



United States Department of Agriculture

Food Safety and
Inspection Service

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AUG 20 2014

Mr. Martin Blake
Chief Veterinary Officer
Department of Agriculture, Food and Marine
Kildare Street
Dublin 2, Ireland

Dear Mr. Blake:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Ireland's meat inspection system from September 12 through September 25, 2012. Enclosed is a copy of the final audit report. Comments received from the government of Ireland have been included as an attachment to the final report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 720-6400, by facsimile number (202) 720-0676, or via electronic mail at international.audit@fsis.usda.gov.

Sincerely,

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

Enclosure

IRELAND
FINAL AUDIT REPORT

June 30, 2014
Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of equivalence verification activities, which included an onsite audit conducted by the Food Safety and Inspection Service (FSIS) from September 12-25, 2012, to verify whether Ireland's meat inspection system continues to be equivalent to that of the United States, with the ability to produce raw, not-ground, pork products that are safe, wholesome, unadulterated, and properly labeled. Ireland currently exports pork products to the United States. At the time of the audit, the World Trade Organization classified Ireland as a controlled risk for Bovine Spongiform Encephalopathy (BSE) for Animal Health (OIE). The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) considered Ireland to be affected with BSE and, therefore, prohibited Ireland from exporting beef products to the United States.

The audit focused on six main system components: (1) Government Oversight; (2) Statutory Authority and Food-Safety Regulations; (3) Sanitation; (4) Hazard Analysis and Critical Control Points (HACCP) Systems; (5) Chemical Residue Control Programs; and (6) Microbiological Testing Programs. In addition, FSIS verified that the corrective actions proffered by the Central Competent Authority (CCA) in response to the May 2008 audit findings were being implemented. The 2008 FSIS audit revealed potential weakness in government oversight, in inspection/enforcement, in the ability of inspection personnel to correctly implement HACCP verification procedures, and in inspection procedures. Corrective actions were completed and are operating effectively.

The onsite portion of the verification audit included four government offices - CCA Headquarters, one regional and two local offices, two of the three certified swine slaughter and processing establishments, and two laboratories - one government laboratory conducting residue testing and one private laboratory conducting microbiological testing.

The on-site audit findings are summarized below and further addressed in the respective sections of the report.

- The CCA's in-plant supervisory inspection personnel informed the FSIS auditor that final post-mortem disposition procedures for retained carcasses were not being followed. In both establishments, the condemned viscera of retained carcasses were being immediately discarded after their initial inspection and were unavailable for final veterinary review.
- The CCA's inspection personnel were not documenting Sanitation Standard Operating Procedures (SSOP) inspection noncompliances in either establishment if the pre-operational and operational procedures noncompliances were corrected immediately.

The audit results indicate that Ireland's food safety inspection system continues to maintain equivalence with the United States' system and is operating at an "adequate" level of performance. An analysis of Point of Entry (POE) findings since the last FSIS audit of Ireland in 2008 found no food safety violations. The CCA meets the core criteria for all six equivalence components, although there is some need for improvement related to verification of sanitation recordkeeping, documentation of inspection verification activities, and post-mortem final disposition procedures. Ireland has had no POE refusals for more than 1 year. During the exit meeting, the CCA noted that it had taken immediate actions to address the above audit observations. FSIS will evaluate the CCA's corrective actions.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an equivalence verification audit of Ireland's meat inspection system that included an onsite visit from September 12 through September 25, 2012. At the time of the audit, Ireland was eligible to export pork to the United States (U.S.). All exported pork is raw, not-ground, and the majority is pork back ribs.

From October 1, 2012 through September 30, 2013, Ireland exported 7,862,876 pounds of pork to the United States of which 1,302,806 pounds were re-inspected. A total of 7,283 pounds were rejected; none for food safety concerns. For the year prior to the audit in October 1, 2011 through September 30, 2012, Ireland exported 8,192,409 pounds of pork to the United States, of which 1,064,392 pounds were re-inspected and 54,049 pounds rejected by FSIS at POE, none of which was rejected because of food safety concerns. An analysis of POE findings between October 1, 2012 and September 30, 2013, showed that 68 of the total 346 lots of meat products imported from three establishments were re-inspected. Of the POE failures, no food safety violations were found. Additionally, no food safety violations were found by FSIS at POE since the last FSIS audit in 2008.

The onsite audit began with an entrance meeting held on September 12, 2012, in Dublin with representatives from the Central Competent Authority (CCA), the Department of Agriculture, Food, and the Marine (DAFM) of Ireland, and FSIS.

This audit was conducted pursuant to 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
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901-1906)

The standards applied during this audit included all applicable legislation and procedures originally determined by FSIS to be equivalent as part of the initial review process for Ireland. In addition, subsequent equivalence determinations made by FSIS under provisions of the Sanitary/Phytosanitary Agreement and the European Community/United States Veterinary Equivalence Agreement were also applied.

Auditors also verified that the system required United States-equivalent EC regulations:

- European Commission (EC) Regulations 852/2004; 853/2004; 854/2004; 882/2004; 178/2002; 2073/2005, 2074/2005; 2075/2005; and 2076/2005;
- Commission Decision 97/747/EC;
- European Union (EU) Regulation 2001/471/EC; and
- Assessment of Council Directives found equivalent under the Veterinary Equivalence Agreement (VEA), 96-22 and 96-23.

Currently, FSIS has found the following requirements under Ireland's inspection system equivalent to FSIS requirements or procedures for Salmonella and generic Escherichia coli.

II. AUDIT OBJECTIVES, SCOPE, AND METHODOLOGY

FSIS' overall goal for the audit was to verify that Ireland's food safety inspection system governing meat products continues to be equivalent to that of the United States with the ability to produce and export meat products that are unadulterated, safe, wholesome, and properly labeled. To achieve this goal, the audit focused on the six equivalence components with the objectives of determining whether each component continues to be equivalent to that of the meat inspection system of the United States. The six equivalence components are the following: (1) Government Oversight; (2) Statutory Authority and Food Safety Regulations; (3) Sanitation; (4) Hazard Analysis and Critical Control Points (HACCP) Systems; (5) Chemical Residue Control Programs; and (6) Microbiological Testing Programs

FSIS conducted an extensive review of the information provided by Ireland through the *Self-Reporting Tool (SRT) for Ongoing Equivalence* and accompanying references. These documents provided a comprehensive overview of all the relevant legislation and documentation supporting Ireland's equivalent swine slaughter/processing inspection system.

The CCA representatives accompanied the FSIS auditors throughout the entire audit. FSIS also verified that the corrective actions taken by the CCA in the response to the May 2008 audit findings were implemented, addressing deficiencies in the principal areas of government oversight and SSOP inspection/enforcement. The auditors also ensured that corrective actions had been taken to address the inability of inspection personnel to correctly implement HACCP verification procedures, inspection procedures (i.e., sub-maxillary lymph nodes were not incised by the responsible official inspector during post-mortem inspection of the head), and generic *E. coli* testing methodology.

Management, supervision, and administrative functions were reviewed at the CCA headquarters in Dublin, a CCA regional office in Carlo, the CCA's satellite office in Backwestern, and inspection offices located within the two audited establishments in Roscreea, County Tipperary and Edenderry, County Offaly. The FSIS auditor evaluated the CCA's management control systems that ensure that the national system of inspection, verification, and enforcement is being implemented as intended.

In order to verify that the CCA provides consistent government oversight, FSIS examined two regions in Ireland by visiting two of the three swine slaughter and processing establishments identified by the CCA as meeting the United States' import requirements and certified by the CCA as eligible to ship to the United States. During establishment visits, particular attention was paid to the extent to which industry and government interact to control hazards and prevent noncompliances that threaten food safety. The auditor also verified that the CCA provided oversight through supervisory reviews conducted in accordance with *Regulation (EC) No 882/2004* and requirements equivalent to Title 9 Code of Federal Regulations (CFR) 327.2.

The FSIS auditor also assessed the CCA's oversight activities for approved chemical residue and microbiology laboratories. FSIS audited two laboratories, one conducting residue testing -- Veterinary Public Health Regulatory Laboratory (VPHRL) -- and the other conducting microbiological testing -- Eurofins Food Ireland Ltd. -- to verify that Ireland's government laboratory (i.e., Veterinary Public

Health Laboratory (VPHL)) and government accredited private laboratory (Eurofins Foods Ireland, Ltd.) testing methods are equivalent to FSIS methods. FSIS reviewed laboratory-related data collected from the period of the 2008 audit through the current audit and analyzed documents in the SRT. FSIS conducted onsite interviews of inspection personnel and reviewed the CCA's laboratory audit reports associated with the chemical residue and microbiological testing programs.

III. BACKGROUND

In FY 2008, FSIS' audit of Ireland identified principal areas of weakness centered on Government Oversight (inspection and enforcement), Sanitation, HACCP systems (the inability of inspection personnel to correctly implement HACCP verification procedures), inspection procedures, and Residue Testing Program. During that FY 2008 audit, the CCA issued a Notice of Intent to Delist (NOID) to one establishment. This NOID was issued for deficiencies concerning Sanitation Standard Operating Procedures (SSOP), HACCP, generic *E. coli* testing methodology, and post-mortem inspection procedures (i.e., sub-maxillary lymph nodes were not incised by the responsible official inspector during post-mortem inspection of the head).

During this audit, the FSIS auditor conducted onsite verification of corrective actions taken in response to the previous FY 2008 audit. The auditor also reviewed documents and observed operations to ensure that similar deficiencies did not exist in either establishment. The results of these activities are included within their respective components.

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT

The first of the six equivalence components that the FSIS auditor reviewed was Government Oversight. FSIS import eligibility requirements for Ireland state that the foreign food safety inspection system must be designed and administered by the national government of the foreign country with standards equivalent to those of the system of meat inspection in the United States. The evaluation of this component includes a review and analysis of documentation previously submitted by the CCA as support for the responses provided in the SRT, as well as onsite record reviews, interviews, and observations made by the FSIS auditor at government offices, two laboratories, and two establishments.

The FSIS auditor assessed the extent to which Ireland's meat inspection system is organized and administered by the government of Ireland and confirmed that the Food Safety Authority of Ireland delegates to the CCA the authority to carry out the food safety legislation enforcement activities. Consequently, the CCA is responsible for the safety of food products and the promulgation of food inspection regulations, while holding the sole authority to enforce the laws and regulations of the export system.

The FSIS auditor verified that the CCA is responsible for direct oversight of Ireland's export meat inspection system and for safety of foods of animal origin, including the control of residues. The primary responsibility is vested with the Minister of Agriculture, Food, and Marine. The State Veterinary Services (SVS) within the CCA advises the Minister on matters of animal health and disease, zoonoses, and public health as they relate to food and products of animal origin. Ireland's meat inspection system is then organized into three levels: central, regional, and local.

The first level is the central office (headquarters) in Dublin. The Chief Veterinary Officer (CVO) and a management team of Senior Veterinary Officers (SVOs) are based in the Agriculture House headquarters. The SVO team consists of a Deputy CVO, two Senior Superintending Veterinary Inspectors (SSVIs), and five Superintending Veterinary Inspectors (SVIs). The Deputy CVO is in charge of the Veterinary Public Health Inspection Service (VPHIS). The VPHIS of the CCA has ultimate control over the slaughtering of livestock and production of food products derived from animals.

The second level has changed since the last FSIS audit in FY 2008. The CCA reorganized six regional offices to create five Regional Veterinary Public Health Inspectorate Regions (Northeast, East, Southeast, West, and Southwest). Each regional office is supervised by a Regional Superintending Veterinary Inspector (RSVI) who oversees the implementation of veterinary controls in the meat establishments in their jurisdiction and reports directly to headquarters.

The third level is comprised of Veterinary Offices located in each of the establishments certified to export to the United States. Each office has a Veterinary Inspector (VI) who is in charge of inspection activities in the establishment. The VI has direct supervision over all other inspection personnel assigned to the certified establishment, including Temporary Veterinary Inspectors (TVIs) and Technical Agricultural Officers (TAOs).

The CCA has an approval process in place for the certification of establishments and is the only body with authority to certify and decertify establishments for export to the United States. The process for registration of premises and related matters for the purpose of trade with non-EU countries is handled through a case-by-case administrative process rather than being defined in legislation. The registration process for meat production for the national or EU market is defined in legislation (i.e., the European Communities [Food and Feed Hygiene] Regulations 2009); however, any establishment seeking to engage in trade with non-EU countries must first be registered under the aforementioned legislation. Once the CCA verifies that establishments fulfill all official EU requirements, they are approved and added to the list of eligible establishments certified by Ireland to export meat to the United States and are notified in writing prior to being granted certification to export.

The majority of the cost of Ireland's inspection program is funded by the National Exchequer with the remaining portion from fees charged to the establishments by government based on a fixed rate per animal. The CCA's central fees unit bills establishments each month and is responsible for the collection of these fees.

The RSVI and the VI assess the eligibility of establishments to export to the United States. They have the authority, under *EU Regulation 178/2002* and *National Legislation S.I. No. 910*, to enforce the necessary requirements to export to another country. Their duties also include initiating investigations into the failure on the part of an establishment to meet the standards of the importing country and to provide documentation to the CCA that will delist those establishments that fail. The VI in certified establishments performs the daily supervision of establishment activities and reports directly to the RSVI, who performs the periodic supervisory reviews.

All inspection personnel assigned to the establishments certified to export meat to the United States are full-time government employees receiving no payment from either industry groups or establishment

personnel. The CCA is responsible for the initial hiring, training, and payment of inspection personnel. The FSIS auditor verified that inspection personnel salary was paid by a government servicing agency, Irish Civil Service by reviewing accountable time worked as recorded in payroll records at the CCA headquarters in Dublin, the regional offices, and in the establishments.

The VIs are permanently located in all the larger meat and processing establishments and are responsible for the supervision of inspection personnel assigned to those establishments. VIs are responsible for ante-mortem and post-mortem inspection, verification of sanitation and HACCP programs, inspection of structural and hygiene standards, controls on animal welfare, and animal identification.

Private veterinary practitioners who serve as TVIs conduct meat inspection duties (ante-mortem and post-mortem inspection) in slaughter establishments. The TVIs, before conducting inspection activities, must undergo a period of on-the-job training under the supervision of the full-time VI. The TVIs are under direct supervision of the VI. The TAOs assist the VI on duties other than ante-mortem and post-mortem inspection activities. All TAOs are trained to the specification of the Food Hygiene Regulations, microbiology, and HACCP.

The CCA has the legal authority and the responsibility to enforce all requisite laws and regulations governing the export of meat to the United States. The VI and other qualified in-plant inspection personnel are authorized to enforce European Commission legislation and United States import requirements under *National Legislation S.I. No. 910* and EU Regulations and take appropriate enforcement actions in the case of noncompliance or breaches of the regulations. Ultimately, the CCA has the authority to suspend or delist establishments to prevent export of unwholesome products to the United States.

The CCA disseminates information throughout all levels of inspection personnel (government offices, establishments, and laboratories) pertaining to regulatory and administrative affairs and maintains current information concerning FSIS requirements related to United States export. The auditor noted that the CCA oversees the functions of the inspection system by designing and implementing inspection-related procedures in accordance with national standards, in addition to those standards imposed by importing countries. All updates received from FSIS are posted to the DAFM intranet site, and inspection personnel are alerted by email instruction. Additionally, all inspection personnel receive email instructions to register on the FSIS website for relevant updates. The FSIS auditor verified through the review of supporting documentation provided by the CCA and the DAFM intranet site that the CCA maintains a communication system to convey United States inspection requirements throughout its inspection system in a timely manner. The documents reviewed support that the CCA provides instructions to field personnel to stay current with new FSIS issuances. The CCA has incorporated an electronic system to transfer the relevant information for inspection activities.

The CCA provides initial and specialized ongoing training to CCA inspection personnel assigned to certified establishments for specific United States import requirements, such as Pathogen Reduction requirements, HACCP system requirements, sanitation requirements, humane handling and slaughter requirements, food safety assessment requirements, and enforcement of United States import requirements. Newly hired inspection personnel complete initial inspection training and, after an evaluation, receive on-the-job training prior to reporting to their final assignments. Ongoing training and support are coordinated primarily by the CCA and provided through the regional staff. As there is a

small quantity of establishments and personnel involved, a formal training program calendar was determined not to be necessary.

The FSIS auditor reviewed the records of training programs at CCA headquarters and individual training records of inspection personnel at local inspection offices to verify that the inspection system assures adequate and timely training of inspection personnel. The FSIS auditor also observed the appropriate application of the training during the establishment audits. The CCA inspection personnel demonstrated the ability to verify the implementation of sanitation, HACCP, and microbiological testing programs consistent with government requirements. These observations verified that the inspection personnel assigned to certified establishments receive adequate training in specific requirements related to United States export at a level that ensures consistent performance; and that their supervisors provide adequate oversight to ensure the proper implementation of the inspection system in maintaining equivalence.

The FSIS auditor verified that the Veterinary Inspector-In-Charge evaluates the performance of inspection personnel quarterly as part of the quarterly pre-audit inspection process and documented on the Pre-Audit Inspection Report (PAIR).

The current audit indicated that Ireland's meat inspection system is organized and administered by the government, and that the CCA officials are assigned to enforce laws and regulations governing meat inspection in official establishments. The CCA has applied these standards uniformly at the two certified swine slaughter and processing establishments that were audited, indicating that FSIS' requirement of ultimate control and supervision over inspectors and inspection verification activities was consistently met. The verification activities of Ireland's inspection system as designed and implemented showed that the CCA continues to demonstrate the ability to meet the equivalence requirements for this component, as articulated by the FSIS import regulations (9 CFR 327.2). FSIS therefore determined that Ireland's inspection system operates at an "average" level of performance as pertains to this component.

V. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS

The second of the six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. For an inspection system to be equivalent, it must be organized and administered by the national government of the foreign country. The inspection system must provide an appropriate regulatory framework to demonstrate equivalence with FSIS' inspection system, including, but not limited to, HACCP, sanitation, chemical residue and microbiological sampling, humane handling, slaughter, ante-mortem inspection, post-mortem inspection, establishment construction, facilities, equipment, daily inspection and periodic supervisory visits to United States-eligible establishments.

The evaluation of this component included a review and analysis of documentation previously submitted by the CCA in the SRT, interviews with government officials, and observations made by the FSIS auditor during the onsite audit of Ireland's inspection system. The FSIS auditor verified that official inspection and verification activities were maintained by the CCA as outlined in official legislation, circulars, and other instructions issued and in accordance with Ireland's inspection law. Ireland provides a statutory framework outlining the requirements of its meat inspection system against the standards promulgated by the CCA that includes separation of domestic and exported products at the

establishment. Periodic supervisory visits are conducted at certified establishment that export to United States.

The audit demonstrated that Ireland's inspection system has the statutory authority to deliver inspection to all certified establishments and to provide requirements for humane handling and slaughter of livestock, ante- and post-mortem inspection, control over establishment construction/facility/equipment, control over inedible and condemned materials, and daily inspection and periodic supervisory reviews of the certified establishments. Additionally, the CCA has regulatory requirements that require official inspection personnel, laboratories, and establishments to meet the United States' requirements to ensure an equivalent system.

During the onsite audit of two swine slaughter and processing establishments, the FSIS auditor accompanied and observed the in-plant inspection verification activities for operational sanitation procedures, HACCP verification activities including the zero tolerance CCP verification, as well as ante-mortem/humane handling and slaughter, post-mortem examination, *Salmonella* spp. and generic *E. coli/Enterobacteriaceae* sample collection.

The FSIS auditor verified that in-plant official veterinarians conducted ante-mortem inspection on the day of slaughter by reviewing the incoming registration and identification documents -- including animal identification documents -- that allow the traceability of the animal to its source. In accordance with procedures and requirements, the official veterinarians observed all animals at rest and in motion in designated holding pens to determine whether they are fit for slaughter. Each establishment had a designated observation pen for further examination of suspect animals. The FSIS auditor observed and verified that all animals had access to water in all holding pens (including those used for suspect animals); if animals were to be held overnight, provisions included feed and water for the animals. The implementation of the ante-mortem inspection procedure was verified to be in compliance with *EU Regulation No. 853/2004 and 854/2004*. Ante-mortem inspection that has been determined equivalent. Ireland has consolidated all aspects of swine intake into one issuance, "Pig Intake SOP 007/2009." The FSIS auditor further verified through onsite record review, interviews, and observations that the CCA's inspection procedures concerning ante-mortem and humane handling/slaughter of livestock verification activities were met in the two audited slaughter and processing establishments.

FSIS assessed post-mortem inspection examinations through onsite record reviews, interviews, and observations of inspection activities in the two audited slaughter and processing establishments. The FSIS auditor observed and verified that proper presentation, identification, examination, and disposition of carcasses and parts were being implemented. The design of the post-mortem inspection stations, including proper lighting and the number of on-line inspectors, are in accordance with Ireland's inspection requirements in *EC Regulation 854 - ANNEX 1*. The FSIS auditor observed and verified that inspection personnel conduct post-mortem inspection of every animal that has been slaughtered at that establishment. Inspection personnel examined visually the heads, viscera, and carcasses, including all required organs and lymph nodes. Proper incision and palpation were made in accordance with the provisions of *ABATTOIRS ACT, 1988 (Veterinary Examination) Regulations, 1992 (S.I. No. 89/1992)*: Part I of the Second Schedule to these Regulations - Post Mortem Examination and *EU Regulation No. 853/2004 and 854/2004*- post-mortem inspection, which has been determined equivalent.

The FSIS auditor verified during this audit that the deficiencies reported during the last FSIS audit were adequately addressed within the inspection system that included post-mortem inspection procedures where the sub-maxillary lymph nodes were not incised and examined by the responsible official inspector. The auditor verified that the sub-maxillary lymph nodes are incised and examined by the TVI through direct observation of post-mortem inspection procedures, including examining the post-chill cooler (current day's kill) and the holding cooler (previous day's kill) carcass heads at both establishments that were audited during this FY 2012 audit. Both permanent veterinary officers and inspectors who are also veterinarians, were performing post-mortem examinations and demonstrated an acceptable level of proficiency performing their duties.

Although the auditor verified that swine carcasses and parts were properly identified and presented, the FSIS auditor identified a deficiency concerning procedures for post-mortem inspection final veterinary disposition. The FSIS auditor interviewed the CCA's supervisory inspection personnel at each of the two swine slaughter and processing establishments that were audited. During the interview, the auditor learned that when a swine carcass is retained for pathological conditions during post-mortem inspection, the viscera are not retained along with carcasses that require final veterinary disposition. Instead, the viscera are condemned immediately. This procedure does not provide the official veterinarian the opportunity to conduct a thorough disposition of the retained carcasses with the corresponding viscera and does not follow procedures determined equivalent by FSIS for final post-mortem disposition.

This procedure, as explained by the establishment VIC and implemented at the local level by the CCA, does not meet the requirements articulated by *EC 853 – ANNEX III, Section 1, Chapter IV, 13*, which requires that, until post-mortem inspection is completed, parts of a slaughtered animal subject to such inspection must remain identifiable as belonging to a given carcass, in accordance with *FSIS Regulation 9 CFR 310.3*. The CCA was not able to provide an explanation as to why procedures outlined in the references stated were not followed by local inspection staff but stated that this procedure was inconsistent with both the CCA's expectation as well as EU requirements. Inspection personnel were immediately instructed to implement the policy outlined in *EC 853 – ANNEX III, Section 1, Chapter IV, 13*.

The FSIS auditor also observed the functions of the off-line veterinary inspectors who have an in-plant supervisory role to ensure continuous daily inspection and to conduct daily inspection verification activities in these two audited establishments. These daily verification activities included direct observation, measurement and review of establishments' records, including HACCP, sanitation SOP and SPS, and *E. coli/Enterobacteriaceae* and *Salmonella* carcass sampling records. The FSIS auditor reviewed 90 days of inspection records and verified that inspection personnel maintain on file written inspection verification records at the two swine slaughter and processing establishments that were audited. The auditor also confirmed that inspection personnel followed verification procedures defined in FSMS - SOP 006/2008 - Procedures for the Performance of Official Controls to Monitor the Food Business Operator's Food Safety Management Systems.

The current audit indicated that Ireland's meat inspection system has the legal authority and a documented regulatory framework to implement requirements equivalent to those governing the system of meat inspection organized and maintained by the United States. The CCA has applied these standards uniformly at the two swine slaughter and processing establishments that were audited and eligible to export to the United States.

Ireland's meat inspection system has legal authority and a regulatory framework to implement requirements equivalent to those governing the FSIS system of meat inspection in the United States, although there was some need for improvement of oversight related to post-mortem final disposition procedures. The analysis and onsite verification activities indicate that the CCA continues to maintain equivalence and is operating at an "adequate" level of performance for this component.

VI. COMPONENT THREE: SANITATION

The third of the six equivalence components that the FSIS auditor reviewed was sanitation. To be equivalent to the United States' inspection system, a foreign system must provide requirements for all areas of sanitation, sanitary handling of products, and the development and implementation of Sanitation Standard Operating Procedures. The FSIS auditor's verification of this component included an analysis of the CCA's SRT responses, review of records at government offices in the establishments, and observations at the two swine slaughter and processing establishments audited.

The auditor's review of legislation, regulations, official instructions, and guidelines demonstrates that the CCA describes a verification process that ensures that the inspection system requires each official establishment to develop, implement, and maintain written standard operating procedures sufficient to prevent direct product contamination or insanitary conditions. An assessment of official regulatory oversight and compliance maintained by the establishments was conducted in accordance with: FSMS SOP 006/2008 ANNEX IV, HACCP Pre-Requisites (HPR) 1, 2 and Guidance Note. The HPRs are equivalent to SSOPs.

The in-plant inspection personnel at the two audited swine slaughter and processing establishments verified sanitary conditions in accordance with the CCA's Article 4.2 of the *EU Regulation No 854/2004 EC*: monitoring and implementation of sanitation procedures, record review, and hands-on verification inspection of both pre-operational and operational procedures. This regulation provides instructions to the official inspection personnel to conduct a continuous and systematic assessment of inspection activities during routine verification of sanitation issues, including maintenance of the facilities and industrial equipment; dressing rooms and restrooms; illumination; ventilation; water supply; waste water; pest control; cleaning and sanitization; hygiene, hygienic habits and the workers' health; and operational sanitary procedures.

The FSIS auditor reviewed sanitation plans and records related to the design and implementation of sanitation programs at the two swine slaughter and processing establishments that were audited. In one of the slaughter and processing establishments, the FSIS auditor verified the actual pre-operational inspection by shadowing and observing the in-plant inspector conducting pre-operational sanitation verification of the loin line area in the boning hall, in addition to the kill floor of the establishment. The in-plant hands-on verification procedures started after the establishment personnel conducted their pre-operational sanitation and determined the facility was ready for in-plant inspector pre-operational sanitation verification activities. The in-plant inspector conducted this activity in accordance with the established procedures that are equivalent to the United States' procedures.

In addition, the FSIS auditor followed the off-line inspector and observed in-plant inspection verification of operational sanitation procedures at the two of audited establishments. These verification activities included direct observation of operations and review of establishment records. Inspection verification

was methodical in its approach and execution. The FSIS auditor also reviewed each establishment's sanitation monitoring and corresponding inspections verification records for approximately ninety (90) days. The auditor noted that the inspection and establishment records mirrored the actual sanitary conditions of the establishment. The audited establishments maintained sanitation records sufficient to document the implementation and monitoring of the SSOP. The establishment employees specified as being responsible for the implementation and monitoring of the SSOP procedures correctly authenticated these records with initials or signatures and the date.

The FSIS auditor's observations of the audited establishments, review of inspection records, interviews of the in-plant inspection officials, and review of the documentation of the periodic supervisory reviews indicated that inspectors were proficient in conducting verification and enforcement activities related to sanitation. However, the auditor was concerned about the lack of noncompliance documentation and incomplete verification of SSOP corrective actions in both audited establishments.

The FSIS auditor identified that establishments' SSOP records were properly documented but also found that inspectors did not consistently verify that they met requirements.

- The CCA's inspection personnel were not routinely documenting SSOP inspection verification noncompliances identified on pre-operational and operational sanitation by inspection personnel when noncompliances were corrected immediately and documented by the establishment in both audited establishments. Inspection personnel do not issue official noncompliance records or any written documentation to the establishments when noncompliances are identified in these situations. Inspection personnel only verbally inform the establishment of the noncompliance for these issues. Only noncompliances that could not be corrected immediately or that presented an imminent food safety concern were documented. The report is then only shown to the establishment to address with corrective actions. The noncompliance report does, however, include actions that were to be taken, a due date, and CCA verification initials with date.

The verification of documented SSOP verification activities indicates that inspection personnel conduct these activities following CCA protocols. The audit found evidence that all parts of 9 CFR 416.15 governing sanitation corrective actions were addressed through the review of documentation in the establishments' SSOP records; however, there was not consistent documentation that inspection personnel verified these actions. The CCA informed the FSIS auditor during the exit conference that inspection personnel were instructed to properly document all noncompliances identified and to verify that establishments addressed and documented all aspects of corrective actions either in their sanitation verification records or in documentation provided to inspection personnel at the establishment.

The previous FSIS 2008 Audit Report pointed out that inspection personnel verified that establishment routinely evaluates the effectiveness of SSOP; however, the CCA did not have a mechanism in place to document this activity. The FSIS auditor verified that this has now been rectified with the modified SSOP verification form FSIS~SSOP (b) (0910) Rev03 that was issued to and implemented by inspection personnel following the FSIS 2008 audit, meeting equivalence.

The current audit indicated that the CCA of Ireland's meat inspection system effectively implements its requirements for sanitation, the development and implementation of sanitation standard operating procedures, and requirements for sanitary handling of meat products intended for export to the United

States. In-plant inspection and supervisory personnel enforce the regulatory requirements and verify that the establishments maintain sanitary conditions. The CCA has applied these requirements uniformly at the two swine slaughter and processing establishments that were audited and eligible to export to the United States.

FSIS analysis and audit verification activities of Ireland's inspection system as designed and implemented indicated that the CCA continues to demonstrate the ability to meet the core equivalence requirements for this component that are articulated by the FSIS import regulations. There was some need found for improvement of oversight related to sanitation recordkeeping, i.e., documentation of inspection verification activity. Therefore, FSIS determined that Ireland's inspection system does support that the CCA operates at an "adequate" level of performance as pertains to this component.

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

The fourth of the six equivalence components that the FSIS auditor reviewed was HACCP. The inspection system must require that each official establishment develop, implement, and maintain a HACCP plan. The FSIS auditor's verification that Ireland met equivalence requirements for this component included review and analysis of the information provided by the CCA in the SRT; review of records at government offices in the establishments; and observations at the two swine slaughter and processing establishments. Ireland's meat inspection system follows EU requirements for United States-eligible establishments, *Regulation 854/2004/EC* and *852/2004/EC*, in which HACCP regulatory requirements are prescribed and found equivalent to 9 CFR Part 417.

The FSIS auditor evaluated the design and verified the adequacy of the implementation of HACCP programs at the two swine slaughter and processing establishments as proscribed in the CCA's "Guideline on USDA Approval." Both establishments had developed, implemented, and maintained a HACCP plan for products eligible to be certified for export to the United States and ensured that the requirements equivalent to 9 CFR 417.1-417.7 are met to remain equivalent.

The FSIS auditor verified through record review and onsite observations that the in-plant inspection personnel at the two swine slaughter and processing establishments conducted and documented official daily verification activities related to HACCP plans in accordance with methodology described in the CCA's FSMS - SOP No 006/2008, - "Procedures for the Performance of Official Controls to Monitor the Food Business Operator's Food Safety Management Systems." These procedures include evaluating written HACCP programs, as well as verifying that establishments meet HACCP plan monitoring, that establishments take corrective actions when required, that establishments meet HACCP record keeping requirements, and that establishments perform hands-on verification that the requirements equivalent to 9 CFR 417.8 are met.

At the two swine slaughter and processing establishments, the FSIS auditor conducted a review of the zero tolerance (i.e., feces, ingesta, and milk) CCP records generated over the past ninety (90) days. At both establishments, monitoring records documented some deviations from the critical limits of the zero tolerance CCP. The corrective actions in response to the deviations indicated that all four parts of the corrective actions, in accordance with 9 CFR part 417.3, were addressed by slaughter and processing

establishment employees and verified by inspection personnel. There were no HACCP noncompliances identified by the CCA within the ninety (90) days of records reviewed by the FSIS auditor.

The FSIS auditor verified the physical CCP locations by observing inspection personnel conducting HACCP hands-on verification activities, as well as performing an independent direct monitoring examination of pork carcasses. The FSIS auditor also verified that the zero tolerance CCP location met the CCA's requirement for proper verification examination. The FSIS auditor did not identify any concerns after reviewing documents at the government offices and establishments or by interviewing official personnel.

All inspection-related reports are maintained in the inspection office at the establishment for supervisory review and necessary further actions. Additionally, the CCA provided documentation to the FSIS auditor that demonstrated the CCA has addressed and verified per FSIS' requirements in the SRT that all establishment records are required to be kept onsite for 6 months, and after 6 months, they can be retrieved within 24 hours if stored off-site.

The current audit found that Ireland's meat inspection system requires operators of certified establishments to develop, implement, and maintain HACCP programs for each operation as set forth in the CCA's "Guideline on USDA Approval" and FSIS regulations. The CCA has applied these standards uniformly at the two swine slaughter and processing establishments that were audited and eligible to export to the United States.

The CCA continues to demonstrate the ability to satisfy the equivalence for this component as articulated in FSIS import regulations (9 CFR 327.2). Therefore, FSIS determined that Ireland's inspection system does support the finding that the CCA operates at an "average" level of performance as pertains to this component.

VIII. COMPONENT FIVE: CHEMICAL RESIDUES CONTROL PROGRAM

The fifth of the six equivalence components that the FSIS auditor reviewed was Chemical Residue Control Programs. For this component, FSIS criteria require the inspection system to have a chemical residue control program designed and administered by the national government that carries out activities equivalent to those employed by FSIS to prevent chemical residue contamination of food products. To be considered equivalent to that of FSIS, the program must include random sampling of the internal organs and fat of carcasses for chemical residues that have been identified as potential contaminants by the exporting countries and FSIS. The CCA must provide a description of its residue sampling and testing plan along with the process used to design the plan. The CCA must maintain oversight of laboratories it employs to ensure the validity and reliability of test data.

FSIS' residue experts thoroughly reviewed documentation pertaining to the design and implementation of CCA's National Residue Program (NRP) and found it to be equivalent. The in-depth review included an analysis of the 2011 and 2012 residue monitoring plan and of additional SRT responses outlining the structure of Ireland's chemical testing program. The auditor also conducted an onsite audit of one residue laboratory that performs residue analysis for United States-certified product.

The auditor's review of the SRT and supporting CCA documentation demonstrates that Ireland has a chemical residue control program that is organized and administered by the national government. This program includes random sampling of internal organs and fat of carcasses for chemical residues identified as potential contaminants by the exporting country's meat inspection authorities or by FSIS.

The FSIS auditor verified that the design of the National Residue Testing Plan meets the FSIS criteria outlined above. The residue plan also describes the various sampling schemes, lists the selected matrices for each compound, and includes a rationale and process for the choice of chemical compounds. It is administered and issued by the CCA and includes a separate sampling guide that provides detailed instructions for field personnel in the collection of samples of specific tissues (i.e., muscle, fat, liver, kidney, retina, urine, and blood [serum, plasma]). The FSIS auditor verified that the official veterinarian performs government sampling, packing all tissues separately and sending them to the VPHRL laboratory in accordance with the Central Meat Control Laboratory (CMCL) Guidance Document.

The FSIS auditor also verified that the implementation of Ireland's National Residue Testing Plan at CCA headquarters, regional, and in-plant level offices, and laboratory audited proceeded in the manner outlined in the plan. A review of Ireland's 2012 National Residue Testing Plan met FSIS' expectations for government verification testing programs.

The Veterinary Medicines Section (VMS) serves as the Competent Authority of the National Residue Control Plan, oversees Government testing programs and is actively involved in setting policy, providing policy guidance, and overseeing implementation of these testing policies. The residue laboratory conducts CHC, PCB, OP, DES, and antibiotic (including sulfonamides) testing. The CCA audits laboratories prior to approval and periodically thereafter. When undertaken in the laboratory, tests are required to be accredited under ISO 17025 and compliance is assessed and verified by INAB in their annual assessment. The VMS has ISO 17025-accredited functions audited by State Veterinary Services Internal Audit Group (SVSIAD) for all Government and State laboratories annually. The VMS receives all audit reports informing them of laboratory noncompliances or other issues. The VMS also verifies that the laboratories provide them with corrective actions in response to those audits for review prior to providing the SVSIAD with their response.

In addition to information on residue testing, SVSIAD also provided an audit report from 2011 on official controls for *Trichinella* for this laboratory.

The FSIS auditor conducted an onsite audit of the VPHRL that provides technical support to Ireland's meat inspection system. The Irish National Accreditation Board (INAB) has accredited the laboratory with meeting the criteria of ISO/IEC 17025 and any further requirements specified by the INAB. The FSIS auditor verified this by the review of the INAB Accreditation Certificate and Scope of Accreditation issued to VPHRL that was last renewed on February 2, 2011. The VPHRL also acts as a National Reference Laboratory (NRL) for Ireland including for *Trichinella* testing and for five (5) residue groups. The FSIS auditor's review of the internal SOPs and onsite observations verified that sampling procedures, analytical procedures, and quality assurance procedures and calibration, temperature recording, and intra-laboratory check samples for this laboratory are being properly implemented and properly documented in records.

The FSIS auditor's review of the VPHRL chemical residue laboratory and, ultimately, the Chemical Residue Control Program as a whole, verified that the following areas are equivalent: sample receipt and tracking, media preparation, integrity of analyses, and oversight and program activity. The auditor did not identify any deficiencies or areas of concern during the audit of this laboratory.

The current audit found that Ireland's Chemical Residue Control Program is managed by the CCA and established to carry out equivalent activities to encourage appropriate use of animal drugs and other chemicals and to act against those products that are contaminated. The inspection system identified the laws, regulations, and other decrees that serve as the legal authority for the implementation of this program. The CCA includes a description of the process used to design the residue testing plan. The plan describes the actual operations of its residue testing process and provides a description of the actions taken to deal with unsafe residues as they occur. The CCA had access to, and oversees, analytical laboratories that have the capability to provide reliable testing results. The CCA has applied sampling standards uniformly at the two swine slaughter and processing establishments that were audited.

FSIS analysis and audit verification activities of Ireland's chemical residue testing program indicated that the CCA continues to demonstrate the ability to meet the equivalence requirements for this component that are articulated by the FSIS import regulations (9 CFR 327.2). Therefore, FSIS determined that Ireland's chemical residue testing program does support that the CCA operates at an "average" level of performance as pertains to this component.

IX. COMPONENT SIX: MICROBIOLOGICAL TESTING PROGRAMS

The last of the six equivalence components that the FSIS auditor reviewed was Microbiological Testing Programs. This component requires that the inspection system have a microbiological testing program organized and administered by the national government to verify that products destined for export to the United States are safe, wholesome, and meet all equivalence criteria.

Ireland requires establishments to test for *Enterobacteriaceae* and Total Viable Count in raw product in lieu of required testing for generic *E. coli* in all slaughter establishments to show process control, which is acceptable for all EU exporting countries and found equivalent by the United States. The establishments that are certified eligible for export to the United States have the option to conduct generic *E. coli* testing instead. Ireland has established microbiological testing programs for generic *E. coli* and *Salmonella* in all three certified swine slaughter and processing establishments.

The auditor's review of this component indicated that the CCA's supporting documentation describes the verification testing processes for generic *E. coli* and *Salmonella* and provides clear written guidance to inspection officials and food operators to ensure that proper verification procedures are applied to all exported products.

Ireland describes its sampling and testing program for generic *E. coli* in raw product in its Guideline on USDA Approval as: one sample per 1,000 carcasses weekly, from chilled carcasses sampling from the ham, belly, and jowl, is done with a sponge. The sample is then sent to an approved laboratory, along with 12 months of records and a process control chart detailing at least the last 13 results. Results for *E. coli* testing by sponging carcasses are evaluated using statistical process control techniques.

Following up on sampling deficiencies identified during the last FSIS audit, the auditor verified carcass sampling for generic *E. coli* (i.e., written procedures, sample collection, analysis results, and records) and found no issues of concern. The auditor verified through the review of establishment SOP and report documentation that random selection of carcasses for generic *E. coli* testing are computer-generated and equivalent to 9 CFR 310.25(a)2(i). The sampling is performed by all certified establishments and then sent to a private laboratory and verified by the CCA. CCA inspection personnel verified that the above sampling frequency is met, that the establishment sample collector is designated in the written plan, that the written plan addresses the location of sampling site on the carcass, samples are collected randomly by the use of a computer generated carcass number selection, sample integrity is addressed for storage and shipping of samples to the laboratory for testing, and that the appropriate carcass sampling methodology is used. The lab is using an appropriate method for analysis, results are correctly evaluated, and establishments take appropriate corrective action when violations occur. Supervisory verification of in-plant inspection personnel's verification activities is also performed monthly.

The FSIS auditor reviewed 180 days of generic *E. coli* results at each of the two swine slaughter and processing establishments that were audited in addition to observing the sampling techniques by personnel in those establishments and verified that they were equivalent to the United States. Ireland describes their sampling program for *Salmonella* species in their Guideline on USDA Approval as follows: one (1) sample per 1,000 carcasses weekly, 55 samples tested, of that a maximum of six (6) may be positive to achieve the standard. This performance standard is identical to that used by FSIS within its domestic inspection system. The FSIS auditor verified that sampling is performed at the two swine slaughter and processing establishments for *Salmonella* testing. The CCA provides oversight and monitoring of sampling procedures as required to maintain equivalence. In addition, the FSIS auditor observed the sampling techniques of establishment personnel and verified that they are equivalent to the United States.

The CCA of Ireland takes immediate action when an establishment fails to meet a *Salmonella* performance standard. Test results are reported back to the official government inspector at the establishment. Any *Salmonella* positive result triggers a HACCP program review and intensified sampling by the CCA in accordance with Regulation (EC) 2073/2005. Additionally, all *Salmonella* test results go into a National and EU database that monitors microbiological performances, and in case of positive results an alert is generated, which in turns triggers an investigation, HACCP review, corrective actions, and intensified sampling by the government.

Verification is carried out by the Official Veterinarian in conjunction with process control verification and evaluation of *E. coli* testing results. The form HPR1 documents compliance with *Commission Regulation 2073/2005* on microbiological (*Salmonella*) criteria for Foodstuffs - Process Hygiene Criteria - Sampling plans, Limits, Corrective Actions regarding meat preparations. The monthly SVI Audit Checklist includes specific verification of corrective actions, reassessment, and written assurance for *Salmonella* performance standards. In the two swine slaughter and processing establishments audited, *Salmonella* performance standards fall within the Group I HPR of Microbiological Testing, and therefore, the CCA performs documented analysis of *Salmonella* Performance Standards at least once every 3 months. The FSIS auditor reviewed approximately 9 months of *Salmonella* testing results at each of the two swine slaughter and processing establishments and found that there were no recent *Salmonella* set failures at either of these audited establishments.

The FSIS auditor reviewed 180 days of CCA forms that document the CCA's verification of generic *E. coli* and *Salmonella* testing. The auditor verified that the forms are completed at the prescribed frequency and with the detail necessary to verify the requisite performance of generic *E. coli* and *Salmonella* testing.

The FSIS auditor conducted a verification audit of Eurofins Food Ireland Ltd., a privately owned laboratory that the CCA-VPHRL oversees. The auditor focused on the verification of analysts' qualifications, sample receiving and handling, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and intra-laboratory check samples. The FSIS auditor verified and found no deficiencies in the review of audit reports that the functions of the laboratory are reviewed once every 12 to 24 months by the Food Safety Authority of Ireland (FSAI)/DAFM.

The FSIS auditor verified that Ireland's private microbiological testing laboratory Eurofins Food Ireland Ltd. was performing analyses in a manner equivalent to the FSIS testing requirements. The auditor also found that the laboratory possessed the technical capacity to ensure that accurate product destined for the United States was adequately tested. The generic *E. coli* testing of swine carcasses is performed by AOAC Official method 998.08. The *Salmonella* testing for swine carcasses is tested by using the method EN/ISO 6579, which has been deemed equivalent to FSIS.

The current audit indicated that Ireland's meat inspection system has a microbiological testing program, organized and administered by the national government and that the CCA has implemented generic *E. coli* and *Salmonella* sampling and testing programs to verify their system. FSIS analysis and audit verification activities of Ireland's microbiological testing program as designed and implemented indicated that the CCA continues to demonstrate the ability to meet the equivalence requirements for this component that are articulated by the FSIS import regulations (9 CFR 327.2). Therefore, FSIS determined that the Ireland's microbiological testing program supports that the CCA operates at an "average" level of performance as pertains to this component.

X. CONCLUSIONS AND NEXT STEPS

The audit results indicate that Ireland's inspection system is performing at an "adequate" level in maintaining its equivalence based on POE and audit findings. An analysis of POE findings revealed no food safety violations since the last FSIS audit in 2008. Ireland is showing good process control for products that it exports to the United States. All corrective actions related to the last audit have been effectively implemented. The CCA met the core criteria for all six equivalence components; however there is some need for improvement of oversight related to sanitation recordkeeping, the documentation of inspection verification activities, and post-mortem final disposition procedures. The onsite audit findings are summarized below and further described in the respective sections of the report:

- The CCA's in-plant supervisory inspection personnel informed the FSIS auditor that final post-mortem disposition procedures for retained carcasses were not being followed. In both establishments, the condemned viscera of retained carcasses were being immediately discarded after their initial inspection and were unavailable for final veterinary review.

- The CCA's inspection personnel were not documenting Sanitation Standard Operating Procedures (SSOP) inspection noncompliances in either establishment if the pre-operational and operational procedures noncompliances were corrected immediately.

The CCA already began to address the identified audit observations by implementing immediate corrective actions to prevent short-term and long-term recurrence of these problems. After receipt and review of the CCA's proposed corrective actions, FSIS will evaluate the effectiveness of the corrective actions.

APPENDICES

APPENDIX A: Individual Foreign Establishment Audit Checklist

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Rosderra Irish Meats Group Ltd. Carrig Roscrea, Co Tipperary (South-West Regional Office)	2. AUDIT DATE 9/18/12	3. ESTABLISHMENT NO. 355	4. NAME OF COUNTRY Ireland
	5. NAME OF AUDITOR(S) Kenneth E. Witek		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.	X	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	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	X
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

10/13/ 51 The FSIS auditor observed that during the shadowing of CCA's pre-operational inspection verification activities that inspectors were proficient in conducting verification and enforcement activities related to sanitation for non-compliances identified. The inspection verification was methodical in its approach and execution. The Official Auxiliaries (OA) identified several insanitary issues and promptly rejected the line area by affixing a Detention Tag on the line. Issues identified included: meat product residues from the previous day's production on two plastic interlock conveyors in the cutting room that carries exposed product, blue plastic caught in rollers of the belt, residue on the wall adjacent to the line. However, a review of documentation and through interviews it was determined that the CCA's inspection personnel were not documenting Sanitation Standard Operating Procedures (SSOP) inspection verification noncompliances identified during pre-operational and operational verification procedures when noncompliances were corrected immediately and documented by the establishment. Inspection personnel do not issue official noncompliance records or any written documentation to the establishments when noncompliances were identified in these situations. Inspection personnel only verbally informed the establishment of the noncompliance for these issues. Only noncompliances that could not be corrected immediately or had an imminent food safety concern were documented on a CAR. That CAR report was then only shown to the establishment to address corrective actions.

The verification of documented SSOP verification activities and supervisory reviews indicates that inspection personnel do conduct these activities following CCA protocols for verification. The FSIS auditor identified that there is evidence that all parts of 9 CFR 416.15 governing sanitation corrective actions were addressed through the review of documentation in the establishments' SSOP records; however, there was not consistent documentation that inspection personnel verified these actions.

The CCA informed the FSIS auditor during the exit conference that inspection personnel were instructed to properly document all noncompliances identified and to verify that establishments addressed and documented all aspects of corrective actions either in their sanitation verification records or in documentation provided to inspection personnel at the establishment.

45/51 The FSIS auditor observed that during the shadowing of CCA's pre-operational inspection verification activities that the OA failed to identify on the kill floor that the carcass splitting saw sterilizer's metal had been torn apart and would not adequately contain the water needed to sterilize the saw. Additionally the OA failed to identify that the condition of several white lugs were severely cracked, rendering them unusable. Appropriate enforcement actions were taken by the OA including the verification of establishment's corrective actions.

51/55 Post-Mortem Inspection: Although the auditor verified that proper presentation and identification of swine carcasses and parts were being implemented, the FSIS auditor identified the following deficiency concerning procedures for post-mortem inspection final veterinary disposition.

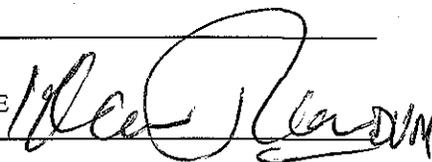
During an interview conducted by the FSIS auditor with the CCA's supervisory inspection personnel at establishments 355, it was conveyed to the auditor that during post-mortem inspection when a swine carcass is retained for pathological conditions the viscera are not retained along with the carcass that requires final veterinary disposition, but rather, that the viscera are condemned immediately. This procedure which was not observed but if implemented as stated by the Veterinary Inspector In-charge (VIC) does not provide the official veterinarian the opportunity to conduct a thorough disposition of the retained carcasses with the corresponding viscera and does not follow procedures determined equivalent by FSIS for final post-mortem disposition.

This procedure as stated by the establishment VIC and implemented at the local level by the CCA does not meet the requirements articulated by *EC 853 – ANNEX III, Section 1, Chapter IV, 13*, which requires that until post-mortem inspection is completed, parts of a slaughtered animal subject to such inspection must remain identifiable as belonging to a given carcass and that was determined by FSIS to be equivalent to *FSIS Regulation 9 CFR 310.3*. The CCA was not able to provide an explanation as to why procedures outlined in the references stated were not followed by local inspection staff but stated that this procedure was inconsistent with both the CCA's expectation as well as EU requirements. However, inspection personnel were immediately instructed to implement the policy outlined in *EC 853 – ANNEX III, Section 1, Chapter IV, 13*.

61. NAME OF AUDITOR

Kenneth E. Witek

62. AUDITOR SIGNATURE AND DATE

for 

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Rosderra Irish Meats Group Ltd. Carrick Edenderry, Co Offaly (Eastern Regional Office)	2. AUDIT DATE 9/20/12	3. ESTABLISHMENT NO. 356	4. NAME OF COUNTRY Ireland
	5. NAME OF AUDITOR(S) Kenneth E. Witek		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
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8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	X	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	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	X
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

13/51 The FSIS auditor observed that during the shadowing of CCA's operational inspection verification activities that inspectors were proficient in conducting verification and enforcement activities related to sanitation for non-compliances identified. However, a review of documentation and through interviews it was determined that the CCA's inspection personnel were not documenting Sanitation Standard Operating Procedures (SSOP) inspection verification noncompliances identified during pre-operational and operational verification procedures when noncompliances were corrected immediately and documented by the establishment. Inspection personnel do not issue official noncompliance records or any written documentation to the establishments when noncompliances were identified in these situations. Inspection personnel only verbally informed the establishment of the noncompliance for these issues. Only noncompliances that could not be corrected immediately or had an imminent food safety concern were documented on a CAR. That CAR report was then only shown to the establishment to address corrective actions.

The verification of documented SSOP verification activities and supervisory reviews indicates that inspection personnel do conduct these activities following CCA protocols for verification. The FSIS auditor identified that there is evidence that all parts of 9 CFR 416.15 governing sanitation corrective actions were addressed through the review of documentation in the establishments' SSOP records; however, there was not consistent documentation that inspection personnel verified these actions.

The CCA informed the FSIS auditor during the exit conference that inspection personnel were instructed to properly document all noncompliances identified and to verify that establishments addressed and documented all aspects of corrective actions either in their sanitation verification records or in documentation provided to inspection personnel at the establishment.

41/51 The FSIS auditor observed that during the shadowing of CCA's operational inspection verification activities CCA inspection personnel identified several noncompliances and took the appropriate enforcement action. However, during inspection verification task inspection failed to identify condensation in the Boning Hall along the air refrigeration units near the Lion Spitting line and Sort Pack line in addition to other areas of the ceiling in the room. The auditor identified the deficiency to the RSVI of the establishment who took immediate enforcement action, which ultimately cause production in the room to be halted and all products was placed on hold pending further investigation. After the establishment completed corrective actions, the auditor verified that the RSVI and VI verified actions taken by the establishment.

Ultimately, the RSVI and VI release the area for production after verifying immediate corrective action. All food contact surfaces were cleaned and sanitized prior to resumption of production. The RSVI determined that even though there was no evidence of condensation dripping over product or food contact surfaces that exposed product in areas where condensation was observed was risk assessed and considered a high risk of contamination due to the proximity to the affected refrigeration units. The product was directed to by-product – Category 2 as per EU Reg. 1069/2009.

The RSVI notified the auditor that he was issuing a Compliance Notice "A" to the establishment do to the nature of the issue, and inadequate corrective actions taken couple with production being stopped by the CCA for three (3) hours. The CCA presented the FSIS auditor with a copy of the Compliance Notice "A" that included the noncompliance, immediate corrective action taken and measure implemented to prevent the non-compliance from happening again, meeting all parts of 9 CFR 416.15 at the Audit Exit Conference on September 25, 2012.

51/55 Post-Mortem Inspection: Although the auditor verified that proper presentation and identification of swine carcasses and parts were being implemented, the FSIS auditor identified the following deficiency concerning procedures for post-mortem inspection final veterinary disposition.

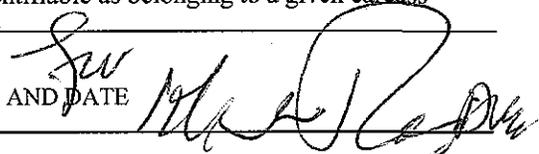
During an interview conducted by the FSIS auditor with the CCA's supervisory inspection personnel at establishment 356, it was conveyed to the auditor that during post-mortem inspection when a swine carcass is retained for pathological conditions the viscera are not retained along with the carcass that requires final veterinary disposition, but rather, that the viscera are condemned immediately. This procedure which was not observed but if implemented as stated by the Veterinary Inspector In-charge (VIC) does not provide the official veterinarian the opportunity to conduct a thorough disposition of the retained carcasses with the corresponding viscera and does not follow procedures determined equivalent by FSIS for final post-mortem disposition.

This procedure as stated by the establishment VIC and implemented at the local level by the CCA does not meet the requirements articulated by EC 853 – ANNEX III, Section 1, Chapter IV, 13, which requires that until post-mortem inspection is completed, parts of a slaughtered animal subject to such inspection must remain identifiable as belonging to a given carcass

61. NAME OF AUDITOR

Kenneth E. Witek

62. AUDITOR SIGNATURE AND DATE



60. Observation of the Establishment

and that was determined by FSIS to be equivalent to *FSIS Regulation 9 CFR 310.3*. The CCA was not able to provide an explanation as to why procedures outlined in the references stated were not followed by local inspection staff but stated that this procedure was inconsistent with both the CCA's expectation as well as EU requirements. However, inspection personnel were immediately instructed to implement the policy outlined in *EC 853 – ANNEX III, Section 1, Chapter IV, 13*.

61. NAME OF AUDITOR

Kenneth E. Witek

62. AUDITOR SIGNATURE AND DATE

10/12/02
KW

APPENDIX B: Foreign Country Response to Draft Final Audit Report



Department of
**Agriculture,
Food and the Marine**
An Roinn
**Talmhaíochta,
Bia agus Mara**

12 August 2014

Dr. Shaukat H. Syed
Director
International Audit Staff
Office of Investigation, Enforcement and Audit
Food Safety Inspection Service Unit
United States Department of Agriculture
Food Safety Inspection Service
1400 Independence Avenue, SW
Washington, D.C.
20250
United States of America

Dear Dr. Syed

Thank you for your letter dated 17th July 2014 enclosing the final draft report of the on-site audit of the Republic of Ireland's meat inspection system conducted from 12th September to 25th September 2012.

I would like to take this opportunity to compliment and thank you and your colleagues for the thorough and professional manner in which the audit was conducted.

I am enclosing a table of responses to the main findings of the audit report for your information.

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.

We look forward to further audit of our inspection system in the future.

Yours sincerely

P.P.
Martin Blake
Chief Veterinary Officer

Response to findings of 2012 USDA audit

USDA Finding	Proposal	Status
<p>The CCA's in-plant supervisory inspection personnel informed the FSIS auditor that final post-mortem disposition procedures for retained carcasses were not been followed.</p> <p>In both establishments, the condemned viscera of detained carcasses were being immediately discarded after their initial inspection and were unavailable for final veterinary review.</p>	<p>In plant supervisory personnel informed the auditor that the viscera of detained carcasses are not retained along with the carcass for final veterinary disposition given all parts of the animal, including the viscera, undergo veterinary inspection conducted by an official veterinarian (OV) (Note: post mortem in Ireland is conducted by Veterinarians)</p> <p>In the situation referred to in the audit report the viscera of all carcasses undergo full veterinary inspection by an OV. For those carcasses that are detained for reasons which might reasonably lead to condemnation of the carcass (pathological findings, lack of identification) the viscera are excluded from the food chain (condemned). This procedure ensures that viscera derived from condemned carcasses do not enter the food chain. It is the opinion of DAFM that this system achieves the same level of public health protection as would be achieved by holding the viscera from detained carcasses separately.</p>	<p>Post mortem of all body parts carried out by Veterinarians.</p>
<p>The CCA inspection personnel were not documenting Sanitation Standard Operating Procedures (SSOP) inspection non-compliances in either establishment if the pre-operational and operational procedures non-compliances were corrected immediately.</p>	<p>Since the 2012 audit non compliances that are corrected immediately are now noted on the FBO's documentation. The QC staff checks and verifies that the noncompliance is corrected and then presents it to inspection personnel for their verification and sign-off.</p> <p>In addition to this procedural change, with respect to immediate correction of non-compliances, DAFM have modified the procedure surrounding the issuance of corrective action reports (CARs). The OV now only lists the non compliances found and then presents these to the FBO to document their corrective actions with the appropriate timescales for agreement. These corrective actions are then verified/closed out by inspection personnel. As part of the close out procedure supporting documentation must be provided by the FBO and this is now also retained on the enforcement file.</p>	<p>Completed and verified</p>