USDA

United States Department of Agriculture

Food Safety and
Inspection Service

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

MAY 17 2018

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

Dear Mr. Blake,

The Food Safety and Inspection Service (FSIS) conducted an onsite audit of Ireland's inspection system from September 11 through September 29, 2017. Enclosed is a copy of the final audit report. The comments received from the Government of Ireland are included as an attachment to the report.

FSIS is the process of evaluating your responses, and upon completion of the document review, FSIS will schedule an onsite audit to verify that the inspection system for raw lamb and mutton is functioning in a manner equivalent to that of the United States prior to permitting the importation of these products from Ireland.

If you have any questions, please feel free to contact the Office of International Coordination by email at InternationalCoordination@fsis.usda.gov.

Sincerely,

Todd Furey
Acting International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN THE

REPUBLIC OF IRELAND

September 11 – 29, 2017

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

MEAT

EXPORTED TO THE UNITED STATES OF AMERICA

May 11, 2018
Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from September 11 – 29, 2017. The purpose of the audit was to determine whether Ireland's food safety system governing raw pork and beef remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. In addition, the audit included an assessment to reinstate Ireland's lamb inspection system, pending the Animal and Plant Health Inspection Service (APHIS) lifting import restrictions on sheep and goats, and their products, based on Bovine Spongiform Encephalopathy (BSE). Ireland currently exports raw pork and beef products to the United States.

The audit focused on six equivalence system components: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditor's analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditor did not identify any systemic findings in the assessment of programs governing raw pork and beef products currently eligible for export.

In reference to reinstatement of equivalence for Ireland's lamb inspection system, the FSIS auditor examined the administrative functions of Ireland's Central Competent Authority (CCA) and the two local inspection offices overseeing the lamb slaughter establishments being audited. The FSIS auditor identified the following findings in regards to the lamb slaughter operations:

Government Statutory Authority and Food Safety and Other Consumer Protection Regulations

- At two lamb slaughter establishments audited:
    - Not all carcass and parts are handled in a manner to identify them with the rest of the carcass and are not available for post-mortem examination and veterinary disposition.
    - The physical critical control point (CCP) monitoring location for government verification of zero tolerance is not before the final wash.

During the audit exit meeting on September 29, 2017, the CCA committed to begin addressing the preliminary findings as presented in this report. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions. FSIS will then determine whether it needs to audit again or whether a records review will be sufficient.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite audit of Ireland's food safety system from September 11 – 29, 2017. The audit began with an entrance meeting on September 11, 2017, in Dublin, Ireland, with the participation of the FSIS auditor and of representatives from the Central Competent Authority (CCA), the Department of Agriculture, Food, and the Marine (DAFM).

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This audit was conducted to verify ongoing equivalence of Ireland's pork and beef inspection system, and to carry out a reinstatement evaluation of Ireland's lamb inspection system. The objective of this audit was to ensure Ireland's food safety system governing meat remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. The scope of this audit included all aspects of Ireland's inspection system for producing and exporting raw meat products to the United States. Ireland is currently eligible to export raw pork and beef products to the United States.

FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, findings of prior audit-related site visits, point-of-entry (POE) testing results, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS over a three-year period, in addition to information obtained directly from the DAFM through a self-reporting process.

Representatives from the DAFM accompanied the FSIS auditor throughout the entire audit. The FSIS auditor focused on the performance within the following six components upon which system equivalence is based: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

FSIS reviewed administrative functions at CCA headquarters in Dublin, one regional office, and nine local inspection offices at the audited establishments. The FSIS auditor evaluated the implementation of control systems in place that ensure that the national system of inspection, verification, and enforcement is being implemented as intended. The FSIS auditor also verified that corrective actions related to the previous 2015 FSIS audit had been effectively implemented. During the 2015 audit, the FSIS auditor identified veterinary post-mortem inspectors were not following the documented post-mortem inspection procedures; slaughter-line installations did not provide for sanitization of the post-mortem viscera pans; deficiencies related to inadequate monitoring and documentation of critical control points; and deficiencies related to the implementation of generic *Escherichia coli* (*E. coli*).

FSIS selected a sample of seven establishments to audit from a total of 13 establishments certified to export pork and beef to the United States, three pork and four beef slaughter and processing establishments. Additionally, the DAFM identified two lamb slaughter and processing establishments for inclusion in the audit, one located in the North Eastern Regional Veterinary Public Health Inspectorate and the other located in the South Eastern Regional Veterinary Public Health Inspectorate.

During the audited establishments' visit, the FSIS auditor paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that threaten food safety. The FSIS auditor examined the CCA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign inspection systems. These requirements are outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) §327.2, the FSIS regulations addressing equivalence determinations for foreign country inspection systems for meat products.

FSIS also audited two laboratories, one private microbiology laboratory located in Newbridge, and one government residue and microbiology laboratory located in Backweston, to verify technical support to the inspection system and to assess the oversight that the DAFM maintains over their functions.

Competent Authority Visits		**#**	**Locations**
Competent Authority	Central	1	• DAFM, Dublin
	Regional Office	1	• North East Regional Office, Navan
Laboratories		2	• Advanced Laboratory Testing LTD (ALT), private microbiology laboratory, Newbridge • Veterinary Public Health Regulatory Laboratory (VPHRL), government residue, microbiology laboratory, Backweston
Beef slaughter and processing establishments		4	• Est. # 292, Carrigans • Est. # 296, Bunclody • Est. # 313, Athleague • Est. # 533, Longford
Pork slaughter and processing establishments		3	• Est. # 332, Grannagh • Est. # 355, Roscrea • Est. # 356, Edenderry
Lamb slaughter and processing establishments		2	• Est. # 313, Athleague • Est. #367, Camolin

The audit was undertaken under the specific provisions of United States' laws and regulations, in particular:

- The Federal Meat Inspection Act (21 United States Code [U.S.C.] 601, *et seq*.);
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901, *et seq*.); and
- The Food Safety and Inspection Service Regulations for Imported Meat (9 CFR Part 327).

The audit standards applied during the review of Ireland's inspection system for meat included: (1) all applicable legislation originally determined by FSIS as equivalent as part of the initial

review process, and (2) any subsequent equivalence determinations that have been made by FSIS under provisions of the World Trade Organization's Sanitary/Phytosanitary Agreement.

Currently, Ireland has equivalence determinations from FSIS for the following regulations and legislation:

- Regulation European Commission (EC) No. 178/2002;
- Regulation (EC) No. 852/2004;
- Regulation (EC) No. 853/2004;
- Regulation (EC) No. 854/2004;
- Regulation (EC) No. 882/2004;
- Regulation (EC) No. 2073/2005;
- Regulation (EC) No. 1099/2009;
- Council Directive 93/119/EC;
- Council Directive 96/22/EC;
- Council Directive 96/23/EC;
- Council Directive 97/747/EC; and
- Council Directive 2000/13/EC.

III. BACKGROUND

Ireland currently exports raw pork and raw intact beef to the United States. From October 1, 2015 to May 31, 2017, FSIS import inspectors performed 100 percent re-inspection for labeling and certification of 27,471,635 pounds of meat exported by Ireland to the United States. FSIS also performed re-inspection on 2,743,597 pounds at POE for additional types of inspection (TOI), of which no product was rejected because of food safety issues and 54,632 pounds were refused entry for issues not involving food safety concerns (e.g., shipping damage, labeling issues, and certificate issues).

In 2015, FSIS conducted an audit of Ireland's pork and beef inspection systems, identifying issues related to the Government Oversight, Government Sanitation, Government HACCP System, Government Chemical Residue Testing Programs, and Government Microbiological Testing Programs components, indicating inadequacies in the DAFM's oversight at the United States-certified establishments. The DAFM proffered and completed acceptable corrective actions to address the audit findings.

Ireland has not exported lamb products to the United States since January 1998, when the United States introduced import restrictions on beef, sheep, and goats and meat products thereof based on Bovine Spongiform Encephalopathy (BSE). In December 2014, Ireland was reinstated to export raw beef products to the United States. In November 2015, the DAFM submitted a request to FSIS for reinstatement to export lamb products to the United States. In order for Ireland to export lamb products to the United States, the DAFM must meet Animal and Plant Health Inspection Service (APHIS) regulation 9 CFR § 94.24, as well as be determined by FSIS to meet the United States level of protection. At the time of this audit and currently, APHIS has not lifted this ban. Therefore, if FSIS were to list Ireland as a country eligible to export lamb products derived from product slaughtered in Ireland, the ability to do so would be limited by APHIS under 9 CFR § 94.24.

Subsequent to the 2015 audit, Ireland submitted documentation for reinstatement of equivalence for its lamb slaughter system. Ireland updated its self-reporting tool (SRT) to provide information pertaining to the lamb slaughter inspection system. FSIS determined that Ireland's system of controls, as represented in its SRT submission, provided an equivalent inspection system to that in the United States. Therefore, FSIS conducted an on-site audit to verify that Ireland's lamb food safety inspection system is being implemented as described in the SRT. For the verification of its lamb inspection program, the DAFM identified two lamb slaughter establishments for inclusion in the current audit.

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

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

The first of six equivalence components that the FSIS auditor reviewed was Government Oversight. FSIS import regulations require the foreign inspection system to be organized by the national government in such a manner as to provide ultimate control and supervision over all official inspection activities. The national government must ensure the uniform enforcement of requisite laws, provide sufficient administrative technical support, and assign competent qualified inspection personnel at establishments where products are prepared for export to the United States. The assessment of this component included a review and analysis of the information provided by the DAFM in the updated SRT and observations during the onsite audit.

The FSIS auditor verified that the inspection system is organized and administered by the national government of Ireland, providing a single standard of inspection and sanitation maintained throughout all United States-certified establishments. There have been no major changes in the CCA's organizational structure since the last FSIS audit in 2015. However, there was an administrative change, the CCA added a new Director of Operations that is responsible for overall program implementation. The organizational structure over which policy and implementation supervise a team of central and regional based superintending veterinary inspectors remains consistent.

Ireland is a member of the European Union (EU), has adopted the EU legislation pertaining to food of animal origin, and has based its authority to enforce inspection laws under Regulation (EC) No. 178/2002. This is reinforced by the National Legislation Statutory Instruments (SI) No. 432/2009, to enforce the necessary requirements to export to another country. The Food Safety Authority of Ireland (FSAI) maintains overarching authority over the nation's food supply, delegating the authority to subordinate agencies to exercise official food inspection controls. The CCA has the responsibility to develop and oversee the implementation of inspection procedures in accordance with national standards, in addition to those standards imposed by importing countries.

In Ireland, the meat inspection system is organized on three levels: central, regional, and local.

- The central level consists of the personnel in the central office (headquarters) in Dublin. The Chief Veterinary Officer (CVO) and a management team of Senior Veterinary Management (SVM) are based in the Agriculture House headquarters. The SVM team consists of a Deputy CVO and two Senior Superintending Veterinary Inspectors (SSVI) supervising a team of Superintending Veterinary Inspectors (SVIs). The Deputy CVO is in charge of the Veterinary Public Health Inspection Service (VPHIS). VPHIS has ultimate control over the slaughtering of livestock and production of food products derived from animals.
- The regional level includes six Regional Veterinary Public Health Inspectorates (East, North East, North West, Mid-West, South East, and South West). Each regional office is supervised by a Regional Superintending Veterinary Inspector (RSVI) who oversees the implementation of veterinary inspection controls in the meat establishments in their jurisdiction and reports directly to headquarters.
- The local level is comprised of the DAFM veterinary offices located in each of the establishments certified to export to the United States. Each office has a Veterinary Inspector (VI) who is in charge of inspection activities in the establishment. The VI has direct supervision over all other inspection personnel assigned to the certified establishment, including Temporary Veterinary Inspectors (TVIs) and Technical Agricultural Officers (TAOs). The RSVI and the VI assess the eligibility of establishments to export to the United States. Their duties also include initiating investigations into the failure of an establishment to meet the standards of the importing country and to provide documentation to the DAFM to support delisting those establishments that fail. The VI in certified establishments performs the daily supervision of establishment activities and reports directly to the RSVI, who performs the periodic supervisory reviews.

All products destined for export to the United States are produced in certified establishments. The DAFM is responsible for official controls on certain products of animal origin (e.g., meat, milk, eggs) from primary production, through slaughter, processing, wholesale and distribution. The DAFM is also responsible for official controls on imports from third countries of products of animal origin at border inspection posts (BIPs).

A number of measures commonly referred to as the Hygiene Package regulate food safety controls in Ireland. Under the Hygiene Package, the DAFM is authorized to carry out inspections of all meat establishments for hygiene approval. Packaging is regulated by Regulation (EC) No. 1935/2004 on food contact materials. Labeling of meat in the EU is regulated by the EU Labeling Regulations (e.g., general labeling requirements). Council Directive 2000/13/EC states that labeling methods must not mislead the consumer. Only products that have passed the required laboratory tests, with the exception being the official residue testing results, will be exported to the United States. In the event that adulterated products were to be shipped to United States, the DAFM is responsible for informing FSIS immediately.

The FSIS auditor examined the DAFM headquarters' oversight activities and verified the implementation and oversight of the periodic supervisory reviews of certified establishments. The DAFM is responsible for conducting audits to determine initial and annual approval of official establishments, including those eligible to export to the United States. The DAFM has

the sole authority to grant final certification of a new establishment or to permit an existing United States-certified establishment to maintain its eligibility to export to the United States. At the central level, the DAFM is responsible for designing policies for primary production, animal welfare, and slaughterhouses.

The DAFM has the legal authority and responsibility to develop and oversee the implementation of inspection procedures in accordance with national standards, in addition to those standards imposed by importing countries. These laws and regulations are applicable to all certified establishments. The laws and regulations provide the DAFM with the legal authority and responsibility to enforce requirements equivalent to those governing the system of meat inspection organized and maintained in the United States, including suspension of operations and removing the eligibility of establishments to export to the United States.

VPHIS operates under the supervision of the Deputy CVO, two SSVIs, and three SVIs based at headquarters, and six regionally based SVIs who oversee the implementation of veterinary controls in the United States-certified establishments in their areas, reporting directly to headquarters. VIs are permanently located in United States-certified establishments and are responsible for the provision of the ante and post-mortem inspection service; checks on hygiene standards; audits of HACCP programs; inspections of structural and operational hygiene standards; controls on animal welfare; animal identification; residues; and reviews for specific biological pathogens such as *Salmonella* and Shiga toxin-producing *E. coli* (STEC) in raw beef products.

The FSIS auditor verified implementation of the certification review process, including audit reports of the establishments, sanitation requirements, facility maintenance, sanitation standard operating procedures (Sanitation SOPs), HACCP programs, and microbial testing. The audit reports demonstrated that the DAFM evaluated the written food safety programs, audited the facilities, and evaluated their compliance with the FSIS requirements before granting certification of eligibility to export meat to the United States.

The current audit included the review of the administrative functions in one regional office. The regional offices provide oversight and are responsible for ensuring that all the FSIS requirements are met at United States-certified establishments within their respective regions. The FSIS auditor verified that the regional offices provide periodic supervisory reviews at the United States-certified establishments. The FSIS auditor examined a sampling of reviews to determine whether these reviews were conducted to ensure that requirements referred to in relevant subsections of 9 CFR Part 327.2 were met. No concerns were identified during the audit of the regional office.

The DAFM ensures that source meat products used in processing operations originate only from certified establishments in accordance with SI No. 893 of 2004, which does not allow the introduction or commingling of meat from ineligible countries or non-certified establishments if the product does not comply with the food law of that importing country. The DAFM has issued to government inspection personnel Veterinary Procedural Notice (VPN) No. 12/2015, which provides instructions regarding non-commingling.

The FSIS auditor verified that DAFM prevents fraud or misuse of export health certificates. The VI signs the certificates, which are recorded in the server register with an embossed stamp on each page and each number being a single unique number. The government seal and security accountability logs are kept in a secured and locked location. A tracking system is in place at the DAFM headquarters and at the establishment level by the VIs who maintain all export certificates, ensuring traceability with each hard copy being kept at the regional offices.

The DAFM maintains a communication system to convey requirements related to United States export throughout its inspection system in a timely manner. The DAFM disseminates information to all levels of government 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 the DAFM's intranet site and distributed by email to inspection personnel. Additionally, all inspection personnel receive email instructions to register on the FSIS Web site for relevant updates.

The FSIS auditor verified that Ireland's meat inspection system provides for inspectors on the line during all slaughter operations and inspection at least once per shift during processing operations through onsite audit of United States-certified establishments, onsite record reviews, interviews, and observations of inspectors. The VI in charge at United States-certified slaughter establishments is headquartered and has a permanent daily presence at the establishment. At certified establishments other than slaughter establishments, there is a permanent presence of the DAFM inspection personnel under the supervision of the VI assigned to the establishment. The inspection system provides for direct and continuous (daily) official supervision of slaughter activities and preparation of products.

All of the DAFM personnel are employees of the government of Ireland and subject to administrative policies that apply to all government officials. Inspection personnel fall into three categories: a) salaried, permanent VPHIS inspectors, b) TVIs serving as contractors to the CCA, and c) salaried, permanent TAOs. All inspectors authorized to perform the controls are government inspectors. They are directly paid by the government; hired and fired by the government (through the DAFM); have the same obligations regarding training, independence, confidentiality, impartiality, and integrity; and have the authorization to act on behalf of the government and to spend government funds. The DAFM has ultimate control and supervision over the activities of all inspectors.

The FSIS auditor verified that all inspection personnel conducting government verification activity including ante-mortem and post-mortem inspection are government inspection personnel. Each category of inspector receives no payment from either industry groups or establishment management. The FSIS auditor verified that the inspection personnel assigned to perform control in United States-certified establishments are employees of the government through a review of letters of appointment and CCA payroll records of inspection personnel salaries. The government pays the personnel responsible for regulatory decisions regarding United States-eligible products.

The DAFM maintains enough competent and qualified personnel to ensure the production of safe, wholesome, and accurately labeled product in certified establishments. In accordance with Regulation (EC) No. 854/2004, Ireland ensures that government inspection personnel have appropriate education credentials, and necessary training and experience to carry out government inspection tasks. Newly hired inspection personnel complete initial inspection training and, after an evaluation, receive on-the-job training prior to reporting to their final assignments. Ongoing training and support are coordinated primarily by and provided through the regional staff. The FSIS auditor verified that the DAFM has implemented and conducted ongoing training programs intended to ensure that government inspection personnel are aware of specific food safety and inspection requirements that pertain to Ireland's meat export to the United States.

The DAFM provides initial and specialized ongoing training to government inspection personnel assigned to certified establishments for specific United States import requirements pertaining to pathogen reduction, HACCP systems, sanitation, humane handling and slaughter, and enforcement. The FSIS auditor determined that the DAFM's supervisory chain of command has a mechanism that assesses the inspectors' training needs and provides recommendations as appropriate. The FSIS auditor verified the training records of official inspection personnel at government and local inspection offices, in addition to observing their performance while conducting inspection activities, concluding they have sufficient training to perform their inspection activities.

The DAFM maintains administrative and technical support to operate its laboratory system. The official tasks of control are performed according to Regulation (EC) No. 854/2004. The DAFM ensures that the laboratories possess the personnel, facilities, equipment, and methods necessary to fulfill their mission. The DAFM laboratories are part of the government service. The Director of Laboratories is a member of the DAFM management structure (MAC) and reports directly to the Secretary General, who in turn reports directly to the Minister. The laboratory has a board of management; participants include several MAC members, including the Chief Veterinary Officer. Government inspection personnel are assisted at all times by technical staff that provide support with documentary checks and such tasks as sample handling, documentation, and submission to laboratory.

Each laboratory is accredited in accordance with the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025, General requirements for the competence of testing and calibration laboratories, standard by the Irish National Accreditation Board (INAB). INAB, the Food Safety Authority of Ireland (FSAI), and the DAFM conduct periodic reviews of the activities of the laboratories that DAFM oversees. Government inspection personnel carry out the sampling for regulatory testing programs. The DAFM has the authority to suspend any laboratory at any time.

The method of analysis for tests conducted relevant to FSIS approval must be equivalent to the latest version of the Microbiology Laboratory Guidebook (MLG) 4 for *Salmonella*, MLG 5 for *E. coli* O157:H7, and MLG 5B for STEC. Monitoring of laboratories accredited by a national accreditation authority or approved by the DAFM is done by means of verifying the laboratory's continuation of accreditation or approval. Accredited laboratories approved for testing product being exported to the United States are required to submit a copy of their annual INAB

assessment to the DAFM's VPHRL for review. The DAFM audits these laboratories every two years.

Laboratories must comply with both national and EU legislative requirements and are subject to various internal and external audits. Laboratories are designated by the DAFM and most testing is carried out in laboratories directly under the control of the DAFM. All laboratories must be accredited and individual contracts specify delivery of testing. As part of the two-year audit by the DAFM, the audit verifies methods/validation reports; staff records, which include training/experience; equipment records/calibration; and laboratory suitability/design.

The FSIS audit included onsite visits to the ALT, a private microbiological laboratory located in Newbridge that conducts microbiological testing of samples for establishments certified to export to the United States; and the VPHRL, a government residue and microbiological laboratory located in Backweston that conducts analytical testing as part of Ireland's national residue program, as well as microbiological testing of official samples. No concerns arose as the result of these reviews.

The FSIS auditor determined that the government of Ireland organizes and administers the meat inspection system, and that the DAFM officials enforce laws and regulations governing production and export of meat at certified establishments.

V. COMPONENT TWO: GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (E.G., INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)

The second of six equivalence components that the FSIS auditor reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of carcasses and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; daily inspection; periodic supervisory visits to official establishments; and requirements for thermally processed/commercially sterile products.

The evaluation of this component included a review and analysis of the information provided by DAFM in the updated SRT and direct observations, onsite records review, and interviews during the onsite audit. The FSIS auditor verified that the DAFM maintains regulatory authority as outlined in official legislation, regulations, decrees, policies, and guidelines. The DAFM's authority is in accordance with the following:

- Regulation (EC) No. 999/2001 on the requirement for removing specified risk materials (SRM) and its disposal as inedible product;
- Regulation (EC) No. 1774/2002 on animal by-products not intended for human consumption;
- Regulation (EC) Nos. 178/2002 and 852/2004 on the hygiene of foodstuffs;
- Regulation (EC) No. 853/2004 describing specific hygiene rules for the food of animal origin;

- Regulation (EC) No. 854/2004 describing specific rules for the organization of official controls on products of animal origin intended for human consumption;
- Regulation (EC) No. 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) No. 1069/2009 describing animal byproducts regulation;
- Regulation (EC) No. 1099/2009 on the legal requirements for the humane handling of animals in the slaughter establishments;
- Decision 98/258/EC on the conclusion of the Agreement between the European Community and the United States on sanitary measures to protect public and animal health in trade in live animals and animal products;
- SI No. 893/2004 on product of animal origin complying with food law of the EC or another equivalent country;
- SI No.183/2009 on measures to monitor certain substances and residues in live animals and animal products;
- SI No. 432/2009 on food and food hygiene as related to the DAFM in regards to the production, control, and marketing of food and feed; and
- SI No. 292/2013 on the protection of animals at the time of slaughter.

The FSIS auditor interviewed the DAFM personnel, and reviewed records maintained at the DAFM headquarters and local inspection offices in each audited establishment. The FSIS auditor verified that the DAFM provides appropriate oversight and direction to government inspection personnel implementation of regulatory authority to enforce requirements for Ireland's meat food safety system. The FSIS auditor, accompanied by the DAFM representatives, observed the performance of verification activities by the government inspection personnel.

The verification activities observed included ante-mortem inspection; humane handling and slaughter verification; post-mortem inspection; zero tolerance verification of establishment's procedures for controlling feces, ingesta, and milk contamination; *Salmonella* performance standard sample collection; analysis of establishment generic *E. coli* sample results; verification of pre-operational and operational sanitation verification procedures; and HACCP verification activities. Additionally, the FSIS auditor assessed the performance evaluation of government inspection personnel and the completion of supervisory reviews of establishments certified as eligible for export to the United States.

Ireland's food safety system provides for the humane handling and slaughter of livestock. The DAFM has the legal power to enforce legislation. Relevant training is provided related to the protection of animals at the time of slaughter and related operations. Regulation (EC) No. 1099/2009 and SI No. 292/2013 describe the legal requirements for the humane handling of animals in the slaughter establishments. The DAFM has implemented comprehensive humane handling standard operating procedures (SOP) No. 01/2014.

The SOP covers all aspects of animal welfare for all species presented for slaughter at the DAFM approved slaughterhouses. It is the responsibility of the VI with the assistance of the government inspection personnel to enforce acts and orders. The DAFM maintains written requirements to provide for the humane treatment of livestock at slaughter. The VI verifies compliance with

relevant EC and national rules on animal welfare (humane handling), such as rules concerning the protection of animals at the time of slaughter and during transport as part of the VI's daily inspection and documentation of the findings.

The FSIS auditor verified through records review and observation that the inspection system ensures requirements for livestock facilities and humane handling and slaughter are equivalent to those of the United States. Government inspection personnel verify that operators comply with humane handling and slaughter requirements. In all the audited establishments, government inspection personnel verified that the animals were insensible to pain; and through observation, the loss of consciousness and accompanying indicative signs of adequate stunning before being shackled and bled.

The FSIS auditor verified that the ante-mortem inspection activities of government inspection personnel complied with Regulation (EC) Nos. 853/2004 and 854/2004. The DAFM has in place SOPs for the ante-mortem inspections of pork, beef, and lamb. Included in these SOPs is the responsibility of DAFM veterinarians, relevant legislation, procedure, and enforcement. Only pork and beef that originate in Ireland are slaughtered at establishments that are eligible to export to the United States. This ensures that only meat products currently not restricted by APHIS are designated for export to the United States. The DAFM ensures that if lamb were to be reinstated, only lamb that originate in Ireland would be slaughtered at establishments that would be eligible to export to the United States.

The government inspection personnel conducted ante-mortem inspection on the day of slaughter and reviewed the incoming registration and identification documents with each load/truck that allows for the traceability of the animal to its source. They also observed all animals while at rest and in motion in the unloading and ante-mortem inspection pens prior to slaughter to determine whether the animals are fit for slaughter. The FSIS auditor observed and verified that all animals had access to water at all times in all holding pens, including the suspect pens, and that if an animal was to be held overnight, feed would be provided. For each inspected lot, the DAFM personnel document the results of ante-mortem inspection and numbers of livestock accompanying each lot to slaughter.

Each audited establishment maintained a designated holding pen for further examination of sick or suspect animals. The VI examines any suspect livestock identified with conditions that may preclude slaughter, and documents the results on a form designated for ante-mortem inspection. Ireland has adopted a zero tolerance policy against the slaughter of non-ambulatory disabled cattle. Additionally, the VI documents livestock condemned on either ante-mortem or post-mortem inspection on a condemnation form and all products are rendered unsuitable for human food. The implementation of ante-mortem inspection complies with United States requirements for ante-mortem inspection of livestock.

The requirements for conducting post-mortem inspection are described in Regulation (EC) No. 854/2004 and are documented procedures of the DAFM. The VI is responsible for supervising post-mortem procedures. Post-mortem inspection must be conducted for every animal slaughtered, whether for domestic use or export to another country. The post-mortem inspection

is conducted by government inspection personnel that must be physically present in the facility during every stage of slaughter.

The FSIS auditor verified that every carcass was subject to post-mortem inspection activities during and after the slaughter of swine, beef, and lamb through onsite record reviews, interviews, and observations of inspectors conducting post-mortem inspection. This includes zero tolerance verification for fecal material, milk, and ingesta performed by the on-line government inspection personnel on each carcass slaughtered during all slaughter operations.

Government inspection personnel are trained in performing post-mortem inspection activities. The FSIS auditor verified that the proper presentation, identification, examination, and disposition of carcasses and parts are being implemented at the United States-eligible pork and beef slaughter establishments. However, the following deficiency was identified at the two lamb slaughter establishments audited.

- Carcass and parts are not handled in a manner to identify them with the rest of the carcass and are not available for post-mortem examination and veterinary disposition.

The FSIS auditor also verified that audited establishments are providing government inspection personnel with the appropriate facilities to conduct post-mortem inspection (i.e., inspection stations, adequate lighting, etc.). The FSIS auditor observed the performance of examination of carcasses and viscera at each certified establishment and verified government inspection personnel were implementing DAFM's government inspection procedures as written. Deficiencies observed in the 2015 audit concerning post-mortem inspection had been corrected, implemented, and confirmed.

During the post- mortem inspection of pork, beef, and lamb the government inspection personnel verify there is no fecal matter, ingesta, or milk contamination. In addition, an official off-line inspection plan must be arranged so that the government inspection personnel can check the absence of contamination by visual inspection, according to predefined procedures, on randomly selected carcasses. The number of carcasses selected for visual inspection of internal and external surfaces depends on the number of animals slaughtered and the random selection procedure is defined in the inspection plan. The sampling location is after the post- mortem inspection station and before the final wash at the United States-eligible pork and beef slaughter establishments. The government inspection personnel also check that there is no non-fecal contamination (e.g., hair, etc.). However, the following deficiency was identified at the two lamb slaughter establishments audited.

- The physical CCP monitoring location for government verification is in the chill room or after the pre-bone chill and not before the final wash.

The FSIS auditor observed the off-line VIs conducting daily inspection and verification activities in the audited pork, beef, and lamb slaughter establishments and verified that government inspection occurs at least once per shift during the processing of meat products and that the government inspector is on the line during all slaughter operations. The VIs are permanently located in all meat and processing establishments and are responsible for the supervision of inspection personnel assigned to those establishments. The inspection system provides for direct and continuous (daily) inspection of preparation of products and oversight by official

supervision. Disposition of suspect animals during ante-mortem and post-mortem inspection and verification of acceptability of the final product are the responsibility of the VI, who prepares daily post-mortem disposition reports to document his/her official control actions.

The VI's verification activities include direct observation and record review procedures related to Sanitation SOPs; sanitation standards; HACCP; residue sampling; *Salmonella* species (spp.), generic *E. coli*, and N60 sampling techniques; and records. DAFM has developed specific risk-based verification frequencies and each establishment VI is responsible for drafting monitoring plans based on those frequencies, which include yearly and weekly schedules. The VI then ensures that inspection personnel perform verification procedures at the frequency identified in the monitoring plan with results documented electronically.

At each audited pork, beef, and lamb slaughter establishment, the FSIS auditor observed the sanitary dressing processes to verify implementation of practices that maximize the prevention of contamination during dressing procedures and viscera removal. The FSIS auditor also observed government inspection personnel conducting verification of monitoring of the critical control point (CCP) for zero tolerance of feces, ingesta, and milk contamination and reviewed documented inspection verification results. The FSIS auditor did not observe any systemic sanitary dressing concerns.

In accordance with Regulation (EC) No. 882/2004 and SI No. 432/2009, DAFM undertakes an annual food safety assessment of all approved plants to determine the frequency of periodic supervisory veterinary inspection reviews to be performed at each plant in a given year. Based on this assessment, regional supervisors carry out annual, semi-annual, or quarterly reviews.

The FSIS auditor reviewed and verified the documentation of conducted supervisory reviews of certified establishments at the DAFM headquarters and the audited establishments. The reviews consisted of the evaluation of the adequacy of establishments' food safety systems; delivery of official inspection and verification services; and the capability of government inspection personnel of conducting inspection activities at certified establishments. During the audit, the FSIS auditor verified that supervisory personnel had documented outcomes of periodic reviews for each of the audited establishments. The FSIS auditor did not identify any negative trends based on the supervisory review records and inspection related verification activity records reviewed. No concerns arose from the review of these documents.

The FSIS auditor verified in the pork and beef slaughter establishments that there is a separation of product eligible for export to the United States from product not meeting requirements. Notice No. 19/2015 and VPN No. 12/2015 contain requirements that establishments approved to export to the United States ensure complete separation of product eligible to export to the United States. Government inspection personnel verify requirements for separation of product destined for the United States and document results. The FSIS auditor verified use of product codes with designated codes to export to the United States and segregation of final boxed product. The FSIS auditor verified that establishments had written programs to define separation of products destined for export to the United States. The FSIS auditor verification activities for the separation of product was limited at the lamb slaughter establishments since the lamb establishments were not producing United States-eligible product.

In order to ensure that pork, beef, and lamb meat products designated for export to the United States are currently not restricted by APHIS, the DAFM monitors USDA bulletin e-mails and keeps its staff informed of changes to USDA product restrictions and disease requirements. These e-mail bulletins can be received by the DAFM staff based at USDA-certified establishments in order to remain informed of Ireland's animal disease status. If any of the diseases listed are identified in Ireland, VIs are notified immediately and there is an immediate shutdown on exports of affected products.

In accordance with Regulation (EC) No. 1069/2009 and SOP No. 4/2007, the DAFM maintains control over the destruction of condemned animals and inedible material. The FSIS auditor verified that these controls include ensuring adequate animal identification, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. The establishments maintain receptacles that are specifically designated for inedible or condemned product, being disposed at special facilities separate from establishments. All establishments are required to have a SOP for animal byproducts. The DAFM ensures control of these materials by performing checks on compliance with the establishments.

The FSIS auditor determined that the DAFM verification procedures ensure United States requirements are met. In addition, the DAFM has consistently ensured the implementation of sufficient official regulatory control actions to prevent products from contamination when insanitary conditions or practices are present in United States-eligible pork and beef slaughter and processing establishments. The FSIS auditor verification activities ensuring United States requirements are met was limited at the lamb slaughter establishments since the lamb establishments were not producing United States-eligible product.

The FSIS auditor identified concerns about the DAFM's lamb slaughter and processing establishments not operating according to the procedures FSIS determined as equivalent (e.g., physical CCP monitoring location for government verification of zero tolerance; not all carcass parts are identified with the carcass at final inspection; and inability to verify separation of lamb product eligible for export to the United States). This concern was discussed at the audit exit meeting and the DAFM indicated that they would provide a response to this issue, as well as any modifications made to the system concerning this component within its comments to this report.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components that the FSIS auditor reviewed was Government Sanitation. The FSIS auditor verified that DAFM requires each official establishment to develop, implement, and maintain written standard operating procedures to prevent direct product contamination or insanitary conditions. The evaluation of this component included a review and analysis of the information provided by DAFM in the updated SRT and observations during the onsite audit.

The FSIS auditor reviewed the legislation, regulations, official instructions, decrees, and guidelines of the DAFM and verified that the DAFM uses its legal authority to require that certified establishments develop and maintain sanitation programs to prevent direct product contamination and the creation of insanitary conditions. The FSIS auditor's verification activity identified in this component demonstrated that the DAFM enforces overarching EU sanitary regulations, including Regulation (EC) Nos. 852/2004; 853/ 2004; 854/2004, which have been determined to be equivalent to the FSIS requirements. In addition to complying with EU hygiene legislation for requiring food operating businesses to maintain sanitary operating conditions and prevent product contamination, the DAFM requires all United States-certified establishments to meet the FSIS requirements for sanitation consistent with provisions specified in 9 CFR Part 416.

The DAFM demonstrated that it enforces these requirements at United States-certified establishments. The DAFM conducts verification of sanitary conditions in accordance with the aforementioned documents, including the evaluation of written sanitation programs, verification of both pre-operational and operational sanitation implementation and monitoring of sanitation procedures, including hands-on verification inspection, and records review. The FSIS auditor confirmed the verification frequency of sanitation requirements. The government inspection personnel conduct verification of Sanitation SOPs requirements daily.

The DAFM 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., Regulation (EC) No. 852/2004 and SI No. 432/2009); however, any establishment seeking to engage in trade with non-EU countries must first be registered under the aforementioned legislation.

Once the DAFM verifies that establishments fulfill all official EU requirements, and any FSIS requirements not otherwise covered by 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 United States and are notified in writing prior to being granted certification to export. The approval inspection carried out by the RSVI for establishment certification confirms that the establishment is in compliance with all national legislation regarding construction, facilities, and equipment; and unique to the premises and thus completely separate from any other EU approved meat establishment. Therefore, all certified establishments are separate from those not certified for export to the United States. The FSIS auditor verified through a review of establishment inspection reports and the DAFM certification documents that the certified establishments have been approved according to EC and Irish requirements.

The FSIS auditor assessed the adequacy of pre-operational sanitation by observing government inspection personnel conducting pre-operational verification of the establishment's sanitation program. The government inspection personnel conducted this activity in accordance with the established procedures, including a pre-operational record review of the establishment monitoring results and an organoleptic inspection of food contact surfaces (FCS) of facilities,

equipment, and utensils; as well as an assessment of sanitation performance standard requirements (e.g., ventilation, condensation, and structural integrity). The FSIS auditor verified the DAFM's ability to identify insanitary conditions and exercise appropriate regulatory control to ensure sanitary conditions and operations.

The FSIS auditor observed the government inspection personnel's verification of operational sanitation procedures in all audited pork, beef, and lamb establishments, comparing the overall sanitary conditions of all audited establishments to the government inspection verification documentation. The verification activities included direct observation of operations and review of the establishments' sanitation monitoring and corrective action records at all establishments. The FSIS auditor also examined the government inspection personnel's documentation of noncompliance reports and supervisory reviews of establishments, noting that the inspection and establishment records were reflective of the actual sanitary conditions at the establishment.

The FSIS auditor observed the government inspection personnel and reviewed establishment records and verified that the government inspection personnel took official regulatory control actions sufficient to ensure sanitary conditions were restored and product was protected from contamination. The DAFM further provided the FSIS auditor with evidence that equipment noncompliances had been corrected and verified to ensure compliance with United States requirements. Deficiencies observed in the 2015 audit concerning lighting and sanitation had been corrected, implemented, and confirmed.

The analysis and onsite verification activities of the FSIS auditor indicate that the meat inspection system of Ireland requires that all certified establishments develop, implement, and maintain sanitation programs, including Sanitation SOPs, to prevent the creation of insanitary conditions and direct product contamination. Government inspection personnel assess the risks posed by conditions that could cause direct product contamination, and when a noncompliance is identified, they require the establishment to implement adequate corrective actions.

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

The fourth of six equivalence components that the FSIS auditor reviewed was Government HACCP System. The inspection system is to require that each official establishment develop, implement, and maintain a HACCP system. The evaluation of this component included a review and analysis of the information provided by the DAFM in the updated SRT and observations during the onsite audit.

Ireland's meat inspection system follows EU requirements for United States-eligible establishments, Regulation (EC) Nos. 852/2004 and 854/2004, in which HACCP regulatory requirements are prescribed and found equivalent to 9 CFR Part 417. DAFM ensures that HACCP- based procedures are satisfactory in all United States-eligible establishments and inspections are performed accordingly. All certified establishments are required to implement HACCP systems. When any modification is made in the product, process, or any step, certified establishments must review the procedure and make the necessary changes. These requirements are applied in Ireland under SI No. 432/2009.

The FSIS auditor conducted an onsite review of each audited pork, beef, and lamb establishment's HACCP system, including hazard analyses, HACCP plans, and CCP records. The FSIS auditor observed the government inspection personnel conducting HACCP inspection verification activities. In addition, the FSIS auditor reviewed the government inspection personnel's HACCP verification records associated with CCPs. The review of the establishments' corrective actions in response to a few deviations from critical limits indicated that the establishments' corrective actions were adequately documented and verified by the government inspection personnel as meeting requirements consistent with HACCP corrective action requirements in 9 CFR Part 417.3(a).

The FSIS auditor's review of documents pertaining to the hazard analysis, HACCP plan, monitoring, verification, and corrective actions implementation by establishments, as well as onsite observation of the inspection personnel conducting inspection tasks and associated inspection verification records, revealed an adequate HACCP food safety system in the audited establishments. The FSIS auditor noted that the beef slaughter establishments eligible for United States export certification maintained written SOPs and verification records for SRM removal in accordance with Regulation (EC) No. 999/2001. The FSIS auditor verified that the DAFM inspection personnel documented SRM removal in Specified Risk Material Checks reports as instructed in SOP No. 4/2007.

The DAFM requires all beef establishments seeking United States export eligibility to address *E. coli* O157:H7 and non-O157 STECs (O45, O26, O103, O111, O121, and O145) as a production hazard within their HACCP plans, and to test all product intended for grinding and non-intact use as a condition of certification for United States export. The DAFM verifies the implementation and effectiveness of the control measures in each certified beef establishment through sampling and testing programs; ongoing review of establishment activities and records (including consideration of high prevalence periods); and by documenting the establishment's compliance history with its HACCP plans, Sanitation SOPs, and prerequisite programs.

The FSIS auditor verified the completion of corrective actions based on the 2015 audit that involved deficiencies related to inadequate monitoring and documentation of CCP. In addition, the FSIS auditor's analysis and onsite verification activities indicate that the DAFM requires operators of establishments certified to export to the United States to develop, implement, and maintain HACCP programs for each processing category for product they export to the United States. FSIS determined that the HACCP program as described is consistent with criteria established for this component.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth of six equivalence components that the FSIS auditor reviewed was Government Chemical Residue Testing Programs. The inspection system is required to maintain a chemical residue testing program, organized and administered by the national government, which includes random sampling of internal organs, fat, and muscle of carcasses for chemical residues identified by the exporting country's meat inspection authorities or by FSIS as potential contaminants.

Prior to the onsite visit, FSIS' residue experts thoroughly reviewed Ireland's National Residue Control Program for 2016, associated methods of analysis, and additional SRT responses outlining the structure of Ireland's chemical residue testing program. There have not been any POE violations related to this component since the last FSIS audit.

Ireland, in accordance with Council Directive 96/23/EC, develops and implements a national residue program each year. This program is furnished to FSIS annually with the previous year's results. Ireland, as a member of the EU, has residue plans that are acceptable by EU standards and therefore equivalent to the FSIS criteria. Overall responsibility for coordination of the residue plan lies with the DAFM, operating under service contract to FSAI. INAB accredits the laboratories in accordance with the ISO/IEC 17025 standard in the specific areas of residues of pesticides and organic contaminants, anabolic steroids, metals, and residues from veterinary medications. The DAFM maintains the legal authority to regulate, plan, and execute activities aimed at preventing and controlling the presence of residues of veterinary drugs and contaminants in the tissues of livestock slaughtered for human consumption.

The requirement of Council Directive 96/23/EC Article 5 mandates that the country update the national residue control plan for the following year based on the results of the previous year in order to consider changes in chemical group and detection measures. The annual monitoring plan takes into consideration the assessment of sampling results obtained from past sampling tests, including regulated use of veterinary drugs. The plan specifies the analytes to be detected, the method of analysis to be used, the matrix to be collected, the tolerance, and the total number of samples to be collected. According to the chemical residue monitoring plan in slaughter animals, there are previously determined targeting criteria that must be respected. They are detailed in the specific instructions for each control plan.

The FSIS auditor verified that the design of the National Residue Testing Plan includes a description of the basis for the plan and the process used to develop it. The 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 DAFM and includes a separate sampling guide that provides detailed instructions for field personnel in the collection of samples of specific tissues (i.e., muscle, fat, liver, kidney, retina, urine, and blood (serum, plasma)). The FSIS auditor verified that the VI performs government sampling by packing all tissues separately and sending them to VPHRL to ensure chain of custody and sample integrity.

The FSIS auditor performed an onsite audit of VPHRL, which serves as the official laboratory conducting analyses of government samples for the presence of chemical residues in meat products. This laboratory is required to be accredited under ISO/IEC 17025 in the specific areas of residues of pesticides and organic contaminants, anabolic steroids, metals, and residues from veterinary medications. The FSIS auditor reviewed the accreditation and found no issues. INAB last audited VPHRL in December 2016.

The document reviews establish that analysts had successfully completed intra- and inter-laboratory evaluations administered by the supervisor and possessed the competencies necessary

to conduct the analyses assigned to them. Additionally, sample handling and frequencies, timely analyses, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective action control are performed in accordance with the laboratory's quality management program.

The FSIS auditor verified receipt of samples in VPHRL. At sample receipt, the laboratory verifies the seal is intact and matches the number on the laboratory submission form. The laboratory verifies and documents the temperature of the sample and, once verification confirms sample integrity, the laboratory assigns a unique laboratory sample number. VPHRL rejects the sample if requirements are not met or sample integrity is not maintained. The laboratory sample number alone accompanies the sample through the analytical process to eliminate any potential bias. The FSIS auditor observed the laboratory personnel at the sample receipt area check sample integrity and security, assign the identification, and store the samples in accordance with the laboratory's SOP.

The FSIS auditor verified that the DAFM has ensured that collection and analyses of tissue samples are conducted in accordance with standard protocols that meet the FSIS criteria. The DAFM requires carcasses to be retained for residue sampling of suspect animals; however, it does not require retention of carcasses for routine residue sampling. The DAFM utilizes a Rapid Alert System that informs another country of residues exceeding established tolerances in the event that such product is shipped. The program contains provisions that ensure any product with residues exceeding established tolerances is condemned and ineligible for use as human food. In addition, to prevent the violations from recurring, the DAFM investigates the cause of the residue violation and initiates intensified sampling from the same supplier for a period of at least six months with products or carcasses being impounded pending the results of analysis of the samples.

The FSIS auditor found no concerns with the DAFM's chemical residue control program. The analysis and onsite audit verification indicated that this component includes a national program that is managed and implemented by the DAFM as intended.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth of six equivalence components that the FSIS auditor reviewed was Government Microbiological Testing Programs. The system implements certain sampling and testing programs to ensure that meat products produced for export to the United States are safe and wholesome.

The evaluation of this component included an analysis of information provided by the DAFM in the SRT and accompanying documents, as well as interviews and observations made during the onsite equivalence verification audit. There have not been any POE violations related to this component since the last FSIS audit.

Ireland requires all slaughter establishments to implement an establishment conducted microbiological testing program for *Enterobacteriaceae* to verify process control. The

inspection system provides for a sampling and testing program for generic *E. coli* or *Enterobacteriaceae* in raw meat product. *Enterobacteriaceae* testing has been accepted as the equivalent to generic *E. coli* by FSIS; however, establishments that are certified eligible to export to the United States have the option of conducting generic *E. coli* testing instead.

The FSIS audit included direct observation, record review, and interviews of the DAFM and private microbiological laboratory personnel to verify microbial process control. *E. coli* sampling is consistent with 9 CFR Part 310.25 for generic *E. coli* and Regulation (EC) No. 2073/2005 for *Enterobacteriaceae* and Total Viable Count (TVC).

The government inspection personnel conducts verification activities that verify written generic *E. coli* testing programs meet requirements including the location of sampling, randomness of sampling, and sample integrity. The government inspection personnel verify establishment sampling collection methodology through direct observation and its secure submission of each sample to the microbiological laboratory for analysis. The government inspection personnel use the test results to verify establishment slaughter dressing controls for fecal contamination. Furthermore, the government inspection personnel verify that each establishment documents and correctly evaluates test results, and takes appropriate corrective actions if the upper control limits are exceeded.

The FSIS audit included direct observation, record review, and interviews of government inspection personnel and private microbiological laboratory personnel to verify microbial process control. The FSIS auditor verified that the audited meat slaughter establishments were testing for generic *E.coli* or *Enterobacteriaceae* and TVC. The FSIS auditor reviewed testing results for the last year showing that the establishments routinely met their limits, and that there has not been any identified loss of process control. No concerns were identified.

The DAFM has a *Salmonella* spp. sampling and testing program in raw product consistent with *Salmonella* performance standards requirements as outlined in 9 CFR Part 310.25. The establishments submit all samples to the microbiology laboratory for analysis for presence of *Salmonella* spp. Government inspection personnel verify that all certified establishments' sample collection procedures are in accordance with the sample collection protocols; and analyze results to determine the effectiveness of the establishments' *Salmonella* control programs. Regulatory *Salmonella* sampling is performed by government inspection personnel with samples analyzed using the ISO/IEC 6579, Microbiology of the food chain -- Horizontal method for the detection, enumeration and serotyping of *Salmonella* -- Part 1: Detection of *Salmonella* spp., method for which an equivalence determination by FSIS has been granted. Establishment approval to export is suspended for failure to comply with Salmonella performance criteria. Deficiencies observed in the 2015 audit concerning sample security procedures of government and private laboratories had been corrected, implemented, and confirmed.

The STEC testing program instituted by the DAFM meets the FSIS criteria for microbiological testing for this pathogen. The DAFM inspection personnel perform STEC sampling of beef carcasses eight times per month for STEC serogroups O157, O26, O45, O103, O104, O111, O121, and O145 in accordance with the carcass swab method prescribed in VPN No. 10/2014, Official Verification Program for Testing for Verotoxigenic *Escherichia coli*. Beef intended for

grinding (BIFG) sampling is performed monthly by DAFM using the N-60 sampling and testing method in arrangement with VPHRL for verification purposes. This frequency is increased as circumstances demand (e.g., during a High Event Period (HEP) or during high risk periods). The BIFG sampling programs are described in: VPN No. 13/2015, Official Verification Program for Testing Shiga-toxin *Escherichia coli* (STEC) in Beef Intended for Grinding (N-60 Testing); VPN No. 14/2015, Official Verification of Food Business Operator's Baseline Survey of Carcass and Meat Intended for Grinding; and VPN No. 01/2017, Official Verification of Food Business Operator Actions in the Event of Positive Test Results for Shiga-toxin *Escherichia coli* (STEC) in Non-intact Beef (Minced and Diced Beef) and Intact Beef Intended for Mincing/Grinding.

The FSIS auditor observed government inspection personnel demonstrating O157:H7/STEC sampling activities. The FSIS auditor verified that government inspection personnel have received training on sample collection methodology and the responsible individuals have the knowledge and skills to implement this type of testing on an ongoing basis. All sampled lots are controlled by the establishment until the test results for the lot have been received as negative. If a positive result is confirmed as being present in the lot the affected lot and any other lots produced from the same source of raw material will not be exported to the United States. The DAFM is responsible for reviewing sampling plans and test result records within the certified establishments. Enforcement action is put into effect where necessary. Deficiencies observed in the 2015 audit concerning STEC sampling schedules of government laboratories had been corrected, implemented, and confirmed.

The FSIS auditor performed an onsite audit of the ALT, which conducts official microbiological testing on raw pork, beef, and lamb products for *Salmonella* performance standards; and on beef products that require testing for *E. coli* O157:H7 and non-O157 STECs. The FSIS auditor verified the following: DAFM last audited ALT in March 2017; ALT holds the accreditations for the analytical methods for *E. coli* O157:H7 and non-O157 STECs; and ALT is accredited as equivalent to ISO/IEC 17025. The accreditation covers the management and quality assurance aspects of the functions of the laboratory to ensure that it has the capability to support the DAFM's inspection program for certified establishments eligible to export to the United States.

The FSIS auditor reviewed the training materials, records, and the results of laboratory proficiency testing. The FSIS auditor observed and verified sample receipt and handling by ALT. The FSIS auditor verified that ALT: performs a timely analysis of samples; reports the number of analyzed samples and the results in a timely manner; applies approved analytical methodologies; and has quality assurance programs. No concerns arose as a result of these observations and reviews.

The FSIS auditor's document analysis and onsite verification activities demonstrate that Ireland's meat inspection system includes requirements for a microbiological sampling and testing program. It is organized and administered by the national government to verify that meat products destined for export to the United States are unadulterated, safe, and wholesome in accordance with United States requirements. The microbiological testing program as described is consistent with the criteria established for this component.

X. CONCLUSIONS AND NEXT STEPS

The FSIS auditor held an exit meeting on September 29, 2017, in Dublin, Ireland with the DAFM. At this meeting, the FSIS auditor presented the preliminary findings from the audit. The audit did not identify any concerns that represented an immediate threat to public health.

The FSIS auditor identified the following findings in regards to lamb slaughter operations:

Government Statutory Authority and Food Safety and Other Consumer Protection Regulations

- At two lamb slaughter establishments audited:
    - Not all carcass and parts are handled in a manner to identify them with the rest of the carcass and are not available for post-mortem examination and veterinary disposition.
    - The physical CCP monitoring location for government verification of zero tolerance is not before the final wash.

The CCA committed to begin addressing the preliminary findings as presented in this report. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions and base its activities for future equivalence verification on the information provided.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklist

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Rosderra Irish Meats Group Ltd CarrickRoad Edenderry	9/13/17	356	IRELAND
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[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	
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. National Residue Sampling	
59.	

60. Observation of the Establishment Est. 356 Rosderra Irish Meats Group, LTD

There were no significant findings to report after consideration of the nature, degree, and extent of all observations.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	Enter Date Here 9/13/17

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
Slaney Foods International T/A Slaney Foods Ryland Lower, Bunclody Co. Wexford, Y21 E1T6, Ireland	9/18/17	296	IRELAND
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[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	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58. National Residue Sampling	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment Est. 296 Slaney Foods

There were no significant findings to report after consideration of the nature, degree, and extent of all observations.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	Enter Date Here 9/18/17

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Queally Pig Slaughtering Limited Grannagh	9/19/17	332	IRELAND
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[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	
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. National Residue Sampling	
59.	

60. Observation of the Establishment Est. 332 Queally Pig Slaughtering Limited

There were no significant findings to report after consideration of the nature, degree, and extent of all observations.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	Enter Date Here 9/19/17

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
Irish Country Meats, Bayland, Camolin Co. Wexford	9/20/17	367 (Sheep)	IRELAND
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[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	
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	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58. Zero Tolerance	X
59. National Residue Sampling	

60. Observation of the Establishment Est 367_Irish Country Meats

This is one of two lamb slaughter establishments proffered by the CCA for the purpose of verifying FSIS requirements.

The following observations were made as not meeting FSIS requirements:

55. Post Mortem Inspection
    - Not all parts are identified with carcass at final inspection, head and edible offal batched prior to final inspection

58. Zero Tolerance
    - The physical CCP monitoring location for government verification of zero tolerance is not before the final wash. Verification of zero tolerance on boning floor post boning chill.

Other:
- Not able to verify separation of product eligible for export to the United States since this lamb slaughter establishment was not producing United States-eligible product.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	Enter Date Here 9/20/17

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Rosderra Irish Meats Group Limited Carrig, Roscrea	9/21/17	355	IRELAND
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[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	
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. National Residue Sampling	
59.	

60. Observation of the Establishment Est. 355 Rosderra Irish Meats

There were no significant findings to report after consideration of the nature, degree, and extent of all observations.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	Enter Date Here 9/21/17

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
Kepak Longford, Ballymahon Co. Longford	9/22/17	533	IRELAND
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[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	
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 Est. 533 Kepak Longford

There were no significant findings to report after consideration of the nature, degree, and extent of all observations.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	Enter Date Here 9/22/17

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
Donegal Meat Processors Ltd., T/A Foyle Donegal	9/25/17	292	IRELAND
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[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	
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. National Residue Sampling	
59.	

60. Observation of the Establishment Est. 292 Donegal Meat Processors, Ltd.

There were no significant findings to report after consideration of the nature, degree, and extent of all observations.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	Enter Date Here 9/25/17

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
Kepak Athleague Athleague, Co. Roscommon	9/26/17	313	IRELAND
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[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	
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. National Residue Sampling	
59.	

60. Observation of the Establishment Est. 313 Kepak Athleague

There were no significant findings to report after consideration of the nature, degree, and extent of all observations.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	Enter Date Here 9/26/17

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
Kepak Athleague Athleague Co. Roscommon	9/27/17	313 (Sheep)	Ireland
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[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	
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	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58. Zero Tolerance	X
59.	

60. Observation of the Establishment Est. 313 Kepak Athleague

The following observations were made as not meeting FSIS requirements:

55. Post Mortem Inspection
    - Not all parts identified with carcass at final inspection, head was condemned prior to final inspection

58. Zero Tolerance
    - The physical CCP monitoring location for government verification of zero tolerance is not before the final wash. Verification of zero tolerance in the chill room.

Other:
- Not able to verify separation of product eligible for export to the United States since this lamb slaughter establishment was not producing United States-eligible product.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	9/27/17

Appendix B: Foreign Country Response to the Draft Final Audit Report

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

Ms Mary Stanley
Acting International Coordination Executive
Office of International Coordination
Food safety and Inspection Services
United States Department of Agriculture
1400 Independence Avenue, SW
Washington, DC
20250

09 March 2018

Response to Draft final report of an audit conducted in The Republic of Ireland September 11 – 29, 2017

Dear Ms Stanley,

I am writing in relation to your correspondence of 09 January 2018 in connection with the FSIS audit in Ireland last September.

Please find attached as requested a written response to the FSIS audit with comments on the audit report (Appendix 1). Procedural enhancements that were put in place prior to and subsequent to the FSIS audit in relation to sheep carcase hygiene are contained in Appendix 2 (attached).

The controls and verifications that will apply to all sheep slaughter plants that seek USDA approval will be forwarded to you within 5 working days, these controls and verifications will deal with the corrective actions relevant to the findings in sheep slaughter plants during the FSIS audit. I apologise for this delay.

The attached documents and any other relevant docs will be inputted to the SRT prior to the May 18 deadline.

I hope that this is satisfactory but please feel free to contact me with any queries.

Yours sincerely,

Dr Martin Blake
Chief Veterinary Officer
Department of Agriculture, Food and the Marine

Appendix 1.

DAFM response

to

FSIS Draft Final Report of January 3rd, 2018

Audit Conducted in Ireland September 11th, 2017 to September 29th, 2017

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

Section A. Factual Errors

Section A. **Factual Errors**

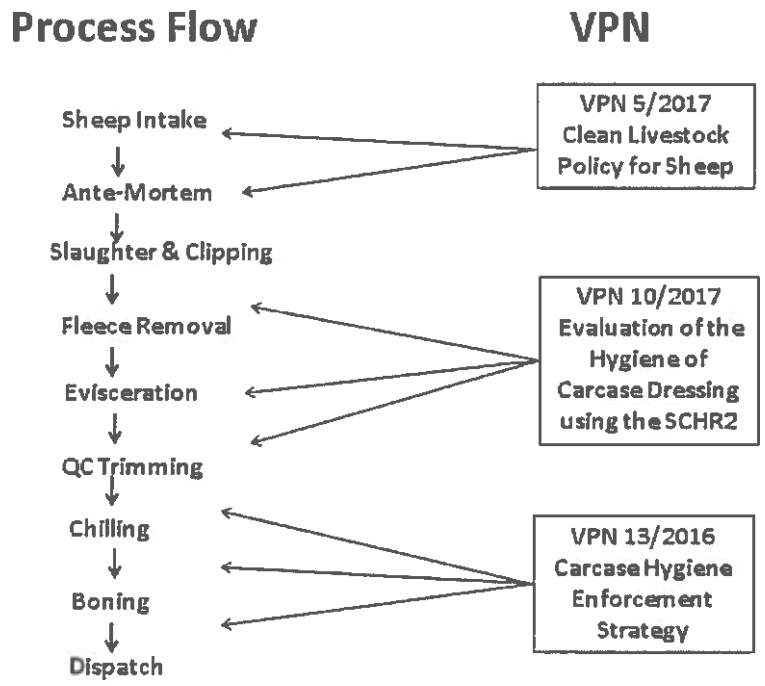
Draft report	Please amend to:
Page 5, paragraph 1, line 3/4 : Senior Veterinary Officers (SVO)	Senior Veterinary Management (SVM)
Page 5, paragraph 1, line 4 : SVO team	SVM team
Page 5, paragraph 3, line 6 : purchaser	consumer
Page 6, paragraph 3, line 1 : four SVIs	three SVIs

Appendix 2. **DAFM's Sheep Carcase Hygiene Strategy in Sheep Slaughter Plants**

Introduction

DAFM has implemented an enhanced carcass hygiene policy in all beef slaughter plants to comply with EU legislation. A similar system for all sheep slaughter plants is being adopted.

The strategy provided for the introduction of 3 new Veterinary Procedures Notices (VPNs). These new VPNs introduced enhanced verification procedures at different points of the sheep slaughter process as illustrated in the following diagram under.



VPN 13/2016 - Carcase Hygiene Enforcement Strategy

This VPN was circulated in September 2016 to introduce enhanced verification of carcase hygiene through:

1. Inspection of a minimum number of carcases.
2. Inspection to be carried out at strategic locations
    a. In the slaughter hall before the chills
    b. At the entrance to the boning/cutting hall
    c. At carcase dispatch (where carcases are traded without boning)
3. Introduction of enhanced enforcement actions, such as:
    a. A progressive reduction in line speed and production to allow FBO time to dress carcases hygienically.
    b. Where reduction in line speed fails to address the underlying issue then complete cessation of production (in consultation with senior DAFM management) may be considered.

The VPN is inserted below:

VPN 13_2016 on Sheep Carcass Hygi

VPN 5/2017 – Clean Livestock Policy for Sheep

In early 2017, discussions were held between the main stakeholders in the sheep industry with a view to agreeing a Clean Livestock Policy (CLP) for sheep.
The main stakeholders were:

- Sheep Farmers
- Sheep Transporters
- Farm Advisory Services – Teagasc
- Food Business Operators
- Competent Authority – DAFM

DAFM considered it necessary to achieve agreement between all the stakeholders to get buy-in on all sides so that the CLP had a reasonable chance of success.

The agreed Clean Livestock Policy is inserted below:

CLP SHEEP- 210217

The CLP document details the principle roles and responsibilities of all the stakeholders. In addition, it describes the agreed categories of fleece contamination as follows:

Category (A) **Satisfactory** – Sheep that can be slaughtered, without an unacceptable risk of contaminating the meat during the slaughter process, by using the standard hygienic dressing procedures routinely employed by the plant.

Category (B) **Acceptable** – Sheep that can only be slaughtered, without an unacceptable risk of contamination of the meat during the slaughter process, by putting in place additional interventions including extra defined dressing controls.

Category (C) **Unacceptable** – Sheep unfit for slaughter because of fleece condition. These sheep must not be presented for ante-mortem in this condition and it is the responsibility of the Food Business Operator (FBO) to take the required remedial action.

To assist FBOs in categorizing sheep, an agreed poster of photos of sheep categorized under each category was published and circulated to industry and farmers. The poster is inserted below:


CLP Poster

Responsibility for verification of compliance with the CLP falls to DAFM officers during sheep intake and ante-mortem inspection. This responsibility is described in VPN 5/2017 inserted below.


VPN 5_2017_Implementat

Two versions of this VPN were issued.

Version 1 (phase 1) was issued in June 2017, and reflected the biphasic approach to implementation of the CLP in sheep slaughter plants.

Version 2 of the VPN (phase 2) was issued in December 2017. The main difference between the two versions is in the extent of the FBO intervention required in phase two.
The additional intervention required in Version 2 is "*completely shearing some animals prior to presentation of the animals for ante mortem examination*".
Version 2 became fully operational on January 1st, 2018 and the enforcement of sheep CLP is currently strictly enforced in all sheep slaughter plants.

VPN 10/2017 – Evaluation of the Hygiene of Sheep Carcase Dressing

The last link in the chain of carcase hygiene verification in sheep slaughter establishments is a system to officially verify that the FBO is hygienically dressing sheep carcases and to identify specific points in the process that might not be functioning correctly.
Such a system already exists in cattle slaughter plants. However, it was impossible to adapt the cattle carcase dressing evaluation system for sheep and so a new bespoke system was developed that could be tailored for each individual sheep slaughter plant.

In December 2017, VPN 10/2017 and the Sheep Carcase Hygiene Report (SCHR2) form were published and circulated to all relevant staff. These documents are inserted below:

VPN
10_2017_Evaluation

Frm_SCHR2_Comple
ted_Woolly Sheep C

This VPN and its associated report form (SCHR2) is designed to guide DAFM staff through the process of verifying carcase dressing procedures and in identifying the process steps and procedures where carcase contamination may be occurring.

Particular emphasis is placed on identifying different issues that may be associated with carcase dressing before fleece removal and after fleece removal. DAFM are working closely with their relevant FBOs to correct any identified deficiencies.

Appropriate enforcement action is taken when non-compliant practices are identified.

Summary

The three VPNs outlined above are designed to be used in concert with each other to give DAFM staff the appropriate tools to verify FBO compliance with the Clean Livestock Policy for Sheep and with hygienic carcase dressing requirements to produce carcases that are free of contamination with faeces, ingesta and milk (as well as wool, bile, etc.).

DAFM is continuing to monitor compliance at a central level and may review any aspect of these VPNs to improve verification and enforcement performance.

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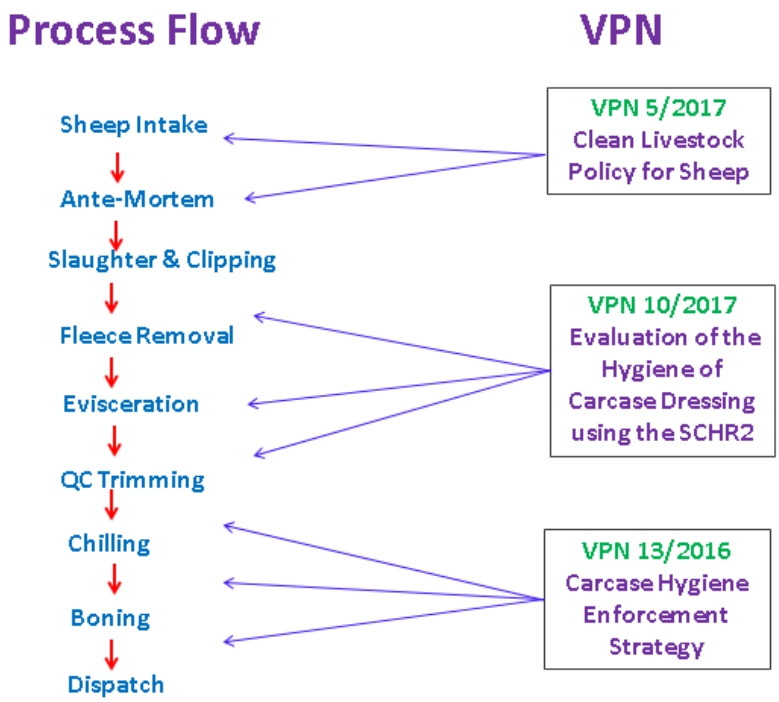

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DAFM is continuing to monitor compliance at a central level and may review any aspect of these VPNs to improve verification and enforcement performance.

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

11 May 2018

Ms. Mary Stanley,
Office of International Coordination,
Food Safety and Inspection Service,
United States Department of Agriculture,
1400 Independence Avenue, SW,
Washington DC,
20250

Subject: FSIS 2017 Audit Findings

Dear Ms. Stanley

Further to your recent communication 21st March 2018 on the FSIS 2017 audit findings please find attached a document detailing our response to these findings (Annex 1).

I wish to apologise for the lateness of our response to your previous queries but we have been making every effort to provide as much information as possible to allow you to evaluate the adequacy of proposed controls for future equivalence verification on the information provided.

I would like to bring the following to your attention:

1. Annex 1

In Annex 1, we have taken the approach of commenting on the non-compliances as a Competent Authority. This is to give assurance to you that the remedial actions are appropriate to remedy the findings in a satisfactory manner, and that they are of a standard to ensure equivalence with the FSIS standards.

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

1. Electronic identification of Sheep

I would also wish to bring to your attention that DAFM have announced the extension of electronic identification (EID) to all sheep. The planning stages for the introduction of EID are underway. Lambs under 12 months of age moving directly to slaughter from the holding of birth will be required to be identified with a single electronic tag. All other sheep will require an EID tag set comprised of two tags – one conventional tag and a corresponding electronic tag. As our planning progresses, it is intended that we will update the SRT at the end of 2018 and ensure that you are aware of our legislation, protocols and procedures on this matter. We hope that this enhancement of our identification system will further support our case for you to give consideration and approval for sheep meat access to be granted on the basis of a records review.

2. <u>Inspection of sheep heads</u>

I reference the finding of the draft audit report: *"Not all carcass and parts are handled in a manner to identify them with the rest of the carcass and are not available for post-mortem examination and veterinary disposition"*,

Our understanding is that this finding pertains to the FSIS requirement to present the sheep head, in addition to the corresponding carcase and offal, for post-mortem inspection. DAFM has verified that all carcass and parts are handled in a manner to identify them with the rest of the carcass and are available for post-mortem examination and veterinary disposition in so far as Regulation (EC) No 854/2004 applies.

In relation to the head, sheep post-mortem inspection is conducted in accordance with Regulation (EC) No 854/2004, whereby examination of the sheep head is not required if the competent authority can guarantee exclusion of the head, including tongue and brains, from the market for human consumption. Current inspection procedures under the EU Regulation permit disposal, without examination, of both the sheep head and tongue, when neither is intended for human consumption. In the event that an Irish food business operator wishes to harvest part of the sheep head for human consumption, the head must be skinned and presented for veterinary post-mortem examination.

In order to ensure that Ireland's inspection system guarantees equivalent food safety standards in sheep meat comparable to those applied within the United States, the

Department of Agriculture, Food and the Marine propose to exclude head meat and tongues from trade with the United States. On that basis, we seek to be derogated from the FSIS requirement to inspect sheep heads.

3. Records Review to gain reinstatement for sheep meat access to US market

The draft audit report states *"FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions. FSIS will then determine whether it needs to audit again or whether a records review will be sufficient."*

On the basis of the information submitted as well as our well established record of maintenance of the equivalence standards for pig meat and beef meat, we request that you give consideration and approval for sheep meat access to be granted on the basis of a records review.

We hope that the information provided will allow FSIS to evaluate the adequacy of the proposed controls for overall equivalence verification, and that this will allow Ireland proceed to market access for sheep meat on the basis of a records review. Additionally we hope that you will look favourably on our request to exclude post mortem inspection of sheep heads

Sincerely

Martin Blake
Chief Veterinary Officer

Annex 1

DAFM RESPONSE TO THE FINDINGS OF DRAFT FINAL REPORT OF AN AUDIT CONDUCTED IN THE REPUBLIC OF IRELAND September 11 – 29, 2017 EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING MEAT EXPORTED TO THE UNITED STATES OF AMERICA

No	Non-Compliance	DAFM comment
1	Post Mortem Inspection Not all parts are identified with carcass at final inspection, head and edible offal batched prior to final inspection	DAFM has carried out a full review of current offal harvesting and associated operational and inspection procedures and are satisfied that they are fully consistent & compliant with EU Regulations. DAFM is aware that the USDA inspection highlighted that some constituents of offal were not correlated to the satisfaction of the FSIS auditor. We understand this related to the heads not being inspected and the batching of some other offal. While this is consistent with EU regulations we are aware that this is not the case regarding FSIS regulations. In the event of U.S. (United States) access for Irish lamb product being agreed, DAFM will ensure this facility will make the necessary adjustments, as agreed between FSIS and DAFM, to achieve equivalence with USDA protocols.
2	Zero Tolerance The physical CCP monitoring location for government verification of zero tolerance is not before the final wash. Verification of zero tolerance on boning floor post boning chill.	The official DAFM verification station to assess carcass dressing takes place prior to carcass washing where carcass washing is carried out. 50 carcasses are inspected twice weekly at the end of the slaughter line, after the FBO control point, for evidence of faecal, ingesta, wool and skin contamination. In addition DAFM inspects 25 carcasses twice weekly at the entrance to the boning hall to for evidence of rail dust etc. There is currently no requirement for a zero tolerance CCP on the slaughter line. There is a detention rail separate to the main rail in both of the sheep slaughter plants that were inspected, for carcases that require further inspection for contamination or assessment for pathological conditions or indeed additional intervention. All such carcasses are not allowed back to the main line until they are assessed and passed by DAFM.

		Since the audit, DAFM have introduced both a Clean Sheep Policy and a Carcass Hygiene Evaluation system in all sheep slaughter plants. These new procedures target carcass hygiene and are outlined in the revised SRT which is being prepared for onward transmission to you prior to May 17 2018.
3	Other: Not able to verify separation of product eligible for export to the United States since this lamb slaughter establishment was not producing United States-eligible product	Sheep slaughter plants are not currently producing sheepmeat for the US market as none are approved given that the TSE rule is still not published. When the TSE rule is amended when Ireland has sheep meat access, to the US, DAFM will have SSOPs, SPS and other controls in place, and they will be implemented to ensure requisite compliance with US requirements as is currently the case for beef plants. All such additional controls are outlined under. Please note this document was already sent to you on the 15th March 2018. The controls also form part of the revised SRT.

Annex 1

Hereunder please find information issued to FSIS on the 15th March:

Procedures which will be implemented in all Sheep Slaughter Plants to verify compliance with USDA standards.

Introduction

When the market is open for sheep meat to the United States (TSE rule), the Department of Agriculture, Food and the Marine (DAFM) will implement a similar set of controls in sheep slaughter plants as are currently in place at all USDA approved beef plants.

Method

The major prerequisite for sheep slaughter and cutting plants is full compliance with all existing EU Regulations.
In addition, applicant sheep slaughter and cutting Food Business Operators (FBOs) will be expected to do the following:

1. Present a work plan to DAFM on the physical and procedural changes that will be put in place before and during the approval process.
2. Use independent trainers to train at least two senior staff from their technical or quality assurance departments in USDA legislative requirements.
3. Adjust their Food Safety Management System and HACCP Plan to have documented procedures for:
    a. **Sanitation Performance Standards** (SPS)
    b. **Sanitation Standard Operating Procedures** (SSOP), for both pre-operational and operational hygiene standards.
    c. **Critical Control Point** (CCP) for carcase inspection with a critical limit of ***zero tolerance*** for faeces, ingesta and milk.
    d. Use comprehensive monitoring and verification of a, b, and c above.
4. Introduce a **Pathogen Reduction Programme** for carcases which involves sampling and testing for:
    a. Generic E. coli ***or*** Enterobacteriaceae (as per EU Regulation 2073/2005)
    b. E. Coli O157:H7/STEC
5. Carry out a detailed **Pre-Shipment Review** before any shipments of US destined sheep meat are shipped.

DAFM will continue to verify compliance with EU Regulations in accordance with existing procedures. In particular, DAFM will continue to implement its carcase hygiene strategy as described in Appendix 1

In addition, when the applicant FBO has implemented points 1 -5 above, DAFM will commence its USDA verification procedures as follows:

1. Conflict of Interest

To ensure that any conflict of interest (CoI) that Temporary Veterinary Inspectors (TVIs) carrying out ante-mortem at sheep slaughter plants may have is declared and managed, TVIs will sign the CoI form below and the Veterinary Inspector (VI) will manage the CoI in accordance with the procedure below:


TVI CoI management procec


FRM_USDA_COI Sheep

2. **Verification of Sanitation Performance Standards**
   These are verified using existing EU HACCP Pre-requisite verification documentation.

3. **Verification of Sanitation Standard Operating Procedures**
   Pre-operational and operational SSOPs will be verified using the following documents:

   a. **USDA_SSOP(a)**
      This form will be used daily to record the results of direct inspection of FBO pre-operational and operational activities. It will also record any enforcement action taken.


USDA Form SSOP Verification (a)

   b. **USDA_SSOP(b)**
      This form will be used weekly to analyse the effectiveness of each SSOP and take any enforcement action necessary to improve effectiveness.


USDA SSOP (b)

4. **Verification of CCPs**
   Each USDA approved sheep slaughter and boning plant will be required to have at least one CCP (carcase inspection for faeces, ingesta and milk). This CCP will be required to be located on the slaughter floor after carcase dressing but before DAFM's TVI post-mortem inspection stand. Some FBOs may include additional CCPs in their HACCP Plans such as carcase chilling.

The USDA CCP form below will be used on a weekly basis to verify each CCP in the HACCP Plan. The CCP Guidance document below was drafted to assist official veterinarians (OV) in this task.


USDA~CCP_Rev03(0116)


USDA~CCP_Guidance_Rev03(0116)

5. Zero Tolerance Verification

In addition to verification of the carcase inspection CCP as described at (4) above, OVs and their technical officers will carry out separate verification of zero tolerance for faecal, ingesta and milk contamination, using the ZFIMT1 form below. To do this check, randomly selected carcases will be inspected after the CCP inspection point on the line. DAFM has prepared guidelines for officers completing the ZFIMT1 in the Guidance document inserted below.


FRM_USDA_ZFIMT1_Carcase ZeroTolera


USDA Guidance Zero Tolerance Faec

6. Verification of Micro Sampling (Pathogen reduction)

DAFM OVs and technical staff will carry out verification checks as follows:

a. Supervision of FBO carcase sampling for salmonella

It is unclear at this time if Salmonella Performance Standards are required for sheep meat. FSIS have been consulted and DAFM await guidance. If salmonella performance standards apply to sheep carcases, DAFM technical staff will supervise FBO sampling of carcases for salmonella and take control of the samples before dispatching to a private laboratory. The Sal1 form inserted below is used to record this supervision.


USDA Form Supervision of Salm

b. Annual Verification of Pathogen Reduction Programme

The OV will verify that sheep FBOs have a sampling programme in place annually using the PatRed(a) form below:

USDA~PatRed_She
epmeat(a)Ver01_031

c. Monthly Check on Results of Pathogen Reduction Testing

The OV will check that all required micro sampling is being carried out and that results are within the specifications permitted by the USDA. It is unclear at this time if Salmonella Performance Standards are required for sheep meat. FSIS have been consulted and DAFM await guidance.

The form used is the PatRed (b) inserted below. Guidance is also provided to OVs and this is also inserted below.

USDA_PatRed_Shee
pmeat(b)Ver01_0318

USDA~PatRed_She
epmeat (0318) Guid

7. Weekly Meeting Record

To ensure effective communication between OVs and USDA approved FBOs it is critical to have regular face to face meetings. DAFM requires its OVS to meet the FBO at least weekly and to record the proceeds of these meetings in the attached Weekly Meeting Record. Guidance regarding what the weekly meeting should entail is also attached below.

USDA Form Weekly
Meeting Record

USDA Guidance
Weekly Meeting Rec

8. Verification of Pre-Shipment Review

Because it will be critically important that FBOs carry out a pre-shipment review before any sheep meat is shipped to the United States, DAFM staff will verify that this is being done monthly. This verification is recorded on the USDA-PSR1 inserted below.

USDA Form
Pre-Shipment Revie

Annex 1

VPHIS

March 2018