIS	Food Safety and Inspection Service
HACCP	Hazard Analysis and Critical Control Point
NOID	Notice of Intent to Delist
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
<i>Salmonella</i>	<i>Salmonella</i> species
SPS	Sanitation Performance Standards
SSOP	Sanitation Standard Operating Procedures

1. INTRODUCTION

The audit took place in Iceland from October 5 through October 16, 2006.

An opening meeting was held on October 5, 2006 in Reykjavik with the Central Competent Authority (CCA). At this meeting, the auditor confirmed the objective and scope of the audit, the auditor's itinerary, and requested additional information needed to complete the audit of Iceland meat inspection system.

The auditor was accompanied during the entire audit by representatives from the CCA, Agricultural Authority of Iceland (AAI), and/or representatives from the district and local inspection offices.

2. OBJECTIVE OF THE AUDIT

This audit was a routine annual audit. The objective of the audit was to evaluate the performance of the CCA with respect to controls over the slaughter and processing establishments certified by the CCA as eligible to export meat products to the United States.

In pursuit of the objective, the following sites were visited: the headquarters of the AAI, located in Selfoss, and two meat slaughter and processing establishments.

Competent Authority Visits			Comments
Competent Authority	Central	1	Selfoss
	Local	2	Establishment level
Meat Slaughter Establishments		2	

3. PROTOCOL

This on-site audit was conducted in three parts. One part involved visits with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records in the country's inspection headquarters or regional offices. The third part involved on-site visits to two ovine slaughter and processing establishments.

Program effectiveness determinations of Iceland's inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures, (2) animal disease controls, (3) slaughter/processing controls, including the implementation and operation of HACCP programs and a testing program for generic *E. coli*, (4) residue controls, and (5) enforcement controls. Iceland's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditor evaluated the nature, extent and degree to which findings impacted on food safety and public health. The auditor also assessed how inspection services are carried out by Iceland and determined if establishment and inspection system controls were in place to ensure the production of meat products that are safe, unadulterated and properly labeled.

At the opening meeting, the auditor explained that Iceland's meat inspection system would be audited against two standards: (1) FSIS regulatory requirements and (2) any equivalence determinations made for Iceland. FSIS requirements include, among other things, daily inspection in all certified establishments, monthly supervisory visits to certified establishments, humane handling and slaughter of animals, ante-mortem inspection of animals and post-mortem inspection of carcasses and parts, the handling and disposal of inedible and condemned materials, sanitation of facilities and equipment, residue testing, species verification, and requirements for HACCP, SSOP, and testing for generic *E. coli*.

Equivalence determinations are those that have been made by FSIS for Iceland under provisions of the Sanitary/Phytosanitary Agreement. Currently, Iceland has two equivalence determinations regarding inspection procedures as follow:

- Removal of sheep heads from carcasses prior to veterinary disposition.
- Slaughter equines and lamb in the same establishment under certain conditions.

4. LEGAL BASIS FOR THE AUDIT

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

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.).
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/HACCP regulations.

5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at the following address:
http://www.fsis.usda.gov/Regulations_&_Policies/Foreign_Audit_Reports/index.asp

The following concerns arose as a result of the FSIS audit of Iceland's inspection system conducted in September 2004:

- In one establishment, pieces of lamb wool were found in 3 knives sanitizers during pre-operational sanitation in the evisceration department.
- In one establishment, dust accumulation was observed in 3 light fixtures during pre-operational sanitation in the deboning department, also meat pieces were observed on the overhead rail during pre-operational sanitation in the evisceration department.

The following concerns arose as a result of the FSIS audit of Iceland's inspection system conducted in September 2005:

- In one establishment, establishment's corrective action records did not include preventive measures in their SSOP program.
- In one establishment, wool fragments were found on 5 carcasses in the lamb cooler room.
- In two establishments, it was noticed during the government inspection's SSOP records review, that preventive measures as a part of the corrective actions were not included for deficiencies observed by the government officials and corrected by the plant management.
- In one establishment, in the dry storage room the packaging material was stored against the wall, which precluded thorough inspection by the government program employees.
- In the Icelandic Fisheries Residue Laboratory:
 - The manual for analysts to operate equipment for the sample analysis of heavy metals was not available at the time of audit.
 - Sample receiving log forms were not completed as required in the sample receiving log book.

Establishments audited during the October 2006 audit, had implemented corrective actions to address the deficiencies identified in the September 2005 audit.

6. MAIN FINDINGS

6.1 Government Oversight

On January 01, 2006, the Agricultural Authority of Iceland (AAI), a government agency under the Ministry of Agriculture, commenced operation as an inspection and administrative body with the following primary roles:

- Veterinary services
- Plant protection services
- Feed, seed and fertilizer services
- Meat classification services
- Services regarding freshwater fisheries
- Food safety, primary production of animal products (except fish products)
- Administration of organic production of agricultural products
- Management, monitoring of supplies and surveillance of animal welfare

The AAI has taken over the tasks that have been carried out by the following authorities:

- The Chief Veterinary Officer (CVO)
- The Feed, Seed and Fertilizer Inspectorate
- The Meat Grading Chairman
- The Plant Protection Service of the Agricultural University of Iceland
- The Directorate of Freshwater Fisheries

- Task regarding organic production from the Ministry of Agriculture
- Administrative tasks carried out by the Farmers' Association of Iceland

The AAI is divided into five sections which are under direct supervision of the director-General of AAI. These sections are as follows:

- 1) Animal Health Section
- 2) Food and Environment Section
- 3) District Offices (DOs)/District Veterinarians (DVs) section
- 4) Legal and Executive Affairs Section
- 5) Administration Section

The director of the Food and Environment Section is responsible for managing Iceland's meat inspection system. The District Offices/District Veterinarians Section conducts the meat inspection activities in the slaughterhouses.

6.1.1 CCA Control Systems

The Iceland's regulatory oversight of its meat inspection program consists of two levels: The Central Level (AAI) and the District Level (District Offices). There are 14 District Offices (DOs) where District Veterinarians (DVs) render services in accordance with the Act No. 66/1988. DVs report directly to the Food and Environment Director and/or Animal Health Chief Veterinary Officer based on their assigned responsibilities.

The Food Safety Division, a branch under the Food and Environment Section, is responsible for direct control of Iceland's meat inspection activities. This division has the organizational structure and staffing to ensure uniform implementation of U.S. requirements. There are a total of 10 ovine slaughterhouses in Iceland. Three of those were U.S. certified at the time of this audit.

6.1.2 Ultimate Control and Supervision

The AAI has ultimate control and supervision over official activities of all employees and certified establishments. The in-plant inspection personnel are supervised by a Veterinarian-in-charge who has the authority to suspend the establishment's production operation any time the wholesomeness and safety of the product are jeopardized. The Chief of the Food Safety Division performs the monthly internal reviews of the establishments certified as eligible to produce products for export to the United States.

6.1.3 Assignment of Competent, Qualified Inspectors

Two of the three ovine's establishments eligible to export to the United States were visited. Both establishments were staffed with full time veterinarians and non-veterinary inspectors who possess the required educational degree necessary to meet minimum qualifications set by AAL. Continuous daily inspection was provided in both establishments.

All inspection personnel assigned to the audited establishments were government employees receiving no remunerations from either industry groups or establishment personnel.

6.1.4 Authority and Responsibility to Enforce the Laws

The AAI has the authority for carrying out Iceland's meat inspection program including oversight and enforcement of the FSIS regulatory requirements. AAI is the level of the government that FSIS holds responsible for ensuring that FSIS requirements are implemented and enforced. AAI not only has the authority to approve establishments for export to the United States, but also has the responsibility for withdrawing such approval when establishments do not meet FSIS requirements.

The *Act No. 80/2005* lays the foundation for the merger of authorities and services dedicated to agriculture-related inspection into a single inspection and administrative body, the Agriculture Authority of Iceland. AAI has complete authority over Veterinarians and Animal Health Services (*Act No. 66/1998*) and Health of Slaughter Animals, Slaughtering, Processing, Health Inspection, and Quality Grading of Slaughter Products (*Act No. 96/1997*).

6.1.5 Adequate Administrative and Technical Support

The CCA has adequate Administrative and Technical Support to implement U.S. requirements.

6.2 Headquarters Audit

The auditor conducted a review of inspection system documents at the headquarters of the inspection service located in Selfoss. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the United States.
- Training records for inspection personnel.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- National residue program.
- Sanitation, slaughter and processing inspection procedures and standards.
- Export product inspection and control including export certificates.

No concerns arose as a result of the examination of these documents.

7. ESTABLISHMENT AUDITS

The FSIS auditor visited two of the three U.S. eligible slaughter and processing establishments. No establishments were delisted or received a Notice of Intent to Delist (NOID).

8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

Residue laboratory audits focus on sample handling, sampling frequency, timely analysis data reporting, analytical methodologies, tissue matrices, equipment operation and printouts, detection levels, recovery frequency, percent recoveries, intra-laboratory check samples, and quality assurance programs, including standards books and corrective actions.

Microbiology laboratory audits focus on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples. If private laboratories are used to test United States samples, the auditor evaluates compliance with the criteria established for the use of private laboratories under the FSIS Pathogen Reduction/HACCP requirements.

- During the current October audit of 2006, no residue or microbiology laboratories were audited.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditor focused on five areas of risk to assess Iceland's meat inspection system. The first of these risk areas that the FSIS auditor reviewed was Sanitation Controls.

Based on the on-site audits of establishments, and expect as noted below, Iceland's inspection system had controls in place for SSOP programs, all aspects of facility and equipment sanitation, the prevention of actual or potential instances of product cross-contamination, good personal hygiene practices, and good product handling and storage practices.

In addition, Iceland's inspection system had controls in place for water potability records, chlorination procedures, back-siphonage prevention, separation of operations, temperature control, work space, ventilation, ante-mortem facilities, welfare facilities, and outside premises.

9.1 SSOP

Two establishments were evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the United States domestic inspection program. The SSOP in the establishments audited were found to meet the basic FSIS regulatory requirements, with the following exception:

- In one establishment, several red color totes (edible product containers) had unidentified grayish color foreign material on both interior and exterior surfaces. These empty totes were being stored in the clean container storage room. They had passed establishment sanitary inspection and were ready to use for edible product.

9.2 SPS

No deficiencies were noted.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, humane handling and humane slaughter, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. The auditor determined that Iceland's inspection system had adequate controls in place. No deficiencies were noted.

There had been no outbreaks of animal diseases with public health significance since the last FSIS audit.

11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor reviewed was Slaughter/Processing Controls. The controls include the following areas: ante-mortem inspection procedures; ante-mortem disposition; post-mortem inspection procedures; post-mortem disposition; ingredients identification; control of restricted ingredients; formulations; processing schedules; equipment and records; and processing controls of cured, dried, and cooked products.

The controls also include the implementation of HACCP systems in all establishments and implementation of a generic *E. coli* testing program in slaughter establishments.

11.1 Humane Handling and Slaughter

No deficiencies were noted.

11.2 HACCP Implementation

All establishments approved to export meat products to the United States are required to have developed and adequately implemented a HACCP program. Each of these programs was evaluated according to the criteria employed in the United States' domestic inspection program.

The HACCP programs were reviewed during the on-site audits of the two establishments. Although the HACCP plans in both establishments were found to meet the basic FSIS regulatory requirements, the following deficiencies were noted:

- In two establishments, the HACCP verification records for CCP1 (Zero Tolerance) did not include the times when the specific events occurred.
- In one establishment, the HACCP monitoring records for CCP1 (Zero Tolerance) did not include the signatures or initials of the establishment employee making the entries.

11.3 Testing for Generic *E. coli*

Iceland has adopted the FSIS regulatory requirements for generic *E. coli* testing. Testing for generic *E. coli* was properly conducted in the two slaughter establishments audited.

11.4 Testing for *Listeria monocytogenes*

Iceland does not export ready-to-eat product to the United States of America, therefore the requirements for testing for *Listeria monocytogenes* do not apply.

12. RESIDUE CONTROLS

During the current October audit of 2006, no residue laboratories were audited. Iceland's National Residue Testing Plan for 2006 was being followed and was on schedule.

13. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditor reviewed was Enforcement Controls. These controls include the enforcement of inspection requirements, the testing program for *Salmonella* in raw products, daily inspection, monthly reviews, and inspection system controls.

13.1 Daily Inspection in Establishments

Daily inspection was provided as required for all establishments audited. No deficiencies were observed.

13.2 Testing for *Salmonella*

FSIS does not require testing for *Salmonella* in lambs.

13.3 Species Verification

Species verification was being conducted as required. No deficiencies were noted.

13.4 Monthly Reviews

During this audit it was found that in the two audited establishments, monthly supervisory reviews were being performed and documented as required.

13.5 Inspection System Controls

The CCA had controls in place for ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; disposition of dead, dying, diseased or disabled animals; shipment security, including shipment between establishments; and prevention of commingling of product intended for export to the

United States with product intended for the domestic market. Iceland has not imported any livestock from other countries.

In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

14. CLOSING MEETING

A closing meeting was held on October 16, 2006 in Selfoss, Iceland, with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the auditor.

The CCA understood and accepted the findings.

for Nader Memarian, DVM
Senior Program Auditor

Mangor H. Chaudry

15. ATTACHMENTS

Individual Foreign Establishment Audit Forms

Foreign Country Response to Draft Final Audit Report *(no comments received)*

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Slaturfelag Sudurlands SVF Selfoss	2. AUDIT DATE 10/11/2006	3. ESTABLISHMENT NO. 81	4. NAME OF COUNTRY Iceland
5. NAME OF AUDITOR(S) Dr. Nader Memarian		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

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

Establishment Name and Number: Slaturfelag Sudurlands SVF - 81
Country and City: Iceland – Selfoss
Type of Operation: Ovine Slaughter/Processing
Date of Audit: October 11, 2006

- 22/51 The HACCP verification records for CCP1 (Zero Tolerance) did not include the times when the specific events occurred {9 CFR § 417.5(b) and 417.8}.
- 10 Several red color totes (edible product containers) had unidentified grayish color foreign material on both interior and exterior surfaces. These empty totes were being stored in the clean container storage room. They had passed establishment sanitary inspection and were ready to use for edible product {9 CFR § 416.13(c)}.

61. NAME OF AUDITOR

Dr. Nader Memarian

62. AUDITOR SIGNATURE AND DATE

Nader Memarian
10-11-06

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Nordlenska Husavik	2. AUDIT DATE 10/09/2006	3. ESTABLISHMENT NO. 31	4. NAME OF COUNTRY Iceland
	5. NAME OF AUDITOR(S) Dr. Nader Memarian		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	O
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Park 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	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

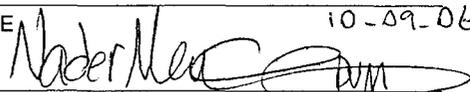
60. Observation of the Establishment

Establishment Name and Number: Nordlenska – 31
 Country and City: Iceland – Husavik
 Type of Operation: Ovine Slaughter/Processing
 Date of Audit: October 09, 2006

22/51 A) The HACCP verification records for CCP1 (Zero Tolerance) did not include the times when specific events occurred {9 CFR § 417.5(b) and 417.8}.

B) The HACCP monitoring records for CCP1 (Zero Tolerance) did not include the signatures or initials of the establishment employee making the entries {9 CFR § 417.5(b) and 417.8}.

61. NAME OF AUDITOR
 Dr. Nader Memarian

62. AUDITOR SIGNATURE AND DATE
 10-09-06

Country Response Not Received