USDA

United States Department of Agriculture

Food Safety and
Inspection Service

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MAR 2 1 2016

Mr. Martin Blake
Chief Veterinary Officer
Department of Agriculture, Food, and the 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 16 through October 1, 2015. Enclosed is a copy of the final audit report. The comments received from the Government of Ireland are included as an attachment to the report.

For technical questions regarding the FSIS audit report, please contact Mr. Vincent Fayne, Acting Director of the International Audit Staff with the Office of Investigation, Enforcement and Audit (OIEA) at (202) 690-5662, or by electronic mail at international.audit@fsis.usda.gov.

If you have any other questions, please feel free to contact me directly.

Sincerely,

Jane H. Doherty

Jane H. Doherty
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

IRELAND

SEPTEMBER 16 TO OCTOBER 1, 2015

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

MEAT PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from September 16 to October 1, 2015. The purpose of the audit was to determine whether Ireland's food safety system governing meat products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and accurately labeled and packaged. Ireland is eligible to export raw intact beef and raw pork to the United States. In December 2014, Ireland was reinstated to export raw beef products to the United States. Products presently received at Point-of-Entry consist primarily of boneless beef sub-primals, primals, and pork ribs.

The audit focused on six system equivalence components: Government Oversight (Organization and Administration), Statutory Authority and Food Safety Regulations (Inspection System Operation and Product Standards), Sanitation, Hazard Analysis and Critical Control Points (HACCP) Systems, Government Chemical Residue Control Programs, and Government Microbiological Testing Programs.

The audit findings showed a need for improvement in Government Oversight, Sanitation, HACCP Systems, and Government Microbiological Testing activities. In particular:

- Two of the audited swine establishments presented slaughter-line installations that did not provide for sanitization of the post-mortem viscera pans as required by the United States equivalence requirements as outlined in EC Regulation 853/2004, Annex III, Chapter II (*Requirements for slaughterhouses*).
- In some instances, veterinary post-mortem inspectors were not following the documented post-mortem inspection procedures.
- Three of the five slaughter establishments had deficiencies related to inadequate monitoring and documentation of their critical control points which the Central Competent Authority (CCA) did not observe until pointed out by the FSIS auditor.
- Three of the five slaughter establishments presented deficiencies related to the implementation of generic *Escherichia coli* (*E. coli)* sampling and testing requirements prescribed in Ireland's *Guideline on USDA Approval*.

During the audit exit meeting, the CCA was made aware of all the FSIS concerns and the CCA noted that it has already begun to address the audit findings by implementing immediate corrective actions. FSIS received a written response from the CCA addressing all outstanding concerns within 60 days of communication of the draft final audit report.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of Ireland's food safety system from September 16 to October 1, 2015. The audit began with an entrance meeting held on September 16, 2015, in Dublin, Ireland with representatives from the Central Competent Authority (CCA) – The Department of Agriculture, Food, and the Marine (DAFM) and two FSIS auditors.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to ensure the food safety system governing meat products maintains equivalence to that of the United States, with the ability to export products that are is safe, wholesome, and correctly labeled and packaged.

FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, Point-of-Entry (POE) testing results, and specific oversight activities and testing capacities of government offices and laboratories. The review process also included an analysis of data collected by FSIS over a three-year timeframe, in addition to information obtained directly from the CCA through the foreign inspection system's Self Reporting Tool (SRT).

CCA representatives accompanied the FSIS auditors throughout the entire audit. FSIS evaluated Ireland's inspection system according to six equivalence components: (1) Government Oversight (Organization and Administration), (2) Statutory Authority and Food Safety Regulations (Inspection System Operation and Product Standards), (3) Sanitation, (4) Hazard Analysis and Critical Control Points (HACCP) Systems, (5) Government Chemical Residues Testing Programs, and (6) Government Microbiological Testing Programs.

The auditors reviewed administrative functions at CCA headquarters, one regional office, and five local inspection offices. During the review, the auditors evaluated the implementation of management control systems in place, which ensure that the national system of inspection, verification, and enforcement is being implemented as intended. The FSIS auditors also verified that corrective actions related to the previous 2014 FSIS audit had been effectively implemented.

A sample of five establishments was selected from a total of nine establishments currently certified to export to the United States. During the establishment visits, particular attention was paid to the extent to which industry and government interact to control hazards and prevent non-compliances that threaten food safety, with an emphasis on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with 9 CFR 327.2.

The auditors reviewed one private laboratory and one government laboratory to verify the ability to provide adequate technical support to the inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	DAFM Headquarters, Dublin
	Regional	1	Southern Regional Office, Cork
Laboratories		2	• Veterinary Public Health Regulatory Laboratory (VPHRL), Backweston (Residue and Microbiology) – Government Laboratory • Advanced Micro Services & Environmental Laboratories Ltd, Clonmel (Microbiology) – Private Laboratory
Establishments		5	• Two (2) bovine slaughter and processing establishments • Three (3) porcine slaughter and processing establishments

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 Humane Methods of Livestock Slaughter Act (7 U.S.C. Title 7), and
- The Food Safety and Inspection Service Regulations for Imported Meat (9 CFR Part 327).

In addition, auditors verified that the system implemented and enforced United States equivalent European Commission (EC) regulations and directives:

- EC Regulations 852/2004; 853/2004; 854/2004; 882/2004, and
- Council Directives found equivalent under the Veterinary Equivalence agreement (VEA), 96-22 and 96-23.

The audit standards applied during the review of Ireland's inspection system for meat products included: (1) All applicable legislation originally determined by FSIS as equivalent during the initial review process, and (2) any subsequent equivalence determinations that FSIS made under provisions of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures.

Currently, FSIS has the following equivalence determinations in place for Ireland :

- Generic *Escherichia coli* (*E. coli*):
  - As applicable to all European Union exporting countries, testing for *Enterobacteriaceae* and Total Viable Count (TVC) in raw product may be substituted for generic *E. coli* testing.

- *Salmonella* testing: Establishment personnel take samples:
  - CCA must have documented plan for sample collection and handling procedures implemented in all United States certified export establishments.
  - Veterinary inspector provides direct supervision over establishment sample collection and handling activity to ensure compliance.
  - Veterinary inspector collects test results to monitor establishment performance over time.

- Veterinary inspector takes immediate enforcement action whenever an establishment fails to meet a *Salmonella* performance standard.

- Private laboratories analyze samples:
  - Private laboratories must be approved and audited by DAFM's Veterinary Public Health Regulatory Laboratory before participating in the *Salmonella* testing program. Ongoing oversight of private laboratories is performed by personnel at the Veterinary Public Health Regulatory Laboratory.
  - Private laboratories maintain competent, professionally trained personnel, suitable facilities and equipment, a documented quality assurance program, and records and reporting system.
  - Private laboratories report test results directly to the veterinary inspector.
- Export of raw intact beef:
  - Certified establishments maintain verifiable intended use controls as part of their HACCP plans to ensure the intact end use of exported raw, intact beef.

III. BACKGROUND

Ireland is eligible to export raw intact beef and raw pork to the United States, with products presently received at POE consisting primarily of boneless beef sub-primals, primals, and pork ribs. An analysis of data from October 1, 2012 to May 30, 2015, showed that FSIS import inspectors performed 100% re-inspection on labeling and certification on 27,591,291 pounds of meat products imported from Ireland. FSIS performed additional types of inspection (TOI) on 4,725,753 pounds at POE with a total of 10,263 pounds (.2%) rejected, predominately for non-food safety reasons (e.g., shipping damage).

The FSIS final audit reports for Ireland's food safety system are available on the FSIS' website at:
http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (ORGANIZATION AND ADMINISTRATION)

The first of six equivalence components that the auditors reviewed was Government Oversight. FSIS import regulations require the foreign inspection system to be organized by the national government in a manner to provide ultimate control and supervision over all official inspection activities; ensure the uniform enforcement of requisite laws; provide sufficient administrative technical support; and assign competent qualified inspection personnel at establishments where products are prepared for export to the United States. The verification of this component was based on information previously submitted in the SRT, in addition to on-site record reviews, interviews, and observations.

The FSIS auditors assessed the extent to which Ireland's meat inspection system is organized and administered by the government of Ireland and confirmed an organizational framework in line with the *National Control Plan for Ireland*, which is renewed every five years as per *EC Regulation 882/2004*. This plan outlines the structure and organization of control systems for

food, feed, plant health, animal health, and animal welfare. Specifically, the Food Safety Authority of Ireland (FSAI) maintains overarching authority over the nation's food supply; however, it delegates that authority to subordinate agencies to exercise official food inspection controls. In Ireland, DAFM is responsible for ensuring the safety of animal-based food products and has the authority to promulgate food inspection regulations, and enforce food safety laws and regulations.

Ireland organizes its meat inspection system on 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 (SVO) are based in the Agriculture House headquarters. The SVO team consists of a Deputy CVO and two Senior Superintending Veterinary Inspectors (SSVI) supervising a team of Superintending Veterinary Inspectors (SVI). 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 includes six Regional Veterinary Public Health Inspectorates (East, North East, North West, Mid West, South East, and South West). Each regional office is supervised by a Regional Superintending Veterinary Inspector (RSVI) who oversees the implementation of veterinary inspection controls in the meat establishments in their jurisdiction and reports directly to headquarters.

The third level is comprised of DAFM 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 (TVI) and Technical Agricultural Officers (TAO).

The RSVI and the VI assess the eligibility of establishments to export to the United States. They have the authority, under *EC Regulation 178/2002* and *National Legislation S.I. No. 432 of 2009*, to enforce the necessary requirements to export to another country. Their duties also include initiating investigations into the failure of an establishment to meet the standards of the importing country and to provide documentation to the CCA to support delisting 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.

The CCA has an approval process in place (*GN USDA-1: Guideline on USDA Approval, Version 5*) for the certification of establishments and is the only body with authority to certify and decertify establishments for export to the United States. Once the CCA verifies that an establishment has fulfilled all official EC requirements and the United States special conditions for equivalence, the CCA approves and adds it to the list of eligible establishments certified by Ireland to export meat to the United States. The CCA notifies the establishment in writing prior to it being granted certification to export. While on-site, the FSIS auditors reviewed documents specifically associated for the approval process of two establishments that were newly certified for export to the United States (establishments EC 533, EC 296). This review indicated that the

above-referenced approval process was implemented as intended at these facilities. However, the FSIS auditors identified the following:

- Two of the audited swine establishments presented slaughter-line installations that did not provide for sanitization of post-mortem viscera pans with 82° C water. This does not meet the approved United States equivalence requirements as outlined in EC Regulation 853/2004, Annex III, Chapter II (*Requirements for slaughterhouses*), and thereby represents a need for DAFM to revisit its establishment approval process. As Ireland is not currently exporting offal to the United States, FSIS requests the certification of offal continue to be withheld until DAFM provides evidence that this issue is resolved on a system-wide basis.

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

Inspection personnel assigned to the establishments certified to export meat to the U.S. are government paid personnel falling into three categories: a) salaried, permanent VPHIS inspectors (VI), b) Temporary Veterinary Inspectors (TVI) serving as contractors to the CCA, and c) salaried, permanent Technical Agricultural Officers (TAO). Each category of inspector receives no payment from either industry groups or establishment management. The CCA is responsible for the initial hiring, training, and payment of inspection personnel. The FSIS auditors verified through a review of letters of appointment and CCA payroll records that payment of inspection personnel salaries was made by a government-servicing agency.

As per 9 CFR 327.2 (a) (2) (D), FSIS requires that final carcass dispositions and certification of product intended for export to the United States be performed by government inspectors. Within Ireland, TVIs are veterinary practitioners engaged by the DAFM on a part-time basis to assist the VIs in slaughter plants with ante-mortem and post-mortem inspection as required. While on-site, the FSIS auditors noted that these are the individuals primarily responsible for conducting final carcass dispositions. All TVIs are contracted by DAFM and paid from the exchequer, as are permanent VIs of DAFM. However, a significant difference between these two groups is that DAFM does not consider TVIs to be employees of their system but rather classifies them as contractors independent of industry, reporting directly to the DAFM VI.

The CCA disseminates information throughout all levels of inspection personnel (government offices, establishments, and laboratories) pertaining to regulatory and administrative affairs, and maintaining current information concerning export requirements. All policy updates received from FSIS are posted to DAFM's intranet site and distributed by email to inspection personnel. Additionally, all inspection personnel receive email instructions to register on the FSIS website for relevant updates. The FSIS auditors verified through the review of supporting documentation provided by DAFM that the CCA maintains a communication system to convey requirements related to United States export 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 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, 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 and provided through the regional staff.

Overall, the audit findings indicated a need for improvement in oversight related to the establishment approval process and enforcement of basic Sanitation and HACCP requirements.

V. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS (INSPECTION SYSTEM OPERATION AND PRODUCT STANDARDS)

The second of six equivalence components that the FSIS auditors reviewed was Statutory Authority and Food Safety Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of carcasses and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; daily inspection; periodic supervisory visits to official establishments; and requirements for thermally processed/commercially sterile products. The verification of this component was based on information previously submitted in the SRT, interviews with government officials, and observations made by the FSIS auditors while on-site.

In accordance with *EC Regulation 882/2004* and *SI 432 of 2009*, DAFM undertakes an annual food safety assessment of all approved plants to determine the frequency of periodic supervisory veterinary inspection reviews to be performed at each plant in a given year. Based on this assessment, regional supervisors carry out annual, semi-annual, or quarterly reviews. During the audit, FSIS verified that supervisory personnel had documented outcomes of periodic reviews for each of the establishments audited, in addition to two newly certified establishments (establishments EC 533, EC 296) that FSIS did not perform on-site visits, because of the low volume of products the establishments export. No concerns arose from the review of these documents.

The FSIS auditors verified that in-plant veterinarians (typically TVIs) conducted ante-mortem inspection on the day of slaughter by reviewing the incoming registration and identification documents that allow the traceability of the animal to its source. This included accompanying "passports" used for age determination and associated with SRM control in cattle. In accordance with procedures and requirements, the official veterinarians observed all animals at rest and in motion to determine whether they are fit for slaughter. Each establishment had a designated observation pen for further examination of suspect animals. The auditors noted that all animals had access to water in all holding pens, and that animals held overnight were fed accordingly. As per its *USDA Notification/ Informational Update (January 2012)*, Ireland has adopted a zero tolerance policy against the slaughter of non-ambulatory disabled cattle. FSIS concluded that food business operators were effectively implementing their documented procedures to preclude

non-ambulatory disabled cattle from entering the facility and being slaughtered for human consumption at the two bovine establishments visited.

The FSIS auditors also verified implementation of corrective actions related to the previous FSIS audit, during which the auditor noted that incomplete documentation of animal welfare controls on the *Protection of Animals at Time of Slaughter* (PAT) was occurring. To address this finding, DAFM had issued a revised PAT form and accompanying instructions to its field personnel. The current review indicated that these new forms were being completed as intended.

FSIS assessed post-mortem inspection examinations through on-site record reviews, interviews, and observations of inspection activities in the five slaughter establishments. The FSIS auditors observed that, for the most part, proper presentation, inspection, and disposition of carcasses were being implemented. However, the following deficiency was identified at two of the three swine slaughter facilities audited.

- Veterinary post-mortem inspectors (TVIs) were not following the procedures outlined in *Regulation (EC) No 854/2004, Section IV* (determined equivalent by FSIS). The following elements were omitted during the auditor's observation of post-mortem inspection activities:
  - Palpation of bronchial and mediastinal lymph nodes,
  - Palpation of the liver and its lymph nodes, and
  - Palpation of the gastric and mesenteric lymph nodes.

  In addition, the FSIS auditors reviewed the most recent performance assessments documented on FORM OCPME (pig): *Evaluation of Post-mortem Official Controls in accordance with Regulation (EC) 854/2004 Annex 1*) for the TVIs in question. In both cases, the documentation indicated that the individuals were able to perform post-mortem inspection procedures correctly at the time the assessment was conducted. Consequently, this indicates a need for greater surveillance on the part of the VI (on daily basis) and supervising veterinarians (during their period reviews) to ensure that that post-mortem inspection procedures are conducted as expected.

  During the exit meeting, the FSIS auditors were informed that the DAFM had followed its established procedures for dealing with inadequate performance, including (for each establishment):
  1. Immediately removing and replacing the TVI at the viscera inspection station,
  2. Issuing official notification (*Clause 1.6 Notification Under the Conditions or Engagement for Temporary Veterinary Inspectors*) that proper inspection procedures were not being conducted,
  3. Retraining, and
  4. Reassessing performance.

There are no other regulatory changes associated with the export of meat products to the United States since the last audit that would have required changes by the CCA. The auditors verified that Ireland's meat inspection system continues to maintain the legal authority and a regulatory framework to implement requirements equivalent to those governing meat inspection in the United States, although there was some need for improvement of oversight related to post-

mortem inspection procedures. While FSIS considers the immediate measures to address these deficiencies appropriate, the audit identified a need for greater surveillance on the part of DAFM officials to ensure that post-mortem inspection procedures are conducted as expected.

VI. COMPONENT THREE: SANITATION

The third of the six equivalence components that the FSIS auditors 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 for the development and implementation of Sanitation Standard Operating Procedures (SSOP). The FSIS auditors' verification of this component was based on SRT responses, review of records at government offices in the establishments, and observations at the five meat slaughter and processing establishments audited.

The FSIS auditors verified that the CCA requires each official establishment to develop, implement, and maintain written standard operating procedures to prevent direct product contamination or insanitary conditions. An assessment of CCA regulatory oversight and establishment compliance was conducted in accordance with: *FSMS SOP 006/2008 ANNEX IV, HACCP Pre-Requisites (HPR) 1, 2* and related *Guidance Note*.

The FSIS auditors reviewed sanitation plans and records related to the design and implementation of sanitation programs at five slaughter and processing establishments certified for export to the United States. The FSIS auditors observed pre-operational sanitation at one establishment by shadowing and observing the VI conduct pre-operational sanitation verification inspection. The auditors also reviewed the establishment's sanitation monitoring and corresponding inspection verification records and noted that the records mirrored the actual sanitary conditions of the establishment. The audited establishment maintained sanitation records sufficient to document the implementation and monitoring of the SSOPs and any associated corrective actions. The establishment employees responsible for the implementation and monitoring of SSOP procedures authenticated these records as directed by *Food Safety Management System SOP 006/2008*.

The FSIS auditors also reported the following findings concerning the CCA's ability to exercise official controls for sanitary operations:

- At one beef slaughter facility, the lighting at the lower range of the mobile stand (corresponding to the carcass forequarter) where government verification of the zero-tolerance CCP occurs was insufficient. The lighting in the area was 520 lux, rather than the 540 lux outlined in Ireland's meat inspection requirements.
- At two of three swine slaughter establishments audited, post-mortem viscera pans were not routinely sanitized with 82° C water. This condition does not meet the approved United States equivalence requirements as outlined in *EC Regulation 853/2004, Annex III, Chapter II* (*Requirements for slaughterhouses*). The significance of this finding is related to the potential for cross-contamination between clean and unwholesome viscera (e.g., presenting feces or other pathological material), either by coming into contact with the previously-used unsanitized surface of the pan, or through manual manipulation of the viscera occurring during post-mortem inspection.

FSIS' ongoing assessment of Ireland's inspection system indicated that it maintains clearly defined requirements and controls that meet the core equivalence requirements for this component; however, there is a need to improve sanitation verification and enforcement activity. At the audit exit conference, DAFM provided the FSIS auditors with evidence that the deficiency related to lighting had been corrected, although resolution regarding sterilization of viscera pans was still pending.

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

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

Ireland's meat inspection system follows EU requirements for United States-eligible establishments, Regulation *854/2004/EC and 852/2004/EC*, where HACCP regulatory requirements are prescribed and found equivalent to 9 CFR Part 417. These requirements are applied in Ireland under *Statutory Instrument 432 of 2009: European Communities (Food and Feed Hygiene) Regulations*, as amended.

The FSIS auditors evaluated the design and verified the implementation of HACCP programs at the five establishments according to the CCA's "*Guideline on USDA Approval*." All audited establishments had developed, implemented, and maintained a HACCP plan for products eligible to be certified for United States export to ensure that the requirements equivalent to *9 CFR 417.1-417.7* are met as required to remain equivalent.

The FSIS auditors noted that both beef slaughter establishments proposed for United States export certification maintained written SOPs and verification records for SRM removal in accordance with *EC Regulation 999/2001*, requiring the removal of SRM material and its disposal as inedible product during beef slaughter operations. The auditors verified that CCA inspection personnel documented SRM removal in *Specified Risk Material Checks* reports as instructed in *SOP 4/2007, Rev. 2, Definition, Handling and Harvesting of Specified Risk Materials (SRM) in Cattle*. Ireland is currently exporting only boneless beef to the United States.

The FSIS auditors verified through record review and on-site observations that the in-plant inspection personnel conducted and documented official daily verification activities related to HACCP systems 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*." This encompasses the evaluation of written HACCP programs and verification of HACCP pre-requisites and plan monitoring, corrective actions, and record-keeping in accordance with *EC Regulation 852/2004* and *9 CFR 417.8*. Furthermore, supervisory reviews (Supervisory Veterinary Inspector audits) of HACCP verification activities by inspection personnel were, for the most part, well-documented. However, the findings related to the CCP for zero tolerance, outlined below, indicate a need for the CCA to improve its HACCP verification activities.

The FSIS auditors reviewed zero tolerance (e.g., feces, ingesta, and milk) CCP records and noted that all five establishments were conducting 100% monitoring. The auditors also verified the physical CCP locations by observing inspection personnel conducting HACCP hands-on verification activities. They also performed an independent direct monitoring examination of beef carcasses and verified that sanitary dressing procedures were conducted in accordance with *Article 4 of EC Regulation 854/2004* and documented by inspectors on the *Slaughtering/Cutting Plant Operational Checks Report* and *Carcass Hygiene Record*. However, deficiencies related to correct implementation of this CCP were identified at three of five slaughter establishments audited:

- At one establishment, monitoring did not routinely include the time when deviations of the CCP occurred.
- At one establishment, the number of carcasses that should be verified through "direct observation of monitoring" procedures was not specified.
- At two establishments, documentation of corrective actions taken in response to deviations from the CCP was general in nature, especially with regards to the portion addressing measures to prevent recurrence. These establishments were using a series of codes such as "1. Talked with operator," rather than including specific details as to what was discussed or what other actions were taken for each particular event.

As outlined in *VPN 10/2014, Official Verification Program for Testing for Verotoxigenic Escherichia coli*, Ireland requires that establishments exporting raw intact beef to the United States conduct random sampling and testing of carcasses for *E. coli* O157:H7 at a minimum of four times a week (carcasses are detained pending test results). Furthermore, DAFM's issuance entitled *Intended Use of Intact Raw Beef being Exported from Ireland to the United States of America,* states that food business operators are required to put in place documented procedures, including (a) a hazard analysis and flowchart demonstrating that raw beef destined to be exported to the United States is intended only for inclusion as intact product at the recipient's premises; and (b) controls that ensure that the product is used as intended, including *letters of guarantee* from the United States purchaser. The FSIS auditors' on-site review of production records verified that these requirements were met at the two beef establishments visited. The auditors further noted that no positives for *E. coli* O157:H7 were identified in either establishment's carcass testing history.

The on-site audit identified procedural weaknesses concerning government enforcement of basic HACCP requirements in this area. During the exit meeting, DAFM had presented evidence that they had taken immediate measures to resolve the weaknesses identified at the three facilities mentioned above, including issuance of Non-compliance Reports (NCR) and verification that food business operators had modified their HACCP programs accordingly. FSIS requests that DAFM provide a description of long-term measures taken to improve the manner in which in-plant officials verify the implementation of establishment HACCP systems.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth of six equivalence components that the FSIS auditors reviewed was Chemical Residues. The inspection system is to present a chemical residue control program, organized and administered by the national government, including random sampling of internal organs, fat, and muscle of carcasses for chemical residues identified by the exporting country's meat inspection authorities or by FSIS as potential contaminants.

As required by equivalent provisions outlined in *EC Directive 96/23, Measures to Monitor Certain Substances and Residues Thereof in Live Animals and Animal Products,* DAFM publishes and implements an annual *National Residue Testing Plan* for Ireland. FSIS' residue experts thoroughly reviewed the 2015 residue testing plan as well as additional SRT responses outlining the structure of Ireland's chemical testing program. There have not been any POE violations related to this component since the last FSIS audit.

Under Ireland's residue control program, samples are taken from live animals and slaughter plants on a *random basis* and also "*on suspicion*."

1. *Random sampling* takes place at various sampling points as documented in the National Residue Plan. Where a positive result is obtained following analysis at the relevant laboratory, the result is recorded by the laboratory on the official sampling and analysis form, and the form is transmitted electronically to Veterinary Medicines Section within 24 hours. Carcasses are not routinely detained during random sampling.
2. Where samples are taken "*on suspicion*," the carcass, animal, or animal product is detained at the sampling point pending the analysis results. Where a positive result is identified following analysis, the carcass, animal or animal product is immediately condemned and excluded from the food chain in the interests of public health and to safeguard consumer protection.

Positive results at slaughter establishments will lead to a follow-up investigation at the farm of origin. This inspection involves not just an examination of the cause of the particular breach but also a general review of the arrangements in place on the farm in relation to veterinary medicines, including recordkeeping. Follow-up measures are taken, including, where appropriate, restriction of farms and application of financial penalties and further legal proceedings. Positive results can result in an increased level of residue monitoring for the supplier concerned.

FSIS's review of non-compliant results for 2014-2015 identified four instances where Maximum Residue Levels (MRL) were exceeded in animals slaughtered at United States-certified establishments, as follows:

Species	Compound	Matrix	Level Found
Bovine	Anthelmintics (Closantel)	Liver	2930µg/kg (MRL 100 µg/kg)

Bovine	Antibiotic (Oxytetracycline)	Muscle	190.5µg/kg (MRL 100µg/kg)
Bovine	Antibiotics (Dihydrostreptomycin)	Muscle	21,000µg/kg (MRL 500µg/kg)
Porcine	Antibiotics (Sulfadiazine Trimethroprim)	Muscle	Sulfadiazine >200µg/kg Trimethroprim >100ug/kg (MRL 50µg/kg)

While on-site, the FSIS auditors were able to verify that the appropriate follow-up procedures were performed in all instances.

During the evaluation of ante-mortem inspection at slaughterhouses, FSIS auditors observed that government inspectors verify that all lots of animals are accompanied by documentation that discloses their origin and includes a signed declaration that attests that owners have adhered to veterinary pharmaceutical withdrawal periods. The FSIS auditors verified that the official veterinarian appropriately coordinates government sampling (typically conducted by the TAOs) in accordance with the *Veterinary Public Health Regulatory Laboratory (VPHRL) Guidance Document* to ensure chain of custody and sample integrity. A review of the sampling records maintained at the five local inspection offices audited indicated that the 2015 sampling program was being adhered to as scheduled.

The FSIS auditors conducted an on-site audit of the VPHRL, the primary laboratory providing technical support to Ireland's meat inspection system. The Irish National Accreditation Board (INAB) has accredited the laboratory as meeting the criteria of ISO/IEC 17025. The FSIS auditors verified the review of the INAB Accreditation Certificate and Scope of Accreditation issued to VPHRL. The FSIS auditors' review of the internal SOPs and on-site observations verified that sampling procedures, analytical procedures, quality assurance procedures, calibration and temperature recording, and intra-laboratory check samples for this laboratory are being properly implemented and properly documented in records.

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.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last equivalence component that the FSIS auditors reviewed was government Microbiological Testing Programs. The system is to implement certain sampling and testing programs to ensure that meat products produced for export to the United States are safe and wholesome. The verification of this component was based on information previously submitted in the SRT, in addition to on-site record reviews, interviews, and observations. There have not been any POE violations related to this component since the last FSIS audit.

In accordance with *EC Regulation 2073/2005* and *S.I. 432 of 2009*, Ireland requires establishments to test for *Enterobacteriaceae* and Total Viable Count (TVC) in raw meat product in lieu of required testing for generic *E. coli* in all slaughter establishments to show process

control, a procedure acceptable for all EU exporting countries and found equivalent by FSIS. The establishments that are certified eligible for export to the United States have the option to conduct generic *E. coli* testing if they prefer, and this was the case at all five slaughter establishments visited during the current audit.

DAFM has adopted 9 CFR 310.25 testing requirements within its *Guideline on USDA Approval* and characterizes its sampling and testing program for generic *E. coli* in raw product as one sponge sample per 300 cattle or 1,000 swine carcasses weekly, with a minimum of one sample per week. The samples are to be taken from chilled carcasses, with sample submission to an approved laboratory. Establishments are to maintain 12 months of records, including a process control chart detailing at least the last 13 results.

- The auditors observed deficiencies related to the interpretation of generic *E. coli* testing results in three of the five slaughter establishments audited.
  - Two establishments were collecting samples via the sponging method but were using m/M excision-method criteria for the interpretation of results. The United States in 9 CFR 310.25 (a) (5) (ii) states that "establishments sponging carcasses shall evaluate *E. coli* test results using statistical process control techniques."
  - One establishment was collecting samples using the sponging method and was using lower and upper control limits based on data from another establishment. The correct implementation of process control techniques includes data specific for a particular establishment, so that a true assessment can be attained.

Considering the very low test results (typically at the limits of detection) observed while reviewing the establishment records, FSIS was able to ascertain that process control was being maintained at these establishments. Nevertheless, it is FSIS' expectation that food business operators who elect to test for generic *E. coli* will interpret the testing results in accordance with 9 CFR 310.25.

Ireland has adopted FSIS performance standards for *Salmonella* for both cattle and swine outlined in 9 CFR310.25 and codified these requirements in their *Guideline on USDA Approval*. FSIS auditors verified that sampling is performed in accordance with the equivalence determination, whereby establishment employees collect the carcass samples for *Salmonella* testing under oversight of the CCA, and testing is performed in government-approved laboratories. Additionally the FSIS auditors observed the sampling technique used by establishment personnel in all audited establishments. No *Salmonella* set failures were identified at the five audited establishments within the past year.

- The auditors noted that at all establishments audited, there was no requirement for the use of security seals or other mechanisms to ensure sample integrity in association with the collection of *Salmonella* samples. Discussions with on-site DAFM personnel indicated that the sample is considered under establishment control (e.g., maintained in the establishment refrigerator) during the period of time between the completion of sample collection and dispatch. This approach represents a potential breach in the chain of sample custody/security.

One private laboratory and one government laboratory were audited to verify their ability to provide adequate microbiological testing support to the inspection system. The FSIS auditors verified that the government-approved private microbiological testing laboratory, Advanced Laboratory Testing, Ltd., was performing analyses in a manner equivalent with the FSIS testing requirements and possessed the technical capability to test product destined for the United States. *Salmonella* testing for beef carcasses is performed using the FSIS MLG 4.08 method. The FSIS auditors verified through the review of accreditation and audit reports that laboratory operations are periodically reviewed by the Food Safety Authority of Ireland (FSAI) and DAFM. The FSIS auditors identified no deficiencies in the review of these documents.

As prescribed in *VPN 10/2014, Official Verification Program for Testing for Verotoxigenic Escherichia coli*, DAFM conducts random sampling and testing of beef carcasses (via sponging) for Shiga-toxin Producing *Escherichia coli* (STEC) serogroups O157, O26, O45, O103, O104, O111, O121, and O145 at the United States-certified eligible establishments with a frequency of eight samples per month. The FSIS auditors verified that this procedure was being followed as described at the two bovine slaughter establishments audited, observing that that neither establishment presented positive results within its testing history. However, the auditors also noted that, while the stated *VPN* calls for random testing, a potential bias was introduced because of the limited operating schedule of the testing laboratory (VPHRL).

- The FSIS auditors noted that STEC sampling occurs during a single week for all establishments, e.g., with five currently-approved beef establishments, 40 samples are collected during the same week (8 samples x 5 establishments) of a particular month. Further conversations with laboratory personnel also indicated that sampling almost always occurs during the same week (e.g., week 2) of the month. Consequently, the testing does not appear to meet the "8 randomly selected carcasses per month" outlined in *VPN 10/2014, Official Verification Program for Testing for Verotoxigenic Escherichia coli.*

  This design raises concerns regarding the potential amount of prior notice afforded to establishments during government verification testing. Consequently, FSIS requests that DAFM provide additional information to explain how the current sampling protocol provides unbiased view of a month's production.

In addition to the chemical residue testing functions outlined under the previous component and its oversight of private laboratories, the primary function VPHRL is to conduct testing of sponge samples for STEC in association with the aforementioned *VPN 10/2014, Official Verification Program for Testing for Verotoxigenic Escherichia coli.*

- During the audit of both government and private laboratories, the auditors noted that procedures related to the receipt of microbiological samples did not address samples received with broken or absent security seals. FSIS expects that measures to prevent tampering with samples will be used in all testing performed in conjunction with government verification of microbiological pathogen standards.

The FSIS auditors found 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*, STEC, and *Salmonella* sampling and testing programs to verify the effectiveness of its system. While Ireland's program includes microbiological sampling requirements that are equivalent to United States standards, the auditors identified certain sampling biases and potential breaches in the chain of sample custody that may have an impact on testing activities and results.

At the audit exit meeting, DAFM provided written copies of updated procedures to address the interpretation of generic *E. coli* testing results (with instructions that statistical process control be used on plant-specific data), *Salmonella* sampling (all samples are to be maintained under government custody until shipped to the laboratory), and the use of security seals for the submission of all microbiological samples to laboratories. Consequently, the outstanding finding remaining at this time relates to potential bias introduced by the current implementation of *VPN 10/2014, Official Verification Program for Testing for Verotoxigenic Escherichia coli*. FSIS requests that DAFM provide a response this issue, as well as any other modifications made to the system concerning this component within its comments to this report.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on October 1, 2015, at DAFM headquarters in Dublin, Ireland. At this meeting, the preliminary findings from the audit were presented by the FSIS auditors. The CCA understood and accepted the findings.

The audit findings indicated a need for improvement in Government Oversight, Sanitation, HACCP Systems, and Government Microbiological Testing activities. In particular:

- Two of the audited swine establishments presented slaughter-line installations that did not provide for sanitization of the post-mortem viscera pans as required by the approved United States equivalence requirements as outlined in EC Regulation 853/2004, Annex III, Chapter II (*Requirements for slaughterhouses*).
- In some instances, veterinary post-mortem inspectors were not following the documented post-mortem inspection procedures.
- Three of the five slaughter establishments had deficiencies related to inadequate monitoring and documentation of their critical control points which the CCA did not observe until pointed out by the FSIS auditor.
- Three of the five slaughter establishments presented deficiencies related to the implementation of generic *Escherichia coli* (*E. coli)* sampling and testing requirements prescribed in Ireland's *Guideline on USDA Approval*.

During the audit exit meeting, the CCA was made aware of all the FSIS concerns and the CCA noted that it has already begun to address the audit findings by implementing immediate corrective actions. FSIS received a written response from the CCA addressing all outstanding concerns within 60 days of communication of the draft final audit report.

Appendices

Appendix A: Individual Foreign Establishment Audit Checklists

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 Grannagh	09/23/2015	332	Ireland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	A. Lauro & G. Brookhouser		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	X
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58. *Salmonella* sample collection	X
59.	

60. Observation of the Establishment

The following non-compliances were not identified by Irish inspection officials during the establishment review:

19/51. Direct observation of monitoring procedures for CCP 1 ("zero tolerance") did not specify how many carcasses should be verified.

22/51. Monitoring records for CCP1 ("zero tolerance") did not routinely include the time when deviations from the CCP occurred.

In addition, the FSIS auditor noted the following findings related to implementation of Ireland's meat inspection system:

58. There is no requirement for the use of security seals or other mechanisms to ensure sample security in association with the collection of *Salmonella* samples.

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
Rosderra Irish Meats Group Limited Carrig, Roscrea	09/28/2015	355	Ireland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	A. Lauro & G. Brookhouser		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives (Regulations)	X
57. Monthly Review	
58. *Salmonella* sampling	X
59.	

60. Observation of the Establishment

The following non-compliances were not identified by Irish inspection officials during the establishment review:

22/51. Documentation of corrective actions taken in response to deviations from CCP1 ("zero tolerance") was general nature, especially with regards to the portion addressing measures to prevent recurrence. The establishment was using a series of codes such as "1. Talked with operator," rather than including specific details as to what was discussed or what other actions were taken for each particular event.

10/51. Post-mortem viscera pans were not routinely sanitized with 82° C water.

In addition, the FSIS auditor noted the following findings related to implementation of Ireland's meat inspection system:

58. There is no requirement for the use of security seals or other mechanisms to ensure sample security in association with the collection of *Salmonella* samples.

55/56. Veterinary post-mortem inspectors were not following the procedures outlined in Regulation (EC) No 854/2004 Section IV (determined equivalent by FSIS). The following elements were omitted during observation of post-mortem (swine) inspection activities:

- palpation of the bronchial and mediastinal lymph nodes (Lnn. *bifucationes*, *eparteriales* and *mediastinales*).
- palpation of the liver and its lymph nodes
- palpation of the gastric and mesenteric lymph nodes

61. NAME OF AUDITOR

A. Lauro & G. Brookhouser

62. AUDITOR SIGNATURE AND DATE

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
Rosderra Irish Meats Group Ltd Carrick Road Edenderry	09/21/2015	356	Ireland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	A. Lauro & G. Brookhouser		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
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17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	X
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives (Regulations)	X
57. Monthly Review	
58. *Salmonella* sample collection	X
59.	

60. Observation of the Establishment

The following non-compliances were not identified by Irish inspection officials during the establishment review:

22/51. Documentation of corrective actions taken in response to deviations from CCP1 ("zero tolerance") was general nature, especially with regards to the portion addressing measures to prevent recurrence. The establishment was using a series of codes such as "1. Talked with operator," rather than including specific details as to what was discussed or what other actions were taken for each particular event.

28/51. In addition to the *Enterobacteriacea* testing conducted to assess control of the slaughter process as per EC requirements, the establishment had elected to conduct generic *E. coli* testing as outlined in 9 CFR 310.25. The establishment was collecting samples via the sponging method, and was using lower and upper control limits based on data from another establishment. The correct implementation of process control techniques includes data which is specific for a particular establishment, so that a true assessment can be attained.

10/51. Post-mortem viscera pans were not routinely sanitized with 82° C water.

In addition, the FSIS auditor noted the following findings related to implementation of Ireland's meat inspection system:

58. There is no requirement for the use of security seals or other mechanisms to ensure sample security in association with the collection of *Salmonella* samples.

55/56. Veterinary post-mortem inspectors were not following the procedures outlined in Regulation (EC) No 854/2004 Section IV (determined equivalent by FSIS). The following elements were omitted during observation of post-mortem (swine) inspection activities:

- palpation of the lungs and the bronchial and mediastinal lymph nodes (Lnn. *bifucationes*, *eparteriales* and *mediastinales*).
- palpation of the liver and its lymph nodes
- palpation of the gastric and mesenteric lymph nodes

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
A. Lauro & G. Brookhouser	Alexander A Lauro, DVM 9/21/2015

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
Dawn Meats Ireland T/A Dawn Charleville Charleville, Cork	09/25/2015	368	Ireland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	A. Lauro & G. Brookhouser		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	X
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58. *Salmonella* sample collection	X
59.	

60. Observation of the Establishment

The following non-compliances were not identified by Irish inspection officials during the establishment review:

28/51. In addition to the *Enterobacteriacea* testing conducted to assess control of the slaughter process as per EC requirements, the establishment had elected to conduct generic *E. coli* testing as outlined in 9 CFR 310.25. The establishment was collecting samples via the sponging method, but was using m/M excision-method criteria for the interpretation of results. 9 CFR 310.25 (a)(5)(ii) states that "establishments sponging carcasses shall evaluate *E. coli* test results using statistical process control techniques." The correct implementation of process control techniques includes data which is specific for a particular establishment, so that a true assessment can be attained.

In addition, the FSIS auditor noted the following findings related to implementation of Ireland's meat inspection system:

58. There is no requirement for the use of security seals or other mechanisms to ensure sample security in association with the collection of *Salmonella* samples.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
A. Lauro & G. Brookhouser	Laurence A. Lauro, DVM 9/25/2015

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
ABP Clones Clones	09/19/2015	378	Ireland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Lauro / Brookhouser		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
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10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
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19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	X
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	X
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58. *Salmonella* sample collection	X
59.	

60. Observation of the Establishment

The following non-compliances were not identified by Irish inspection officials during the establishment review:

28/51. In addition to the *Enterobacteriacea* testing conducted to assess control of the slaughter process as per EC requirements, the establishment had elected to conduct generic *E. coli* testing as outlined in 9 CFR 310.25. The establishment was collecting samples via the sponging method, but was using m/M excision-method criteria for the interpretation of results. 9 CFR 310.25 (a)(5)(ii) states that "establishments sponging carcasses shall evaluate *E. coli* test results using statistical process control techniques." The correct implementation of process control techniques includes data which is specific for a particular establishment, so that a true assessment can be attained.

40/51. The lighting at the lower range of the mobile stand (corresponding to the carcass forequarter) where government verification of the zero-tolerance CCP occurs was insufficient. The lighting in the area was 520 lux, rather than the 540 lux outlined in Ireland's meat inspection requirements.

In addition, the FSIS auditor noted the following findings related to implementation of Ireland's meat inspection system:

58. There is no requirement for the use of security seals or other mechanisms to ensure sample security in association with the collection of *Salmonella* samples.

61. NAME OF AUDITOR

Lauro / Brookhouser

62. AUDITOR SIGNATURE AND DATE

Alexander R. Lauro, DVM 9/19/2015

Appendix B: Foreign Country Response to Draft Final Audit Report

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

12 February 2016

Jane Doherty, International Coordination Executive
USDA, FSIS, OA, Office of International Coordination
Room 3143-S
1400 Independence Ave., SW
Washington, DC 20250

Draft report of on-site audit of Ireland's beef slaughter inspection system

Dear Ms. Doherty,

I refer to the draft report of the FSIS on-site audit held from September 16 - 1 October 2015 of Ireland's meat inspection system which I received on 18 December 2015.

I am now pleased to enclose the corrective actions and verification information to address the identified findings during the audit. In addition I also enclose comments and clarifications on the report.

I trust the enclosed provides all the documentation requested.

However, should any further documentation or clarification be required, please do not hesitate to contact me.

Yours sincerely,

Martin Blake
Chief Veterinary Officer

c. c. Mr. Steve Knight, USDA, Embassy of the USA, London

2 Enclosures

DAFM response

to

FSIS Draft Final Report of December 17th, 2015

Audit Conducted in Ireland September 16th 2015 to October 1st, 2015

Evaluation of the Food Safety Systems Governing Meat Products Exported to the United States of America

Section A. **Factual Errors**

Section B. **Duplications & Omissions**

Section A. Factual Errors

Factual error	FSIS Audit Draft report	Please amend to:
Page 3 Under bullet point "Private laboratories analyze samples"	"Private laboratories must be approved and audited by DAFM's Central Meat Control Laboratory before participating in the *Salmonella* testing program. Ongoing oversight of private laboratories is performed by personnel at the Central Meat Control Laboratory."	Private laboratories must be approved and audited by DAFM's **Veterinary Public Health Regulatory** Laboratory before participating in the *Salmonella* testing program. Ongoing oversight of private laboratories is performed by personnel at the **Veterinary Public Health Regulatory** Laboratory.
Page 4 paragraph beginning "The RSVI and the VI" line 2	"S.I. No. 910"	S.I. No. **432 of 2009**
Page 5 paragraph beginning "As per 9 CFR" line 9	"independent contractors"	contractors **independent of industry, reporting directly to the DAFM VI**

Factual error	Draft report	Please amend to:
Page 9 paragraph beginning "Ireland's meat inspection" line 4	"Statutory Instrument 432"	Statutory Instrument 432 **of 2009**
Page 11 paragraph beginning "All positive results" line 5	"Positive results can"	Positive results **at slaughter plants will**
Page 12 paragraph beginning "During the evaluation" line 3	"affidavit" (**Comment:** In Ireland, an affidavit is a sworn legal document)	**owner declaration**
Page 12 paragraph beginning "During the evaluation" line 6	"Central Meat Control Laboratory (CMCL)"	**Veterinary Public Health Regulatory** Laboratory **(VPHRL)**

Factual error	Draft report	Please amend to:
Page 12 last sentence line 1	"S.I. 402"	S.I. **432**
Page 14 second paragraph line 5	"eight times per month"	eight **samples once** per month
Page 14 second paragraph line 9	"(VPHS)"	(VPHRL)

Section B. Duplications & Omissions

Duplication

Appendix A **Foreign Establishment Audit Checklist**

Queally Pig Slaughtering Limited (IE 332 EC) audit checklist repeated.

Omission

Appendix A **Foreign Establishment Audit Checklist**

Checklist for Rosderra Irish Meats Group, Roscrea (IE 355 EC) omitted from the draft report.

FSIS 2015 Audit Draft Report Findings - DAFM Close Out

FSIS Draft Report Section No.	FSIS Findings	DAFM Action Implementation
Section IV	**<u>Component One: Government Oversight</u>** **<u>Page 5, bullet point</u>** "Two of the three audited swine establishments presented slaughter-line installations that did not provide for sanitization of post-mortem viscera pans with 82° C water. This does not meet the approved United States equivalence requirements as outlined in *EC Regulation 853/2004, Annex III, Chapter II* (*Requirements for slaughterhouses*) and thereby represents a need for DAFM to revisit its establishment approval process. As Ireland is not currently exporting offal to the United States, FSIS requests that certification of offal continue to be withheld until DAFM provides evidence that this issue is resolved on a system-wide basis." **<u>Page 6, last sentence of Component One section</u>** "Overall, the audit findings indicated a need for improvement in oversight related to the establishment approval process and enforcement of basic sanitation and HACCP requirement."	DAFM addressed this non-compliance with the two swine establishments and also verified, in a third swine establishment, that required controls were in place DAFM has now verified that the three swine establishments have installations in place for sanitation of post-mortem viscera pans with water at not less than 82°C (**Appendices 1a, 1b, 2 & 3**) Sanitation of equipment is now included as a documented requirement in approval of establishments for the U.S. market: DAFM Guidance Notice GN USDA_1 for approval of U.S. - eligible establishments circulated both to Veterinary Public Health Inspection Service (VPHIS) and industry [**Appendix 4** Section 2(b) highlighted] No offal exports to U.S. currently

FSIS 2015 Audit Draft Report Findings - DAFM Close Out

FSIS Draft Report Section No.	FSIS Findings	DAFM Action Implementation
Section V	**<u>Component Two: Statutory Authority & Food Safety Regulations</u>** **<u>Page 7, bullet point</u>** At two of the three swine slaughter facilities audited: "Veterinary post-mortem inspectors (TVIs) were not following the procedures outlined in *Regulation (EC) No 854/2004, Section IV* (determined equivalent by FSIS). The following elements were omitted during the auditor's observation of post-mortem inspection activities: Palpation of bronchial and mediastinal lymph nodes, Palpation of the liver and its lymph nodes, and Palpation of the gastric and mesenteric lymph nodes. In addition, the FSIS auditors reviewed the most recent performance assessments documented on FORM OCPME (pig): *Evaluation of Post-mortem Official Controls in accordance with Regulation (EC) 854/2004 Annex 1*) for the TVIs in question. In both cases, the documentation indicated that the individuals were able to perform post-mortem inspection procedures correctly at the time the assessment was conducted. Consequently, this indicates a need for greater surveillance on the part of the VI (on daily basis) and supervising veterinarians (during their period reviews)"	As per FSIS draft report: "During the exit meeting, the FSIS auditors were informed that the DAFM had followed its established procedures for dealing with inadequate performance, including (for each establishment): 1. Immediately removing and replacing the TVI at the viscera inspection station 2. Issuing official notification (*Clause 1.6 Notification Under the Conditions or Engagement for Temporary Veterinary Inspectors*) that proper inspection procedures were not being conducted 3. Provision of professional development to TVIs 4. Reassessing performance. In addition, continuing professional development on post-mortem inspection has been added to the Training Plan for Official Veterinarians during 2016 (**Appendix 5c** TVI Evaluation_IE356E) (**Appendix 6b** TVI Evaluation_IE355EC)

FSIS 2015 Audit Draft Report Findings - DAFM Close Out

FSIS Draft Report Section No.	FSIS Findings	DAFM Action Implementation
Section VI	**<u>Component Three: Sanitation</u>**	
	<u>Page 8, first bullet point</u> "At one beef slaughter facility, the lighting at the lower range of the mobile stand (corresponding to the carcass forequarter) where government verification of the zero- tolerance CCP occurs, was insufficient. The lighting in the area was 520 lux, rather than the 540 lux outlined in Ireland's meat inspection requirements."	During closing meeting, DAFM provided FSIS with evidence that this deficiency had been corrected DAFM Non-Compliance Report issued to the Food Business Operator [**Appendix 7a** NCR item no. 2 (highlighted)] Additional spot light and new LED light installed by the Food Business Operator DAFM-verified Lux reading: 735 Lux {**Appendix 7b Lighting**)

FSIS 2015 Audit Draft Report Findings - DAFM Close Out

FSIS Draft Report Section No.	FSIS Findings	DAFM Action Implementation
Section VI	**<u>Component Three: Sanitation</u>**	
	<u>Page 8, second bullet point</u> "At two of three swine slaughter establishments audited, post-mortem viscera pans were not routinely sanitized with 82° C water. This condition does not meet the approved United States equivalence requirements as outlined in *EC Regulation 853/2004, Annex III, Chapter II* (*Requirements for slaughterhouses*). The significance of this finding is related to the potential for cross-contamination between clean and unwholesome viscera (e.g., presenting feces or other pathological material), either by coming into contact with the previously-used unsanitized surface of the pan, or through manual manipulation of the viscera occurring during post-mortem inspection."	DAFM addressed this non-compliance with the two swine establishments and also verified, in a third swine establishment, that required controls were in place DAFM has now verified that the three swine establishments have installations in place for sanitation of post-mortem viscera pans with water at not less than 82°C (**Appendices 1a, 1b, 2 & 3**) Sanitation of equipment is now included as a documented requirement in approval of establishments for the U.S. market: DAFM Guidance Notice GN USDA_1 for approval of U.S. - eligible establishments circulated both to Veterinary Public Health Inspection Service (VPHIS) and industry [**Appendix 4** Section 2(b)(highlighted)]

FSIS 2015 Audit Draft Report Findings - DAFM Close Out

FSIS Draft Report Section No.	FSIS Findings	DAFM Action Implementation
Section VII	**<u>Component Four: Hazard Analysis and Critical Control Points (HACCP)</u>**	
	<u>Page 10, first bullet point</u> "At one establishment, monitoring did not routinely include the time when deviations of the CCP occurred". **<u>Page 10, second bullet point</u>** "At one establishment, the number of carcasses that should be verified through "direct observation of monitoring" procedures was not specified". **<u>Page 10, third bullet point</u>** "At two establishments, documentation of corrective actions taken in response to deviations from the CCP was general in nature, especially with regards to the portion addressing measures to prevent recurrence. These establishments were using a series of codes such as "1. Talked with operator," rather than including specific details as to what was discussed or what other actions were taken for each particular event."	DAFM issued Non-Compliance report FBO now recording time when CCP deviations occur Verification by DAFM [**Appendix 8a** (NCR 05/2015; item no. 5 (highlighted)] DAFM issued Non-Compliance report The number of carcasses that need to be verified is now documented Verification by DAFM [**Appendix 8b** (NCR 05/2015; item no. 6 (highlighted)] Establishment 1: IE 355 EC DAFM issued Non-Compliance report NCR 15/2015 [**(Appendix 9**: item no. 2 (highlighted)] Food business operator reviewed, and amended, Food Safety Management System, verification by DAFM Establishment 2: IE 356 EC Food business operator reviewed, and amended, Food Safety Management System, verification by DAFM [**Appendix 10** CCP_ IE 356 EC, page 5 (highlighted)]

FSIS Draft Report Section No.	FSIS Findings	DAFM Action Implementation
Section VII *continued*	**Page 10, last sentence** "FSIS requests that DAFM provide a description of long-term measures taken to improve the manner in which in-plant officials verify the implementation of establishment HACCP systems."	DAFM Revision of DAFM Food Safety Management System audit procedures Enforcement SOP 2 of 2015, Revision 2 circulated to VPHIS personnel January 26th, 2016 (**Appendix 11,** Section 7.4 (highlighted)) Revision of DAFM CCP audit form (highlighted) (**Appendix 11a**) Revision of DAFM CCP Guidance Note (highlighted) (**Appendix 11b**

FSIS 2015 Audit Draft Report Findings - DAFM Close Out

FSIS Draft Report Section No.	FSIS Findings	DAFM Action Implementation
Section IX	**Component IX: Government Microbiological Testing Programs**	
	Page 13, first bullet point, first indent "The auditors observed deficiencies related to the interpretation of generic *E. coli* testing results in three of the five slaughter establishments audited. ➢ Two establishments were collecting samples via the sponging method but were using m/M excision-method criteria for the interpretation of results. The United States in 9 CFR 310.25 (a) (5) (ii) states that "establishments sponging carcasses shall evaluate *E. coli* test results using statistical process control techniques."	Both establishments reviewed their controls The first establishment is now using the equivalent *Enterobacteriaceae* testing Process Hygiene Criterion as per Regulation (EC) No 2073 of 2075 in lieu of testing for generic *E.coli* (**Appendix 12**) The second establishment, having applied Statistical Process Control methods and achieved consistent test results indicating no E.Coli detected, is now using the equivalent *Enterobacteriaceae* testing Process Hygiene Criterion as per Regulation (EC) No 2073 of 2075 in lieu of testing for generic *E.coli* (**Appendix 13**)

FSIS Draft Report Section No.	FSIS Findings	DAFM Action Implementation
Section IX *continued*	**Component IX: Government Microbiological Testing Programs**	
	Page 13, first bullet point, second indent ➢ "One establishment was collecting samples using the sponging method and was using lower and upper control limits based on data from another establishment. The correct implementation of process control techniques includes data specific for a particular establishment, so that a true assessment can be attained."	Revision of controls by Food Business Operator DAFM receipt of Statistic Process Control report from Food Business Operator confirming utilisation of own data generated on site (**Appendix 14**)

FSIS 2015 Audit Draft Report Findings - DAFM Close Out

FSIS Draft Report Section No.	FSIS Findings	DAFM Action Implementation
Section IX	**Component IX: Government Microbiological Testing Programs**	
	Page 13, last bullet point "The auditors noted that at all establishments audited, there was no requirement for the use of security seals or other mechanisms to ensure sample integrity in association with the collection of *Salmonella* samples. Discussions with on-site DAFM personnel indicated that the sample is considered under establishment control (e.g., maintained in the establishment refrigerator) during the period of time between the completion of sample collection and dispatch. This approach represents a potential breach in the chain of sample custody/security". **Page 14, second bullet point** "During the audit of both government and private laboratories, the auditors noted that procedures related to the receipt of microbiological samples did not address samples received with broken or absent security seals. FSIS expects that measures to prevent tampering with samples will be used in all testing performed in conjunction with government verification of microbiological pathogen standards".	Revision of DAFM sample security procedures Veterinary Procedural Notice VPN 12 of 2014, Revision 2 circulated to VPHIS personnel January 15th, 2016 (**Appendix 15**)

FSIS 2015 Audit Draft Report Findings - DAFM Close Out

FSIS Draft Report Section No.	FSIS Findings	DAFM Action Implementation
Section IX	**Component IX: Government Microbiological Testing Programs**	
	Page 14, second paragraph, line 7 "However, the auditors also noted that, while the stated *VPN* calls for random testing, a potential bias was introduced because of the limited operating schedule of the testing laboratory (VPHS)." **Page 14, first bullet point** "The FSIS auditors noted that STEC sampling occurs during a single week for all establishments, e.g., with five currently-approved beef establishments, 40 samples are collected during the same week (8 samples x 5 establishments) of a particular month. Further conversations with laboratory personnel also indicated that sampling almost always occurs during the same week (e.g., week 2) of the month. Consequently, the testing does not appear to meet the "8 randomly selected carcasses per month" outlined in *VPN 10/2014, Official Verification Program for Testing for Verotoxigenic Escherichia coli.* This design raises concerns regarding the potential amount of prior notice afforded to establishments during government verification testing. Consequently, FSIS requests that DAFM provide additional information to explain how the current sampling protocol provides unbiased view of a month's production."	DAFM Veterinary Public Health Regulatory Laboratory reviewed sampling schedules Revision of procedure FRM.013, Revision EV.03 (**Appendix 13_Lab**) Week of sampling each month now varied and random