United States Department of Agriculture

Food Safety and
Inspection Service

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

June 30, 2023

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

Dear Mr. Blake,

The United States Department of Agriculture, Food Safety and Inspection Service conducted an ongoing verification audit of Ireland's meat inspection system from September 12 – September 28, 2022. Enclosed is a copy of the final audit report. The comments received from the Government of Ireland are included as an attachment to the final audit report.

Sincerely,

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED OF

IRELAND

SEPTEMBER 12 TO 28, 2022

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

MEAT PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

June 28, 2023

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit of Ireland conducted by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) September 12–28, 2022. The purpose of the audit was to determine whether Ireland's food safety inspection system governing meat products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Ireland currently exports the following categories of beef and pork products to the United States: raw-intact and raw-non intact.

The audit focused on six system equivalence 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 Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

FSIS concluded that Ireland's food safety inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. The Department of Agriculture, Food and the Marine (DAFM), Ireland's Central Competent Authority, has required that the establishments certified as eligible to export products to the United States implement sanitation requirements and a HACCP system designed to ensure the safety of their products. In addition, DAFM has implemented official microbiological and chemical residue testing programs that are organized and administered by the national government to verify its system. An analysis of each component did not identify any systemic findings representing an immediate threat to public health.

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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 September 12–28, 2022. The audit began with an entrance meeting September 12, 2022, in Dublin, Ireland, to discuss the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA)–Department of Agriculture, Food and the Marine (DAFM). Representatives from DAFM accompanied the FSIS auditors throughout the entire audit. The audit concluded with an exit meeting conducted via videoconference on September 28, 2022.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to determine whether the food safety inspection system governing meat products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Ireland is eligible to export the following categories of products to the United States:

Process Category	Product Category	Eligible Products[1]
Raw - Non Intact	Raw Ground, Comminuted, or Otherwise Non-intact Beef	Beef - All Products Eligible except Advanced Meat Recovery Product (AMR); Low Temperature Rendered Product (LTRP); Partially Defatted Beef Fatty Tissue (PDBFT); Partially Defatted Chopped Beef (PDCB); Finely Textured Beef
Raw - Non Intact	Raw Ground, Comminuted, or Otherwise Non-intact Meat-other (sheep, goat)	Lamb and Mutton - All Products Eligible except Mechanically Separated and Advanced Meat Recovery Product (AMR)
Raw - Non Intact	Raw Ground, Comminuted, or Otherwise Non-intact Pork	Pork - All Products Eligible except Mechanically Separated and Advanced Meat Recovery Product (AMR)
Raw - Intact	Raw Intact Beef	Beef - All Products Eligible
Raw - Intact	Raw Intact Meat-Other (Sheep, Goat)	Lamb and Mutton - All Products Eligible
Raw - Intact	Raw Intact Pork	Pork - All Products Eligible

[1] All source meat used to produce products must originate from eligible countries and establishments certified to export to the United States.

The USDA's Animal and Plant Health Inspection Service (APHIS) recognizes Ireland as subject to foot-and-mouth disease requirements specified in Title 9 of the United States Code of Federal Regulations (9 CFR) 94.11. Additionally, beef is subjected to bovine spongiform encephalopathy requirements specified in 9 CFR 94.18 or 9 CFR 94.20 and pork is subjected to African swine fever requirements specified in 9 CFR 94.8, classical swine fever requirements specified in 9 CFR 94.31, and swine vesicular disease requirements specified in 9 CFR 94.13.

Prior to the onsite equivalence verification audit, FSIS reviewed and analyzed Ireland's Self-Reporting Tool (SRT) responses and supporting documentation. During the audit, the FSIS auditors conducted interviews and reviewed records to determine whether Ireland's food safety inspection system governing meat products is being implemented as documented in the country's SRT responses and supporting documentation.

FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, point-of-entry (POE) reinspection and testing results, specific oversight activities of government offices, and testing capabilities and 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 DAFM through the SRT responses and supporting documentation.

Determinations concerning program effectiveness focused on 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 Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditors reviewed records related to administrative functions and oversight from DAFM headquarters, 2 regional offices, and 10 local inspection offices within the establishments. The FSIS auditors evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

A sample of 10 establishments was selected from a total of 14 establishments certified to export to the United States. This included seven beef slaughter and processing establishments, two pork slaughter and processing establishments, and one beef processing establishment. The products these establishments produce and export to the United States include raw intact pork, raw intact beef, and raw ground, comminuted, or otherwise non-intact beef.

During the establishment visits, the FSIS auditors paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that threatens food safety. The FSIS auditors assessed DAFM's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in 9 CFR Part 327.2.

The FSIS auditors also visited one microbiological and one chemical residue laboratory to verify that these laboratories can provide adequate technical support to the food safety inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• DAFM Headquarters, located in Dublin
	Regional	2	• North-West Regional VPH Office, located in Castlebar • South-East Regional VPH Office, located in Carlow
Laboratories		2	• ALS Life Sciences Microbiology Laboratory (private), located in Clonmel • The State Laboratory, government chemical residue, located in Backweston
Beef slaughter and processing establishments		7	• Establishment No. 292, Donegal Meat Processors T/A Foyle Donegal, located in Carrigans • Establishment No. 325, Liffey Meats (Cavan) UC T/A Liffey Meats, located in Ballyjamesduff • Establishment No. 317 Kepak (Clonee) Ltd., located in Dublin • Establishment No. 368, Dawn Meats Ireland UC, T/A Dawn Charleville, located in Charleville • Establishment No. 296, Slaney Foods International UC T/A Slaney Foods, located in Bunclody • Establishment No. 378, Anglo Beef Processors Ireland UC T/A ABP Clones, located in Clones • Establishment No. 300, Anglo Beef Processors Ireland UC T/A ABP Cahir, located in Kilcommon
Pork slaughter and processing establishments		2	• Establishment No. 332, Queally Pig Slaughtering Ltd., T/A Dawn Pork & Bacon, located in Grannagh • Establishment No. 355, Rosderra Irish Meats Group, located in Roscrea
Beef processing establishment		1	• Establishment No. 533, Kepak Longford, located in Ballymahon

FSIS performed the audit to verify that the food safety inspection system meets requirements equivalent to those under the specific provisions of United States laws and regulations, in particular:

- The Federal Meat Inspection Act (21 United States Code (U.S.C.) Section 601 et seq.);
- The Humane Methods of Slaughter Act (7 U.S.C. Sections 1901-1906); and
- The Meat Inspection Regulations (9 CFR 301 to the end).

The audit standards applied during the review of Ireland's inspection system for meat products included: (1) all applicable legislation originally determined by FSIS as equivalent 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 Agreement on the Application of Sanitary and Phytosanitary Measures.

III. BACKGROUND

From May 1, 2019, to April 30, 2022, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 85,944,278 pounds of meat from Ireland. This included 51,021,118 pounds of raw intact beef; 1,285,780 pounds of raw non-intact beef; and 33,637,380 pounds of raw intact pork exported by Ireland to the United States. Of these amounts, additional types of inspection were performed on 5,580,918 pounds of raw intact beef; 153,445 pounds of raw non-intact beef; and 3,682,025 pounds of raw intact pork. These additional types of inspection included physical examination, chemical residue analysis, and testing for microbiological pathogens. As a result of this additional testing, 108,662 pounds of raw intact, boneless beef trimmings were refused entry for Shiga toxin-producing *Escherichia coli* (STEC) positives. An additional 161,275 pounds of beef and pork products were refused for other issues not related to public health including shipping damage, labeling or other miscellaneous issues. FSIS evaluated corrective action responses provided by DAFM, found them sufficient, and closed the respective POE violation cases.

The previous FSIS audit in 2019 identified the following findings:

Summary of Findings from the 2019 FSIS Audit of Ireland
Component 1: Government Oversight (e.g., Organization and Administration)
• Government inspection personnel are not confirming acceptable testing results from livestock carcasses and parts subjected to routine government chemical residue testing prior to signing the export certificate.
Component 3: Government Sanitation
• In six of the eight audited establishments, there was inadequate government verification of sanitation performance standard requirements – Facility and equipment maintenance. In-plant inspection personnel (IIP) failed to observe one or more of the following issues: extensive rust buildup on overhead structures in slaughter areas, equipment in the slaughter halls, on chains, rollers, steels, fan guards/fans for cooling units, etc. • In five of the eight audited establishments, there was inadequate government verification of sanitation performance standard requirements – Ventilation. IIP failed to observe poor ventilation, resulting in beaded or dripping condensation on ceilings, cooling units and other overhead structures both in the slaughter and processing areas.
Component 4: Government Hazard Analysis and Critical Control Point (HACCP) System
• In four of the eight audited establishments, IIP did not identify that the establishments' written HACCP plan did not include one or more of the elements required for HACCP ongoing verification activities: direct observation, record review, and calibration of process monitoring instruments. • In five of the eight audited establishments, the HACCP zero tolerance critical control point (CCP) monitoring records did not include the time and/or identification of the monitored carcasses or the initials of the monitor.

- In three of the eight audited establishments, the HACCP zero tolerance recordkeeping documents did not include all parts of corrective actions for zero tolerance failures.

During the current audit, the FSIS auditors verified that the corrective actions for the above findings reported in 2019 were effectively implemented to resolve the findings.

The most recent FSIS final audit reports for Ireland's food safety inspection system are available on the FSIS website at: www.fsis.usda.gov/foreign-audit-reports.

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

The first equivalence component the FSIS auditors reviewed was Government Oversight. FSIS import regulations require the foreign food safety 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; 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.

DAFM is the CCA of Ireland's meat inspection system and has the overall authority and responsibility for policy decisions, legislation and implementation and enforcement of legislation in supervised establishments. Ireland adheres to European Union (EU) legislation and thereby is authorized to enforce food inspection laws based on EU regulations. The FSIS auditors confirmed that there have been two slight changes to the organizational chart one in name as Veterinary Public Health Inspection Service has changed and is now called Veterinary Public Health Operations (VPHOps). The other change was the addition of a seventh region.

Official controls are administered through VPHOps which consists of three layers of structure including headquarters level with superintending veterinary inspectors (SVI), technical and administrative staff, regional level with regional superintending veterinary inspectors (RSVI) and district superintendent (DS) of technical staff, and local within plant staff of veterinary inspectors (VI) as supervisors of the temporary veterinary inspectors (TVI) and technical staff which consist of supervisory agricultural officers (SAO) and technical agricultural officers (TAO).

DAFM ensures staffing levels are adequate and program verification tasks are completed according to schedule for each day and each shift of operation, and that official sampling tasks are performed. The FSIS auditors verified that DAFM has procedures in place to ensure an effective level of oversight is maintained by VIs and SAOs, TVIs are present to inspect every carcass and parts during slaughter and VIs and TAOs conduct processing inspection activities at least once per shift. The FSIS auditors verified that TVIs are government contracted employees and are paid directly by DAFM, while all other staff are government employees and paid directly by DAFM.

The FSIS auditors verified the process for certification of an establishment as eligible to export meat products to the United States. An establishment must apply to DAFM which then provides

an information packet that includes all requirements an establishment must meet for certification. An establishment must then have a third-party independent audit of their food safety control system and make changes as identified from that audit. DAFM officials including the RSVI, VI, and a headquarters VPHOps SVI will then conduct a certification inspection and provide a written report documenting all findings which must be corrected prior to a follow-up inspection. DAFM officials will conduct additional follow-up certification inspections as needed to verify any required changes and corrections were made. An establishment must have an acceptable inspection prior to DAFM certification of an establishment as eligible to export to the United States. DAFM will then request that FSIS list the establishment as certified to export to the United States.

DAFM officials are authorized under EU legislation to take actions in establishments as necessary to ensure compliance with requirements. DAFM has several levels of action they may take based on the type of observation and potential severity of its effects. Actions which may be taken include verbal direction which may be given by any government official, documentation and issuance of a non-compliance report, issuance of a fixed payment notice or fine, issuance of a compliance notice or possible prosecution if warranted. DAFM would also remove certification of an establishment's eligibility to export meat products to the United States when appropriate. At each level of action, DAFM documents findings and performs follow-up verification of certified establishment corrective actions.

DAFM ensures that only products that have been inspected and certified as eligible for export to the United States are issued an export certificate. A certified establishment is responsible for providing all information in order for the VI to certify and sign the export certificate verifying that the meat products meet United States requirements. The VI and TAO conduct random checks of consignments to ensure all United States requirements are met prior to certification of the export. Export certificates are issued and stamped at the local level on secure certificate paper, which has a watermark and holographic security seal and is individually numbered and tracked.

DAFM requires certified establishments to conduct species testing on an annual basis. Certified establishments are required to maintain separation of pork and beef products eligible for export to the United States from that which is not eligible and from products originating in non-approved establishments. Pork and beef products intended for export to the United States must be clearly identified and stored in a designated area to ensure adequate separation by time and space. The FSIS auditors verified DAFM requirements for identification and separation are being met at certified establishments.

DAFM requires all establishments to maintain traceability of all pork and beef products received and distributed and be able to withdraw or recall products if necessary. Establishments must maintain a written recall plan and they must conduct a test recall yearly as part of the plan. Establishments are required to immediately inform DAFM of the shipment of adulterated product. The FSIS auditors verified that DAFM has a mechanism in place to notify FSIS of the shipment of non-compliant or adulterated products. There have been no recalls of pork or beef products exported from Ireland to the United States since the last prior FSIS audit in 2019.

DAFM requires chemical residue and microbiological laboratories conducting analysis of official samples to be accredited by the Irish National Accreditation Board (INAB) according to International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025 standards. The FSIS auditors confirmed that INAB conducts an accreditation audit of the official laboratories on a yearly basis. The FSIS auditors interviewed staff and reviewed documents from laboratories to verify adequate controls are in place to ensure package and sample integrity including DAFM sample seals at receiving, use of recognized and approved analysis methods, calibration of laboratory equipment, ongoing control testing to verify methods, proficiency testing, sample tracking and recordkeeping, and results of analyses are reported according to DAFM procedures and systems. The FSIS auditors also reviewed internal employee training and proficiency requirements and the results of the most recent internal audits.

DAFM educational requirements are set within EU regulations with training sessions for all employees held upon initial hiring of an official and subsequent refresher type training held on a continuing basis. Employees are trained based on their specific job duties including ante-mortem, post-mortem, animal welfare and humane handling, transport of animals, export certification, sanitation, HACCP, and sampling techniques. Employees are also provided training about specific FSIS requirements including labeling, test and hold, pre-shipment review and any changes or updated procedures.

The auditors verified that Ireland's meat inspection system is organized and administered by the national government, and that DAFM inspection officials are authorized and assigned to enforce the laws and regulations governing meat products, providing ultimate control, supervision, and enforcement of regulatory requirements.

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 equivalence component the FSIS auditors 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 every carcass and its parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; at least once per shift inspection during processing operations; and periodic supervisory visits to official establishments.

The FSIS auditors verified that ante-mortem inspection is performed according to DAFM requirements. Ante-mortem inspection is carried out by a TVI according to EU regulations with inspection taking place within 24 hours of the animal's arrival and less than 24 hours prior to slaughter. The TVI determines if the health and welfare of the animal is compromised, any abnormality or disease condition which may affect the suitability of the animal for human consumption, and any use of prohibited or unauthorized substances. The TVI and TAO review animal identification tags, passports and Food Chain Information documents which provide information on any completed or pending animal health testing, origin of the animal and any prior veterinary treatments and associated withdrawal periods.

DAFM follows EU legislation regarding animal protections during transport, protection of animals during slaughter, and animal welfare to verify humane handling occurs from the initial starting point of moving animals from the farm through the process until animals are slaughtered. The TAO/SAO and VI observe and verify daily operations for conditions and construction of holding pens, animal spacing to prevent overcrowding, ventilation, water and feed availability in pens, movement of animals to slaughter, and stunning effectiveness. The FSIS auditors verified that any observation of concerns or findings result in immediate enforcement measures taken to ensure corrective actions occur dependent on the specific observation and prior to resuming operations.

The FSIS auditors verified post-mortem inspection is conducted according to DAFM requirements. DAFM requires TVIs to conduct post-mortem inspection of every carcass, head and viscera under the supervision of the VIs. A visual inspection of carcass surfaces and cavities is performed, as well as palpation and incisions made to the head and viscera allowing for a full evaluation of each carcass. DAFM ensures adequate removal of specified risk materials (SRMs) in beef slaughter operations through visual inspections, and also conduct a zero-tolerance check of each carcass for fecal, milk, and ingesta prior to the carcass entering the chillroom. Based on EU regulations, SRMs are removed and identified as category 1 materials and are controlled and handled accordingly. The FSIS auditors also verified that DAFM ensures the control of condemned materials and animals as part of their routine verification procedures of identification and marking control systems at each certified establishment.

DAFM RSVIs conduct two supervisory audits per year at each establishment certified to export meat products to the United States. During the supervisory audit, the RSVI reviews both certified establishment programs and records for compliance as well as performance of DAFM staff and government contracted TVI employees. The DAFM DS also conducts a review of SAO and TAO job duty performance four times per year at each establishment. DAFM VIs conduct routine audits of establishment programs and records and conduct weekly meetings with establishment management which are documented and maintained on file. All reviews, supervisory visits and audits include written documentation of any findings and follow-up verification of corrective actions when necessary.

The FSIS auditors verified that DAFM requires certified establishments to properly label products according to the FSIS requirements. Labels must include product name, shipping identification mark, country of origin, name and address of the manufacturer or distributor, net weight of the product, a handling statement, and safe handling instructions. Any labels with claims must be approved by FSIS prior to their use by a certified establishment. VIs and TAOs conduct reviews of labels for specific FSIS labeling requirements during the export verification process.

The FSIS analysis and verification activities indicate that DAFM maintains the legal authority and a regulatory framework that is consistent with the criteria for this component and therefore continues to meet the core requirements.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third equivalence component the FSIS auditors reviewed was Government Sanitation. The FSIS auditors verified that DAFM requires each certified establishment to develop, implement, and maintain written sanitation standard operating procedures (SOP) to prevent direct product contamination or insanitary conditions, and to maintain requirements for sanitation performance standards (SPS) and sanitary dressing.

The FSIS auditors verified that DAFM requires certified establishments to comply with the document Guideline on USDA Approval dated May 5, 2022. Certified establishments are required to develop, implement, and maintain sanitation SOPs to ensure operations occur under sanitary conditions. The document requires certified establishments to have written programs and include procedures conducted before and during production and to identify the frequency of procedures. DAFM also requires certified establishments to take corrective actions including disposition of contaminated product, restoration of hygienic conditions, and measures to prevent recurrence of product contamination including evaluation and modification of the written sanitation SOP programs. Certified establishments must also maintain daily sanitation SOP records of implementation, monitoring, and corrective actions.

DAFM VIs and TAOs are responsible for verification that certified establishment meet SPS and sanitation SOP requirements. The VIs and TAOs document results of their verification procedures on a daily basis and follow DAFM enforcement protocol regarding corrective actions the establishment may need to take. Pre-operational verification of a certified establishment's sanitation SOP program is performed by the TAO by observing the designated establishment employee perform their cleanliness check or by inspecting establishment equipment prior to operations.

DAFM requires certified establishments to maintain written carcass hygiene programs to prevent contamination of carcasses, organs, and other parts throughout the slaughter and dressing process. Certified establishments must maintain daily records sufficient to document implementation and monitoring of procedures which are written as SOP programs. The FSIS auditors verified through observation and review of records that the VIs and TAOs routinely perform verification of sanitary dressing procedures through conducting their own carcass hygiene evaluation procedure.

The FSIS auditors verified through observations and review of records that TVIs perform carcass by carcass inspection and identify any fecal, ingesta or milk contamination which is recorded as a zero-tolerance failure and requires corrective action by the certified establishment. VIs and TAOs also conduct random carcass checks during each production shift with any findings of fecal, ingesta or milk identified as a zero-tolerance failure requiring corrective actions by the certified establishment.

The FSIS auditors assessed the adequacy of inspection verification by observing in-plant inspection officials conducting pre-operational sanitation in two of the certified establishments. DAFM officials conducted verification procedures after the certified establishment had conducted its own pre-operational sanitation verification procedures. The FSIS auditors also

observed in-plant inspection officials verification of operational sanitation procedures and sanitary dressing procedures. FSIS auditors' review of DAFM records at each certified establishment indicated that in-plant inspection officials identify, and document findings with sanitation and dressing procedures and require certified establishments to take corrective actions.

The FSIS analysis and verification activities indicate that DAFM requires operators of certified establishments to develop, implement, and maintain sanitation programs, including requirements for SPS, sanitation SOPs and sanitary dressing procedures. FSIS concluded that DAFM continues to meet the core requirements for this component.

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

The fourth equivalence component the FSIS auditors reviewed was Government HACCP System. The food safety inspection system is to require that each certified establishment develop, implement, and maintain a HACCP system.

The FSIS auditors verified that DAFM requires certified establishments to comply with the document Guideline on USDA Approval which indicates certified establishments must specifically meet 9 CFR Part 417 HACCP regulations. Certified establishments are required to develop and implement a HACCP system to control food safety hazards identified within their hazard analysis. RSVIs verify HACCP system design, implementation, validation, recordkeeping, supporting documentation, reassessment records and pre-shipment reviews as part of their supervisory audit conducted twice yearly at each certified establishment.

The FSIS auditors verified that VIs and TAOs verify critical control points (CCPs) as part of official controls of certified meat establishments. Results of verifications are documented on daily DAFM check reports with enforcement actions documented when observation of non-conformance are observed. Certified establishments must take corrective actions and identify the cause of the deviation, ensure the CCP is under control, prevent reoccurrence of the deviation and ensure all affected product is identified and proper disposition occurs.

The FSIS auditors conducted onsite observation and document review of CCPs in certified establishments which were visited as part of the audit. FSIS auditors observed DAFM verification of establishment personnel conducting zero-tolerance monitoring for fecal, ingesta and milk. The FSIS auditors reviewed DAFM records including findings when there was a CCP failure, and documentation of actions taken by DAFM, and the records of corrective actions taken by the certified establishment in response to DAFM findings.

The FSIS auditors verified that certified slaughter establishments have controls in place to ensure carcasses are chilled in a manner to prevent the outgrowth of pathogens. Certified establishments visited as part of the audit implement microbial testing for indicator organisms and certified beef slaughter establishments conduct testing of carcasses for *Escherichia coli* (*E. coli*) O157:H7 according to DAFM requirements. Sampling according to these DAFM requirements provides for verification of the certified establishment's food safety system and supports their programs as effective in controlling the identified hazards.

The FSIS audit verification activities indicate that DAFM requires operators of certified establishments to develop, implement, and maintain a HACCP system. FSIS concludes that DAFM continues to meet the core requirements for this component.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

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

Prior to the onsite audit, and as part of the annual SRT review for ongoing equivalence determinations, FSIS reviewed Ireland's National Residue Control Plan (NRCP), associated methods of analysis, reported results of the testing program, and additional official documentation outlining the structure of Ireland's official chemical residue testing program.

The FSIS auditors verified that DAFM continues to maintain the legal authority to regulate, plan, and execute activities of the inspection system that are aimed at preventing and controlling the presence of residues of veterinary drugs and chemical contaminants in the tissues of bovine, porcine and ovine animals slaughtered for human consumption. DAFM implements requirements in accordance with Regulation (EU) 2017/625 to ensure acceptable standards with reference to veterinary drug, pesticide, and other chemical contaminant maximum residue limits (MRLs) in food products.

The NRCP sampling plan lists the residue group, the number of samples for the group, the matrix, and number samples each month. These instructions include random sampling and testing of internal organs, fat, or muscle of carcasses for substances and appropriate corrective actions in the event an MRL is exceeded. DAFM VIs also identify animals for suspect residue sampling based on observations of the live animal at ante-mortem or based on carcass condition at post-mortem inspection. For carcasses where a sample is found violative, an investigation is carried out to ascertain the origin of the animal and root cause of the chemical residue violation.

The FSIS auditors verified that in-plant government inspection personnel who collect the residue samples are following DAFM's sampling protocol. This protocol includes sampling methodology, identification of animals, sampling frequency, traceability, and secure delivery of residue samples to designated laboratories. The NRCP includes both an official sampling program conducted by DAFM and requires a self-monitoring program with sampling conducted by slaughter establishments. DAFM issued Veterinary Procedure Notice 9/2019 requiring that all animals and carcasses sampled under the official DAFM routine and targeted official sampling programs are excluded and are not eligible for export to the United States. Animals and carcasses sampled as part of the slaughter establishment's self-monitoring sampling program are also excluded and not eligible for export unless the food business operator holds the carcasses and parts which were tested pending results of analysis.

The FSIS analysis and onsite verification activities indicate that DAFM has overall authority of a chemical residue testing program which is designed and implemented to prevent and control the presence of veterinary drugs and contaminants in meat products destined for export to the United States.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last equivalence component the FSIS auditors reviewed was Government Microbiological Testing Programs. The food safety inspection system is to implement certain sampling and testing programs to ensure that meat products prepared for export to the United States are safe and wholesome.

DAFM requires all certified establishments to implement a sampling program and test according to Commission Regulation (EC) No. 2073/2005 for process hygiene criteria of carcasses. Establishments are required to conduct indicator organism testing on carcasses for total viable count and Enterobacteriaceae, and to analyze the data using standards set as lower limit (m) and upper limit (M) based on the species. The FSIS auditors confirmed that DAFM verifies certified establishments adhere to sampling frequencies and take action when an individual test is beyond the upper limit (M), or a trend is identified based on levels above the lower limit (m). The FSIS auditors interviewed government inspection personnel, reviewed records, and directly observed sampling with no findings identified with the hygiene criteria sampling programs at each certified establishment visited as part of the audit.

DAFM additionally requires certified establishments exporting pork products to the United States to follow procedures outlined in a DAFM document titled New Carcass Sampling Requirements at USDA Certified Pig Slaughter Plants. DAFM requires random carcass sampling to be conducted at two points in the slaughter process: pre-evisceration and post-chill. Establishments must analyze samples for an approved indicator organism in a laboratory accredited to carry out the specific test method. The results of testing must be evaluated for the overall levels of microbial contamination as well as the reduction in contamination between the pre-evisceration and post-chill location as indicators of process control. DAFM inspection personnel verify that establishments perform swine carcass sampling and review results to assess process control. If evaluation of test results indicates the loss of process control, establishments must take corrective action. The FSIS auditors interviewed government inspection personnel, reviewed records, and directly observed sampling with no findings identified.

DAFM requires certified establishments to conduct official *Salmonella* sampling of bovine carcasses consistent with FSIS' *Salmonella* performance standards criteria as described in 9 CFR 310.25(b). DAFM officials supervise and verify certified establishment implementation of the *Salmonella* program to ensure it meets criteria including random selection of carcasses, locations of sampling, sampling methodology, evaluation criteria, and frequency of sampling. DAFM requires that an approved laboratory conduct analysis for detection of *Salmonella* consistent with FSIS' Microbiology Laboratory Guidebook (MLG), Chapter 4. DAFM inspection personnel verify that the certified establishment's *Salmonella* sampling and testing performance meet

requirements including implementation of corrective actions when required. The FSIS auditors interviewed government personnel, reviewed records, and observed sampling with no findings identified with DAFM's required *Salmonella* verification sampling program.

DAFM implements an official government sampling program for STEC at establishments certified for export of raw beef intended for grinding to the United States. The program outlines selection of samples, sampling methodology, and frequency of sampling. Official samples are sent under DAFM seal to a DAFM laboratory for STEC analysis using a testing method approved by DAFM. The FSIS auditors interviewed government personnel, reviewed government records, and observed the sampling with no findings identified concerning the DAFM STEC verification sampling program.

DAFM requires N60 testing and a negative result for STEC for each lot of beef intended for grinding prior to certification for export to the United States. Certified establishments must follow the same N60 collection method and sampling analysis as DAFM conducts for official samples. DAFM also requires certified beef slaughter establishments to conduct four weekly swab samples of carcasses with analysis of the swab for *E. coli* O157:H7. Samples must be sent to laboratories that are approved by DAFM for N60 STEC and *E. coli* O157:H7 analysis respectively. Laboratories performing analysis on samples submitted by certified establishments must follow methods approved by DAFM. The FSIS auditor interviewed government personnel, reviewed records, and observed sampling with no findings identified.

The FSIS auditor's onsite verification determined that DAFM maintains the legal authority to implement its microbiological sampling and testing programs to ensure that products destined for export to the United States are unadulterated, safe, and wholesome.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held September 28, 2022, by videoconference with representatives from DAFM. FSIS concluded that Ireland's food safety inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. The Department of Agriculture, Food and the Marine (DAFM), Ireland's Central Competent Authority, has required that the establishments certified as eligible to export products to the United States implement sanitation requirements and a HACCP system designed to ensure the safety of their products. In addition, DAFM has implemented official microbiological and chemical residue testing programs that are organized and administered by the national government to verify its system. An analysis of each component did not identify any systemic findings representing an immediate threat to public health.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklists

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Donegal Meat Processors. Carrigans	09/16/2022	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. Periodic Supervisory Reviews	
52. Humane Handling	X
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57.	
58.	
59.	

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	

60. Observation of the Establishment

52. During the site visit, rubber mats in the suspect animal pen were observed to have large tears and holes, a condition which could cause injury to live animals due to the potential of tripping. No animals were observed in the pen and DAFM took action to prevent use of the pen until repairs were completed.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	09/16/2022

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 Bunclody	09/21/2022	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
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.	X
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	X
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
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.	
58.	
59.	

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	Raw beef

60. Observation of the Establishment

18: During the site visit, a CCP failure was observed as fecal contamination was identified on a carcass hind shank on chill room #4. DAFM ensured and verified the establishment took immediate corrective actions including verification of no other affected products.

41: During the site visit, condensation in droplet form was observed on the ceiling over the carcass rail entering chill room #3, no product contamination was observed.

46: During the site visit, rail dust was observed on a carcass after the trim step in the boning hall; the establishment took immediate corrective actions to restore sanitary conditions.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	09/21/2022

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
Anglo Beef Processors Ireland T/A ABP Cahir	09/14/2022	300	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. Periodic Supervisory Reviews	
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.	
58.	
59.	

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	

60. Observation of the Establishment

No observations identified.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	09/14/22

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 Clonee Dublin	09/21/2022	317	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.	X
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
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.	
58.	
59.	

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	

60. Observation of the Establishment

18: During the site visit, a zero tolerance FIM failure was observed as ingesta was identified on a tail on a cooling rack in the chill room. DAFM ensured and verified the establishment took immediate corrective actions regarding all affected products.

46: During the site visit, non-product contact equipment used for flipping overhead rail switches for carcass was observed to be resting on the floor creating the potential for cross contamination due to insanitary conditions--no product observed to be affected.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	09/21/2022

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
Liffey Meats Cavan Ballyjamesduff	09/14/2022	325	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.	X
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.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
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.	
58.	
59.	

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	

60. Observation of the Establishment

8: During the site visit, it was determined that daily SSOP records did not include all corrective actions taken in response to an observation of non-conformance with the written program.

22: During the site visit it was determined that HACCP CCP records did not include all corrective actions taken in response to a CCP deviation.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	09/14/2022

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Dawn Pork and Bacon Grannagh	09/16/2022	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.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
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	X
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	X
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
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.	
58.	
59.	

Establishment Operations:	Pork slaughter and processing.
Prepared Products:	

60. Observation of the Establishment

10 and 47: During the site visit, an employee moving carcass parts on a tree was not following the written SSOP and did not have the appropriate clothing—no product contamination was observed.

39: During the site visit, floors in the boning and primal areas (halls) had several cracks and crevices. These areas are not maintained in a manner to facilitate effective cleaning therefore the potential exists for spreading of microorganisms or contamination throughout the plant—no product contamination was observed.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	09/16/2022

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 Roscrea	09/19/2022	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	X
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. Periodic Supervisory Reviews	
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.	
58.	
59.	

Establishment Operations:	Pork slaughter and processing.
Prepared Products:	

60. Observation of the Establishment

39: During the site visit, in the fabrication area a hole was observed in the ceiling and two pipes running through the ceiling were not appropriately sealed whereby they had openings around the pipes—no product contamination was observed.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	09/19/2022

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Dawn Charleville Charleville	09/13/2022	368	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	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
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.	
58.	
59.	

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	

60. Observation of the Establishment

39/46: During the site visit a black foreign material was observed on carcass hind shanks after implementation of the establishments control procedures. The plant did corrective actions, immediately found root cause and re-inspected product. The cause was determined to be foam wrapping material from overhead structures that had deteriorated. The area was rechecked twice before the end of the establishment site visit including extra product checks.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	09/13/2022

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
ABP Clones Clones	09/15/2022	378	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
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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.	
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19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
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	X
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
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.	
58.	
59.	

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	

60. Observation of the Establishment

45. During the site visit, non-product contact equipment used for flipping overhead rail switches for carcass movement were observed to have open ends which could not easily be cleaned.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	09/15/2022

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	09/20/2022	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.	X
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.	
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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	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

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. Periodic Supervisory Reviews	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	
55. Post Mortem Inspection	O
	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57.	
58.	
59.	

Establishment Operations:	Beef processing.
Prepared Products:	

60. Observation of the Establishment

16. During the site visit, it was determined that the establishment did not maintain adequate support for decisions in their hazard analysis; some product temperatures were observed to be outside of establishment program operational parameters. No evidence of product adulteration was identified.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	09/20/2022

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

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

Ref: NMcG/15/06/23

15 June 2023

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination
Food Safety and Inspection Service-USDA
Room 3143, South Building
Washington, DC 20250
USA

Subject: DAFM comments on USDA Audit Report

Dear Dr. Catlin,

I would like to reiterate our thanks to your audit team for their visit last year.

We have reviewed the report and are pleased with the outcome.

There are some minor comments/clarifications included in the annex attached.

An electronic copy of this notification will also be sent to Steve Knight at the Foreign Agriculture Service in London.

Thank you for your continued co-operation.

Yours sincerely,

p.p. Dr Martin Blake
Chief Veterinary Officer
Delegate to the WOAH

DAFM Comments on USDA Systems Audit Report:

The following are some comments/clarifications from DAFM on the draft audit report from the USDA.

Page 8 of document (numbered page 5):

'Veterinary Public Health Inspection Service has changed to Veterinary Public Health (VPH) with two divisions now referred to as VPH Policy and VPH Operations (VPHOps)'

DAFM: Clarification on changes to organisation chart. Veterinary Public Health Inspection Service (VPHIS) has changed name and is now called Veterinary Public Health Operations (VPHOps). Veterinary Public Health Policy is a separate division and was not previously part of VPHIS.

'Official controls are administered through VPHOps which consists of three layers of structure including headquarters level with supervisory veterinary inspectors (SVI), technical and administrative staff, regional level with regional supervisory veterinary inspectors (RSVI) and district supervisor (DS) of technical staff'

DAFM: The highlighted words should read 'superintending', 'superintending' and 'superintendent', respectively.

Page 11 of document (numbered page 8):

First paragraph:

'animal identification tags and passports which provide information on any completed or pending animal health testing, origin of the animal and any prior veterinary treatments and associated withdrawal periods.'

This should read: 'animal identification tags, passports, and Food Chain Information (FCI)…'

Second paragraph:

'The TVI and VI observe and verify daily operations for conditions and construction of holding'

This should read: 'The TAO/SAO and VI…'

Page 14 of document (numbered page 11):

Second last paragraph:

'The NRCP sampling plan lists the residue group, the number of samples for the group, the matrix, and number and days of sampling each month.'

This should read: 'The NRCP sampling plan lists the residue group, the number of samples for the group, the matrix, and number of samples each month'

Same paragraph as above:

'DAFM VIs also identify animals for targeted residue sampling based on observations of the live animal at ante-mortem or based on carcass condition at post-mortem inspection.'

This should read: 'DAFM VIs also identify animals for suspect residue sampling…'

Page 16 of document (numbered as page 13):

Second Paragraph:

'DAFM implements an official government sampling program for STEC at establishments certified for export of raw beef to the United States. The program outlines selection of samples, sampling methodology, and frequency of sampling. The program specifies that beef trim samples are collected once monthly according to the N60 collection method.'

DAFM: Only BIFG included in programme at that time. Beef trim sampling for STEC was not in place at the time of the audit.