Food Safety and Inspection Service Washington, D.C. 20250

NOV - 4 2005

Mr. Patrick J. Rogan Chief Veterinary Officer Department of Agriculture and Food and Rural Development (DAFRD) Kildare St. Dublin 2, Ireland

Dear Mr. Rogan:

The Food Safety and Inspection Service conducted an on-site audit of the Republic of Ireland's meat inspection system from May 25 through June 15, 2005. Comments from the Republic of Ireland have been included as an attachment to the final report. Enclosed is a copy of the final report.

If you have any questions regarding the audit, please contact me at my telephone number (202) 720-3781. You may also reach me at my facsimile number (202) 690-4040 or e-mail address sally.white@fsis.usda.gov.

Sincerely,

Sally White, Director

International Equivalence Staff Office of International Affairs

Enclosure

cc:

Besa Kotati, Minister Counselor, American Embassy, London

Michael Hanley, Agriculture Attaché, American Embassy, Dublin

Aingeal O'Donoghue, First Secretary, Embassy of the Republic Ireland, Wash DC

Canice Nolan, Agric. / Consumer Affairs, EU Mission to the U.S.

Norval Francis, Minister-Counselor, US Mission to the EU in Brussels

Scott Bleggi, FAS Area Director

Mike Woolsey, ITP, FAS

Amy Winton, State Department

Barbara Masters, Administrator, FSIS

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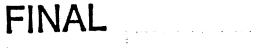
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Country File (Republic of Ireland Annual Audit, FY 2005)



NOV - 1 2005

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

MAY 25, 2005 THROUGH JUNE 15, 2005

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

Food)

DAF Department of Agriculture and Food

PHIS Public Health Inspection Service

CVO Chief Veterinary Officer

DCVO Deputy Chief Veterinary Officer

SSVI Senior Superintending Veterinary Inspector

SVI Superintending Veterinary Inspector

RSVI Regional Superintending Veterinary Inspector

VI Veterinary Inspector

TVI Temporary Veterinary Inspector

TAO Technical Agricultural Officer

DVO District Veterinary Officer

FSIS Food Safety and Inspection Service

VEA European Community/United States Veterinary Equivalence

Agreement

PR/HACCP Pathogen Reduction/Hazard Analysis and Critical Control Point

Systems

SSOP Sanitation Standard Operating Procedures

E. coli Escherichia coli

Salmonella Salmonella species

- 14. CLOSING MEETING
- 15. ATTACHMENTS TO THE AUDIT REPORT

1. INTRODUCTION

The audit took place in the Republic of Ireland from May 25 to June 15, 2005.

An opening meeting was held on May 25, 2005, in Dublin 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 Ireland's meat inspection system.

The auditor was accompanied during the entire audit by representatives from the CCA, the Department of Agriculture and Food, and/or representatives from the regional 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 CCA, two regional inspection offices, five laboratories performing analytical testing on United States-destined product, two swine slaughter/processing establishments, and one meat processing establishment proposed for future certification (this establishment was presented as fully meeting the FSIS inspection requirements).

Competent Authority Visits			Comments
Competent Authority	Central	1	DAF in Dublin
	Regional	2	South west and South regional offices.
	Local	3	At the establishment level.
Laboratories		5	Independent Micro Lab Ltd (private) is conducting analysis for Northern Ireland
Meat Slaughter/Processing Establishments		2	
Meat Processing Establishment		1	This establishment was proposed for future certification

3. PROTOCOL

This on-site audit was conducted in four 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 three

establishments: two slaughter/processing establishments and one processing establishment. The fourth part involved visits to three government and two private laboratories. The Microchem Laboratories was conducting analyses of field samples for the presence of generic *Escherichia coli* (*E. coli*) and *Salmonella*. The Independent Micro Lab. Ltd. was conducting analyses of field samples for the presence of generic *Escherichia coli* (*E. coli*) for Northern Ireland. The DAF Central Meat Control laboratory and the Pesticide Control Service Laboratory were conducting analyses of field samples for Ireland's national residue control program. The DAF Central Veterinary Research Laboratory was conducting analyses of field samples for the presence of *Salmonella* for confirmation.

Program effectiveness determinations of 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 programs and a testing program for generic *E. coli*, (4) residue controls, and (5) enforcement controls, including a testing program for *Salmonella*. Ireland'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 Ireland 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 to the CCA that their inspection system would be audited in accordance with three areas of focus. First, under provisions of the European Community/United States Veterinary Equivalence Agreement (VEA), the FSIS auditor would audit the meat inspection system against European Commission Directive 64/433/EEC of June 1964; European Commission Directive 96/22/EC of April 1996; and European Commission Directive 96/23/EC of April 1996. These directives have been declared equivalent under the VEA.

Second, in areas not covered by these directives, the auditor 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, and requirements for HACCP, SSOP, testing for generic *E. coli* and *Salmonella*.

Third, the auditor would audit against any equivalence determinations that have been made by FSIS for Ireland under provisions of the Sanitary/Phytosanitary Agreement. Currently, Ireland has an equivalence determination from FSIS regarding their Salmonella testing program. These differences can be reviewed under Section 13.2 of this report.

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.

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/Regulations & Policies/Foreign Audit Reports/index.asp

The following deficiencies were identified during the FSIS audit of Ireland's meat inspection system conducted in June/July 2003.

- A build-up of dust or debris and cobwebs was observed in the dry storage room and packaging materials were not stored on racks or racks were not high enough to monitor pest control and sanitation programs. Numerous holes through the walls to out side premises and gaps at the sides of the door were not sealed properly to prevent the entry of rodents and other vermin.
- The sequence of swine carcass sponging for *E. coli* was not being followed as required: ham, belly and jowl.
- The sequence of swine carcass sponging for *Salmonella* was not being followed as required: ham, belly and jowl.

The following deficiencies were identified during the FSIS audit of Ireland's meat inspection system conducted in June 2004.

• In two of the four establishments, the FSIS regulatory requirements were not enforced by the CCA such as:

- In one establishment EU Directive 64/433 was not adequately enforced such as the DAF meat inspectors were not palpating the mesenteric lymph nodes of swine viscera.
- In one establishment, the review of the monitoring records for carcass temperature (CCP2) indicated that the establishment did not document all six temperature readings in the cooler according to the HACCP plan which required readings to be taken from two carcasses (each carcass at three locations). The establishment employee documented an average of three temperatures readings instead of each temperature reading separately. The records did not include the time and signatures or initials of the establishment employee performing the monitoring activity each time as described in the HACCP plan.
- In one establishment, most of the time, DAF meat inspection officials did not verify any corrective actions taken by the establishment including preventive measures for the identified deficiencies for pre-operational Sanitation SOPs.
- In one residue laboratory, the following information was missing in the official standards book such as from where the standard solutions/reagent/media ingredients were purchased, lot numbers, and expiration dates for trace elements. There was no comprehensive documentation of the preparation of standard solutions such as chemical inventory number (unique standard number or unique reagent number) amount used with units, expiration date, and initial for trace elements.
- The Laboratory Quality Assurance Manager (LQAM) audited Pesticide Control Service Laboratory and found that quality system needs to be updated to define procedure for installation of a new column.

6. MAIN FINDINGS

6.1 Legislation

The auditor was informed that the relevant EC Directives, determined equivalent under the VEA, had been transposed into Ireland legislation.

6.2 Government Oversight

6.2.1 CCA Control Systems

The CCA, the Department of Agriculture and Food (DAF), is responsible for direct oversight of Ireland's export meat inspection system. The management structure of the department under the Secretary General comprises nine Assistant Secretaries, the Chief Veterinary Officer (CVO), and the Chief Agricultural Inspector. The CVO is assisted by three Deputy Chief Veterinary Officers (DCVO), one of whom is responsible for all matters relating to veterinary public health.

The Food Safety Authority of Ireland was established by national legislation in 1998. It has legal responsibility under Irish law for the enforcement of all food safety legislation in Ireland and discharges that responsibility by having Service Contracts with the agencies (including the Department of Agriculture and Food) that carry out the enforcement activities.

The CVO and a management team of senior veterinary officers are based in department headquarters in Agriculture House in Dublin. There are six Regional Veterinary Public Health Inspectorate Regions in the country and each region is under the supervision of a Superintending Veterinary Inspector (SVI). There are 27 District Veterinary Offices, each of which is under the supervision of a SVI and staffed by Veterinary Inspectors, Agricultural Officers and administrative and clerical staff. The District Veterinary Officers are responsible for animal health and welfare, and for the implementation of controls on residues in live animals. Slaughterhouses and meat processing plants are supervised by Veterinary Inspectors (VI) of the Veterinary Public Health Inspection Service (VPHIS) of the Department of Agriculture and Food. VI are permanently located in all the large meat and poultry slaughtering and processing plants. The 77 VI are assisted by 300 Technical Agricultural Officers, and by 700 part-time Temporary Veterinary Inspectors (TVI).

6.2.2 Ultimate Control And Supervision

The Veterinary Inspector in charge of the VPHIS, DAF had 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 a Regional Superintending Veterinary Inspector (RSVI), who in turn reports directly to a Senior Superintending Veterinary Inspector (SSVI) at the DAF headquarters. The decision as to whether the establishment is failing to meet U.S. requirements and the recommendation that de-listing should occur is the responsibility of the DCVO, who would reach his/her decision after considering reports from VI, RSVI, SSVI and carrying out an audit of the establishment.

6.2.3 Assignment of Competent, Qualified Inspectors

Full-time VI and TVI are registered university graduates. Upon entering government employment, VI and TVI undergo induction training as well as participate in on-the-job practical training under the supervision of experienced veterinarians; this has been supplemented by refresher seminars on ante-mortem and post-mortem inspections of cattle, sheep and pigs given by DAF in conjunction with the representative organization and Food Safety Authority of Ireland. Since the adoption of EU Commission Decision 2001/471/EC requiring the introduction of controls based on HACCP Principles, the DAF has instigated a program of HACCP training for all its employees.

Technical Agricultural Officers engaged to assist the official veterinarian at meat plants (on duties other than ante-mortem and post-mortem inspections) are required to have a third level qualification in agriculture-related studies to National Certificate level or equivalent. Upon recruitment, the appointed officers undertake induction courses involving classroom and on-the-job training under the supervision of the official veterinarian, and supervisory, regional and HQ Agricultural Officers.

- Training programs for permanent veterinary inspectors in PR/HACCP and SSOP system implementation, *E. coli*, *Salmonella*, and *Listeria monocytogenes* testing were conducted since the last audit.
- The training records of DAF meat inspection personnel indicated that the TVI did not receive any training for PR/HACCP and SSOP system implementation including *E. coli*, *Salmonella*, and *Listeria monocytogenes* testing.

6.2.4 Authority and Responsibility to Enforce the Laws

Veterinary officers are authorized under the relevant legislation to enforce EU and national measures relating to animal health and welfare, including legislation concerning the control of animal disease, veterinary medicines, and the hygienic production of foods of animal origin, by routine inspection and sampling, by investigation and the acquisition of evidence, and by legal process in the courts, often in co-operation with the Gardi (police) and Customs officers.

DAF has the authority and responsibility to enforce the applicable laws relevant to U.S. certified establishments. The SSVI are in charge of verifying and evaluating the implementation of the official directives, guidelines and instructions. Veterinary Inspectors have been given the necessary powers under national legislation to take appropriate enforcement actions in case of non-compliance or breaches of the regulations.

6.2.5 Adequate Administrative and Technical Support

During the audit, the auditor found that the CCA has administrative and technical support to operate Ireland's inspection system and has the resources and ability to support a third-party audit. DAF demonstrated an adequate amount of supervisory oversight and a sufficient number of inspection personnel had been assigned to the three meat establishments certified by DAF as eligible to export meat and meat products to the United States.

6.3 Headquarters Audit

The auditor conducted a review of Ireland meat inspection system documents at DAF headquarters in Dublin. In addition, the auditor reviewed meat inspection records at the two DAF regional offices and the three local sites at the establishment level. The records' review focused primarily on food safety controls relative to meat exports to the United States. This included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- Training records for inspectors.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses for residues and Salmonella.
- Export product inspection and control including export certificates.
- Sanitation, slaughter and processing inspection procedures and standards.

• Enforcement records, including examples of recalls, control of noncompliant product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

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

6.3.1 Audit of Regional Inspection Sites

The FSIS auditor reviewed Ireland's meat inspection records at the DAF's two regional offices; the South West Regional Office in Limerick and the South Regional Office in Cork. The auditor interviewed both regional SVI.

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 auditor 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 sometimes by e-mail.
- Copies of all relevant regulations, notices, and other inspection documents and records were maintained at the regional offices.
- Both regional superintending veterinary inspectors were knowledgeable of U.S. import requirements relative to the two certified establishments producing or exporting meat to the United States.
- Both offices demonstrated adequate administrative assistance to ensure that official inspection personnel were assigned to the two certified establishments.
- The auditor found that the instructions had been received and implemented by the regional office visited.

Local Inspection Sites

The FSIS auditor reviewed Ireland's meat inspection records maintained at the local inspection sites. In addition, the auditor interviewed the senior veterinarians at each establishment and their inspection teams, which consisted of veterinary inspectors and technical agricultural officers.

The auditor concluded that:

- All relevant regulations, notices, and other inspection documents and records were adequately disseminated from headquarters through the regional offices to the three 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.

• The auditor found that the instructions had been received and implemented by the certified establishments visited.

7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of three establishments. Two establishments were certified to export pork to the United States, and one processing establishment was not certified, but presented to FSIS as fully meeting the U.S. import inspection requirements. No establishments were delisted by DAF and no establishments received a Notice of Intent to Delist (NOID) from DAF.

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 United States' 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 United States samples, the auditor evaluated compliance with the criteria established for the use of private laboratories under the PR/HACCP requirements.

The following laboratories were reviewed:

- The DAF Central Meat Control Laboratory is a government laboratory, located in Dublin, which conducts analyses of field samples for Ireland's national residue program.
- The DAF Pesticide Control Service Laboratory is a government laboratory, located in Dublin, which conducts analyses of field samples for Ireland's national residue program. This laboratory has received ISO Standard 17025 accreditation.
- The DAF Central Veterinary Research Laboratory is a government laboratory, located in Dublin, which conducts analyses of field samples for the confirmation of *Salmonella* species.
- Microchem Laboratories is a private laboratory, located in Dungarvan, which conducts analyses of field samples for the presence of *Salmonella* species and generic *Escherichia coli* (*E. coli*). This laboratory has received ISO Standard 17025 accreditation.
- Independent Micro Lab. Ltd is a private laboratory, located in Portlaoise, which conducts analyses of field samples for the presence of generic *Escherichia coli* (*E.*

coli) for Northern Ireland. This laboratory has received ISO Standard 17025 accreditation.

The following deficiency was noted:

• One laboratory audited was not using the FSIS method, or a method determined equivalent to the FSIS method, to analyze the *Salmonella* samples from swine carcasses.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditor focuses on five areas of risk to assess an exporting country'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 except as noted below, 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, and except as noted below, 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 Sanitation Standard Operating Procedures

Each establishment was 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 all three establishments were found to meet the basic FSIS regulatory requirements with no deficiencies.

• In all three establishments audited, the specific deficiencies for SSOP on-going requirements were not implemented.

The specific deficiencies are noted in the attached individual establishment reports.

9.2 Sanitation Performance Standards

In two of three establishments audited, the specific provisions of the United States regulations were not implemented.

The specific deficiencies are noted in the attached individual establishment reports.

9.2 EC Directive 64/433

In all three establishments, the specific provisions of EC Directive 64/433 were not implemented.

The specific deficiencies are noted in the attached individual establishment reports.

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, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. The auditor determined that 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 the Republic of Ireland due to Bovine Spongiform Encephalopathy (BSE), and special import restrictions on pork products regarding Rinderpest and Swine Vesicular Disease.

APHIS declared the Republic of Ireland free of FMD effective December 17, 2002, although subject to special export conditions.

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, humane handling and humane slaughter, 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 testing program for generic *E. coli* in slaughter establishments.

11.1 Humane Handling and Humane 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 three establishments. All three establishments had adequately implemented the basic HACCP requirements.

All the three establishments had adequately performed all of the on-going requirements under HACCP.

11.3 Testing for Generic E. coli

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

Two of the three establishments audited were required to meet the basic FSIS regulatory requirements for testing for generic *E. coli* and were evaluated according to the criteria employed in the United States' domestic inspection program.

Testing for generic *E. coli* was properly conducted in both slaughter establishments.

11.4 Testing for Listeria monocytogenes

Two certified establishments audited were not producing ready-to-eat products for export to the United States so testing for *Listeria monocytogenes* was not required. These two establishments are only exporting fresh pork ribs to the United States.

One processing establishment that was audited (proposed for future certification), was producing fully cooked (not shelf stable) product. This product was not exposed to the environment after having undergone a lethality treatment.

No deficiencies were noted.

11.5 EC Directive 64/433

In all three establishments, the provisions of EC Directive 64/433 were not effectively implemented.

Specific deficiencies are noted in the attached individual establishment reports.

12. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditor 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.

The DAF Central Meat Control Laboratory is a government laboratory, located in Dublin, which conducts analyses of field samples for Ireland's national residue program.

The DAF Pesticide Control Service Laboratory is a government laboratory, located in Dublin, which conducts analyses of field samples for Ireland's national residue program. This laboratory has received ISO Standard 17025 accreditation.

Ireland's National Residue Control Program for 2005 was being followed and was on schedule.

12.1 EC Directive 96/22

In both the Central Meat Control and Pesticide Control Service Laboratories, the provisions of EC Directive 96/22 were effectively implemented.

12.2 EC Directive 96/23

In both the Central Meat Control and Pesticide Control Service Laboratories, the provisions of EC Directive 96/23 were effectively implemented.

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 and the testing program for *Salmonella*.

13.1 Daily Inspection in Establishments

Inspection was being conducted daily in all slaughter and processing establishments.

13.2 Testing for Salmonella

Ireland has adopted the FSIS requirements for testing for *Salmonella* with the exception of the following equivalent measure(s).

- 1. Establishments take samples.
- 2. Private laboratories analyze samples.

Two of the three establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing and were evaluated according to the criteria employed in the United States' domestic inspection program.

The following deficiency was noted:

• One establishment was shipping swab samples for *Salmonella* analysis to a private laboratory "Q LAB" in Wexford, Ireland. The government officials of Ireland had not informed FSIS of the use of this laboratory service.

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 counties 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.

The CCA, however, did not have all enforcement controls in place that are required by FSIS regulations.

14. CLOSING MEETING

A closing meeting was held on June 15, 2005, in Dublin with the CCA and by teleconference with a member of the European Community in Brussels and the Office of International Affairs (OIA) in Washington, D.C. At this meeting, the primary findings and conclusions from the audit were presented by the auditor.

Mangers H. Chaudry

The CCA understood and accepted the findings.

Farooq Ahmad, DVM
Senior Program Auditor

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15. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Forms 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	2. AUDIT DATE	3. ESTABLISHMENT NO. 4. NAME OF COUNTRY	
Queally Pig Slaughtering Limited. Also	June 7, 2005	Republic of Ireland	
trading as: Dawn Pork and Bacon	5. NAME OF AUDITO	OR(S) 6. TYPE OF AUDIT	
	Dr. Faroog Ah	mad iv	
	·		DOCUMENT AUDIT
		liance with requirements. Use O if not appl	icable.
Part A - Sanitation Standard Operating Procedures (Basic Requirements	(SSOP) Audit Resuits	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	i
10. Implementation of SSOP's, including monitoring of implem	nentation.	36. Export	·
11. Maintenance and evaluation of the effectiveness of SSOP's	i.	37. Import	
 Corrective action when the SSOPs have failed to prevent d product contamination or adulteration. 	lirect	38. Establishment Grounds and Pest Control	<u>:</u>
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	i	40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	!
15. Contents of the HACCP list the food safety hazards, critical points, critical limits, procedures, corrective actions.	al control	42. Plumbing and Sewage	!
Records documenting implementation and monitoring of the HACCP plan.	9	43. Water Supply	!
17. The HACCP plan is signed and dated by the responsible establishment individual.	i	44. Dressing Rooms/Lavatories 45. Equipment and Utensils	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	I	46. Sanitary Operations	X
18. Monitoring of HACCP plan.			
19. Verification and validation of HACCP plan.	1	47. Employee Hygiene	<u> </u>
		48. Condemned Product Control	
20. Corrective action written in HACCP plan.		Part F - Inspection Requirements	1
21. Reassessed adequacy of the HACCP plan.	(1)-	- Turr mepodien requirements	·
critical control points, dates and times of specific event oc		49. Government Staffing	:
Part C - Economic / Wholesomeness	1	50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		32. Transact tenanty	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Mo	oisture)	53. Animal Identification	
Part D - Sampling Generic <i>E. coli</i> Testing	į	54. Ante Mortem Inspection	
27. Written Procedures		55. Post Mortem Inspection	
28. Sample Collection/Analysis			
29. Records	:	Part G - Other Regulatory Oversight Requireme	ents
		56. European Community Directives	X
Salmonella Performance Standards - Basic Requi	rements		
30. Corrective Actions		57. Monthy Review	<u>. </u>
31. Reassessment		58.	
32. Written Assurance	X	59.	· .

60. Observation of the Establishment

Country: Ireland Establishment # 332 (Slaughter & Processing) Date of audit: June 7, 2005

- The preventative measures after the corrective action was taken were not included in the establishment's Operational SSOP records.

 9 CFR 416.15 (b)
- The establishment was shipping swab samples for *Salmonella* analysis to a private laboratory "Q LAB" in Wexford, Ireland. The government officials of Ireland had not informed use of this laboratory services to the Office of International Affairs (OIA) in Washington, DC.
- 47/51/56 It was observed during the employee break that the used employee aprons, some of them with excessive blood stains were hanged outside the cabinets which were used to store clean aprons. This practice could be a potential source of cross contamination to the clean aprons stored in these cabinets.

 9 CFR 416.5 (a) & (b)

 EC Directive 64/433, ANNEX 1, CHAPTER 111.3

61. NAME OF AUDITOR
Dr. Farooq Ahmad

62. AUDITOR SIGNATURE AND DATE

8/4/05

United States Department of Agriculture Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY	
Glanbia Fresh Pork Ltd.	May 31, 2005	355	Republic of Ireland	
Carrig, Roscrea	5. NAME OF AUDITO	DR(S)	6. TYPE OF AUDIT	
-	Dr. Faroog Ahı	mad		
				IENT AUDIT
Place an X in the Audit Results block to	·			
Part A - Sanitation Standard Operating Procedure Basic Requirements	S (SSOP) Audit Results		rt D - Continued onomic 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 (SSC Ongoing Requirements	OP)	Part E -	Other Requirements	
10. Implementation of SSOP's, including monitoring of impl	ementation.	36. Export		
11. Maintenance and evaluation of the effectiveness of SSO	P's.	37. Import		0
 Corrective action when the SSOPs have failed to prever product contamination or adulteration. 	t direct	38. Establishment Grounds	and Pest Control	X
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construc	tion/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light		
14. Developed and implemented a written HACCP plan .	<u> </u>	41. Ventilation		
 Contents of the HACCP list the food safety hazards, cri points, critical limits, procedures, corrective actions. 	tical control	42. Plumbing and Sewage		-
 Records documenting implementation and monitoring of HACCP plan. 	the	43. Water Supply		
The HACCP plan is signed and dated by the responsib establishment individual.	le	44. Dressing Rooms/Lavato		
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		46. Sanitary Operations		
18. Monitoring of HACCP plan.		47. Employee Hygiene		
19. Verification and validation of HACCP plan.		48. Condemned Product Co	ntrol	ı
20. Corrective action written in HACCP plan.				_~
21. Reassessed adequacy of the HACCP plan.		Part F - Ir	spection Requirements	İ
 Records documenting: the written HACCP plan, monito critical control points, dates and times of specific event 		49. Government Staffing		!!
Part C - Economic / Wholesomeness	-	50. Daily Inspection Coverag	ge	
23. Labeling - Product Standards		51. Enforcement		
24. Labeling - Net Weights		51. Enforcement		
25. General Labeling		52. Humane Handling		
26. Fin. Prod. Standards/Boneless (Defeds/AQL/Pork Skins/	Moisture)	53. Animal Identification		i
Part D - Sampling Generic <i>E. coli</i> Testing	ř.	54. Ante Mortem Inspection		
27. Written Procedures		55. Post Mortem Inspection		
28. Sample Collection/Analysis		Dt C Oth D	Latana O a mainta Da a visa manata	
29. Records	į	Part G - Other Regu	latory Oversight Requirements	
Salmonella Performance Standards - Basic Rec	quirements	56. European Community Dir	ectives	X
30. Corrective Actions		57. Monthly Review		
31. Reassessment	:	58.		
32. Written Assurance		59.		

60. Observation of the Establishment

Country: Ireland

Establishment # 355 (Slaughter & Processing)

Date of audit: May 31, 2005

- It was noticed during the SSOPs record review that in couple of instances the preventative measures as a part of the corrective actions were not addressed in the establishment's SSOPs records.

 9 CFR 416.15 (b)
- 38/56 The sole entry into an office was through the dry storage room. Boxes stored on the floor and against the wall in the dry storage room could have precluded thorough inspection by Government program employees.

 9 CFR 416.2 (a)
 EC Directive 64/433, ANNEX 1, CHAPTER 111.3

61. NAME OF AUDITOR Dr. Farooq Ahmad

52. AUDITOR SIGNATURE AND DATE

3/4/05

United States Department of Agriculture Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. E	STABLISHMENT NO.	4. NAME OF COUNTRY	
RIB WORLD June 10, 2005		P 799 EEC		Ireland	
Carrigeen Industrial Estate Clonmel, County-Tipperary	5. NAME OF AUDITOR(S)			6. TYPE OF AUDIT	
Dr. Farooq Ahmad		<u> </u>	X ON-SITE AUDIT	DOCUMENT AUDIT	
Place an X in the Audit Results block to indi	icate noncomp	liand	ce with requirem	nents. Use O if not a	pplicable.
Part A - Sanitation Standard Operating Procedures (S Basic Requirements	SOP) Audit Results			art D - Continued onomic 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	<u></u> -		Part E	- Other Requirements	1
10. Implementation of SSOP's, including monitoring of implement	ation. X	36.	Export	The second secon	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37.	Import	, , , , , , , , , , , , , , , , , , ,	
 Corrective action when the SSOPs have falled to prevent dire product contamination or adulteration. 	ct	38.	Establishment Grounds	and Pest Control	:
13. Daily records document item 10, 11 and 12 above.	· X	39.	Establishment Construc	ction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements			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.	ons.	42.	Plumbing and Sewage		İ
16. Records documenting implementation and monitoring of the HACCP plan.			Water Supply		
 The HACCP plan is signed and dated by the responsible establishment individual. 	:	\vdash	Dressing Rooms/Lavato		
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	1	46.	Sanitary Operations		
18. Monitoring of HACCP plan.		47.	Employee Hygiene	-	i
19. Verification and validation of HACCP plan.		48.	Condemned Product Co	ontrol	
20. Corrective action written in HACCP plan.					<u> </u>
21. Reassessed adequacy of the HACCP plan.	i		Part F - II	nspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of critical control points, dates and times of specific event occurr		49.	Government Staffing		
Part C - Economic / Wholesomeness		50.	Daily Inspection Covera	age	
23. Labeling - Product Standards		51.	Enforcement		
24. Labeling - Net Weights		ļ	,		:
25. General Labeling		52.	Humane Handling		
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moist	ture)	53.	Animal Identification		0
Part D - Sampling Generic <i>E. coli</i> Testing		54.	Ante Mortem Inspection		0
27. Written Procedures	0	55	Post Mortem Inspection	****	0
28. Sample Collection/Analysis	0				
29. Records	. 0		Part G - Other Regu	latory Oversight Require	nents
Salmonella Performance Standards - Basic Require		56.	European Community Di	rectives	X
30. Corrective Actions	0	57.	Manthly Review		
31. Ræssessment	0	58.			
32. Written Assurance	0	59.			
	· · · · · · · · · · · · · · · · · · ·				

60. Observation of the Establishment

Country: Ireland

Est. # P 799 EEC (Processing only)

Date of audit: June 10, 2005

10/56 The Clean In Place (CIP) system for the pipes which transports brine solution to be injected into the pork ribs, needed to be established in the SSOP program in order to be able to inspect these pipes during pre-op-sanitation. 9 CFR 416.13

EC Directive 64/433, ANNEX 1, CHAPTER 111.3

10/56 The trays which were used to cook the pork ribs had a build up of brine solution and product residues from the previous days production.

9 CFR 416.13

EC Directive 64/433, ANNEX 1, CHAPTER 111.3

It was noticed during the SSOPs record review that preventative measures as a part of the corrective actions were not addressed in the establishment's SSOPs records.

9 CFR 416.15 (b)

Note: This establishment has been proposed to be certified in the future to export product (RTE) to USA.

62. AUDITOR SIGNATURE AND DATE

61. NAME OF AUDITOR

Dr. Faroog Ahmad

\$14/05



An Roinn Talmhaíochta agus Bia (Department of Agriculture and Food)

BAILE ÁTHA CLIATH 2 (DUBLIN 2)

Ms Sally White Director International Equivalence Staff US Department of Agriculture Food Safety Inspection Service Washington DC, 20250 United States of America

7.7- October 2005

Re: FSIS Audit of the Meat inspection System in Ireland from 25th May through 15th June 2005

Dear Ms White

Thank you for your letter and the draft final report relating to the above audit carried out earlier this year and I would like to take this opportunity to compliment you and Dr. Farooq Ahmad for the thorough and professional manner in which the audit was conducted.

I have no comments to make regarding the information in the report, which fairly reflects the findings noted during the audit.

I wish to assure you that all deficiencies found during the establishment audits have been addressed to the satisfaction of our Veterinary Public Health Inspection Service officials.

Your will note that your services kindly agreed to have Dr. Ahmad carry out an audit of an additional meat processing establishment (No P799) during his visit to Ireland. This establishment was placed on his itinerary as it was proposed to add it in the future to the list of establishments that are certified to export product to the USA.

It is now our intention to add this establishment to the list of USDA approved plants and the US embassy will be notified accordingly in the usual manner.

Kind regards.

Yours sincerely,

Martin C. O'Sullivan

Deputy Chief Veterinary Office