



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

MAR 15 2004

Mr. Robert M. Houston
Chief Veterinary Officer
Department of Agriculture and Rural Development
Veterinary Service
Dundonald House, Upper Newtownards Road
Belfast BT4 3SB
Northern Ireland

Dear Mr. Houston:

Enclosed is the final report of the Food Safety and Inspection Service (FSIS) on-site audit of Northern Ireland's meat inspection system. This audit was conducted July 16-29, 2003. Comments received from the government of Northern Ireland have been included as an attachment to the final report.

If you have any questions regarding the FSIS audit or the final audit report, please contact me at telephone number 202-720-3781, facsimile number 202-690-4040, or at email address sally.stratmoen@fsis.usda.gov.

Sincerely,

Sally Stratmoen
Director, International Equivalence Staff
Office of International Affairs

Enclosure

cc:

Peter Kurz, Minister Counselor, American Embassy, London
James Hughes, First Secretary, Agriculture and Trade Policy, British Embassy, Wash., DC
Tony Van der haegen, EU Mission to the US, Washington, DC
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Country File (N. Ireland Audits)

FINAL

FEB 10 2004

FINAL REPORT OF AN AUDIT CARRIED OUT IN
NORTHERN IRELAND COVERING NORTHERN IRELAND'S
MEAT INSPECTION SYSTEM

JULY 16 THROUGH JULY 29, 2003

Food Safety and Inspection Service
United States Department of Agriculture

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority (Department of Agriculture and Rural Development – DARD)
DARD	Department of Agriculture and Rural Development
FSA	Food Standards Agency
CVO	Chief Veterinary Officer
DCVO	Deputy Chief Veterinary Officer
OVS	Official Veterinary Surgeon
TVO	Temporary Veterinary Official
SMI	Senior Meat Inspector
MI	Meat Inspector
NIFSG	Northern Ireland Food Safety Group
NIFLEG	Northern Ireland Food Law Enforcement Group
FSIS	Food Safety and Inspection Service
VEA	European Community/United States Veterinary Equivalence Agreement
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point System
SSOP	Sanitation Standard Operating Procedures
<i>E. coli</i>	<i>Escherichia coli</i>
<i>Salmonella</i>	<i>Salmonella</i> species

1. INTRODUCTION

The audit took place in Northern Ireland from July 16 to July 29, 2003.

An opening meeting was held on July 16, 2003 in Belfast with the Central Competent Authority (CCA). At this meeting, the audit team confirmed the objective and scope of the audit, the audit team's itinerary, and requested additional information needed to complete the audit of Northern Ireland's meat inspection system.

The audit team was accompanied during the entire audit by a representative from the Department of Agriculture and Rural Development (DARD) and, when appropriate, representatives from the regional and local inspection/establishment offices.

2. OBJECTIVE OF THE AUDIT

This audit was an enforcement audit to determine whether Northern Ireland would retain eligibility to continue exporting meat to the United States. The objective of the audit was to evaluate the performance of the CCA with respect to controls over meat producing/storage 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 CCA, two regional inspection offices, three laboratories performing analytical testing on U.S. destined product, one swine slaughter establishment, and one cold storage facility.

Competent Authority Visits			Comments
Competent Authority	Central	1	DARD in Belfast
	Regional	2	North Region and South Region
	Local	2	Establishment level
Laboratories		3	
Meat Slaughter Establishments		1	
Cold Storage Facilities		1	

3. PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with CCA and the Food Standards Agency (FSA) 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 and regional offices. The third part involved on-site visits to two establishments: one swine slaughter establishment and one cold storage facility. The fourth part involved visits to three government laboratories. The DARD Food Microbiology Food Science Division was conducting analyses of field

samples for the presence of *Salmonella*. The DARD Food Services Division, Food Chemistry Analytical Unit and DARD Veterinary Services Division, Chemical Services Department Laboratories were conducting analyses of field samples for Northern Ireland's national residue control program.

Generic *E. coli* sampling was being conducted by a private laboratory in England accredited by the United Kingdom Accreditation Service. This laboratory was not included in this audit.

Program effectiveness determinations of Northern Ireland'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 program and a testing program for generic *E. coli*, (4) residue controls, and (5) enforcement controls, including a testing program for *Salmonella*. Northern Ireland's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the audit team evaluated the nature, extent and degree to which findings impacted on food safety and public health. The audit team also assessed how meat inspection services are carried out by Northern Ireland and determined if establishment and inspection system controls were in place to ensure the production and distribution of meat products as imports into the United States are safe, unadulterated and properly labeled.

At the opening meeting, the audit team explained to the CCA that their inspection system would be audited in accordance with three areas of focus. First, under provisions of the VEA, the FSIS audit team would audit Northern Ireland's meat inspection system against European Community (EC) Directive 64/433 of June 1964; EC Directive 96/22 of April 1996; and EC Directive 96/23 of April 1996. These directives have been declared equivalent by FSIS under the VEA.

Second, in areas not covered by these directives, the audit team would audit against FSIS requirements. FSIS requirements include daily inspection in all certified establishments, humane handling and slaughter of animals, the handling and disposal of inedible and condemned materials, species verification testing, requirements for HACCP, SSOP, testing for generic *E. coli* and *Salmonella*, and government oversight/enforcement.

Third, the audit team would audit against any equivalence determinations that have been made by FSIS for Northern Ireland under provisions of the WTO Sanitary and Phytosanitary Agreement. Accordingly, DARD had previously advised FSIS that they have adopted the FSIS regulatory requirements for HACCP and SSOP programs and *Salmonella*/generic *E. coli* laboratory testing.

4. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of U.S. 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 U.S. import requirements listed in 9 CFR 327 and the Pathogen Reduction/HACCP and SSOP regulations.

In addition, compliance with the following European Community Directives was also assessed:

- Council Directive 64/433/EEC of June 1964 entitled Health Problems Affecting Intra-Community Trade in Fresh Meat
- Council Directive 96/23/EC of 29 April 1996 entitled Measures to Monitor Certain Substances and Residues Thereof in Live Animals and Animal Products
- Council Directive 96/22/EC of 29 April 1996 entitled Prohibition on the Use in Stockfarming of Certain Substances Having a Hormonal or Thyrostatic Action and of B-agonists

5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at the following address:
<http://www.fsis.usda.gov/OPPDE/FAR/index.htm>

In May 2000, FSIS reviewed the only certified establishment and rated it as acceptable/re-review by FSIS. The following deficiencies were identified:

- Inadequate pre-operational sanitation, which included: Many plastic trays used for edible product were in need of repair or replacement; some metal bins used for holding edible product were damaged; A conveyor belt for bones positioned directly above exposed product was in poor condition, and the stainless steel guard beneath the conveyor belt would not completely protect the exposed product below; and black debris on the majority of cutting boards and stainless steel product-contact surfaces.
- Documentation of operational sanitation activities needed improvement.
- Inadequate handling results and corrective actions taken regarding water potability testing.
- No documentation for HACCP pre-shipment review.

In November 2001, no establishments were certified for export to the United States at the time of this audit. The audit was limited to visits to laboratories conducting residue and microbiology testing of meat products destined for the United States. The following deficiencies were identified:

- No intra-laboratory check samples being performed in the hormone section of the Veterinary Services Laboratory.
- There were insufficient turnaround times in the Food Chemistry Analytical Unit Laboratory regarding obtaining results for chlorinated hydrocarbons and organophosphates.
- Expired standards were being used in the Food Chemistry Analytical Unit Laboratory.

In August 2002, no establishments were certified for export to the United States at the time of this audit. At the request of DARD, FSIS conducted a special audit consisting solely of reviewing establishment UK 9014, which was not certified to export to the United States. During the previous two FSIS audits, UK 9014 was rated as acceptable/re-review in May 2000 and was delisted by DARD immediately prior to the November 2001 audit. The following deficiencies were identified during the August 2002 audit:

- SSOP documents did not accurately reflect the conditions of the establishment.
- SSOP documents were not descriptive enough for some deficiencies and did not include preventive measures.
- HACCP plan and implementation did not contain some of the requirements for verification, corrective action, and pre-shipment review.
- Inadequate maintenance of doors to outside premises, rusty fan over boning table, and a conveyor belt in poor condition.
- Inedible product was not denatured and properly stored.
- No timely response to correct the deficiencies by establishment personnel.
- Enforcement controls by inspection service did not meet FSIS requirements.

6. MAIN FINDINGS

6.1. Legislation

The audit team was informed that the relevant EC Directives, determined equivalent under the VEA, had been transposed into Northern Ireland's legislation.

6.2. Government Oversight

Northern Ireland's meat inspection system is primarily administered by the Veterinary Service Group, an agency within DARD. In addition, the Northern Ireland meat inspection system is under the auspices of the FSA, an agency within the United Kingdom's parliament, which was established in 2000 to provide food safety oversight for both Great Britain and Northern Ireland. FSA has an office in Belfast and works closely with DARD.

The responsibility of government oversight relative to meat exports to the United States is shared with two other agencies within DARD with regard to residues and food safety policy. These are Science Service Group and Central Policy Group.

The Veterinary Service Group employs approximately 137 veterinarians, 145 meat inspectors and 204 animal health and welfare inspectors to carry out the responsibility of its domestic and export meat inspection programs including related enforcement activities. All inspection personnel assigned to establishments certified to export meat to the United States are full-time government employees receiving no remuneration from either industry or establishment personnel. Inspection personnel cannot attain outside employment.

6.2.1 CCA Control Systems

The Veterinary Service is headed by a Chief Veterinary Officer (CVO) and two Deputy CVOs. Together, with the assistance of several veterinary staff officers assigned to headquarters, they provide direct oversight of two regional offices (North Regional Office and South Regional Office). Relative to meat exports to the United States, each regional office is headed by a supervisory divisional veterinary officer (circuit supervisor), who provides direct authority over official veterinarians and inspectors assigned to establishments certified to export meat to the United States. The Veterinary Service also has authority over live animal matters in Northern Ireland relative to movement controls and livestock diseases.

6.2.2 Ultimate Control And Supervision

The senior Official Veterinary Surgeon (OVS) has the authority to cease the establishment's production operations any time the wholesomeness and safety of the product is jeopardized. He/she reports directly to their circuit supervisor and consults all decisions regarding enforcement activities. The decision as to whether the establishment is failing to meet U.S. import requirements and the recommendation that it should be delisted is a combined effort of the OVS, regional supervisor, and headquarters' officials. The CVO will make the ultimate decision and will advise FSA authorities.

The senior OVS has direct supervision over all other inspection personnel assigned to certified establishments. This would include supervision over veterinary officers, senior meat inspector, and meat inspectors. For the two establishments certified to export meat to the United States, the Veterinary Service Group has placed a sufficient number of official inspection personnel to adequately carry out the U.S. import requirements.

6.2.3 Assignment of Competent, Qualified Inspection Personnel

All inspection personnel assigned to certified establishments undergo induction training as well as participate in on-the-job practical training under the supervision of experienced veterinarians. Continual training is provided for all inspection personnel as needed. The Veterinary Service Training Branch maintains individual training records of inspection personnel.

The majority of the meat inspectors have received the meat hygiene inspector's diploma from the Royal College of Veterinary Surgeons. All official veterinarians are qualified veterinarians who have obtained their college veterinary degree.

6.2.4 Authority and Responsibility to Enforce the Laws

Veterinary officers and meat inspectors are authorized to enforce EU legislation and U.S. import requirements including animal health and welfare, control of animal disease, veterinary medicines, and the production of safe foods of animal origin. Through legal process in the courts, DARD, with the assistance of FSA, has the authority to suspend and delist certified establishments to prevent the export of unsafe meat to the United States.

6.2.5 Adequate Administrative and Technical Support

During this audit, the FSIS audit team determined that the CCA has administrative and technical support to operate Northern Ireland's meat inspection system and has resources and the capability to support a third-party audit. DARD demonstrated an adequate amount of supervisory oversight to ensure compliance with U.S. import requirements.

6.3 Headquarters Audit

The audit team conducted a review of Northern Ireland meat inspection system documents at DARD headquarters in Belfast. In addition, the audit team reviewed meat inspection records at the two DARD regional offices, the two certified establishments and the three government laboratories. The records' review focused primarily on food safety controls relative to meat exports to the United States. This included the following:

- Internal audit reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- Training records for inspectors and laboratory personnel.
- Applicable laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses for residues and *Salmonella*.
- Sanitation, slaughter and processing inspection procedures and standards.
- Export product inspection and control including export certificates.
- Enforcement records including examples corrective action reports, consumer complaints, recalls, seizure and control of noncompliant product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export meat products to the United States.

The following concerns arose as a result the examination of these documents:

- Control numbers of official export health certificates were not assigned and centrally controlled by the CCA. Instead, the establishment OVS assigned a unique number to each health certificate. DARD agreed to modify their health certificate program relative to exports to the United States by assigning control numbers from headquarters.
- The laboratory testing method for *Salmonella* was a method that had not been submitted to FSIS for an equivalence judgment. The CCA submitted this method to FSIS for equivalence judgment at the closing meeting. FSIS advised the CCA to immediately implement and use the FSIS testing method for *Salmonella* while the alternative method is being reviewed.

6.3.1 Audit of Regional and Local Inspection Sites

Regional Offices

The FSIS audit team reviewed Northern Ireland's meat inspection records at DARD's two regional offices; the North Regional Office in Coleraine and the South Regional Office in

Newry. The audit team interviewed the Circuit Supervisor of the North office and the Circuit Supervisor of the South office.

The purpose of the interviews was to review the meat inspection records and determine the level of government oversight and control provided by the regional offices relative to the certified establishments.

The audit team concluded that:

- All relevant regulations, notices, and other inspection documents and records were adequately disseminated from headquarters through the regional offices to the two certified establishments (local inspection sites). This was accomplished by both hard copy and emails.
- Copies of all relevant regulations, notices, and other inspection documents and records were maintained at the regional offices.
- Both circuit supervisors were knowledgeable of U.S. import requirements relative to the two certified establishments producing or exporting meat to the United States.
- Both regional offices demonstrated adequate administrative assistance to ensure that official inspection personnel were assigned to the two certified establishments.

Local Inspection Sites (Certified Establishments)

The FSIS audit team reviewed Northern Ireland's meat inspection records maintained at the local inspection sites certified to produce or export meat to the United States. In addition, the audit team interviewed the senior veterinarians (OVS) at each establishment and their inspection teams, which consisted of veterinary officers, senior meat inspectors and meat inspectors.

The audit team concluded that:

- All relevant regulations, notices, and other inspection documents and records were adequately disseminated from headquarters through the regional offices to the two local inspection sites). This was accomplished by both hard copy and emails.
- Inspection personnel demonstrated adequate knowledge of inspection requirements relative to the export and distribution of meat to the United States.

7. ESTABLISHMENT AUDITS

The FSIS audit team visited a total of two establishments; one was a swine slaughter establishment and the other was a cold storage facility. No establishments were delisted by DARD and no establishments received a notice of intent to delist (NOID) from DARD.

Specific deficiencies are noted on the attached individual establishment reports.

8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

During the laboratory audits, emphasis was placed on the application of procedures and standards that are equivalent to U.S. requirements.

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 U.S. samples, the audit team evaluated compliance with the criteria established for the use of private laboratories under the PR/HACCP requirements.

The slaughter certified establishment uses a private laboratory in England to perform testing for *generic E. coli*. This laboratory was not reviewed by the audit team.

The following laboratories were reviewed:

- The DARD Food Science Division, Chemistry Analytical Unit is a government laboratory located in Belfast (Newforge), which conducts analyses of field samples for Northern Ireland's national residue program. This laboratory has received ISO Standard 17025 accreditation.
- The DARD Veterinary Services Division Laboratory is a government laboratory located in Belfast (Stormont), which conducts analyses of field samples for Northern Ireland's national residue program. This laboratory is undergoing the process to receive ISO Standard 17025 accreditation
- The DARD Food Science Division, Microbiology Division Unit is a government laboratory located in Belfast (Newforge), which conducts analyses of field samples for the presence of *Salmonella*.

The findings at the DARD Food Chemistry Analytical Unit laboratory and DARD Food Microbiology Food Science Division laboratory will be discussed in Section 12 (Residue Controls). No deficiencies were noted in the DARD Veterinary Services Division Laboratory.

9. SANITATION CONTROLS

As previously stated, the FSIS audit team focuses on five areas of risk to assess an exporting country's meat inspection system. The first of these risk areas that the audit team reviewed was Sanitation Controls.

Except as noted below, Northern Ireland'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 and practices, and good product handling and storage practices.

In addition, Northern Ireland'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

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the U.S. domestic inspection program. The SSOP in the both establishments were found to meet the basic FSIS regulatory requirements, with the following deficiencies.

- In the slaughter establishment, the inspection officials were monitoring/verifying the adequacy and effectiveness of the pre-operational sanitation once a week and operational sanitation twice a week. This frequency does not meet FSIS requirements. DARD officials indicated that they would immediately comply with this FSIS requirement.

9.2 EC Directive 64/433

In all establishments, the provisions of EC Directive 64/433 were effectively implemented. Specific deficiencies, if applicable, are noted in the attached individual establishment reports.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS audit team reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. The audit team determined that Northern Ireland'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. APHIS continues to have import restrictions on beef products from Northern Ireland due to the presence of BSE, and special import restrictions on pork products regarding Rinderpest and Swine Vesicular Disease.

11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS audit team reviewed was Slaughter/Processing Controls. The controls include the following areas: ante-mortem inspection procedures, ante-mortem disposition, humane handling and humane slaughter, post-mortem inspection procedures, post-mortem disposition, ingredients identification, control of restricted ingredients, formulations, processing schedules, equipment and records.

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

11.1 Humane Handling and Humane Slaughter

No deficiencies were noted.

11.2 HACCP Implementation

Non-cold storage establishments certified to export meat products to the United States are required to have adequately developed and implemented a HACCP program. The HACCP program was evaluated according to the criteria employed in the U.S. domestic inspection program.

During this audit, the one establishment that was required to meet the HACCP programs requirements had adequately implemented the HACCP requirements.

11.3 Testing for Generic *E. coli*

Northern Ireland has adopted the FSIS regulatory requirements for testing generic *E. coli*.

Only one of the two establishments audited was required to meet the basic FSIS regulatory requirements for testing for generic *E. coli* and was evaluated according to the criteria employed in the U.S. domestic inspection program.

FSIS findings concluded that testing for generic *E. coli* was properly conducted in the one establishment (swine slaughter) with the following exception:

- The sequence of swine carcass sponging for generic *E. coli* was not being followed as required: ham, belly and jowl. Instead, the sequence being used was belly, ham and jowl. Accordingly, FSIS Directive 5000.1, Attachment 1, and 9 CFR 310.25(a)(2)(ii)(c) were not adequately met. This deficiency was the result of a misunderstanding of the *E. coli* sample collection requirements due to referencing a different FSIS document. Establishment officials took corrective action immediately.

11.4 Testing for *Listeria monocytogenes*

Both establishments audited were not producing ready-to-eat products for export to the United States and therefore were not required to meet the FSIS requirements for *Listeria monocytogenes* testing.

11.5 EC Directive 64/433

In both establishments, the provisions of EC Directive 64/433 were effectively implemented.

12. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS audit team reviewed was Residue Controls. These controls include sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions.

In the DARD Food Chemistry Analytical Unit laboratory, the following deficiencies were noted:

- Turnaround times of test results for chlorinated hydrocarbons and organophosphates ranged between 25 to 40 days.
- Documentation of corrective actions was provided, but there was very little formal written description of actions to be taken in the event that an analyst's performance did not meet expected standards for chlorinated hydrocarbons, organophosphates and trace elements.

These were repeat deficiencies from the last laboratory audit, which occurred in 2000. Current laboratory records had shown no residue violations and no deviation in proficiency testing.

No deficiencies were noted at the DARD Veterinary Services Division.

Northern Ireland's National Residue Control Program for 2003 was being followed as scheduled.

The findings of DARD Food Microbiology Food Science Division laboratory will be discussed in Section 13 (Enforcement Controls).

12.1 EC Directive 96/22

In the DARD Food Chemistry Analytical Unit laboratory and the DARD Veterinary Services Division Laboratory, the provisions of EC Directive 96/22 were effectively implemented.

12.2 EC Directive 96/23

In the DARD Food Chemistry Analytical Unit laboratory and the DARD Veterinary Services Division Laboratory, the provisions of EC Directive 96/23 were effectively implemented.

13. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS audit team reviewed was Enforcement Controls. These controls include the enforcement of inspection requirements and the testing program for *Salmonella*.

13.1 Daily Inspection in Establishments

Inspection was being conducted daily in both certified establishments.

13.2 Testing for *Salmonella*

One of the two establishments audited was required to meet the basic FSIS regulatory requirements for *Salmonella* testing and was evaluated according to the criteria employed in the U.S. domestic inspection program. The following deficiencies were noted:

- The sequence of swine carcass sponging for *Salmonella* was not being followed as required: ham, belly and jowl. Instead, the sequence being used was belly, ham and jowl. Accordingly, FSIS Directive 5000.1, Attachment 1, and 9 CFR 310.25(a)(2)(ii)(c) were not adequately met. This deficiency was the result of a misunderstanding of the *Salmonella* sample collection requirements due to referencing a different FSIS document. DARD inspection officials took corrective action immediately.
- Northern Ireland had initially advised FSIS that it had adopted the FSIS laboratory testing methods for *Salmonella*. However, DARD had changed the laboratory testing method without submitting it to FSIS for equivalence review. DARD submitted the alternative method to FSIS for equivalence determination.

13.3 Species Verification

Species verification was being conducted in those establishments in which it was required.

13.4 Monthly Reviews

During this audit, it was found that in all establishments visited, monthly supervisory reviews of certified establishments 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.

In addition, controls were in place for the importation of only eligible livestock from other countries, i.e., only from eligible third countries and certified establishments within those countries, and the importation of only eligible meat products from other countries for further processing.

Lastly, 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 July 29, 2003, in Belfast with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the audit team.

The CCA understood and accepted the findings.

Mr. Steven McDermott
Audit Team Leader
Office of International Affairs

A handwritten signature in black ink, reading "Steven McDermott". The signature is written in a cursive style with a long horizontal flourish extending to the right.

15. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Laboratory Review forms

Individual Foreign Establishment Audit Checklists

Foreign Country Response to Draft Final Audit Report

FOREIGN COUNTRY LABORATORY REVIEW

07/23/03

Chemical Surveillance Department
 Veterinary Science Division

FOREIGN GOV'T AGENCY
 Department of Agriculture and Rural
 Development

CITY & COUNTRY
 Stormont (Belfast),
 Northern Ireland

ADDRESS OF LABORATORY
 Belfast BT4 3 SD
 Northern Ireland

NAME OF REVIEWER
 Dr. Faiz R. Choudry & Mr. S. McDermott

NAME OF FOREIGN OFFICIAL
 Dr. Robert Huey

Residue Code/Name

200 203 500 501 800 900 907 923

SAMPLING PROCEDURES

REVIEW ITEMS	ITEM #
Sample Handling	01
Sampling Frequency	02
Timely Analyses	03
Compositing Procedure	04
Interpret Comp Data	05
Data Reporting	06

EVALUATION CODE

A	A	A	A	A	A	A	A
A	A	A	A	A	A	A	A
A	A	A	A	A	A	A	A
O	O	O	O	O	O	O	O
O	O	O	O	O	O	O	O
A	A	A	A	A	A	A	A

ANALYTICAL PROCEDURES

Acceptable Method	07
Correct Tissue(s)	08
Equipment Operation	09
Instrument Printouts	10

EVALUATION CODE

A	A	A	A	A	A	A	A
A	A	A	A	A	A	A	A
A	A	A	A	A	A	A	A
A	A	A	A	A	A	A	A

QUALITY ASSURANCE PROCEDURES

Minimum Detection Levels	11
Recovery Frequency	12
Percent Recovery	13
Check Sample Frequency	14
All analyst w/Check Samples	15
Corrective Actions	16
International Check Samples	17

EVALUATION CODE

A	A	A	A	A	A	A	A
A	A	A	A	A	A	A	A
A	A	A	A	A	A	A	A
A	A	A	A	A	A	A	A
A	A	A	A	A	A	A	A
A	A	A	A	A	A	A	A
A	A	A	A	A	A	A	A

REVIEW

Corrected Prior Deficiencies 18

EVAL. CODE

A	A	A	A	A	A	A	A
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OTHER REVIEW

19
20

EVAL. CODE

SIGNATURE OF REVIEWER

Dr. Faiz R. Choudry

DATE

7/23/03

FOREIGN COUNTRY LABORATORY REVIEW

(Comment Sheet)

REVIEW DATE

07/23/03

NAME OF FOREIGN LABORATORY

Chemical Surveillance Department
Veterinary Science Division

FOREIGN GOV'T AGENCY

Department of Agriculture and Rural
Development

CITY & COUNTRY

Stormont (Belfast),
Northern Ireland

ADDRESS OF LABORATORY

Belfast BT4 3 SD
Northern Ireland

NAME OF REVIEWER

Dr. Faiz R. Choudry & Mr. S. McDermott

NAME OF FOREIGN OFFICIAL

Dr. Robert Huey

RESIDUE

ITEM NO.

COMMENTS

REVIEW DATE

NAME OF FOREIGN LABORATORY

FOREIGN COUNTRY LABORATORY REVIEW

07/24/03

DARDNI Food Microbiology Food Science Division

FOREIGN GOV'T AGENCY
 Department of Agriculture and Rural
 Development (DARD)

CITY & COUNTRY
 Belfast, Northern Ireland

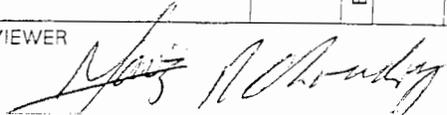
ADDRESS OF LABORATORY
 Newforge Lane, Belfast BT9 5PX

NAME OF REVIEWER
 Dr. Faiz Choudry & Mr. S. McDermott

NAME OF FOREIGN OFFICIAL
 Dr. Robert Huey & Mr. Eric Espie

Residue Code/Name		Sal																		
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE																	
	Sample Handling	01		A																
	Sampling Frequency	02		A																
	Timely Analyses	03		A																
	Compositing Procedure	04		O																
	Interpret Comp Data	05		O																
	Data Reporting	06		A																
ANALYTICAL PROCEDURES	Acceptable Method	07	C																	
	Correct Tissue(s)	08	A																	
	Equipment Operation	09	A																	
	Instrument Printouts	10	A																	
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	O																	
	Recovery Frequency	12	O																	
	Percent Recovery	13	A																	
	Check Sample Frequency	14	A																	
	All analyst w/Check Samples	15	A																	
	Corrective Actions	16	A																	
	International Check Samples	17	A																	
REVIEW	Corrected Prior Deficiencies	18	EVAL. CODE	A																
OTHER REVIEW		19	EVAL. CODE																	
		20	EVAL. CODE																	

SIGNATURE OF REVIEWER



DATE

07/24/03

FOREIGN COUNTRY LABORATORY REVIEW

(Comment Sheet)

REVIEW DATE

07/24/03

NAME OF FOREIGN LABORATORY

DARDNI Food Microbiology Food Science Division

FOREIGN GOV'T AGENCY

Department of Agriculture and Rural Development (DARD)

CITY & COUNTRY

Belfast, Northern Ireland

ADDRESS OF LABORATORY

Newforge Lane, Belfast BT9 5PX

NAME OF REVIEWER

Dr. Faiz Choudry & Mr. S. McDermott

NAME OF FOREIGN OFFICIAL

Dr. Robert Huey & Mr. Eric Espie

RESIDUE

ITEM NO.

COMMENTS

Sal.

07

Northern Ireland had initially adopted the FSIS regulatory requirements for Salmonella testing but changed the method without submitting it to FSIS for equivalence review.

FOREIGN COUNTRY LABORATORY REVIEW

07/24/03

DARDNI Food Science Division

FOREIGN GOV'T AGENCY

Department of Agriculture and Rural Development

CITY & COUNTRY

Belfast, Northern Ireland

ADDRESS OF LABORATORY

Newforge Lane, Belfast BT9 5PX

NAME OF REVIEWER

Dr. Faiz Choudry & Mr. S. McDermott

NAME OF FOREIGN OFFICIAL

Dr. Robert Huey & Mr. Trevor Oliver, Laboratory Manager

Residue Code/Name

100 300 400

	REVIEW ITEMS	ITEM #	EVALUATION CODE																
			100	300	400														
SAMPLING PROCEDURES	Sample Handling	01	A	A	A														
	Sampling Frequency	02	A	A	A														
	Timely Analyses	03	C	C	A														
	Compositing Procedure	04	O	O	O														
	Interpret Comp Data	05	O	O	O														
	Data Reporting	06	A	A	A														
ANALYTICAL PROCEDURES	Acceptable Method	07	A	A	A														
	Correct Tissue(s)	08	A	A	A														
	Equipment Operation	09	A	A	A														
	Instrument Printouts	10	A	A	A														
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	A	A	A														
	Recovery Frequency	12	A	A	A														
	Percent Recovery	13	A	A	A														
	Check Sample Frequency	14	A	A	A														
	All analyst w/Check Samples	15	A	A	A														
	Corrective Actions	16	C	C	C														
International Check Samples	17	A	A	A															
REVIEW	Corrected Prior Deficiencies	18	NO	NO	NO														
OTHER REVIEW		19																	
		20																	

SIGNATURE OF REVIEWER *Dr. Faiz Choudry*

DATE 07/24/03

FOREIGN COUNTRY LABORATORY REVIEW <i>(Comment Sheet)</i>		REVIEW DATE 07/24/03	NAME OF FOREIGN LABORATORY DARDNI Food Science Division
FOREIGN GOV'T AGENCY Department of Agriculture and Rural Development	CITY & COUNTRY Belfast, Northern Ireland	ADDRESS OF LABORATORY Newforge Lane, Belfast BT9 5PX	
NAME OF REVIEWER Dr. Faiz Choudry & Mr. S. McDermott		NAME OF FOREIGN OFFICIAL Dr. Robert Huey & Mr. Trevor Oliver, Laboratory Manager	

RESIDUE	ITEM NO.	COMMENTS
100,300	3	Turnaround times for chlorinated hydrocarbons and organophosphates ranged between 25 to 40 days.
100,300, 400	16	Documentation of corrective actions was provided, but there was very little formal written description of actions to be taken in the event that an analyst's performance did not meet expected standards for chlorinated hydrocarbons, organophosphates and trace elements. These were repeated deficiencies from the last laboratory audit. Laboratory records had shown no residue violations and no deviation in proficiency testing.

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Interfrigo Ltd Steeple Industrial Estate, Steeple Road ANTRIM, Co Antrim BT41 1AB	2. AUDIT DATE 07/21/03	3. ESTABLISHMENT NO. UK9028	4. NAME OF COUNTRY Northern Ireland
5. NAME OF AUDITOR(S) Dr. F. Choudry & Mr.S. McDermott		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		O
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 .		O	41. Ventilation		
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		O	42. Plumbing and Sewage		
16. Records documenting implementation and monitoring of the HACCP plan.		O	43. Water Supply		
17. The HACCP plan is signed and dated by the responsible establishment individual.		O	44. Dressing Rooms/Lavatories		
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements			45. Equipment and Utensils		
18. Monitoring of HACCP plan.		O	46. Sanitary Operations		
19. Verification and validation of HACCP plan.		O	47. Employee Hygiene		
20. Corrective action written in HACCP plan.		O	48. Condemned Product Control		
21. Reassessed adequacy of the HACCP plan.		O	Part F - Inspection Requirements		
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		O	49. Government Staffing		
Part C - Economic / Wholesomeness			50. Daily Inspection Coverage		
23. Labeling - Product Standards		O	51. Enforcement		
24. Labeling - Net Weights			52. Humane Handling		O
25. General Labeling			53. Animal Identification		O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Park Skins/Moisture)		O	54. Ante Mortem Inspection		O
Part D - Sampling Generic E. coli Testing			55. Post Mortem Inspection		O
27. Written Procedures		O	Part G - Other Regulatory Oversight Requirements		
28. Sample Collection/Analysis		O	56. European Community Directives		O
29. Records		O	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 #UK9028 Date 07/21/03

61. NAME OF AUDITOR

Dr. Faiz R. Choudry, DVM.

62. AUDITOR SIGNATURE AND DATE

Faiz R. Choudry 7/21/03

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Grampian Country Foods LTD 70 Molesworth Road, Co Tyrone BT80 8PJ Cookstown	2. AUDIT DATE 07/18/03	3. ESTABLISHMENT NO. UK9052	4. NAME OF COUNTRY Northern Ireland
5. NAME OF AUDITOR(S) Faiz R. Choudry & S. McDermott		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

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

60. Observation of the Establishment

Establishment # UK9052 Dated 07/18/03

- 10. The DARDNI inspection officials were monitoring/verifying the adequacy and effectiveness of the pre-operational once a week and operational twice a week. GONI officials indicated that they would conduct pre-operational and operational sanitation daily.

- 28. The sequence of swine carcass sponging for generic *E. coli* was not being followed as required: ham, belly and jowl. Instead, the sequence being used was belly, ham and jowl. FSIS Directive 5000.1, Attachment 1, and 9 CFR 310.25 (a) (2) (ii)(c) were not adequately met. This deficiency was the result of a misunderstanding of the *E. coli* sample collection requirements due to referencing a different FSIS document. Establishment officials took corrective action immediately.

- 58. The sequence of swine carcass sponging for *Salmonella* was not being followed as required: ham, belly and jowl. Instead, the sequence being used was belly, ham and jowl. FSIS Directive 5000.1, Attachment 1, and 9 CFR 310.25 (a) (2) (ii)(c) were not adequately met. This deficiency was the result of a misunderstanding of the *Salmonella* sample collection requirements due to referencing a different FSIS document. GONI inspection officials took corrective action immediately.

61. NAME OF AUDITOR
 Dr. Faiz R. Choudry, DVM.

62. AUDITOR SIGNATURE AND DATE

Dr. Faiz R. Choudry 7/18/03

Department of Agriculture and Rural Development

VETERINARY SERVICE

28 January 2004

Dear Ms Stratmoen

Thank you for the copy of the draft final audit report received 3rd November 2003. I attach my comments on the findings contained in the report and an outline of the corrective actions taken to address the non-compliances identified.

I welcome the overall finding that Northern Ireland's food regulatory system is meeting the U.S. import requirements and instituting adequate controls to ensure the export of safe, wholesome and accurately labeled pork products to the United States. Achieving this positive conclusion was greatly assisted by the professional and courteous attitude displayed by the FSIS auditors and by the telephone conferences which we held last year.

I would welcome the opportunity to participate in another such conference prior to our next audit later this year. This would give my official the opportunity to clarify any points which may arise in the new edition of FSIS Directive 5000.1 which I received recently.

Yours sincerely,



R M Houston
Chief Veterinary Officer

Sally Stratmoen
Director, International Equivalence Staff
Office of International Affairs
Food Safety and Inspection Service
United States Department of Agriculture
1400 Independence Avenue, SW
South Building
WASHINGTON, DC
20250-3700



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**Food Safety and Inspection Service, United States Department of
Agriculture audit of Northern Ireland's meat inspection system**

Audit carried out 16th to 29th July 2003

Comments on draft final audit report

Headquarters Audit

Control numbers of official export health certificate

Control numbers of official export health certificates were not assigned and centrally controlled by the CCA. Instead, the establishment OVS assigned a unique number to each health certificate.

Certificates are now produced and officially numbered at DARD Headquarters and released in batches of 25 to the Official Veterinarian at a USDA export establishment.

The laboratory testing method for Salmonella

Northern Ireland had initially adopted the FSIS regulatory requirements for Salmonella testing but changed the method without submitting it to FSIS for equivalence review.

The laboratory testing method, NF11, utilised by the Northern Ireland government laboratory at the time of this audit was the same as has been used to test official USDA Salmonella samples for several years. It had been audited by FSIS officials on at least three previous occasions. The method is UKAS accredited to the International Standard ISO 17025.

Information on the NF11 methodology was supplied to the Audit team for consideration by FSIS. If this methodology requires FSIS equivalence determination, an appropriate comparative study can be undertaken in accordance with FSIS requirements. DARD Science Service are happy to work with FSIS technical staff to achieve this, if this is required.

DARD Science Service have not implemented the cited FSIS methodology in Northern Ireland following the audit, as they have experienced difficulties in sourcing the culture media constituents designated by them. This is still being explored and therefore we have continued to employ the NF11 UKAS accredited method until the media acquisition problem is resolved or the equivalence determination is ruled on.

As an alternative, for immediate or future use, DARD Science Service could employ another UKAS-accredited Salmonella Test Procedure, NF10, which is more conventional. I have enclosed a copy of the protocol for FSIS examination. This method is currently being further validated by the International Organisation for Standardisation, under upgraded standard ISO 6579 (2002) and the results of this should be known at the time of the next Accreditation visit in 2004.

Establishments Audits

Frequency of Pre-operational and operational hygiene checks.

The auditors noted that the inspection officials were monitoring/verifying the adequacy and effectiveness of pre-operational hygiene sanitation once a week and operational hygiene twice a week.

The Inspection officials monitor/verify the adequacy and effectiveness of pre-operational hygiene sanitation on a randomly selected part of the establishment daily, ensuring that the entire establishment receives a pre-operational check at least once each week.

Daily operational hygiene checks are now carried out.

Testing for Generic E.coli

The sequence of swine sponging for generic E. coli was not being followed: ham, belly and jowl.

The auditors noted that sampling was being carried out in the order belly, ham and jowl rather than that indicated in FSIS Directive 5000.1.

This procedure was corrected immediately. The FSIS recognised that the error was due to a misunderstanding resulting from the Northern Ireland officials using an official FSIS training document that was incorrect.

Testing for Salmonella

The sequence of swine sponging for Salmonella was not being followed as required: ham, belly and jowl.

The auditors noted that sampling was being carried out in the order belly, ham and jowl rather than that indicated in FSIS Directive 5000.1.

This procedure was corrected immediately. The FSIS recognised that the error was due to a misunderstanding resulting from the Northern Ireland officials using an official FSIS training document that was incorrect.

Residue controls

Turnaround times

The auditors noted that the turnaround times of test results for chlorinated hydrocarbons and organophosphates ranged between 25 and 40 days.

Immediate action was taken on this issue following the FSIS audit. Turnaround times have improved and the '30 day' target is now being met.

Documentation of corrective actions

Documentation of corrective actions was provided, but there was very little formal written description of actions to be taken in the event of the analyst's performance did not meet expected standards for chlorinated hydrocarbons, organophosphates and trace elements.

The documentation referred to contained within the 'National National Surveillance Study Plan' has been made. It now reads: 'During analysis of a batch of samples, if any analyte recovery does not meet the QC criteria established during validation of the method, then the batch of samples will be re-analysed'.