United States Department of Agriculture

Food Safety and Inspection Service

1400 Independence Avenue, SW.
Washington, D.C. 20250

December 30, 2014

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

Dear Mr. Blake:

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of Ireland's beef slaughter inspection system from June 30 – July 7, 2014. Enclosed is a copy of the final audit report for that audit. In addition, Ireland's comments to the FSIS draft final audit report have been attached to the final audit report. The final audit report will now be posted on the FSIS website.

The Ireland's Department of Food, Agriculture, and the Marine provided FSIS with inspection and laboratory records evidencing its implementation of the identified corrective actions noted in the final audit report. Based on the FSIS evaluation of the evidence provided in the records, FSIS has concluded that Ireland has consistently and effectively implemented a beef slaughter inspection system that satisfies all criteria for equivalence with the FSIS meat inspection system. Accordingly, Ireland is now eligible to resume the shipment of beef carcasses to the United States. Before Ireland can ship beef carcasses, FSIS requests that you provide official notification of the Irish establishments certified to export beef carcasses to the United States.

Sincerely,

Alfred Almanza
Acting Administrator
Food Safety and Inspection Service

Enclosure

Notation for the update: "FSIS has replaced this report with a new version that corrects references to Ireland's sampling programs for generic *Escherichea coli* and *Salmonella* for beef carcasses. The previous version incorrectly referenced swine sampling frequencies."

IRELAND

BEEF EQUIVALENCE REINSTATEMENT AUDIT

June 30 – July 7, 2014

December 2014
Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

In March 2014 USDA's Animal and Plant Health Inspection Service (APHIS) issued a final rule that lifted restrictions on the importation of beef from countries classified by the World Animal Health Organization (OIE) as a "controlled risk" for Bovine Spongiform Encephalopathy (BSE). Commensurate with this change, USDA's Food Safety and Inspection Service (FSIS) decided that it would consider reinstating the eligibility to ship beef to the United States of countries affected by the APHIS rule change. To assess the equivalence of those countries, the countries would need to pass an FSIS audit of their food safety system for beef. This report describes the equivalence verification activities and onsite audit that FSIS conducted from June 30 – July 7, 2014, to determine whether Ireland is eligible to resume beef exports to the United States. Ireland intends to ship beef carcasses to the U.S., should it become eligible to resume beef exports to the United States. The audit focused on six components of Ireland's food safety system for beef products: (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.

The onsite portion of the verification audit included the headquarters offices of Ireland's Central Competent Authority (CCA); the Department of Agriculture, Food, and the Marine (DAFM); an interview with DAFM's Northwest Regional Supervisory Veterinary Inspector (with oversight responsibility for the two beef slaughter establishments proposed by DAFM for U.S. certification); and two laboratories - one government laboratory conducting residue and microbiological 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.

While Ireland's inspection system for beef is designed and organized in a manner that meets FSIS equivalence criteria, and the country has implemented an equivalent inspection system for the slaughter of cattle and processing of beef products, the on-site audit identified procedural weakness, but not failure, in the government's delivery of certain aspects of the program, including the verification of establishment pre-operational and operational sanitation, animal welfare checks, inspector conflicts of interest, and establishment microbiological sampling activity. In particular:

- No protocol existed for the direct reporting of private laboratory test results to DAFM. Microbiological sampling test results are reported by the lab to the establishment and by the establishment to DAFM.
- No official procedure existed for the handling of inconclusive STEC sample results.
- DAFM lacked official controls to prohibit conflicts of interest arising from the engagement of independent professional veterinarians known as Temporary Veterinary Inspectors (TVIs) who maintain business relationships with suppliers of animals to the regulated establishments.
- No procedure existed requiring inspection personnel to document their verification of establishment microbiological sampling activity.

In response to these findings, the CCA proposed corrective actions to require:

- the direct transmittal of accredited laboratory test results both veterinary inspectors and management at certified establishments,
- declarations of conflict of interest by temporary veterinary inspectors who also provide private veterinary services to suppliers of animals to certified establishments
- consistent and complete verification of animal welfare checks
- documented verification by DAFM inspectors of establishment microbiological sampling activity, and

- laboratory confirmatory testing of inconclusive STEC screen results prior to reporting test results to the official veterinarian at certified establishments.

At the audit exit conference and in subsequent email communication, the CCA provided the auditors with new and updated veterinary procedural notices and laboratory instructions to implement the corrective actions outlined above. Based on its analysis of these corrective actions, FSIS has determined that they address the concerns identified during the audit. In addition, DAFM provided FSIS with inspection and laboratory records evidencing its implementation of the identified corrective actions. Based on its evaluation of this evidence, FSIS concludes that Ireland has consistently and effectively implemented a beef slaughter inspection system that satisfies all criteria for equivalence with the United States system. Accordingly, Ireland is eligible to resume the shipment of beef carcasses to the United States.

TABLE OF CONTENTS

I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an equivalence reinstatement audit of the Ireland's beef slaughter inspection system that included an onsite visit from June 30 through July 7, 2014. Ireland is currently eligible to export pork to the United States and, with the March 2014 lifting of European beef import restrictions by USDA's Animal and Plant Health Inspection Service, seeks to reestablish its eligibility to export beef products to the United States. Ireland has not exported beef to the U.S. since 1998.

The onsite audit began with an entrance meeting held in Dublin on June 30, 2014, at the headquarters of Ireland's Central Competent Authority (CCA), the Department of Agriculture, Food, and the Marine (DAFM). The beef equivalence reinstatement audit was conducted to assess whether the country maintains an inspection system for beef with requirements equivalent to those under the specific provisions of the 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 et seq.)

In addition, auditors verified that the system implemented and enforced U.S.-equivalent European Commission (EC) regulations and directives:

- EC Regulations 999/2001 *as amended*, 178/2002; 1774/2002; 726/2004; 852/2004; 853/2004; 854/2004; 882/2004; 41/2004; 396/2005; 2073/2005; 1881/2006; 1883/2006; 333/2007; 470/2009; 1069/2009; 1099/2009; and 37/2010.
- Council Directives found equivalent under the Veterinary Equivalence Agreement (VEA), 96-22 and 96-23 were assessed.

The audit standards included: (1) All applicable legislation and procedures originally determined by FSIS to be equivalent as part of the initial equivalence review process, and (2) any subsequent equivalence determinations that have been made by FSIS under provisions of the Sanitary/Phytosanitary Agreement, and the European Community/United States Veterinary Equivalence Agreement.

Currently, FSIS has found the following requirements under Ireland's inspection system equivalent to FSIS requirements or procedures:

- *Salmonella*:
  Ireland has adopted FSIS standards and procedures for *Salmonella* with the following exceptions:
  - Private laboratories analyze the samples
  - Establishment employees collect the samples for *Salmonella* testing, and the CCA provides oversight and monitoring of the establishment's sampling procedures
  - ISO 6579:2002 may be used to detect *Salmonella*
- Generic *Escherichia coli (E. coli)*:

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

II. AUDIT OBJECTIVES, SCOPE, AND METHODOLOGY

The audit objective was to verify that Ireland's food safety system governing beef slaughter inspection is equivalent to that of the United States and is capable of ensuring that beef products exported to the United States are safe, wholesome, unadulterated, and properly labeled. In pursuit of this objective and prior to the onsite portion of the audit, FSIS conducted an extensive review of the information provided by Ireland through the *Self-Reporting Tool (SRT) for On-going Equivalence* and accompanying references. These supporting documents provided a comprehensive overview of all the relevant legislation, regulations, and operational documentation characterizing the equivalence of Ireland's beef slaughter inspection system.

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

The FSIS auditors reviewed administrative, management, and supervision functions at the CCA headquarters in Dublin and during an interview with the Northwest Regional Supervisory Veterinary Inspector. The FSIS auditors evaluated the CCA's official controls that ensure that the national system of inspection, verification, and enforcement related to beef slaughter is being implemented as intended.

FSIS audited two establishments proposed by the CCA for U.S. export certification. Inspection personnel at one establishment were under the supervision of the Northwest Regional Supervisory Veterinary Inspector and the inspection personnel at the other establishment were under the North East Regional Supervisory Veterinary Inspector. The Northwest Regional Supervisory Inspector was interviewed by the auditors at DAFM headquarters in Dublin. During the 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 auditors verified that the CCA provided oversight through supervisory reviews of inspection personnel conducted in accordance with *Regulation (EC) No 882/2004* and requirements equivalent to Title 9 Code of Federal Regulations (CFR) 327.2.

The FSIS auditors also assessed the CCA's verification activities for approved chemical residue and microbiology laboratories. FSIS audited two laboratories, one conducting residue and microbiological testing – DAFM's Veterinary Public Health Regulatory Laboratory (VPHRL), and a private laboratory, Advanced Laboratory Testing, Ltd., approved by DAFM and contracted by an establishment to conduct microbiological testing, to verify that their testing methods are those determined by FSIS to be equivalent to FSIS methods. FSIS reviewed 18 months' worth of laboratory data related to the collection of *Salmonella* and generic *E.coli*, as well as the entirety of data related to shiga-toxin producing *Escherichia coli* (STEC) samples in establishments proposed by DAFM for U.S. export certification. FSIS conducted onsite interviews of inspection personnel and reviewed the CCA's and independent laboratory audit reports associated with the chemical residue and microbiological testing programs.

III. BACKGROUND

In March 2014 USDA's Animal and Plant Health Inspection Service (APHIS) issued a final rule that lifted restrictions on the importation of beef from countries classified by the World Animal Health Organization (OIE) as controlled risk for Bovine Spongiform Encephalopathy (BSE). Commensurate with this change in APHIS regulation, USDA's Food Safety and Inspection Service (FSIS) made a policy decision to require reinstatement audits of the inspection systems for beef of countries affected by the APHIS rule change in order to reaffirm the equivalence of those systems. This report describes the outcome of equivalence verification activities and an onsite audit conducted by FSIS from June 30 – July 7, 2014, to determine Ireland's eligibility to resume beef exports to the United States. The audit focused on six components of Ireland's food safety system for beef products: (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.

The onsite portion of the verification audit included the CCA's headquarters offices in Dublin, an interview with DAFM's Northwest Regional Supervisory Veterinary Inspector (with oversight responsibility for the two beef slaughter establishments proposed by DAFM for U.S. certification), and two laboratories - one government laboratory conducting residue and confirmatory microbiological testing and one private laboratory conducting microbiological testing.

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT

The first of the six components that the FSIS auditors reviewed was Government Oversight. FSIS' import eligibility requirements state that the foreign inspection system must be designed and administered by the national government of the foreign country with standards equivalent to those of meat inspection in the United States (9 CFR 327.2). The evaluation of this component included a review and analysis of documentation previously submitted by the CCA as support for the responses provided in the SRT and onsite record reviews, interviews, and observations made by the FSIS auditors at government offices, two laboratories, and audited establishments.

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 and which outlines the structure and organization of control systems for food, feed, plant health, animal health, and animal welfare in Ireland as required by *EC Regulation 882/2004*. 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.

The FSIS auditor verified that the CCA is responsible for direct oversight of the Ireland's meat inspection system and for the safety of foods of animal origin, including the control of residues. The

primary responsibility is vested with the Minister of Agriculture, Food, and the Marine. The State Veterinary Services (SVS) within the CCA advises the Minister on matters of animal health and disease, zoonoses, and public health as these relate to food and products of animal origin. Ireland's meat inspection system is 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 (SVO) are based in the Agriculture House headquarters. The SVO team consists of a Deputy CVO, two Senior Superintending Veterinary Inspectors (SSVI), and five 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 VPHIS is organized into six Regional Veterinary Public Health Inspectorates (Northeast, Northwest, East, South, Southeast, and Southwest). 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 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.

In accordance with *EC Regulation 882/2004* and *SI 432 of 2009*, as amended, DAFM undertakes an annual food safety assessment of all approved plants not engaged in slaughter activities to determine the frequency of supervisory veterinary inspection reviews to be performed at each plant in a given year by both the veterinary inspector (VI) in charge of the plant and the regional supervisors. In the case of the VI, the reviews and oversight of non-slaughter activities occur weekly, every three weeks, or monthly depending on the risk score, while regional supervisors carry out annual, semi-annual, or quarterly reviews. Each certified slaughter establishment has a VI assigned to the plant, and there is an ongoing presence of an official veterinarian during ante-mortem and post-mortem. The same methodology applies to the frequency of Regional Supervisory Inspection Audits at certified establishments, with such audits occurring quarterly, semi-annually, or annually. The two beef slaughter establishments proposed by DAFM for U.S. export certification have been audited on an annual basis. The risk assessment takes into account compliance history, response by establishment management to noncompliances and legal notices, the effectiveness of sanitation and HACCP controls, type and volume of production, and the risk profile of the product. Veterinary inspection reviews encompass an audit of the establishment's food safety management system, quarterly evaluation of CCPs, HACCP pre-requisite programs, and equipment and structure maintenance.

Noncompliances identified by the VI are documented to establishment management in the form of corrective action reports (CARs) (Form AR1a). Operational checks of sanitation and HACCP-based procedures were also being carried out by inspection personnel using check-sheets issued as part of "General Guidelines for Technical Agricultural Officers – 10/2007." Technical Agricultural Officers (TAO) provide a check sheet summary report daily to the VI, noting daily checks performed, any non-compliances identified, and associated resolution as appropriate. Noncompliances noted in checks reports completed by subordinate inspectors resulted in the issuance of CARs by the VIs at the

establishments visited. The FSIS auditors noted that CARs were responded to immediately by the establishments with the effectiveness of the corrective action verified by the VI.

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 on 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., *EC Regulation 852/2004* and *SI 432, 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, and any FSIS requirements not otherwise covered the EC Food and Feed Hygiene Regulations, they are approved and added to the list of eligible establishments certified by Ireland to export meat to the U.S. and are notified in writing prior to being granted certification to export. The approval inspection carried out by the Regional Supervisory Veterinary Inspector (RSVI) for establishment certification confirms that the establishment is unique to the premises and thus completely separate from any other EU approved meat establishment. Therefore, all U.S. certified establishments are separate from those not certified for export to the United States. The FSIS auditors verified through a review of establishment inspection reports and DAFM certification documents that the two beef slaughter plants proposed for U.S. export certification have been approved according to EC and Irish requirements.

The RSVI and the VI oversee the maintenance of eligibility to export to the U.S. They have the authority, under *EU Regulation 178/2002* and *National Legislation S.I. No. 432 of 2009*, to enforce the necessary requirements to export to another country. Their responsibilities include initiating investigations into establishment failure to meet the standards of the importing country and to provide documentation to support the CCA's decision to delist substandard establishments. The VI in certified establishments performs the daily supervision of establishment activities. The VI reports directly to the RSVI who performs the periodic supervisory reviews at least once annually. The auditors reviewed the RSVI audit reports for both beef slaughter establishments visited and verified that these included assessments of DAFM official controls in both establishments, as well as a review of the establishments' food safety management system audits performed by the VI, and enforcement actions taken in response to non-compliances.

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, 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 auditor 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.

The VIs are permanently located in all 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 on an intermittent or relief basis (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. TAO s help perform 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.

Because TVIs continue to practice veterinary medicine privately while providing official inspection services for DAFM, the auditors noted a conflict of interest with respect to TVI ante-mortem inspection assignments in the beef slaughter establishments audited. While acting in an official capacity, TVIs have access to animal and supplier identification records maintained at animal intake in each establishment and thus have the potential to influence disposition decisions for animals from locations where they provide private veterinary services. Although *EU Regulation 882/2004* requires Member States to establish mechanisms to prevent inspector conflict of interest, with such restrictions also codified in the Terms and Conditions of Employment of the Irish Civil Service, these requirements apply only to permanent employees of the government and not contractors. No such conflict of interest controls were in evidence for the contract TVIs assigned to the two beef slaughter plants audited, nor do they exist for the inspection system as a whole. In addition, no mechanism existed for preventing conflict of interest in TVI inspection assignments. DAFM acknowledged this deficiency during the audit exit conference and issued a new requirement for establishments to list the suppliers associated with each shift's animal intake and an associated veterinary procedural notice requiring TVIs to declare any conflicts of interest associated with those suppliers so that the VI can make the necessary staffing reassignments at ante-mortem to eliminate the conflict. To verify implementation of this corrective action, DAFM provided copies of signed TVI conflict of interest affidavits, including evidence that TVI inspection dispositions were rendered in the presence of the official veterinarian when conflicts of interest were declared. The auditors reviewed these records and concluded that they satisfactorily addressed the issues associated with this finding.

The CCA has the legal authority and the responsibility to enforce all requisite laws and regulations governing the export of meat to the U.S. The VI and other qualified in-plant inspection personnel are authorized to enforce European Commission legislation and U.S. import requirements under *National Legislation S.I. No. 432 of 2009*, as amended, and EU Regulations, to take appropriate enforcement actions in the case of noncompliance or breaches of the regulations. Ultimately, the CCA has the authority to suspend and/or delist establishments to prevent export of unwholesome products to the U.S.

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 the CCA, including the DAFM intranet site, that the CCA maintains a communication system to convey U.S. 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.

Official veterinarians in Ireland must complete 20 credits in veterinary public health, animal health, and animal welfare annually, or a total of 60 credits over the previous three years, in order to maintain their veterinary registration. Upon their appointment to the VPHIS, veterinarians must undergo an additional 200 hours of job-specific training to satisfy the requirements of Regulation EC 854/2004. The CCA provides initial and specialized on-going training to CCA inspection personnel assigned to certified establishments for specific U.S. import requirements, such as Pathogen Reduction requirements, HACCP system requirements, sanitation requirements, humane handling and slaughter requirements, food safety assessment requirements, and enforcement of U.S. 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 in the form of an official mentoring program for veterinary inspectors is coordinated by VPHIS and provided through the regional staff. The mentoring program encompasses 12 modules, including: establishment approvals, livestock intake, ante mortem inspection, animal welfare, post mortem inspection, establishment operations, residue and microbiological sampling, animal by-products, certification and intake of product, labeling and traceability, internal audits, and enforcement. The FSIS auditors reviewed the records of training programs at CCA headquarters and individual training records of inspection personnel assigned to the two beef slaughter establishments designated for U.S. export and verified that the inspection system assures adequate and timely training of inspection personnel in U.S. requirements.

The FSIS auditors verified that the VI evaluates the performance of subordinate inspection personnel quarterly. The performance evaluation of inspection personnel is conducted 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 beef slaughter inspection system is organized and administered by the government, and that the CCA officials are assigned to enforce laws and regulations governing beef slaughter in official establishments. The auditors noted that CCA regulatory verification is delivered through inspection-related procedures developed in accordance with both national and importing country standards. The majority of the cost of the Ireland's inspection program is funded by the National Exchequer with the remaining portion from fees assessed based on a fixed rate per animal the government charges the establishments. The CCA's Central Fees Unit bills establishments each month and is responsible for the collection of these fees.

While Ireland's inspection system for beef is designed and organized in a manner that meets FSIS equivalence criteria, and Ireland has implemented an equivalent inspection system for cattle slaughter and processing of raw beef products, the on-site audit identified procedural weakness in the government's delivery of certain aspects of the program, including the verification of establishment pre-operational and operational sanitation, animal welfare checks, inspector conflicts of interest, and establishment microbiological sampling activity. In particular:

- No protocol existed for the direct reporting of private laboratory test results to DAFM. Microbiological sampling test results are reported by the lab to the establishment and by the establishment to DAFM.
- No official procedure existed for the handling of inconclusive STEC sample results.

- DAFM lacked official controls to prohibit conflicts of interest arising from the employment of Temporary Veterinary Inspectors (TVIs) who maintain business relationships with suppliers of animals to the regulated establishments.
- No procedure existed directing inspection personnel to document their verification of whether establishment microbiological sampling met requirements.

Ireland has acknowledged these deficiencies and has implemented corrective actions deemed acceptable by FSIS to correct them. In particular, the CCA proposed corrective actions to require:

- the direct transmittal of accredited laboratory test results to both veterinary inspectors and management at certified establishments,
- declarations of conflict of interest by temporary veterinary inspectors who also provide private veterinary services to suppliers of animals to certified establishments,
- consistent and complete verification of animal welfare checks,
- documented verification activities by DAFM inspectors of establishment microbiological sampling activity, and
- laboratory confirmatory testing of inconclusive STEC screen results prior to reporting test results to the official veterinarian at certified establishments

DAFM has provided inspection and laboratory records to evidence the effective implementation of these corrective actions. Accordingly, the auditors conclude that the evidence sufficiently addresses the findings of the audit and thus, all issues of concern have been satisfactorily addressed.

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 administrated 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 U.S.-eligible establishments.

FSIS has determined that the European Union's Food Hygiene regulations meet the criteria for meat inspection equivalence outlined in 9 CFR 327.2. The 2004 food hygiene laws cover all stages of the production, processing, and distribution of food intended for human consumption. The package consists of *Regulation (EC) 852/2004* on the hygiene of foodstuffs, *Regulation (EC) 853-2004* on specific hygiene rules for food of animal origin, *Regulation (EC) 882-2004* on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, *Regulation (EC) 854/2004* on official controls for products of animal origin intended for human consumption, and *Directive 2004/41/EC* repealing certain directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption. Subsequent regulations adopted in 2005 (*EU Regulation 2073/2005 on Microbiological Criteria for Foodstuffs*) also provide equivalent requirements for microbiological

criteria for food, health certification of products of animal origin, and examination for *Trichinella* in slaughtered swine. Equivalent chemical residue controls exist in *EC Directive 96/22*, concerning the prohibition on the use in livestock of certain substances having a hormonal or thyrostatic action and of beta-agonists, and *EC Directive 96/23* on measures to monitor certain substances and residues thereof in live animals and animal products.

The EC legislation depends on the central competent authorities of each EU Member State to carry out the inspection and audit activities to ensure proper implementation of the principles of the food hygiene rules. In order to ensure a uniform approach with regard to official food controls, EU Member States are required to establish and implement national food hygiene control plans and to update them every five years. When properly executed, the national control plans establish a solid basis for auditors to verify whether the official controls of the EU Member State are organized in conformity with the criteria set down in EC legislation. The auditors verified that DAFM operates Ireland's meat inspection program in accordance with the National Control Plan for Ireland for the period January 1, 2012, to December 31, 2016.

Ireland has implemented the EC food hygiene legislation through a series of Statutory Instruments that lay out the national framework for inspection program delivery related to beef slaughter and processing:

> **SI 432 – European Communities (Food and Feed Hygiene) Regulations 2009 (as amended)**. This instrument gives legal effect to Directive 2004/41/EC and Regulations (EC No. 852/2004, 853/2004, 854/2004, 882/2004, 183/2005, and 2073/2005 concerning food and feed hygiene legislation (the Hygiene Package), insofar as they relate to the Department of Agriculture, Food, and the Marine. The Hygiene Package revises and consolidates legislation in relation to food and feed hygiene and the production, control and marketing of food and feed. It requires that primary producers of food and feed products be registered with the Department of Agriculture, Food, and the Marine and that certain activities are subject to formal approval.
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> **SI 252 – European Communities (Transmissible Spongiform Encephalopathies and Animal By-Products) Regulations 2008**
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> **SI 292/2013 – European Union (Protection of Animals at the Time of Killing) Regulations 2013**
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> **SI 183 – European Communities (Control of Animal Remedies and Their Residues) Regulations 2009 –** implementing EC Directive 96/22/EC prohibiting in animal agriculture certain substances having hormonal or thyrostatic action and of beta agonists and EC Directive 96/23 on measures to monitor certain substances and residues thereof in live animals and animal products.
>
> **Abattoir Act Veterinary Examination Regulations of 1992**

These Statutory Instruments form the basis for a series of standard operating procedures (SOP) and veterinary procedural notices (VPN) that contain specific provisions for the delivery of the inspection program in Ireland. The SOPs and VPNs detailing regulatory oversight of beef slaughter operations include:

- SOP No. 1/2014: Official Controls on Animal Welfare at DAFM Supervised Slaughter Plants
- SOP No. 03: Ante-Mortem Inspection of Bovines in DAFM-Approved Beef Slaughter Premises
- SOP No. 04/2007: Animal By-Products at DAFM-Approved Meat Establishments
- SOP No. 06/2008: Procedures for the Performance of Official Controls to Monitor the Food Business Operator's Food Safety Management Systems
- SOP 14/2011: Procedures for BSE Controls and Sampling of Bovines at DAFM-Approved Slaughter Plants
- VPN No. 7/2004: Enforcement Procedures at Approved Meat and Dairy Plants

- VPN No. 2/2006: Sampling of Casualty Animals for Inhibitory Substances under the National Residue Plan
- VPN No. 6/2010: Slaughter of Bovines Which Have Reacted Positively or Inconclusively to a Tuberculin or a Brucellosis Test
- VPN No. 4/2011: Verification by Veterinary Inspectors of Compliance by Food Business Operators (FBOs) with Regulation 2073/2005 (as amended) on Microbiological Criteria for Foodstuffs in DAFM-Approved Plants.
- VPN No. 11/2012: Hide Cleanliness of Cattle Presented for Ante-Mortem Inspection Prior to Slaughter for Human Consumption at DAFM-Approved Slaughter Plants
- VPN No. 7/2014: Official Verification Program for Testing for Verotoxigenic *Escherichia coli* (VTEC)

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 auditors during the onsite audit of Ireland's inspection system. The FSIS auditors confirmed that official inspection and verification activities were carried out by the CCA as outlined in official legislation, circulars, and other instructions, including the enforcement of requirements for the humane handling and slaughter of livestock, ante and post-mortem inspection, control over establishment construction/ facility/equipment, control over inedible and condemned materials.

During the onsite audit of two beef slaughter establishments, the FSIS auditors observed and verified the inplant 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, and process control as measured by *Salmonella* spp. and generic *E. coli/Enterobacteriaceae* sampling.

The FSIS auditors verified that in-plant official veterinarians conducted ante-mortem inspection on the day of slaughter by reviewing the in-coming 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 in order to determine whether they are fit for slaughter. Each establishment had a designated observation pen for further examination of suspect animals. The implementation of the ante-mortem inspection procedure verified compliance with *EU Regulations 853/2004 and 854/2004*, which have been determined equivalent by FSIS. Ireland has consolidated all aspects of bovine intake into two issuances, "*Beef Meat SOP No. 02/2006 Rev. 2, Bovine Welfare at DAFM Approved Beef Slaughter Establishments*" and "*Beef Meat SOP No. 3, Procedure for Ante-mortem Inspection of Bovines*." The FSIS auditors observed and verified that all animals in holding pens, including suspect animals, had access to water. The FSIS auditors further verified through onsite record review, interviews, and observations that the CCA's inspection procedures concerning ante-mortem inspection and the verification of humane handling/slaughter of livestock were met in the two audited beef slaughter establishments.

FSIS assessed post-mortem inspection examinations through onsite record reviews, interviews, and observations of inspection activities in the two audited slaughter establishments. The FSIS auditors observed and verified the proper presentation, identification, examination, and disposition of carcasses and parts. The design of the post-mortem inspection stations included sufficient lighting and the number of on-line inspectors was in accordance with Ireland's inspection requirements expressed in *EC Regulation 854/2004*. The FSIS auditors observed and verified that inspection personnel conduct post-mortem inspection of every animal slaughtered at that establishment. Inspection personnel examined the heads, viscera, carcasses, including all required organs and lymph nodes by visual inspection, proper incision and palpation, in accordance with the provisions of the *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 Regulations 853/2004 and 854/2004*- post-mortem inspection, which have been determined equivalent by FSIS.

Although the auditors verified that ante-mortem inspection of beef cattle was performed in accordance with DAFM's documented procedures, the FSIS auditors identified deficiencies in the documentation of animal welfare checks in one establishment. Incomplete documentation of animal welfare controls on the Protection of Animals at Time of Slaughter (PAT) report was observed by the FSIS auditors and brought to the attention of the Veterinary Inspector. In particular, notes characterizing deficiencies were identified in the margins of one report without being identified as "unacceptable" on the form, a circumstance that requires the filing of an accompanying non-compliance report, which in fact was done. Additionally, PAT records did not indicate that Stun to Stick Intervals, Sticking/Bleeding Procedures, and Stick to Dress Intervals were verified as required by *SI 292/2013, European Union (Protection of Animals at the Time of Killing) Regulations 2013* and outlined in *SOP No. 1/2014: Official Controls on Animal Welfare at DAFM Supervised Slaughter Plants.* To address this finding, DAFM revised the PAT form and issued new field instructions to clarify that all animal welfare checks listed on the form must be verified and documented as satisfactory, unsatisfactory, or not evaluated. DAFM provided copies of the completed, revised PAT forms to evidence the consistent and complete verification of animal welfare checks. The auditors reviewed this documentation and determined that it satisfactorily addressed the audit finding.

The 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 U.S. The CCA has applied these standards uniformly at the two beef slaughter establishments that were audited and proposed for U.S. export certification. FSIS' analysis and audit of Ireland's inspection system indicates that the CCA demonstrates the ability to satisfy equivalence criteria for this component for beef.

VI. COMPONENT THREE: SANITATION

The third of the six equivalence components that the FSIS auditors reviewed was sanitation. To be equivalent to the U.S. 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 included an analysis of the CCA's SRT responses, review of records at government offices in the establishments, and observations at the two beef slaughter establishments audited.

The FSIS auditors' review of legislation, regulations, official instructions, and guidelines demonstrates that there are no fundamental differences between U.S. and EU sanitary controls. 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 Guidance Note. The HPRs are equivalent to SSOPs.

The FSIS auditors reviewed sanitation plans and records related to the design and implementation of sanitation programs at the two beef slaughter establishments proposed for U.S. export certification. The FSIS auditors observed pre-operational sanitation at one establishment by shadowing and observing the VI as she conducted 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 isolated findings concerning the CCA's ability to exercise official controls for sanitary operations. These findings were based on observation of the following deficiencies in both establishments:

- In one establishment, persistent contamination of the carcass splitting saw with organic material was not observed by inspection personnel. A design deficiency of the carcass split saw resulted in the build-up of organic debris that was not removed by the routine sanitation process between carcasses. While no contamination of carcasses was observed by the FSIS auditors, the finding was based on the observation that the debris build-up could lead to cross-contamination of carcasses. The inspection personnel assigned to the establishment failed to identify this occurrence as a noncompliance but, after being apprised of the situation by the FSIS auditors, promptly documented the finding and later verified that modifications to the saw effectively eliminated the build-up of organic debris. Since only animals under 30 months of age were being slaughtered that day, no danger existed of cross-contaminating under 30 month carcasses with Specified Risk Material (SRM) from carcasses of over 30 month animals. Routine animal identification, segregation, and sanitation procedures for the slaughter of cattle over 30 months of age prevent the possible cross-contamination of carcasses of cattle under 30 months of age. Furthermore, both beef slaughter establishments slaughter animals over 30 months of age during the last shift of operation and do not commingle carcasses over and under 30 months of age on the slaughter line.

- In one establishment the boning room hooks, prior to use, contained blood residue that was not observed by inspection personnel. After this condition was pointed out by the FSIS auditors, it was discovered that the hook sterilizer was not powered on during the boning operation. The VI issued the establishment a noncompliance and corrective action report, and the establishment took immediate action to sanitize the hooks and power on the hook sterilizer. In the process, establishment maintenance personnel brushed against product moving down the conveyor belt. This product was immediately condemned by the VI, who then issued another noncompliance and corrective action report which resulted in the retraining of the establishment maintenance operative.

- In pre-operational sanitation inspection at one establishment, inspection personnel failed to observe that electrical cords running from an electrical power box and above a boning room conveyor belt, a food contact surface, displayed worn and frayed, particulate plastic insulation. After this was pointed out by the FSIS auditors, the VI issued the establishment a noncompliance

and corrective action report. The establishment took immediate action to isolate and secure the frayed cords pending the identification of a permanent solution.

FSIS' analysis and audit verification activities 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 prerequisite verification and enforcement activity. DAFM's mechanisms for verifying establishment sanitation are comprehensive and complete, but additional effort is needed to ensure that they are consistently and uniformly implemented in all certified establishments.

At the audit exit conference and in email follow-up, DAFM provided the FSIS auditors with a set of corrective action reports and associated establishment actions taken in response to those CARs. FSIS recommended that DAFM require inspection personnel to be retrained in the verification of pre-operational and operational sanitation. In addition to these corrective action records, DAFM provided a copy of the training material and signed attendance rosters to evidence the retraining of inspection personnel assigned to the two beef slaughter establishments proposed for U.S. export certification. Accordingly, the auditors were able to determine that the issues associated with these audit findings have been satisfactorily addressed.

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

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.

To determine whether equivalence was achieved for this component, the FSIS auditors reviewed the information provided by the CCA in the SRT; reviewed records at government offices in the establishments; and observed operations at the two beef slaughter establishments proposed for U.S. export certification. Ireland's meat inspection system follows EU requirements for U.S.-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. These requirements are applied in Ireland under *Statutory Instrument 432: European Communities (Food and Feed Hygiene) Regulations 2009,* as amended.

The FSIS auditors evaluated the design and verified the implementation of HACCP programs at the two beef slaughter establishments according to the CCA's "Guideline on USDA Approval." Both establishments had developed, implemented, and maintained a HACCP plan for products eligible to be certified for U.S. export and ensured that the requirements equivalent to 9 CFR 417.1-417.7 are met as required to remain equivalent. No HACCP plan or recordkeeping deficiencies were identified during this audit.

The FSIS auditors verified through record review and onsite observations that the in-plant inspection personnel at the two beef slaughter establishments 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," which 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 well documented.

The FSIS auditors noted that both beef slaughter establishments proposed for U.S. export certification maintained written SOPs and verification records for SRM removal in accordance with *EC Regulation 999/2001*, which requires 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*.

The FSIS auditors reviewed zero tolerance (feces, ingesta, and milk) CCP records at both establishments and verified the physical CCP locations by observing inspection personnel conducting HACCP hands-on verification activities. No HACCP deviations were identified. 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. The establishments' zero tolerance CCP location coincided with DAFM's verification station, but establishment monitoring and verification checks occurred separately and at a different frequency than DAFM's.

The audit confirmed that Ireland's meat inspection system requires that operators of certified establishments to develop, implement, and maintain HACCP programs for each operation as set forth in accordance with *EC Directives 852 and 854/2004*, the CCA's "Guideline on USDA Approval," and FSIS regulations. The CCA has applied these standards uniformly at the two beef slaughter establishments that were audited.

The CCA continues to demonstrate the ability to satisfy equivalence criteria for this component as required by 9 CFR 327.2.

VIII. COMPONENT FIVE: CHEMICAL RESIDUES CONTROL PROGRAMS

The fifth of the six equivalence components that the FSIS auditors reviewed was Chemical Residue Control Programs. FSIS criteria for this component require the inspection system to have a chemical residue control program designed and administered by the national government that functions to prevent chemical residue contamination of food products. To be considered equivalent to FSIS' program, the program must include random sampling of carcasses and parts for chemical residues identified by the exporting countries and FSIS as potential contaminants. The CCA must provide a description of its residue sampling and testing plan and the process used to design the plan. The CCA must maintain oversight of laboratories to assure the validity and reliability of test data.

The FSIS auditors' review of the SRT and supporting CCA documentation demonstrates that Ireland's chemical residue control program is organized and administered by the national government and

includes random sampling of carcasses and parts for chemical residues identified in the 2014 residue testing plan and 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 residue testing plan for Ireland. FSIS' residue experts thoroughly reviewed the 2013 residue testing plan as well as additional SRT responses outlining the structure of Ireland's chemical testing program. The auditors also conducted an onsite audit of one residue laboratory that performs residue analysis for U.S. certified product.

The FSIS auditors verified that the design of the National Residue Testing Plan includes a description of the basis for the residue plan and the process used to develop it. The residue plan 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 auditors verified that the official veterinarian performs government sampling by packing all tissues separately and sending them to the VPHRL in accordance with the Central Meat Control Laboratory (CMCL) Guidance Document to ensure chain of custody and sample integrity.

The Veterinary Medicines Section (VMS) oversees activities of government testing programs conducted under the National Residue Control Plan and is actively involved in setting and implementing testing policy. The VPHRL conducts all analytical methodologies for compounds in the annual residue plan. . When undertaken in the laboratory, tests are required to be accredited under ISO 17025 and compliance is assessed and verified by the Irish National Accreditation Board (INAB) in its annual assessment. INAB conducted its most recent assessment on September 13, 2013 The VMS has ISO 17025 accredited functions periodically audited by State Veterinary Services Internal Audit Group (SVSIAD). 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 audit findings for review prior to providing the SVSIAD with their response.

The FSIS auditors conducted an onsite audit of the VPHRL, the primary laboratory providing technical support to Ireland's meat inspection system. INAB has accredited the laboratory as meeting the criteria of ISO/IEC 17025, which the FSIS auditors verified by the review of the INAB Accreditation Certificate and Scope of Accreditation issued to VPHRL that was last renewed on February 3, 2011, and by a review of the September 2013 INAB annual assessment report. The FSIS auditors' review of the internal SOPs and onsite observations verified that sampling procedures, analytical procedures, 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 audit of the VPHRL chemical residue laboratory and, ultimately, the chemical residue control program as a whole verified that the following areas met equivalence requirements: sample receipt and tracking, media preparation, integrity of analyses, and oversight and program activity. The auditors did not identify any deficiencies or areas of concern during the audit of this laboratory.

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 as expressed in the FSIS import regulations (9 CFR 327.2).

COMPONENT SIX: MICROBIOLOGICAL TESTING PROGRAMS

The last of the six equivalence components that the FSIS auditors reviewed was Microbiological Testing Programs. This component pertains to the microbiological testing programs organized and administered by the CCA to verify that products destined for export to the U.S. are safe, wholesome, and meet all equivalence criteria.

In accordance with *EC Regulation 2073/2005* and *S.I. 402 of 2009*, Ireland requires establishments to test for *Enterobacteriaceae* and Total Viable Count in raw meat 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 U.S. The establishments that are certified eligible for export to the U.S. have the option to conduct generic *E. coli* testing if they prefer. Ireland has established microbiological testing programs for generic *E. coli* and *Salmonella* both beef slaughter establishments proposed for U.S. export certification.

The auditors' review of this component indicated that DAFM's procedures outlined in *VPN 4/2011, Verification by Veterinary Inspectors of Compliance by Food Business Operators (FBOs) with EC Regulation 2073/2005 (as amended) on Microbiological Criteria for Foodstuffs in DAFM approved Plants,* are being followed by inspection officials to verify sampling for generic *E. coli* and *Salmonella* in the two beef slaughter establishments proposed for U.S. export certification.

In its "Guideline on USDA Approval," DAFM characterizes its sampling and testing program for generic *E. coli* in raw product as: one sample per 300 carcasses weekly or a minimum of one sample per week, from a chilled carcasses, using a sponge, sampling from the flank, brisket, and rump with sample submission to an approved laboratory, and the maintenance of 12 months of records, including 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.

The FSIS auditors 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 DAFM-approved private laboratory and verified by the CCA. Inspection personnel verified that the sample collector is designated in the written plan, the written plan addresses the location of sampling, randomness, sample integrity, appropriate 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.

The FSIS auditors observed the *Salmonella* sampling technique by establishment personnel in those establishments and verified that sampling was being done as per the equivalence determination made by FSIS. In their review of establishment sampling records, however, the FSIS auditors noted that sample dispatch forms were signed by establishment personnel but not countersigned by a DAFM inspector, although the forms noted the name of the inspector who was present when the sample was taken. DAFM

has acknowledged the need for corrective action and has since updated its veterinary procedure notice to require the documentation of sample verification activity by DAFM inspectors. Together with its comments on this report, DAFM provided copies of completed and signed *Salmonella* sampling supervision forms to evidence the verification of establishment *Salmonella* sampling activity by DAFM inspection personnel. Accordingly, the auditor determined that the issue associated with this audit finding had been satisfactorily addressed.

Ireland describes in their Guideline on USDA Approval their sampling program for *Salmonella* species as follows: Steers/Heifers – 82 samples tested with no more than 1 allowable positive; Cows/Bulls – 58 samples tested with no more than 2 allowable positives. The FSIS auditors verified that sampling is performed at the two beef slaughter establishments by establishment employees who collect the samples for *Salmonella* testing and the CCA which provides oversight and monitoring of the establishment's sampling procedures as required to maintain equivalence. Additionally the FSIS auditors observed the sampling technique applied by establishment personnel in those establishments and verified its equivalence to U.S. procedure. The auditors noted that test results for *Salmonella*, generic *E. coli*, and *Enterobacteriaceae* are notified by the laboratory directly to the establishment and not to the Veterinarian-in-Charge at either establishment. The official veterinarian at both establishments had to request laboratory results from establishment personnel. The FSIS auditors addressed this deficiency to DAFM during the audit, and the CCA took immediate corrective action by updating and reissuing its field instruction to require direct transmittal of laboratory results to official veterinarians at certified establishments. Together with its comments on this report, DAFM provided examples of direct email transmittal from the laboratory to the DAFM veterinary inspector of *Salmonella* and *E. coli* test results for the two beef slaughter establishments proposed for U.S. export certification. Accordingly, the auditor determined that the issue associated with this audit finding had been satisfactorily addressed.

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 government *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 in respect of meat preparations. The monthly SVI Audit Checklist includes specific verification of corrective actions, reassessment, and written assurance for *Salmonella* performance standards. In the two beef slaughter 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 auditors reviewed approximately eighteen (18) months of *Salmonella* testing results at each of the two beef slaughter establishments and found that there were no *Salmonella* set failures at either of these establishments that were audited.

The FSIS auditors verified that 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 auditors verified that in both beef slaughter establishments proposed for U.S. export certification, DAFM inspection personnel performed *Shiga-toxin Producing Escherichia coli* (STEC) sampling of beef carcasses eight times per month for the presence of serotypes O157, O26, O145, O111, O104, and O103 in accordance with the carcass swab method prescribed in *VPN 10/2014, Official Verification Program for Testing for Verotoxigenic Escherichia coli*. DAFM has supplied data from studies conducted internally and by the European Food Safety Authority to evidence why STEC O121 and O45 are not public health hazards likely to occur and therefore are not included in its STEC sampling program. VPN 10/2014 prescribes an N60 sampling protocol for beef trim and ground product, although such products are not planned for U.S. export at this time. Establishment samples are taken from four randomly selected carcasses per week in the cooler. Carcasses are held pending receipt of test results from the laboratory, and no product from a carcass associated with a positive test result may be exported to the U.S. Regulatory samples taken by DAFM inspectors are sent to VPHRL for analysis and test results are reported by VPHRL directly to the official veterinarian at the establishment. Establishment STEC samples are sent for analysis to private laboratories accredited by DAFM. The FSIS auditors reviewed sampling records compiled by inspection personnel and noted the recording of inconclusive test results in a few instances. The FSIS auditors conveyed this observation to DAFM personnel during the audit, who acknowledged the deficiency and the need for corrective action. At the audit exit meeting DAFM provided the FSIS auditors with an updated version of VPN 10/2014 containing new instructions for the confirmatory testing of inconclusive STEC screen results by the laboratory prior to reporting analytical results to the official veterinarian. DAFM provided examples of laboratory emails transmitting VTEC confirmatory test results to official veterinarians in accordance with the newly issued laboratory instruction. As result, the issues associated with this audit finding have been satisfactorily resolved.

The FSIS auditors verified that Ireland's 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 accurately test product destined for the U.S. The generic *E. coli* testing of beef carcasses is performed using ISO Method16649-1:2001. The *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.

The current audit 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. FSIS's analysis and audit verification activities of Ireland's microbiological testing program determined that, while Ireland's program includes microbiological sampling requirements that are equivalent to U.S. standards, the manner in which the CCA performed those activities did not, in fact, result in satisfactory verification. DAFM acknowledged this deficiency and provided copies of updated veterinary procedure notices conveying new instructions to inspection personnel regarding the direct reporting of private laboratory test results to DAFM, new procedures for the confirmatory testing of inconclusive STEC sample results, and new procedures for documenting the verification of establishment

microbiological sampling activity. As indicated above, records provided by DAFM evidence the satisfactory implementation of the proffered corrective actions and thus resolve the issues associated with this audit finding.

IX. CONCLUSIONS AND NEXT STEPS

Audit findings indicated a need for improvement in oversight related to the documentation of animal welfare checks, potential conflicts of interest among contract veterinarians, pre-operational and operational sanitation, and verification of micro-sampling activity and test results. These issues were discussed at the audit exit meeting in Dublin on July 7, 2014. The CCA understood and accepted the findings. In the exit conference and in email follow-up, the CCA provided the FSIS auditors with a set of corrective actions taken to address audit findings. For individual establishment findings those included corrective actions reports and associated establishment actions taken in response to those CARs. For findings of a systemic nature, DAFM provided copies of updated veterinary procedure notices conveying new instructions to inspection personnel to correct deficiencies.

While the audit results show that Ireland's inspection system as designed provides equivalent safeguards to the U.S. inspection system for beef, the audit identified some inconsistent or incomplete implementation of equivalent inspection, sanitation, and microbiological testing procedures that necessitated corrective actions by the CCA. DAFM provided records to evidence the satisfactory implementation of corrective actions found acceptable by FSIS. Accordingly, FSIS concludes that Ireland has consistently and effectively implemented a beef slaughter inspection system that satisfies all the criteria for equivalence with the United States system and, consequently, is eligible to resume beef carcass shipments to the United States.

APPENDIX A: Individual Foreign Establishment Audit Checklist

APPENDIX B: Ireland's Comments to FSIS's Draft Final Audit Report

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Foyle Donegal	7-2-2014	EC 292	Ireland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	David Smith, DVM, Robert Tuverson		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.	X
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	
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	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
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.	
59.	

10/14/46 – Carcass splitting saw not properly sanitized between splits; organic matter observed on blade housing after blade sanitation during multiple carcass splits. Temporary corrective action was implemented by including a low pressure hose that followed the splitting saw in tandem. 9 CFR §416.4 (a); 9CFR § 416.13(c); EC Regulations 852 and 853/2004 on the Hygiene of Foodstuffs, and EC Regulation 854/2004 on Official Controls for Products of Animal Origin Intended for Human Consumption..

11 – Electrical cords running from electrical box and above the boning room conveyor belt (food contact surface) showed worn and frayed insulation. Temporary corrective action was taken to reposition cord away from conveyor belt until replacement line could be installed. 9 CFR §416.4(a); 9CFR § 416.13(c); EC Regulations 852 and 853/2004 on the Hygiene of Foodstuffs, and EC Regulation 854/2004 on Official Controls for Products of Animal Origin Intended for Human Consumption.

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	7-3-2014	EC 378	Ireland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	David Smith, DVM, Bob		[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	
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	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
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.	
59.	

60. Observation of the Establishment Date: July 3, 2014 Est #:378)

46. Several carcasses in the cooler were in direct contact with each other creating the possibility of cross contamination. 9 CFR 416.4(a).

46. Several carcass hooks that were used to rehang carcasses in the boning room had blood residues on them. 9 CFR 416.4(a). The cause of the residual blood on the hooks was identified as being the sterilizer was not turned on.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Oto Urban, DVM	

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

5th December 2014

Dr. Andreas Keller,
Director
International Equivalence Staff,
Office of Policy and program Development,
Food Safety and Inspection Service
1400, Independence Avenue, SW
Washington D.C. 20250

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

Dear Dr. Keller

I refer to the draft report of the FSIS on-site audit held from June 30 –July 7, 2014 of Ireland's beef slaughtering system which was received on 20th November 2014.

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 text of the report itself for the sake of accuracy.

I trust the enclosed provides all the documentation requested and that this will enable your services make a timely decision.

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

3 Enclosures

Comments on the FSIS report from the on-site audit of Ireland's beef slaughter inspection system from June 30-July 7, 2014.

1. Page ii, Executive Summary, 3rd indent under paragraph 3:
DAFM lacked official controls to prohibit conflicts of interest arising from the employment of Temporary Veterinary Inspectors (TVIs) who maintain business relationships with suppliers of animals to the regulated establishments.

for clarity, an amendment is proposed -

DAFM lacked official controls to prohibit conflicts of interest arising from the ~~employment~~ engagement of independent professional veterinarians known as Temporary Veterinary Inspectors (TVIs) who maintain business relationships with suppliers of animals to the regulated establishments.

Rationale: Temporary Veterinary Inspectors (TVIs) are not employees of DAFM.

2. Page 2, II. Audit Objectives, scope and methodology, 4th paragraph
FSIS audited two establishments proposed by the CCA for U.S. export certification. Inspection personnel at both establishments were under the supervision of the Northwest Regional Supervisory Veterinary Inspector interviewed by the auditors at DAFM headquarters in Dublin.

for clarity, an amendment is proposed -

FSIS audited two establishments proposed by the CCA for U.S. export certification. Inspection personnel at one establishment were~~both establishments were~~ under the supervision of the Northwest Regional Supervisory Veterinary Inspector and the inspection personnel at the other establishment were under the North East Regional Supervisory Veterinary Inspector. The Northwest Regional Supervisory Veterinary Inspector was interviewed by the auditors at DAFM headquarters in Dublin.

Rationale: The two establishments are in different geographical regions, and are under two different Regional Superintending Veterinary Inspectors.

3. Page 2, II. Audit Objectives, scope and methodology, 5th paragraph
The FSIS auditors also assessed the CCA's verification activities for approved chemical residue and microbiology laboratories. FSIS audited two laboratories, one conducting residue and microbiological testing- DAFM's Veterinary Public Health Regulatory Laboratory (VPHRL), and a private laboratory contracted by DAFM to conduct microbiological testing, Advanced Laboratory Testing, Ltd., to verify that their testing methods are those determined by FSIS to be equivalent to FSIS methods.

for clarity, an amendment is proposed -

The FSIS auditors also assessed the CCA's verification activities for approved chemical residue and microbiology laboratories. FSIS audited two laboratories, one conducting residue and microbiological testing - DAFM's Veterinary Public Health Regulatory Laboratory (VPHRL), and a private laboratory approved by ~~contracted by~~ DAFM which was contracted by an establishment to conduct microbiological testing, Advanced Laboratory Testing, Ltd., to verify that their testing methods are those determined by

FSIS to be equivalent to FSIS methods.

Rationale: DAFM does not contract the private laboratories; this is the obligation of the food business operator.

4. Page 4, 2nd paragraph, last sentence

The VPHIS of the CCA has ultimate control over the slaughtering of livestock and production of food products derived from

Comment- Sentence is incomplete.

5. Page 4, 5th paragraph,

In accordance with *EC Regulation 882/2004* and *SI 432 of 2009,* as amended, DAFM evaluates each certified establishment at least annually to determine the frequency of supervisory veterinary inspection reviews to be performed at each plant in a given year. Based on an establishment's risk score, reviews by the VI occur weekly, every three weeks, or monthly. The same methodology applies to the frequency of Regional Supervisory Inspection Audits at certified establishments, with such audits occurring quarterly, semi-annually, or annually.

for clarity, an amendment is proposed -

In accordance with *EC Regulation 882/2004* and *SI 432 of 2009,* as amended, DAFM undertakes an annual risk assessment of all approved plants not engaged in slaughter activities ~~evaluates each certified establishment at least annually~~ to determine the frequency of supervisory veterinary inspection reviews to be performed at each plant in a given year by both the veterinary inspector (VI) in charge of the plant and the Regional supervisors. In the case of the VI the reviews/oversight of non-slaughter activities occur weekly, every three weeks, or monthly depending on the risk score while Regional inspectors carry out annual or semi-annual or quarterly reviews. Each certified slaughter establishment has a VI assigned to the plant, and there is an ongoing presence of an official veterinarian during ante-mortem and post-mortem. Based on an establishment's risk score for the non-slaughter activities of the establishment, reviews by the VI occur weekly, every three weeks, or monthly. The same methodology applies to the frequency of Regional Supervisory Inspection Audits at certified establishments, with such audits occurring quarterly, semi-annually, or annually.

Rationale: As a slaughter plant has an ongoing presence of a VI for ante-mortem and post-mortem, there is no need for risk assessments of slaughter houses for VIs. However, a risk basis is established for the periodic visits of the Regional supervisory Inspector to each slaughter establishment.

6. Page 5, 3rd paragraph

Inspection personnel assigned to the establishments certified to export meat to the U.S. are full-time, government-paid employees falling into three categories: a) salaried, permanent VPHIS inspectors, b) Temporary Veterinary Inspectors (TVI) serving as contractors to the CCA, and c) salaried, permanent Technical Agricultural Officers (TAO).

for clarity, an amendment is proposed -

Inspection personnel assigned to the establishments certified to export meat to the U.S. are ~~full-time,~~ government-paid personnel ~~employees~~ falling into three categories: a) salaried, permanent VPHIS inspectors, b) Temporary Veterinary Inspectors (TVI) serving as contractors to the CCA, and c) salaried, permanent Technical Agricultural Officers (TAO).

Rationale: TVIs are not full time or employees of DAFM

7. Page 6, 2nd paragraph

Because TVIs continue to practice veterinary medicine privately while performing their official inspection duties for DAFM, the auditors noted a conflict of interest with respect to TVI ante-mortem inspection assignments in the beef slaughter establishments audited. While acting in an official capacity, TVIs have access to animal and supplier identification records maintained at animal intake in each establishment and thus have the potential to influence disposition decisions for animals from locations where they provide private veterinary services. Although *EU Regulation 882/2004* requires Member States to establish mechanisms to prevent inspector conflict of interest, with such restrictions also codified in the Terms and Conditions of Employment of the Irish Civil Service, these requirements apply only to permanent employees of the government and not contract employees.

for clarity, an amendment is proposed -

Because TVIs continue to practice veterinary medicine privately while ~~performing~~ providing ~~their~~ official inspection services~~duties~~ for DAFM, the auditors noted a conflict of interest with respect to TVI ante-mortem inspection assignments in the beef slaughter establishments audited. While acting in an official capacity, TVIs have access to animal and supplier identification records maintained at animal intake in each establishment and thus have the potential to influence disposition decisions for animals from locations where they provide private veterinary services. Although *EU Regulation 882/2004* requires Member States to establish mechanisms to prevent inspector conflict of interest, with such restrictions also codified in the Terms and Conditions of Employment of the Irish Civil Service, these requirements apply only to permanent employees of the government and not contractors. ~~contract employees.~~

Rationale: TVIs are not contract employees.

8. Page 6, 5th (last) paragraph

Official veterinarians in Ireland must complete 250 credit hours in veterinary public health in order to maintain their veterinary certification.

for clarity, an amendment is proposed -

Official veterinarians in Ireland must complete 20 ~~250~~ credits ~~hours~~ in veterinary public health, animal health and animal welfare annually, or a total of 60 credits over the previous 3 years in order to maintain their veterinary registration~~certification~~.

Rationale: To give full clarity on the continuing education programme of VPHIS of DAFM.

9. Page 8, Part V, 2nd para within Part V, 10th line

Subsequent rulings adopted in 2005 *(EC Regulation 2003/2005)* also provide equivalent

requirements for microbiological criteria for food, health certification of products of animal origin, and examination for *Trichinella* in slaughtered swine.

for clarity, an amendment is proposed -

Subsequent rulings adopted in 2005 *(e.g. ~~EC~~ EU Regulation 2073/2005 ~~2003120005~~*on microbiological criteria for foodstuffs*)* also provide equivalent requirements for microbiological criteria for food, health certification of products of animal origin, and examination for *Trichinella* in slaughtered swine.

Rationale: To correct an incorrect reference to a Regulation

10. Page 9, 2nd para,
SI 311/2010 – Welfare of Farmed Animals

should be replaced by

SI 292/2013 - European Union (Protection of Animals at the Time of Killing) Regulations 2013

SI 292 of 2013 Reg 1099.pdf

Rationale: animal welfare at slaughter is now regulated by EU Regulation 1099/2009 which is implemented in Irish law by SI 292/2013 European Union (Protection of Animals at the Time of Killing) Regulations 2013

11. Page 9: 3rd paragraph, 1st indent
SOP No 02/2006: Bovine Welfare at DAFM Approved Beef Slaughter Establishments

should be replaced by -

SOP No 1/2014: Official Controls on Animal Welfare at DAFM Supervised Slaughter Plants

AnimalWelfareSOP01 2014270114.pdf

Rationale: Due to the introduction of EU Regulation 1099/2009 (referred to above) a new animal welfare SOP was introduced which replaced all existing animal welfare SOPs. This SOP is attached.

12. Page 11, Top of page 1st line
Additionally, PAT records did not indicate that Stun to Stick Intervals, Sticking/Bleeding Procedures, and Stick to Dress Intervals were verified as required by *SI 311, Welfare of Farmed Animals Regulations* and outlined in *SOP 02/2006, Bovine Welfare at DAFM Approved Beef Slaughter Establishments.*

for clarity, an amendment is proposed -

Additionally, PAT records did not indicate that Stun to Stick Intervals, Sticking/Bleeding Procedures, and Stick to Dress Intervals were verified as required by SI 292/2013 European Union (Protection of Animals at the Time of Killing) Regulations 2013 ~~*SI 311, Welfare of Farmed Animals Regulations*~~ and outlined in SOP No 1/2014: Official Controls

on Animal Welfare at DAFM Supervised Slaughter Plants ~~*SOP 02/2006, Bovine Welfare at DAFM Approved Beef Slaughter Establishments.*~~

Rationale: To correct an incorrect reference to a Statutory Instrument and an SOP, which was issued in January 2014, after the SRT was finalised and submitted to USDA / FSIS.

13. Page 17, 5th paragraph

The FSIS auditors verified that in both beef slaughter establishments proposed for U.S. export certification, DAFM inspection personnel performed *Shiga-toxin Producing Escherichia coli* (STEC) sampling of beef carcasses eight times per month for the presence of serotypes 0157, 026, 0145, 0111, 0104, and 0103 in accordance with the carcass swab method proscribed in *VPN 10/2014, Official Verification Program for Testing for Verotoxigenic Escherichia coli.* DAFM has supplied data from studies conducted internally and by the European Food Safety Authority to evidence why STEC 0121 and 045 are not public health hazards likely to occur and therefore are not included in its STEC sampling program. VPN 10/2014 proscribes an N60 sampling protocol for beef trim and ground product, although such products are not planned for U.S. export at this time.

for clarity, an amendment is proposed -

The FSIS auditors verified that in both beef slaughter establishments proposed for U.S. export certification, DAFM inspection personnel performed *Shiga-toxin Producing Escherichia coli* (STEC) sampling of beef carcasses eight times per month for the presence of serotypes 0157, 026, 0145, 0111, 0104, and 0103 in accordance with the carcass swab method prescribed~~proscribed~~ in *VPN 10/2014, Official Verification Program for Testing for Verotoxigenic Escherichia coli.* DAFM has supplied data from studies conducted internally and by the European Food Safety Authority to evidence why STEC 0121 and 045 are not public health hazards likely to occur and therefore are not included in its STEC sampling program. VPN 10/2014 prescribes~~proscribes~~ an N60 sampling protocol for beef trim and ground product, although such products are not planned for U.S. export at this time.

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