



United States Department of Agriculture

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Food Safety and  
Inspection Service

FEB 12 2020

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Washington, D.C.  
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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 (USDA), Food Safety and Inspection Service (FSIS) conducted an on-site verification audit of Ireland's inspection system from June 17 through June 28, 2019. 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.

Should you have any questions regarding the FSIS audit report, please contact the Office of International Coordination, by electronic mail at [InternationalCoordination@usda.gov](mailto:InternationalCoordination@usda.gov).

Sincerely,

A handwritten signature in blue ink, appearing to read "Michelle Catlin".

Michelle Catlin, PhD  
International Coordination Executive  
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

IRELAND

JUNE 17 - 28, 2019

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

RAW BEEF AND RAW PORK

EXPORTED TO THE UNITED STATES OF AMERICA

February 5, 2020

Food Safety and Inspection Service  
United States Department of Agriculture

## **Executive Summary**

This report describes the outcome of an on-site equivalence verification audit conducted by the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) from June 17 - 28, 2019. The purpose of the audit was to determine whether Ireland's food safety inspection system governing raw beef and raw pork 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 raw beef and raw pork products to the United States.

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.

An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors identified the following findings:

### **GOVERNMENT OVERSIGHT**

- 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.

### **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.

### **GOVERNMENT 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 audit exit meeting, the CCA committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

# TABLE OF CONTENTS

I.	INTRODUCTION.....	1
II.	AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY .....	1
III.	BACKGROUND.....	4
IV.	COMPONENT ONE: GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION) .....	5
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) .....	9
VI.	COMPONENT THREE: GOVERNMENT SANITATION.....	12
VII.	COMPONENT FOUR: GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM .....	14
VIII.	COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS.....	16
IX.	COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS.....	17
X.	CONCLUSIONS AND NEXT STEPS.....	20
	APPENDICES .....	21
	Appendix A: Individual Foreign Establishment Audit Checklists	
	Appendix B: Foreign Country Response to the Draft Final Audit Report	

## I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of Ireland’s food safety system from June 17 through 28, 2019. The audit began with an entrance meeting held on June 17, 2019, in Dublin, Ireland, during which the FSIS auditors discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – The Department of Agriculture, Food and the Marine (DAFM). Representatives from the CCA accompanied the FSIS auditors throughout the entire audit.

## II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to determine whether the food safety system governing raw beef and raw pork 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
Raw - Non-Intact	Raw ground, comminuted, or otherwise non-intact beef	Beef patty product; bench trim from non-intact; formed steaks; ground beef; hamburger; non-intact cuts; other non-intact; sausage; trimmings from non-intact
Raw - Non-Intact	Raw ground, comminuted, or otherwise non-intact pork	Ground product; other non-intact; sausage
Raw - Intact	Raw intact beef	Boneless manufacturing trimmings; carcass (including carcass halves or quarters); cheek meat; cuts; edible offal; head meat; heart meat; other intact; primals and subprimals; weasand meat.
Raw - Intact	Raw intact pork	Boneless manufacturing trimmings; carcass (including carcass halves or quarters); cuts; edible offal; other intact; primals and subprimals.

The USDA’s Animal and Plant Health Inspection Service (APHIS) recognizes Ireland as a country that is free of foot-and-mouth disease, free of swine vesicular disease, free or with low risk of classical swine fever (CSF) as part of the APHIS-defined European CSF region. APHIS also recognizes Ireland as having a controlled risk for bovine spongiform encephalopathy and a scrapie risk status for ovine/caprines. Currently, APHIS has placed restrictions on the importation

of meat and edible products from ovine and caprine due to transmissible spongiform encephalopathy (TSE) as specified in Title 9 of the United States Code of Federal Regulations (9 CFR) § 94.24.

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 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 CCA through the self-reporting tool (SRT).

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.

Administrative functions were reviewed at the CCA headquarters, two regional offices, and eight local inspection offices. The FSIS auditors visited a sample of eight establishments from a total of 13. This included five beef slaughter/processing establishments and three pork slaughter/processing establishments. The products these establishments produce and export to the United States include raw beef and raw pork. The FSIS auditors evaluated the implementation of control systems in place that ensure that the national system of inspection, verification, and enforcement is being implemented as intended.

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 threaten food safety. The FSIS auditors assessed the CCA’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 § 327.2.

Additionally, FSIS 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 DAFM maintains over their functions.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	<ul style="list-style-type: none"> <li>Department of Agriculture, Food and the Marine, Dublin</li> </ul>
	Regional Offices	2	<ul style="list-style-type: none"> <li>East Regional Office, Backweston</li> <li>North-East Regional Office, Cavan</li> </ul>

Laboratories	2	<ul style="list-style-type: none"> <li>• Advanced Laboratory Testing (ALT) Ltd., private microbiology laboratory, Newbridge</li> <li>• Veterinary Public Health Regulatory Laboratory (VPHRL), government residue and microbiology laboratory, Backweston.</li> </ul>
Beef slaughter and processing establishments	5	<ul style="list-style-type: none"> <li>• Establishment # 292, Donegal Meat Processors, Carrigans</li> <li>• Establishment # 296, Slaney Foods, Bunclody</li> <li>• Establishment # 317, Kepak Clonee Ltd., Clonee</li> <li>• Establishment # 325, Liffey Meats, Ballyjamesduff</li> <li>• Establishment # 378, ABP Clones, Clones</li> <li>•</li> </ul>
Pork slaughter and processing establishments	3	<ul style="list-style-type: none"> <li>• Establishment # 332, Queally Pig Slaughtering Ltd., Grannagh</li> <li>• Establishment # 355, Rosderra Irish Meat Group, Roscrea</li> <li>• Establishment # 356, Rosderra Irish Meat Group, Edenderry</li> </ul>

FSIS performed the audit to verify the food safety inspection system met 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.] 601 *et seq.*);
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901-1906); and
- The Food Safety and Inspection Service Regulations (9 CFR Parts 301 to the end).

The audit standards applied during the review of Ireland’s inspection system for raw beef and raw pork 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*; and includes the following:

- 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. 1/2005;
- Regulation (EC) No. 2073/2005;
- Regulation (EC) No. 1069/2009;
- Regulation (EC) No. 1099/2009;

- Regulation (EU) No. 142/2011;
- Regulation (EC) No. 1169/2011;
- EC Directive No. 93/119/EC;
- EC Directive No. 96/22/EC; and
- EC Directive No. 96/23/EC.

### III. BACKGROUND

From January 1, 2016 to February 28, 2019, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 17,154,698 pounds of raw beef and 32,758,134 pounds of raw pork exported by Ireland to the United States (beef: intact cuts, primals and subprimals, edible offal, boneless manufacturing, heart meat; pork: intact cuts, primals and subprimals). FSIS also performed re-inspection on 5,679,373 pounds of raw pork and raw beef products at POE for additional types of inspection, including laboratory testing for chemical residues and microbiological pathogens (e.g., Shiga toxin-producing *Escherichia coli* (*E. coli*) (STEC) O157:H7, O26, O45, O103, O111, O121, O145 and *Salmonella*), of which a total of 19,678 pounds raw beef and raw pork were rejected for issues not related to public health (shipping damage, labeling, etc.).

The previous audit in 2017 identified the following findings:

#### **GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS**

- At two audited lamb slaughter establishments:
  - Not all carcass 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.

The FSIS auditors did not verify the implementation and effectiveness of the corrective actions associated with the previously reported findings because lamb slaughter was not part of the scope of this audit due to the current APHIS restrictions on the importation of meat and edible products from ovine and caprine due to TSE as specified in 9 CFR § 94.24.

Prior to the on-site equivalence verification audit, FSIS reviewed and analyzed Ireland's SRT responses and supporting documentation. During the audit, the FSIS auditors conducted interviews, reviewed records, and made observations to determine whether Ireland's food safety inspection system governing raw beef and raw pork is being implemented as documented in the country's SRT responses and supporting documentation.

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

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

The first of six equivalence components that 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. The FSIS auditors verified that the inspection system is organized and administered by the national government of Ireland. There have been no major changes in the CCA's organizational structure since the last FSIS audit conducted in 2017.

As a member of the EU, Ireland follows EU legislation regarding food of animal origin, and derives its authority to enforce food inspection laws from Regulation (EC) No. 178/2002. The *National Legislation Statutory Instruments (SI) No. 432/2009* sets the necessary requirements to export to another country. The Food Safety Authority of Ireland (FSAI) maintains overarching authority over the nation's food supply and delegates that authority to subordinate agencies, by means of a service contract, to exercise official food inspection controls. In Ireland, DAFM is responsible for ensuring safety of animal-based food products and has the authority to promulgate food inspection regulations and enforce food safety laws and regulations. DAFM 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.

Ireland organizes its meat inspection system on three levels: central, regional, and local. The central level consists of the headquarters offices in Dublin led by the Chief Veterinary Officer (CVO) and a management team of Senior Veterinary Officers (SVOs). The SVO team includes a Director of Operations (Veterinary Public Health Inspection Service (VPHIS) Implementation), a Deputy Chief Veterinary Officer (VPHIS Policy) and two Senior Superintending Veterinary Inspectors (SSVIs) (VPHIS Policy and VPHIS Implementation, respectively), supervising a team of central and regional-based Superintending Veterinary Inspectors (SVIs). VPHIS has ultimate control over the slaughtering of livestock for export and production of food products derived from animals.

The regional level encompasses 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 Supervisory 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 consists of DAFM veterinary offices located in each slaughtering establishment certified to export to the United States. Each office has a Veterinary Inspector (VI) in charge of inspection activities in the establishment. The VI has direct supervision over inspection personnel assigned to the certified establishment, including Temporary Veterinary Inspectors (TVI) and Technical Agricultural Officers (TAO). The VI in certified establishments performs

daily supervision of establishment activities and reports directly to the RSVI, who performs periodic supervisory reviews twice a year. The RSVI and VI assess the eligibility of establishments to export to the United States using the Veterinary International Trade 01, Guideline on USDA Approval. They have the authority, under Regulation (EC) No. 178/2002 and *National Legislation Statutory Instruments (SI) No. 432 of 2009* to enforce the necessary requirements for export, including to require corrective actions in certified establishments and to take additional enforcement measures as appropriate. They may also initiate investigations into the failure of an establishment to meet the standards of the importing country and may provide documentation to DAFM to support the de-listing of non-compliant establishments.

All products destined for export to the United States are produced in certified establishments. Under Regulation (EC) No. 882/2004, 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. Furthermore, DAFM is also responsible for official controls on imports from third countries of products of animal origin at border inspection posts. Additionally, the DAFM requires establishments to have procedures in place to ensure that only products eligible for export to the United States are exported.

Food safety controls in Ireland are regulated by the *Hygiene Package* which contains EC regulations. Under the *Hygiene Package*, DAFM is legally authorized to carry out inspections of meat establishments for hygiene approval and to implement EU Regulations and certification obligations through SIs, the method by which EU Regulations are enforced in Ireland. Regulation (EC) No. 1935/2004 governs packaging of food contact materials in the entire EU while labeling of meat in the EU is regulated by the 2014 Food Information to Consumers (FIC) Regulation (EC) No. 1169/2011. At the national level, the *VPHIS Guidance Note (GN USDA Adulteration Misbranding) – Control of Adulterated or Misbranded Products* provides DAFM with the responsibility to control misbranded/mislabeled and adulterated/contaminated foodstuffs. In the event that adulterated product is shipped to the United States, DAFM is responsible for informing FSIS immediately. The FSIS auditors, through interviews and records review, found no products exported to the United States that were recalled.

At DAFM headquarters and at two of DAFM's regional offices (East and North-East), the FSIS auditors verified, through document review and interviews, DAFM's oversight activities as well as the supervisory reviews of certified establishments. DAFM is responsible for conducting audits to determine initial and ongoing approval of official establishments, including those eligible to export products to the United States.

As the only body with the legal authority to certify and decertify establishments for export to the United States, DAFM is also responsible for designing policies for primary production, animal welfare, and slaughterhouses. At certified establishments, twice a year, the RSVIs conduct periodic reviews that include a full inspection of the facilities and a review of the non-compliances and other basic requirements. Then the RSVIs forward their audit report to the central headquarters SSVI (VPHIS Implementation) upon completion. When the inspection of a certified establishment indicates that the establishment does not meet the requirements for trade with the United States, the inspecting officer forwards a report to the supervisory VPHIS personnel at DAFM headquarters. The SSVI VPHIS Implementation evaluates the facts and

decides if suspension or delisting is warranted. If such action is necessary, DAFM issues a letter to the management of the noncompliant establishment indicating their ineligibility to export products to the United States and notifies FSIS accordingly.

In order to relist an establishment, the establishment must notify DAFM that the observed deficiencies have been corrected. After that, the VPHIS personnel conduct another site inspection to verify and evaluate all relevant facts before a decision to relist is made. Then DAFM notifies FSIS of the relisting and informs the relisted establishment management that they can only export products to the United States after the establishment's name is added to the list of the Ireland certified establishments list that is posted on the FSIS website.

The VPHIS personnel at headquarters monitor the FSIS website daily and disseminate information regarding United States requirements to inspection personnel using the Ezone intranet. The VPHIS senior management also translates EU regulations and FSIS requirements into standard operating procedures (SOPs) and veterinary procedures notices (VPNs), emails them to the inspection force, and publishes them on the DAFM's Ezone intranet. Ezone has a feature that ensures VPHIS personnel receive relevant updates when new issuances are posted. In addition to Guidance Notes issued to VPHIS staff, relevant United States inspection requirements are also communicated electronically to industry food business operators by way of Trader Notices and are available on the DAFM website.

Through on-site observation of inspection activities, records review, and interviews, the FSIS auditors verified that Ireland's meat inspection system assigns inspectors on the line during all slaughter operations and inspection at least once per shift during processing operations. A VI is permanently assigned to the certified slaughter establishments, maintains a daily presence at the facilities, and provides direct and continuous supervision to the other inspectors during slaughter and preparation of products.

The FSIS auditors verified that government inspection personnel assigned to certified establishments exporting meat products to the United States are employed and paid by the government of Ireland and are bound by 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 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. DAFM has ultimate control and supervision over the activities of all inspectors.

The FSIS auditors verified, through document reviews and interviews, that all TVIs conducting ante-mortem inspection on animals fill out a *Conflict of Interest Declaration* daily to state whether the animals or the herds are under their care or under the care of the practice of which they are members. If there is conflict of interest, then ante-mortem inspection is conducted by (1) a different TVI, (2) the DAFM VI, or (3) the TVI who has declared a conflict under the supervision of the VI when the VI is present in the lairage.

The FSIS auditors 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 DAFM headquarters and at the establishment level by the VIs who maintain control of all export certificates, seals, and stamps. DAFM's routine chemical residue testing program does not require the selected carcass and product thereof be held or controlled until sample results are received and therefore found negative. However, they do require non-routine samples (for cause) to be held pending results. The FSIS auditors identified the following:

- 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.

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 duty stations. 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. DAFM's supervisory chain of command has a mechanism that assesses the inspectors' training needs and provides recommendations as appropriate. The FSIS auditors verified the training records of official inspection personnel at government and local inspection offices, observed their inspection performance, and concluded that they have sufficient training to perform their inspection activities.

DAFM maintains administrative and technical support to operate its laboratory system in accordance with Regulation (EC) No. 854/2004. DAFM ensures that the laboratories possess the personnel, facilities, equipment, and methods necessary to fulfill their mission. DAFM laboratories are part of the government service. The Head of Laboratories is a member of the DAFM management structure and reports directly to the Secretary General, who in turn reports directly to the Minister. Government inspection personnel are always assisted by technical staff that provide support with documentary checks and such tasks as sample handling, documentation, and submission to a 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, FSAI, and DAFM conduct periodic reviews of the activities of the laboratories that DAFM oversees. Government inspection personnel carry out the sampling for regulatory testing programs. DAFM has the authority to suspend any laboratory at any time.

Monitoring of laboratories accredited by a national accreditation authority or approved by 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 VPHRL for review. 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 DAFM and most testing is carried out in laboratories directly under the control of DAFM. All laboratories must be accredited, and individual contracts specify delivery of testing. Part of the two-year audit by DAFM verifies methods and validation reports; staff records, which include training and experience; equipment records/calibration; and laboratory suitability and design.

The FSIS auditors conducted an on-site audit of ALT Ltd., which conducts official microbiological testing on raw pork and beef products for *Salmonella* performance standards; and on beef products that require testing for *E. coli* O157:H7 and non-O157 STECs. The audit included interviews with the laboratory management, document reviews that included the Quality Control Manual, and observations of the laboratory. The FSIS auditors verified that the laboratory conducting microbiological analytical testing for products destined for export to the United States was accredited by INAB in 2018 as equivalent to the ISO/IEC 17025 standard. Additionally, the FSIS auditors verified that DAFM conducted their last routine surveillance audit of ALT Ltd. in 2019; ALT Ltd. holds the accreditations for the analytical methods for *E. coli* O157:H7 and non-O157 STECs. The accreditation covers the management and quality assurance aspects of the functions of the laboratory to ensure that it has the capability to support DAFM's inspection program for certified establishments eligible to export to the United States.

The FSIS auditors reviewed the training materials, records, and the results of laboratory proficiency testing. The FSIS auditors also observed and verified sample receipt and handling by the ALT Ltd. personnel and found that ALT Ltd. performed a timely analysis of samples; reported the number of analyzed samples and the results in a timely manner; applied approved analytical methodologies; and had valid quality assurance programs. No concerns were identified.

The FSIS auditors 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 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 each and every carcass and 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 reviewed records maintained at DAFM headquarters, two regional office (supervisory) records, and local inspection records for each audited establishment. The FSIS auditors also verified that DAFM provides appropriate oversight and direction to inspection personnel for them to use their regulatory authority to enforce requirements for Ireland's meat food safety system. Moreover, accompanied by DAFM officials, the FSIS auditors observed the performance of verification activities by the inspection personnel and verified that an SVI conducts periodic supervisory visits to each certified establishment twice a year.

The RSVIs conduct the performance appraisals of the in-plant team at the end of the calendar year (with a mid-year review in between) and document the appraisals in the Performance Management Development System. Unsatisfactory performance is addressed through retraining of poor performers and follow up review with supervision.

In order to ensure that pork and beef products designated for export to the United States are currently not restricted by APHIS, DAFM monitors the FSIS and APHIS internet sites, and sends e-mails to its personnel in order to keep them informed of changes to the APHIS product restrictions and disease requirements. 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. According to DAFM, the recently established Veterinary Internal Trade and Certification Division routinely monitors for updated information. Information is then filtered to the in-plant personnel (IIP) and establishments.

IIP conduct ante-mortem inspection on the day of slaughter and ensure that all incoming cattle are properly registered in DAFM's Animal Identification and Movement (AIM) database and incoming pigs are also registered in DAFM's National Pig Identification and Tracing System (NPITS) database. The AIM and NPITS databases allow for the identification of animals that are moved off farm with a mark and the identification of breeding stock with an individual number, thereby facilitating the traceability of the animal to its source. Government inspectors also observe 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 auditors observed and verified that all animals have access to water 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, DAFM personnel document the results of ante-mortem inspection and numbers of livestock accompanying each lot to slaughter.

Each audited establishment maintains 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 along with all products that 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 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 for 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.

IIPs are trained in performing post-mortem inspection activities. The FSIS auditors verified that every carcass was subject to post-mortem inspection activities during and after the slaughter of swine and beef through on-site records review, interviews, and observations of inspectors conducting post-mortem inspection. This includes zero tolerance verification for fecal material, milk, and ingesta performed by the online IIP on each carcass slaughtered during all slaughter operations.

The FSIS auditors verified the adequate identification, removal, and disposal of specified risk materials (SRMs) in beef slaughter/processing establishments through observation, records review, and interviews of VIs. The FSIS auditors observed that at all beef slaughter/processing establishments a knife of different color is used to remove SRMs, which are then conveyed directly to rendering through a designated chute. DAFM follows Regulation (EC) No. 999/2001, which defines SRMs as the tonsils, the intestines from the duodenum to the rectum, and the mesentery of animals of all ages; the skull excluding the mandible and including the brain and eyes, and the spinal cord of animals aged over 12 months; the vertebral column excluding the vertebrae of the tail, the spinous and transverse processes of the cervical, thoracic and lumbar vertebrae and the median sacral crest and wings of the sacrum, but including the dorsal root ganglia, of animals aged over 30 months.

The DAFM definition of SRMs is consistent with FSIS' definition of SRMs. DAFM requires the removal of SRMs at the slaughterhouses and disposal as Category 1 Animal By-Products. In addition, DAFM has also developed an SOP instructing the inspection personnel to conduct official checks and verify that the establishments remove and handle SRMs according to regulations. The FSIS auditors verified that the *SRM Check Reports* were being generated and maintained at the local inspection offices of the audited establishments. At each audited beef slaughter/processing establishment, SRMs are identified as a biological hazard in the hazard analysis and controls are applied.

The FSIS auditors also verified that DAFM ensures complete separation of certified meat products from non-certified meat products through the *VPN No. 12/2015 Non-commingling of Beef from non-USDA Approved Plants with that from USDA Approved Plants* policy at the beef slaughter establishments. The policy requires that (a) exposed meat and wrapped/packaged meat from certified establishments shall not mix with meat originating from non-certified establishments and must be stored in such a way as to ensure that no cross contamination occurs, (b) a designated area for the exclusive storage of products must be provided either in cold storage on the site of slaughter or deboning or in a stand-alone cold store, and (c) establishments must have an SOP on how to ensure certified and non-certified product are not commingled.

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 laws of that importing country. DAFM has issued to government inspection personnel *VPN No. 12/2015*, which provides instructions regarding prevention of commingling of beef from non-certified establishments with beef from certified establishments. The FSIS auditors verified, through observation and interviews, that the policy preventing commingling was being implemented at the certified beef processing establishments.

The FSIS auditors verified that condemned and inedible materials are denatured and destroyed. In fact, Regulations (EC) Nos. 1069/2009 and 142/2011 govern the conditions of storage, handling, transport and disposal of animal by-products. VPHIS has developed an SOP regarding the control of carcasses and partial carcasses. The SOP describes the official controls for VPHIS officers to verify compliance by establishments with regulatory requirements for production, storage, handling and transport of animal by-products in DAFM-approved meat establishments (i.e., slaughter halls, cutting halls, minced meat, meat preparation plants and meat products plants), and to provide clarification and guidance on these requirements. The FSIS auditors observed the VPHIS personnel implement the SOP through checks on compliance by the establishments with the animal by-products legislation and checks on the SOP presented by the establishment. Each establishment is required to have an SOP for animal by-products and VPHIS may legally use *SI Nos. 432/2009* and *187/2014* to enforce animal by-product legislation.

Ireland's food safety system continues to maintain the legal authority, a regulatory framework, and adequate verification procedures to ensure sufficient official regulatory control actions to prevent products from contamination when insanitary conditions or practices are present, which as described, is consistent with criteria established for this component.

## **VI. COMPONENT THREE: GOVERNMENT SANITATION**

The third of six equivalence components that the FSIS auditors reviewed was Government Sanitation. The FSIS auditors verified that the CCA requires each official establishment to develop, implement, and maintain written sanitation standard operating procedures (sanitation SOPs) to prevent direct product contamination or insanitary conditions.

Ireland follows and enforces overarching EU sanitary regulations, which describe the rules for the organization of official controls on products of animal origin intended for human consumption and requires that each official establishment operates in a sanitary manner to prevent insanitary conditions and direct contamination of meat products. The inspection system focuses on the aspects of the establishment's sanitation that pose a risk of causing direct product contamination. The establishments must put structures and procedures in place so that food can be produced in a sanitary manner. DAFM's in-plant inspection team verifies that these structures and procedures are in place. In addition, the establishment is required to have a functional Food Safety Management System which consists of HACCP-based procedures and HACCP prerequisites, including the development, implementation, and maintenance of written sanitation SOPs.

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

The FSIS auditors observed IIP's verification of operational sanitation procedures in all audited pork and beef 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 actions records at all establishments. The FSIS auditors also reviewed the government inspection personnel's documentation of noncompliance reports (NCRs) and supervisory reviews of establishments. They also reviewed establishment sanitation SOPs and sanitation performance standard (SPS) 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. DAFM further provided the FSIS auditors with evidence that noncompliance had been corrected and verified to ensure compliance with United States requirements and shared a copy of the NCRs that were issued as a result of the audit findings.

At the audited establishments, the FSIS auditors verified, through observation, interviews and records reviews, that government inspection personnel perform routine SPS verifications and maintain records documenting their verification. In addition, the SPS requirements are also verified during the SVI's bi-annual audit of certified establishments and findings are recorded under the SPS/HPR (HACCP Pre-requisites) Requirements. The FSIS auditors found the following facility maintenance and ventilation deficiencies; however, no product was contaminated, and establishments were maintaining sanitary conditions:

- In six of the eight audited establishments, there was inadequate government verification of SPS requirements – Facility and equipment maintenance. 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 SPS 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.

The FSIS auditors verified at the audited slaughter establishments that sanitary dressing and process control procedures (during hide removal, cross-contact between carcasses with hide-on and skinned carcasses, etc.) were being followed and that carcasses, organs, and other parts were being handled in a sanitary manner to prevent contamination with fecal material, urine, bile, hair,

dirt, or foreign matter. In addition, the FSIS auditors also observed government inspection personnel conducting verification of monitoring of the CCP for zero tolerance of feces, ingesta, and milk contamination and reviewed documented inspection verification results. The FSIS auditors did not observe any sanitary dressing concerns.

Regarding enforcement, DAFM implements EU regulations through *SIs Nos. 432/2009* (implements the *Hygiene Package*), *187/2014* (Animal By-Products) and *392/2013* (animal welfare at slaughter). The EU regulations require that all officers implementing them must be authorized under the relevant legislation. The authority of DAFM allows the inspection staff to provide verbal direction, the issuance of NCRs, the issuance of compliance notices and prosecution to the establishments. The FSIS auditors reviewed the NCRs issued by IIP at each audited establishment and found no concerns.

The FSIS auditors concluded that DAFM requires establishments certified to export to the United States to develop, implement, and maintain sanitation programs consistent with EC sanitary regulations that have been found equivalent with 9 CFR § 416 to ensure that establishment construction, facilities, and equipment prevent the contamination or adulteration of meat products destined for export to the United States.

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

The fourth of six equivalence components that the FSIS auditor reviewed was Government HACCP System. The food safety inspection system is to require that each official establishment develop, implement, and maintain a HACCP system.

Ireland follows and enforces overarching EC sanitary regulations, equivalent to 9 CFR § 417. Chapter II, Article 5 of Regulation (EC) No. 852/2004 requires each establishment to develop, implement, and follow procedures based on the HACCP principles. Article 5, Section 1(a) requires establishments to identify hazards which can be prevented, eliminated, or reduced to an acceptable level. Article 5, Sections (e) and (f) of this same EC regulation requires that food business operators take corrective actions if a CCP is not under control, and they must develop and implement procedures to routinely ensure that the procedures based on the HACCP principles (HACCP plan) are efficient. In accordance with *SI No. 432/2009*, when any modification is made in the product, process, or any step, certified establishments must review the procedure (reassess) and make the necessary changes to the HACCP plan.

DAFM's *Guideline on USDA Approval* requires that every certified establishment develop, implement, and maintain a HACCP plan covering each product produced and including the five HACCP regulatory requirements (monitoring, verification, recordkeeping, corrective actions and reassessment). Moreover, in slaughter establishments, all carcasses must be examined during slaughter for fecal contamination, milk, and ingesta at final inspection (zero tolerance policy) as a CCP. Additionally, ongoing verification activities must include the calibration of the process monitoring instruments, direct observation of the monitoring activity and a review of records and corrective actions must cover all requirements specified in Regulation (EC) No. 852/2004 and No. 854/2004, which are equivalent with 9 CFR § 417.4. The FSIS auditors reviewed records

associated with the hazard analyses, HACCP plans, monitoring, verification, and corrective actions implementation by establishments, observed IIP conducting inspection verification and observed the following deficiencies of inadequate government verification of HACCP requirements in HACCP plan content and HACCP recordkeeping:

- 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 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.

The FSIS auditors verified that DAFM inspection personnel conduct and document official daily verification activities related to food safety management systems in accordance with methodology described in the *VPHIS - SOP No. 006/2008*, which includes an evaluation of written HACCP programs and verification of HPRs and establishment monitoring, corrective actions, and record-keeping. Through record review, the FSIS auditors confirmed that once a year, the VIs were evaluating the establishment HPRs, the CCPs, and the HACCP system and keeping records of their evaluation. In addition, the FSIS auditors confirmed that the DAFM personnel were verifying that all certified establishments perform initial validation of their HACCP system to demonstrate that the HACCP system, as designed, can adequately control potential hazards to produce a safe, unadulterated product. The FSIS auditors also verified that certified establishment were conducting pre-shipment review for each export destined to the United States.

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. 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 auditors' on-site verification activities and analysis indicate that DAFM requires operators of establishments certified to export to the United States to develop, implement, and maintain HACCP systems. However, the current audit identified noncompliance with HACCP requirements and HACCP recordkeeping at some audited establishments. The FSIS auditors analyzed these findings at each establishment including the production processes, sampling results, export history, and overall food safety controls before concluding there were not any immediate concerns regarding the safety of products destined for export or of those previously exported to the United States.

## 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 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, and 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 on-site visit, FSIS' residue experts reviewed Ireland's National Residue Control Plan (NRCP) for 2019, associated methods of analysis, and additional SRT responses outlining the structure of Ireland's chemical residue testing program. As a member of the EU, Ireland's NRCP is based on EC Directive No. 96/23/EC; it prescribes measures to monitor certain substances and residues in live animals and animal products, and describes provisions for the prohibition or authorization of substances and residues as well as their distribution and marketing. Therefore, each year, in accordance with EC Directive No. 96/23/EC, DAFM, operating under service contract to FSAI, has the overall legal authority and responsibility to develop, implement, and coordinate a national residue program aimed at preventing and controlling the presence of residues of veterinary drugs and contaminants in the tissues of livestock slaughtered for human consumption. In that regard, each year, DAFM provides FSIS with the NRCP's previous year's results. Ireland has residue plans that are acceptable by EU standards.

INAB is the national body with responsibility for the accreditation of laboratories in accordance with the relevant ISO 17025 standards and guides in the specific areas of residues of pesticides and organic contaminants, anabolic steroids, metals, and residues from veterinary medications. Article 5 of EC Directive No. 96/23/EC mandates that the country update the NRCP 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 NRCP takes into consideration the assessment of sampling results obtained from past sampling tests, including regulated use of veterinary drugs. The NRCP describes the general compound class, the specific chemical compound, matrix, screening method, CC beta, confirmation method, CC alpha, level for regulatory action, number of samples to be collected, location of sampling (slaughterhouse or farm) and laboratory doing the analysis. According to the NRCP for slaughter animals, there are previously determined targeting criteria that must be adhered to. These criteria are detailed in the specific instructions for each control plan.

The FSIS auditors verified implementation of the NRCP at the eight audited slaughter and processing establishments. A review of the sampling records maintained at the local inspection office of the audited slaughter and processing establishments indicated that the 2019 sampling program was being adhered to as scheduled. The official monitoring is conducted according to the NRCP, which is defined every year. The FSIS auditors verified that the inspection personnel are following the *280a Appendix 3 Sampling Protocol NRP*, which provides instructions to VI personnel who collect monitoring samples for residue analyses and describes the collection, security, storage, and dispatch of samples.

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. These instructions include random sampling and testing of internal organs, fat, and muscle of carcasses for targeted residues, and secure delivery of residue samples to the VPHRL laboratory in accordance with the prescribed methodology provided by DAFM. Once samples are collected, the VI completes the laboratory submission form and a copy is packaged in the sample shipment cooler which the government inspector secures and ships under a numbered inspection seal to maintain integrity. The sample is then transported by official courier to the laboratory. Residue results are communicated to DAFM headquarters through e-mail. VIs only receive the results telephonically and through e-mail when there is a violative sample result. The FSIS auditors verified that the VIs perform government sampling by packing all tissues separately and sending them to the VPHRL laboratory to ensure proper chain of custody and sample integrity.

The FSIS auditors performed an on-site audit of the VPHRL laboratory, 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 auditors reviewed the accreditation and found no issues. INAB last audited the VPHRL laboratory in 2015.

The FSIS auditors verified that analysts assigned to the chemical residue laboratory have completed academic work and specialized training that qualify them to conduct the analytical methods for detection and quantification of chemical residues in their scope of accreditation. The FSIS auditors also reviewed intra- and inter-laboratory proficiency testing associated with the methods and found the results to be acceptable. The FSIS auditors verified that the audited laboratory ensured traceability throughout sample receipt, analysis, and reporting per the laboratory Quality Control Manual, and that the laboratory performs a timely analysis of samples and reports the number of analyzed samples and the results to DAFM in a timely manner. No concerns arose from these observations and reviews.

The FSIS auditors verified that Ireland's food safety inspection system continues to maintain a chemical residue testing program, organized and administered by the national government. The CCA maintains 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 contaminants in beef and pork products destined for export to the United States. FSIS has not identified any POE violations related to this component since the last FSIS audit in 2017.

## **IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS**

The sixth of six equivalence components that the FSIS auditor 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.

The FSIS auditors verified Ireland's microbiological sampling and testing programs through direct observation, document reviews, and interviews of DAFM personnel at the local inspection offices of the audited slaughter and processing establishments and microbiological laboratory personnel to verify government microbiological testing programs. Ireland requires all slaughter establishments to implement an establishment-conducted microbiological testing program for *Enterobacteriaceae* to verify process control in accordance with Regulation (EC) No. 2073/2005, which describes sampling procedures for *Enterobacteriaceae* presence in cattle, sheep and pig carcasses. DAFM issued *VPN No. 15/2015* for government inspection personnel to verify the implementation of *Enterobacteriaceae* sampling by establishments for process hygiene criteria through the monitoring of indicators of fecal contamination. Establishments that are certified to export to the United States have the option of conducting generic *E. coli* testing instead of *Enterobacteriaceae* sampling. The inspection system provides for a sampling and testing program for generic *E. coli* or *Enterobacteriaceae*/Total Viable Count in raw meat product.

The FSIS auditors confirmed that government inspection personnel conduct verification activities that verify written generic *E. coli* testing programs meet requirements including the location of sampling, randomness of sampling, and sample integrity. IIP verify establishment sampling collection methodology for indicator organisms through direct observation of establishment sampling 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.

Regulation (EC) No. 2073/2005 and *SI No. 402 of 2009* also require that the DAFM personnel at the establishments use microbiological test results to establish trends and take appropriate corrective action when a trend indicates potential or actual worsening of process hygiene. At the eight audited slaughter and processing establishments, the FSIS auditors verified that government inspectors were using *Form Microcriteria 1 – Annex of VPN No. 04/2011* to record their verification activities, as required. Furthermore, at the certified slaughter establishments that elected to perform generic *E. coli* sampling, the FSIS auditors verified that the test results were recorded onto a process control chart showing at least the 13 most recent results (moving window) and that a statistical process control (SPC) was being used to evaluate the results. The FSIS auditors reviewed testing results for the last year showing that the results were routinely meeting SPC criteria, and that there has not been any identified loss of process control. No concerns were identified.

The FSIS auditors reviewed DAFM's *Salmonella* sampling and testing program which is consistent with FSIS' *Salmonella* performance standards for carcass samples as defined in 9 CFR §310.25(b). The FSIS auditors verified that the implementation of the program in the eight audited beef and pork slaughter and processing establishments met the CCA's requirements outlined in Regulation (EC) No. 2073/2005. In beef slaughter establishments, DAFM has an approved individual sanitary measure allowing *Salmonella* sampling to be conducted by establishments under direct supervision of DAFM officials while DAFM inspection personnel collect hog carcass samples for *Salmonella* testing. The FSIS auditors verified that the

government inspection personnel were supervising the sample collection by the establishments and documenting their sample collections in pig slaughter establishment using *VPN No. 15/2015*, as required.

ALT Ltd. uses the FSIS Microbiology Laboratory Guidebook (MLG) method 4.09 for official analysis of *Salmonella* in beef and pork samples collected by establishment employees, and is in the process of implementing MLG 4.10 in its place. Government inspection personnel (1) verify that all certified establishments' sample collection procedures are in accordance with the sample collection protocols and (2) analyze results to determine the effectiveness of the establishments' *Salmonella* control programs. *Salmonella* sampling is performed by IIP 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. The FSIS auditors' review of the CCA's program and inspection records identified no sample set failures for the period reviewed and no concerns regarding DAFM's *Salmonella* sampling program.

The FSIS auditors verified that DAFM's STEC testing program continues to meet the FSIS criteria for microbiological testing for this pathogen. The government 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. 13/2015* and the *Official Verification Program for Testing for Shiga Toxin Escherichia Coli (STEC) in Beef Intended for Grinding [BIFG] (N = 60)*, the DAFM personnel conduct monthly sampling using the N-60 sampling and testing method as part of their verification responsibilities. The FSIS auditors observed government inspection personnel demonstrate how they collect N-60 (trimming) samples for STEC analyses; *E. coli* O157:H7 and non-O157:H7 STEC analysis. The FSIS auditors also confirmed that the DAFM personnel were verifying that the establishments had an SOP in place that included the lot identification, the N-60 sampling procedure, and actions to be taken in the event of a positive test result for STEC.

The FSIS auditors verified that IIP 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 STEC positive is confirmed, the affected lot and any other lots produced from the same source of raw material will not be exported to the United States. DAFM is responsible for reviewing sampling plans and test result records within the certified establishments. Enforcement action is put into effect when necessary.

The FSIS auditors verified that Ireland's food safety inspection system continues to maintain the legal authority to regulate, plan, and execute activities of the inspection system aimed at controlling the presence of microbiological pathogens in beef and pork products exported to the United States, and ensures that those beef and pork products are unadulterated, safe, and wholesome in accordance with FSIS requirements. The CCA's meat inspection system continues to meet the FSIS requirements for this component. There have not been any POE violations related to microbiological testing conducted by FSIS at POE since the last FSIS audit in 2017.

## **X. CONCLUSIONS AND NEXT STEPS**

An exit meeting was held on June 28, 2019, in Dublin, Ireland, with the DAFM officials. At this meeting, the FSIS auditors presented the preliminary findings from the audit. An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors identified the following findings:

### **GOVERNMENT OVERSIGHT**

- 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.

### **GOVERNMENT SANITATION**

- In six of the eight audited establishments, there was inadequate government verification of sanitation performance standard requirements – Facility and equipment maintenance. 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.

### **GOVERNMENT 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 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 audit exit meeting, the CCA committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

# APPENDICES

## **Appendix A: Individual Foreign Establishment Audit Checklists**

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

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Donegal Meat Processors Ltd. T/A Foyle Donegal Drumnashear, Carrigans, Co. Donegal	2. AUDIT DATE 6/20/2019	3. ESTABLISHMENT NO. 292	4. NAME OF COUNTRY Ireland
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP	X	33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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.	X	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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57.	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

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60. Observation of the Establishment

06/20/2019|Est. #: 292| Donegal Meat Processors Ltd|[S/P][Cattle] Ireland

7. Written SSOP:

- The SSOP program does not specify the frequency at which operational sanitation procedures are conducted.

10. SSOP Monitoring & Implementation

- Fat particles, black specks, meat residue found on numerous food-contact surfaces of equipment and non-food contact surfaces throughout facility: blue conveyor belt that carried meat cuts; stainless steel bars, undersurface of hopper, scale, etc.

15. HACCP Plan Content:

- Ongoing verification activities (Direct observation; Record review; & Calibration of process monitoring instruments) were not listed in the HACCP plan.

39. Establishment Construction/Maintenance

- Heavy/extensive rust buildup on overhead structures: fan/fan guards of cooling units in all 4 chill rooms; in storage room; in packing area; on 4 coils above blast freezer; on product racks; on door jamb of blast freezer; on 4 drop chains above blast freezer door.

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61. AUDIT STAFF

OIEA International Audit Branch (IAB)

62. DATE OF ESTABLISHMENT AUDIT

06/20/2019

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United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Slaney Foods International UC T/A Slaney Foods Ryland Road, Buncloody Co. Wexford	2. AUDIT DATE 6/19/2019	3. ESTABLISHMENT NO. 296	4. NAME OF COUNTRY Ireland
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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	X
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Periodic Supervisory Reviews	
<b>Salmonella Performance Standards - Basic Requirements</b>		58. Export Certificates – Residue Sampling Results	X
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

## 60. Observation of the Establishment

**The following non-compliances were not identified by Ireland's inspection officials during the establishment review:**HACCP – Basic Requirements:

- 15/51 The establishment's written HACCP plan did not include or adequately describe the following elements required by 9 CFR Part 417.2(c):
- The procedures, and the frequency with which those procedures will be performed, that will be used in verification each of CCP1 monitoring to ensure compliance with the critical limit

HACCP – Ongoing Requirements:22/51 Recordkeeping (Monitoring and Corrective Actions):

- CCP1 monitoring records did not record the carcasses that were monitored only the deficiencies that were identified
- CCP1 did not include all 4 parts of corrective action required by 9 CFR 417 for all identified monitoring deviations from the critical limit of CCP1

Sanitation SPS

The FSIS auditor observed the following non-compliances during the establishment tour. No product contamination was observed.

39/51 Establishment Maintenance:

- Carcass Cooler: overhead rail and rail switches – surface rust developing in multiple areas
- Slaughter Floor area: overhead transfer rail and switch, and overhead carcass pass through from establishment CCP1 monitoring area to carcass rinse – surface rust developing in multiple areas

41/51 Ventilation:

Two Carcass Coolers - beaded condensation was observed on the overhead cooling unit and pipes. CCA inspection personnel took immediate action and rejected the area until adequate immediate actions were taken. No product was in the area of the observed condensation.

Export Certificates – Residue Sampling Results

- 58 The CCA inspection officials at establishment 296 confirmed to the FSIS auditor that routine residue control program sample products are allowed to be included in the export of product to the United States. Ireland's inspection officials signed export certificates for product destined to the United States even though inspection laboratory verification sample test results have not been received and found acceptable/negative.

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Kepak (Clonee) Ltd Clonee Co. Meath.	2. AUDIT DATE 6/25/2019	3. ESTABLISHMENT NO. 317	4. NAME OF COUNTRY Ireland
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP	X	33. Scheduled Sample	
8. Records documenting implementation.	X	34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.	X	35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57.	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

6/25/2019|Est.#: 317| Kepack (Clonee) Ltd.|[S/P][Cattle]| Ireland

8. Records documenting SSOP Implementation

- The SSOP operational sanitation records did not include the date the records were generated.

9. Signed and Dated SSOP

- The written SSOP program was not signed and dated by an individual with overall authority.

10. SSOP Implementation

- At the Government zero tolerance verification station, the FSIS auditor observed rail dust on numerous carcasses and showed them to the inspector and Establishment manager.

15. HACCP Plan Content

- Direct observation of the monitoring activities and its frequency was not listed in the Beef Slaughter HACCP plan.

22. Records Documenting HACCP event

- The HACCP Final Carcass QC Inspection Check record (CCP monitoring record) did not include the time the entries are made.
- The documented corrective actions for zero tolerance failures did not include all 4 parts of 417.3(a).

39. Establishment Construction/Maintenance

- Rust on overhead structures, on chains and rollers in the sticking area (Slaughter Hall)
- Rust on fan guards of overhead cooling units in the chill rooms, the decanting room, the boning hall and throughout the establishment.
- Cracks on the floor in the cold storage room

41. Ventilation

Beaded condensations was observed:

- on ceilings of cold storage room
- on ceiling of chill room 1 and 6
- on ceiling of slaughter hall above the offal processing area
- on fresh carcass transfer line to chill room
- on overhead elbow pipe above the Packing line

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Liffey Meats (Cavan) UC.TA Liffey Meats Ballyjamesduff, Co. Cavan	2. AUDIT DATE 6/19/2019	3. ESTABLISHMENT NO. 325	4. NAME OF COUNTRY Ireland
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP	X	33. Scheduled Sample	X
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.	X	35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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 SSOPs have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	X
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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.	X	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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57.	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment 6/19/2019|Est. #: 325|Liffey Meats (Cavan) UC T/A|[S/P][Cattle] Ireland

7. Written SSOP

- The frequencies of pre-operational and operational sanitation procedures were not listed in the SSOP program.

9. Signed and Dated SSOPs.

- The SSOP program is not signed and dated by an individual with overall authority.

13. Daily SSOP Records

- SSOP corrective actions are not described on the monitoring forms; only "CA taken" or "Yes" under the corrective actions column of the form are noted.

15. Contents of HACCP plan

- Returned products are not addressed in the Beef Slaughter flow chart and hazard analysis while the establishment does accept returned products and has an area in the cold storage room that is dedicated to United States returned products.

33. Scheduled Sampling

- In April 2019, Inspection Program Personnel did not collect the 8 STEC verification samples that are required monthly by VPN 13/2015 (Official verification program for testing of Shiga toxin Escherichia coli (STEC) intended for grinding).

39. Establishment Construction/Maintenance

- Next to the Vacuum Pack Chill Room, the FSIS auditor observed two overhead pipes with exposed insulation and tape peeling off.

61. AUDIT STAFF

OIEA International Audit Branch (IAB)

62. DATE OF ESTABLISHMENT AUDIT

06/19/2019

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Queally Pig Slaughtering Ltd T/A Dawn Pork & Bacon Grannagh Co. Waterford	2. AUDIT DATE 6/20/2019	3. ESTABLISHMENT NO. 332	4. NAME OF COUNTRY Ireland
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOPs 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	X
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Periodic Supervisory Reviews	
<b>Salmonella Performance Standards - Basic Requirements</b>		58. Export Certificates – Residue Sampling Results	X
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

## 60. Observation of the Establishment

**The following non-compliances were not identified by Ireland's inspection officials during the establishment review:**

Sanitation SOP – Ongoing Requirements10/51 Implementation:

- Slaughter Floor – Carcass splitting step; Establishment employee splitting the swine carcass was not properly sanitizing carcass splitting saw after each carcass as required by establishments sanitation SOP procedure

Sanitation SPS

The FSIS auditor observed the following non-compliances during the establishment tour. No product contamination was observed.

39/51 Establishment Maintenance:

- Carcass Breaking Room: overhead beams and structures - white oxidized mineral deposits developing throughout the production room
- Carcass Coolers (all): overhead rail switches – surface rust developing on all rail switches
- Boning Hall: overhead air hose reels for wizard knives, in-line air filters, and latches – developing rust in an exposed product area
- Rib Packaging Area: ceiling over product packaging area - peeling paint

41/51 Ventilation:

Beaded condensation was observed on the ceiling in the hot carcass cooler. CCA inspection personnel took immediate action and retain the carcasses under the affected ceiling area and rejected the area until adequate immediate actions were taken.

45/51 Equipment and Utensils:

Boning Hall: Interlinking plastic fiber conveyor belt system – side wear strips cracked and frayed white fiber (incidental contact area)

Export Certificates – Residue Sampling Results

- 58 The CCA inspection officials at establishment 332 confirmed to the FSIS auditor that routine residue control program sample products are allowed to be included in the export of product to the United States. Ireland's inspection officials signed export certificates for product destined to the United States even though inspection laboratory verification sample test results have not been received and found acceptable/negative.

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Rosderra Irish Meats Group Carrig Roscrea Co. Tipperary	2. AUDIT DATE 6/24/2019	3. ESTABLISHMENT NO. 355	4. NAME OF COUNTRY Ireland
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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	X
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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.	X	43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.	X	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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57.	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment 6/24/2019|Est.#: 355|Rosderra Irish Meats Group-Roscrea|[S/P][Pork]Ireland
16. Records documenting Implementation & Monitoring of HACCP plan
- The HACCP monitoring and verification records did not include the time the entries were made.
18. Monitoring of HACCP plan
- The CCP monitor does not thoroughly examine the carcasses for fecal matter and ingesta when conducting the carcass-by-carcass check.
22. HACCP Records
- The documented corrective actions for zero tolerance failures did not include all 4 requirements of 9 CFR 417.3(a).
39. Establishment Construction/Maintenance
- Heavy and extensive rust buildup was observed on almost all overhead structures as well as in the animal-hanging area.

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61. AUDIT STAFF

OIEA International Audit Branch (IAB)

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62. DATE OF ESTABLISHMENT AUDIT

06/24/2019

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United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Rosderra Irish Meats Group Carrick Road Edenderry Co. Offaly	2. AUDIT DATE 6/24/2019	3. ESTABLISHMENT NO. 356	4. NAME OF COUNTRY Ireland
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Periodic Supervisory Reviews	
<b>Salmonella Performance Standards - Basic Requirements</b>		58. Export Certificates – Residue Sampling Results	X
30. Corrective Actions		59. Gov't Sanitation Verification Procedure	X
31. Reassessment			
32. Written Assurance			

## 60. Observation of the Establishment

**The following non-compliances were not identified by Ireland's inspection officials during the establishment review:**

HACCP – Ongoing Requirements:22/51 Recordkeeping (Monitoring):

Establishment CCP 2 monitoring records do not include the time each monitoring entry occurred and was not signed or initialed by the establishment employee making the entry.

Sanitation SOP13/51 Recordkeeping:

Establishment Sanitation SOP monitoring records did not adequately describe deficiencies observed and corrective action taken to prevent direct contamination or adulteration of product(s).

Sanitation SPS

The FSIS auditor observed the following non-compliances during the establishment tour. No product contamination was observed.

41/51 Ventilation:

Boning Hall - Beaded condensation was observed on the overhead area at the product transfer rail area from the cooler to the carcass fabrication line

Slaughter floor - Beaded condensation was observed on the overhead area prior to the establishments CCP1 monitoring area

Immediate enforcement action was taken by the CCA inspection personnel in both these situations.

45/51 Equipment and Utensils:

Boning Hall: white plastic fiber tubs used for the collection of exposed raw pork product - cracked and frayed white fiber (product contact)

Export Certificates – Residue Sampling Results

58 The CCA inspection officials at establishment 356 confirmed to the FSIS auditor that routine residue control program sample products are allowed to be included in the export of product to the United States. Ireland's inspection officials signed export certificates for product destined to the United States even though inspection laboratory verification sample test results have not been received and found acceptable/negative.

Government Sanitation - Verification Procedure

59 The government inspection pre-operational verification does not select direct product contact areas each time they conduct the verification task. The government inspection pre-operational sanitation verification requires the task to be conducted once a week, one area. In-plant inspection has 18 area that they have determined as selection areas for pre-operational verification. Most of these areas are not product contact production areas.

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Anglo Beef Processors Ireland UC T/A ABP Clones Teehill, Clones, Co Monaghan	2. AUDIT DATE 6/18/2019	3. ESTABLISHMENT NO. 378	4. NAME OF COUNTRY Ireland
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57.	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

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60. Observation of the Establishment

6/18/2019|Est. #:378|Anglo Beef Processors|[S/P][Cattle] Ireland

15. HACCP Plan Content

- Ongoing verification activities (Calibration of process monitoring instruments; Direct observation of CCP monitoring; and record review) are not listed in the Beef Slaughter HACCP plan.

41. Ventilation

- The auditor observed heavily beaded condensation on one overhead cooling unit in the Corridor Room and beef carcasses we hung in close proximity. No product contamination was observed.

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61. AUDIT STAFF

OIEA International Audit Branch (IAB)

62. DATE OF ESTABLISHMENT AUDIT

06/18/2019

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17 January 2019

Michelle Catlin PhD  
International Coordination Executive  
Office of International Coordination  
Food safety and Inspection Services  
United States Department of Agriculture  
1400 Independence Avenue, SW  
Washington DC  
20250

**Response to Draft Final Audit Report of an audit conducted in Ireland from 17 to 28 June 2019**

Dear Dr. Catlin,

Further to my letter of 6 January 2020, I am now forwarding a finalised Corrective Action Plan and associated directives issued to industry and DAFM veterinary staff to address systematic and plant-specific non-compliances documented in the Draft Final Audit Report (DFAR) on the June 2019 audit.

I am pleased to enclose with this letter:

1. Annex 1 – DAFM’s finalised Corrective Action Plan;
2. Annex 2 – Information Note to FBOs on exclusion of carcasses and offal sampled under the NRCP or the Self-Monitoring Plan from US destined consignments;
3. Annex 3 – VPN to DAFM staff instructing them to verify that the establishments are complying with the carcase exclusion requirements;
4. Annex 4 – Trader Notice MH 01/2020 on ‘Reminder of Maintenance, Ventilation and Condensation’ issued to industry and published on DAFM’s website on 14 January 2020;
5. Annex 5 – E-mail to DAFM veterinary staff dated 15 January 2020 reminding them to verify FBO compliance with EU regulations and their Food Safety Management Systems; and
6. Annexes 6A & 6B – updated Guidance Notes on the verification procedures for plant CCPs and SSOPs issued to DAFM veterinary staff on 16 January 2020.

The attached documents and all other relevant documents, including those previously forwarded in relation to the ‘hold and test’ requirement, will be inputted to the SRT prior its 2020 submission deadline.

This concludes DAFM’s response to the DFAR. I trust that this is satisfactory but please feel free to contact me with any queries.

Yours sincerely,

 D. BLAKE

*pp.*  
Martin Blake  
Chief Veterinary Officer  
Delegate of the OIE



6<sup>th</sup> January 2019

Michelle Caitlin, PhD  
International Coordination Executive  
Office of International Coordination  
Food safety and Inspection Services  
United States Department of Agriculture  
1400 Independence Avenue, SW  
Washington, DC  
20250

**Response to Draft Final Audit Report of an audit conducted in the Republic of Ireland June 17- 28, 2019**

Dear Dr. Caitlin,

I wish to refer to my last letter to you dated 11<sup>th</sup> December 2019 in which I indicated that the Department of Agriculture, Food and the Marine (DAFM) would return our full response to the Draft Final Audit Report (DFAR) of FSIS' audit in Ireland by 6<sup>th</sup> January 2020.

I can confirm that all establishment-specific non-compliances recorded in the DFAR, have been fully addressed and corrected. As stated in my previous letter of 11<sup>th</sup> December 2019, no further product will be certified for export to USA unless it meets with the 'hold and test' requirement as per VPN 09/2019.

In addition DAFM is in the process of addressing the systemic aspects of other non-compliances. These actions will include:

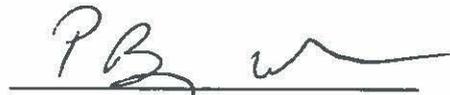
1. A Trader Notice will be issued to Industry restating the absolute importance of
  - a. Facility and equipment maintenance
  - b. HACCP Prerequisites with emphasis on adequate ventilation to prevent condensationThis will be issued this month (Jan 2020)
2. Amendment of Guidance to verification procedures for SSOPs, HACCP, Zero Tolerance and CCPs. This work will also be completed before the end of this month (January 2020)
3. A Training Day for DAFM staff to restate the verification and enforcement procedures involved in Sanitation Performance Standards. This training will be held before the end of Q1 2020.

However, I would ask for an added extension in forwarding the supporting documents to you. I wish to extend my apologies for this, but unfortunately the delay has arisen due to unanticipated absences of key staff in the run up to and after the Christmas period this year and I rely on your office's understanding in this regard. I will forward DAFM's full written response to the FSIS audit including a

Corrective Action Plan along with substantiation of the corrective actions taken in response following the audit last June, within 10 working days, by the 17<sup>th</sup> January 2020.

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

Yours sincerely,

A handwritten signature in black ink, appearing to read 'PB' followed by a stylized flourish.

PP

Martin Blake  
Chief Veterinary Officer  
Delegate of the OIE

# Veterinary Public Health Inspection Service

DOC No. VPN 9/2019	Title: Exclusion of Carcasses and offal sampled under the NRCP or the Self-Monitoring Plan from US Consignments	Version: 01	Issue Date: 22/11/2019
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**TO: Regional Veterinary Officers and Veterinary Inspectors**

**Subject: Exclusion of Carcasses and offal sampled under the NRCP or the Self-Monitoring Plan from US Consignments**

[This is a new Document and does not replace any previous documents]

## Background

The report of the recent USDA audit of Ireland's control systems listed a few non-compliances in relation to Central Competent Authority oversight of USDA certified FBOs.

One of these non-compliances related to carcasses of cattle and pigs that were sampled for residues. It was expressed in two ways in the report:

- *The Central Competent Authority (CCA) allows inspection personnel to issue an export certificate for product intended for export to the United States before test results are known from the CCA's routine chemical residue program.*
- *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.*

The immediate corrective action required to close out this non-compliance is to immediately cease issuing pre-export or final US export certificates for batches of product that include product from carcasses sampled under the National Residue Control Plan (NRCP) or the FBO's Self-monitoring Plan if negative results for these are not available.

## Scope

This VPN applies to beef and pork carcasses and offal that have been sampled under the National Residue Control Plan (NRCP) and the FBO's Self-Monitoring Plan at USDA Approved Plants.

## Role of the FBO

FBOs must immediately draft a carcass and offal exclusion SOP (or section in other SOPs) that details how they will exclude from US destined batches of beef or pigmeat all carcasses (and their associated offal) that have been sampled under the NRCP or Self-monitoring Plans and for which no results are available. This exclusion only applies to individual sampled carcasses (and their associated offal) and not to the herds or batches from which they originated as follows:

### 1. Carcasses sampled under the Self-Monitoring Plan

The FBO must record the carcass number of every carcass sampled under its own Self-monitoring Plan and send a list of these to the Veterinary office (preferably by e-mail). The FBO must ensure by electronic marking or other controls that these carcasses (and their associated offal) cannot enter US destined batches if negative results are not available.

# Veterinary Public Health Inspection Service

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If the FBO wishes to include carcasses (and their associated offal) from which samples have been taken under the Self-Monitoring Plan, these carcasses must be placed “on-hold” until the results are known.

## 2. Carcasses sampled under the NRCP

[VPN 8/2017](#) details how DAFM staff must notify to the FBO all carcasses that have been detained or sampled. These carcasses are listed on the [Detention/Sampling Record \(DSR1\)](#) and include carcasses sampled under the NRCP. The DSR1 is handed or e-mailed to the FBO at the end of each day. The FBO must note the carcass numbers of carcasses sampled under the NRCP or as suspects on the DSR1 and ensure by electronic marking or other controls that these carcasses cannot enter US destined batches.

The FBO must put in place a verification procedure to check that the system of exclusion of these sampled carcasses is working. This verification must be included as part of the FBO’s **Pre-Shipment Review**.

### Role of DAFM Staff

- DAFM staff must ensure that the FBO has a carcass exclusion SOP (or section in other SOPs) and that it is effective. This verification should be carried out by random checks on the location and destination of carcasses sampled under the NRCP and the FBO’s Self-monitoring plan.
- DAFM staff must also verify that the FBO’s Pre-Shipment Review is comprehensive enough to ensure that sampled carcasses are excluded from US shipments.

If breaches of the carcass exclusion SOP are detected by finding evidence that sampled carcasses (or associated offal) are included in US destined batches where the results are unavailable, or if there is doubt as to the final destination of sampled carcasses (or associated offal), the affected US destined batch is to be deemed not eligible for the US and no US pre-export or final certificate is to be issued. The RSVI must be informed.

No further US pre-export or final certificates are to be issued until the FBO can conclusively prove that sampled carcasses will be excluded from US destined batches.

Peter Maher

Joe O’Flaherty

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**ANNEX 1: Corrective Action Plan USDA Audit 2019**

	<b>Audit Finding</b>	<b>Proposed Corrective Action</b>	<b>Proposed Completion Date</b>
1	<p><b>Government Oversight</b></p> <p>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.</p>	<p>DAFM (CCA) has issued notifications</p> <ol style="list-style-type: none"> <li>To USDA Certified slaughter plants (Information Note), instructing them to exclude carcasses sampled under the National Residue Control Plan or their own Self-Monitoring Plan from US destined consignments.</li> </ol> <p> Information Note Exclusion of Sampled</p> <ol style="list-style-type: none"> <li>To DAFM staff (VPN 9/2019) instructing them to verify that the establishments are complying with the carcass exclusion requirements.</li> </ol> <p> VPN 9_2019 - Exclusion of Residue :</p>	Complete
2	<p><b>Government sanitation</b></p> <p>In six of the eight audited establishments, there was inadequate government verification of sanitation performance standard requirements – Facility and equipment maintenance. IIP failed to observe one or more of the following issues: extensive rust build-up on overhead structures in slaughter areas, equipment</p>	<ol style="list-style-type: none"> <li>At Establishment level, all of the facility and equipment maintenance non-compliances have been corrected either immediately or over the weeks following the audit. These completed corrections have been verified by on-site official veterinarians.</li> <li>A <b>Trader Notice</b> has been issued to all establishments to remind them of the importance of having effective reactive and preventative maintenance (rust control) and effective ventilation (condensation</li> </ol>	Complete

	<b>Audit Finding</b>	<b>Proposed Corrective Action</b>	<b>Proposed Completion Date</b>
	in the slaughter halls, on chains, rollers, steels, fan guards/fans for cooling units, etc.	control). This trader Notice was also copied to all DAFM staff so they are aware of the establishments' obligations.	Complete
	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.	 <p>Trader Notice_01_2020 Main</p> <p>3. At CCA level senior HQ management has met with regional managers (December 2019) to reiterate the necessity to continue to use the inspection and enforcement tools available to VIs to ensure that establishments continue to maintain their premises, including the removal and prevention of rust.</p>  <p>E-mail to VPHIS Staff on Prerequisites_15J:</p> <p>This requirement has also been reiterated in updated training for staff at USDA establishments.</p> <p>4. A staff training session is to be held later to reiterate the importance of verification of compliance with Sanitation Performance Standards, particularly maintenance and ventilation/condensation prevention.</p>	End Q1 2020  Complete
3	<b>Government HACCP System</b>		
	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	1. At Establishment level, all of the HACCP and CCP recording non-compliances have been corrected immediately by the establishments. These completed corrections have been verified by on-site official veterinarians.	Complete

	<b>Audit Finding</b>	<b>Proposed Corrective Action</b>	<b>Proposed Completi on Date</b>
	observation, record review, and calibration of process monitoring instruments.	<p>2. The Guidance to DAFM staff on the verification of HACCP (CCPs) has been amended to ensure DAFM staff check that:</p> <ul style="list-style-type: none"> <li>a. The establishment HACCP verification includes direct observation, record review and calibration of process monitoring instruments.</li> <li>b. The Establishment Carcase Inspection CCP monitoring (zero tolerance) records <ul style="list-style-type: none"> <li>i. Time</li> <li>ii. ID of the monitored Carcases</li> <li>iii. The initials of the Monitor</li> </ul> </li> <li>c. The establishment corrective actions for a CCP (zero tolerance) failure include all of those prescribed by <b>9CFR 417.3</b>, i.e. <ul style="list-style-type: none"> <li>i. The cause of the deviation is identified and eliminated;</li> <li>ii. The CCP will be under control after the corrective action is taken;</li> <li>iii. Measures to prevent recurrence are established; and</li> <li>iv. No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.</li> </ul> </li> </ul> <div style="text-align: center;">  <p>USDA~CCP_Guidance_Ver 05_100120</p> </div> <p>Additionally:</p> <ul style="list-style-type: none"> <li>• DAFM has amended the guidance to staff involved in SSOP verification to include a check that:</li> </ul>	Complete
	In five of the eight audited establishments, the HACCP zero tolerance 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.		

	Audit Finding	Proposed Corrective Action	Proposed Completion Date
		<ul style="list-style-type: none"> <li>○ SSOPs are dated and physically signed off by a person in authority.</li> <li>○ When non-compliance is detected (by establishment or DAFM) in the implementation of an SSOP the establishment's written corrective action must include <b>all</b> of the core requirements of <b>9CFR 416.15</b>, i.e. <ul style="list-style-type: none"> <li>▪ appropriate disposition of product(s) that may be contaminated,</li> <li>▪ restore sanitary conditions, and</li> <li>▪ Prevent the recurrence of direct contamination or adulteration of product(s), including appropriate re-evaluation and modification of the Sanitation SOPs.</li> </ul> </li> </ul> <div style="text-align: center;">  <p>USDA Guidance SSOP Verification - Re</p> </div>	Complete

## **ANNEX 2**

### **Department of Agriculture, Food and the Marine**

#### **Information Note**

**To: All Food Business Operators at premises approved to export Pigmear and Beef Products to the US**

**Subject: Exclusion of Carcasses and Offal sampled under the NRCP or the Self-Monitoring Plan from US Consignments**

#### **Introduction**

This information note is to advise US approved FBOs of a new requirement on the exclusion of carcasses and offal sampled under the NRCP or their own self-monitoring plans from meat batches intended for export to the US.

#### **Background**

Following the receipt of the draft report of the recent USDA audit of Ireland's control systems, DAFM has been instructed that in order to retain USDA certified equivalence it must immediately cease issuing pre-export or final US export certificates for batches of product which do not exclude product (including offal) from carcasses sampled under the National Residue Control Plan (NRCP) or the FBO's Self-Monitoring Plan if negative results for these are not available.

#### **Scope**

This information note applies to individual beef and pork carcasses and offal that have been sampled under the National Residue Control Plan (NRCP) and the FBO's Self-Monitoring Plan at USDA Approved Plants for all US intended batches produced on or after 14 November 2019.

#### **Role of FBO**

FBOs must immediately draft a carcass and offal exclusion SOP (or section in other SOPs) that details how they will exclude from US destined batches of beef or pigmeat all carcasses (and their associated offal) that have been sampled under the NRCP or Self-Monitoring Plans, in the absence of negative results. This exclusion only applies to individual sampled carcasses (and their associated offal) and not to the herds or batches from which they originated as follows:

##### **1. Carcasses sampled under the Self-Monitoring Plan**

The FBO must record the carcass number of every carcass sampled under its own Self-Monitoring Plan and send a list of these to the Veterinary Office, preferably by

## ANNEX 2

e-mail. The FBO must ensure by electronic marking or other controls that these carcasses (and their associated offal) cannot enter US destined batches if negative results are not available. If the FBO wishes to include carcasses (and their associated offal) from which samples have been taken under the Self-Monitoring Plan, these carcasses must be placed “on-hold” until the results are known.

### **2. Carcasses sampled under the NRCP**

VPN 8/2017 details how DAFM staff must notify to the FBO all carcasses that have been detained or sampled. These carcasses are listed on the Detention/Sampling Record (DSR1) and include carcasses sampled under the NRCP. The DSR1 is handed or emailed to the FBO at the end of each day. The FBO must note the carcass numbers of carcasses sampled under the NRCP or as suspects on the DSR1 and ensure by electronic marking or other controls that these carcasses cannot enter US destined batches.

The FBO must put in place a verification procedure to check that the system of exclusion of these sampled carcasses is working. This verification must be included as part of the FBO’s **Pre-Shipment Review**.

If DAFM plant staff do detect relevant breaches of the carcass exclusion SOP by finding evidence that products from sampled carcasses are included in US destined batches where results are unavailable, or if there is doubt as to the final destination of sampled carcasses, they will deem the affected US destined batch not eligible for the US and no US pre-export or final certificate will be issued. The DAFM Regional Superintending Veterinary Inspector will be notified of all breaches and suspect cases.

No further US pre-export or final certificates will be issued from that plant until the FBO can conclusively prove that sampled carcasses will be excluded from US destined batches in the absence of negative results.

Market Access Unit  
Meat & Dairy Policy Division  
22 November 2019

# Veterinary Public Health Inspection Service

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**Subject: Exclusion of Carcasses and offal sampled under the NRCP or the Self-Monitoring Plan from US Consignments**

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## Background

The report of the recent USDA audit of Ireland's control systems listed a few non-compliances in relation to Central Competent Authority oversight of USDA certified FBOs.

One of these non-compliances related to carcasses of cattle and pigs that were sampled for residues. It was expressed in two ways in the report:

- *The Central Competent Authority (CCA) allows inspection personnel to issue an export certificate for product intended for export to the United States before test results are known from the CCA's routine chemical residue program.*
- *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.*

The immediate corrective action required to close out this non-compliance is to immediately cease issuing pre-export or final US export certificates for batches of product that include product from carcasses sampled under the National Residue Control Plan (NRCP) or the FBO's Self-monitoring Plan if negative results for these are not available.

## Scope

This VPN applies to beef and pork carcasses and offal that have been sampled under the National Residue Control Plan (NRCP) and the FBO's Self-Monitoring Plan at USDA Approved Plants.

## Role of the FBO

FBOs must immediately draft a carcass and offal exclusion SOP (or section in other SOPs) that details how they will exclude from US destined batches of beef or pigmeat all carcasses (and their associated offal) that have been sampled under the NRCP or Self-monitoring Plans and for which no results are available. This exclusion only applies to individual sampled carcasses (and their associated offal) and not to the herds or batches from which they originated as follows:

### 1. Carcasses sampled under the Self-Monitoring Plan

The FBO must record the carcass number of every carcass sampled under its own Self-monitoring Plan and send a list of these to the Veterinary office (preferably by e-mail). The FBO must ensure by electronic marking or other controls that these carcasses (and their associated offal) cannot enter US destined batches if negative results are not available.

# Veterinary Public Health Inspection Service

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If the FBO wishes to include carcasses (and their associated offal) from which samples have been taken under the Self-Monitoring Plan, these carcasses must be placed “on-hold” until the results are known.

## 2. Carcasses sampled under the NRCP

[VPN 8/2017](#) details how DAFM staff must notify to the FBO all carcasses that have been detained or sampled. These carcasses are listed on the [Detention/Sampling Record \(DSR1\)](#) and include carcasses sampled under the NRCP. The DSR1 is handed or e-mailed to the FBO at the end of each day. The FBO must note the carcass numbers of carcasses sampled under the NRCP or as suspects on the DSR1 and ensure by electronic marking or other controls that these carcasses cannot enter US destined batches.

The FBO must put in place a verification procedure to check that the system of exclusion of these sampled carcasses is working. This verification must be included as part of the FBO’s **Pre-Shipment Review**.

### Role of DAFM Staff

- DAFM staff must ensure that the FBO has a carcass exclusion SOP (or section in other SOPs) and that it is effective. This verification should be carried out by random checks on the location and destination of carcasses sampled under the NRCP and the FBO’s Self-monitoring plan.
- DAFM staff must also verify that the FBO’s Pre-Shipment Review is comprehensive enough to ensure that sampled carcasses are excluded from US shipments.

If breaches of the carcass exclusion SOP are detected by finding evidence that sampled carcasses (or associated offal) are included in US destined batches where the results are unavailable, or if there is doubt as to the final destination of sampled carcasses (or associated offal), the affected US destined batch is to be deemed not eligible for the US and no US pre-export or final certificate is to be issued. The RSVI must be informed.

No further US pre-export or final certificates are to be issued until the FBO can conclusively prove that sampled carcasses will be excluded from US destined batches.

Peter Maher

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Joe O’Flaherty

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## Department of Agriculture, Food and the Marine

### Trader Notice Number MH 01/2020

To: All Food Business Operators Approved by DAFM

### Reminder of Maintenance, Ventilation and Condensation

#### Background

Recent Third Country audits of DAFM approved premises have revealed an upward trend of non-compliances in two critical areas:

1. Maintenance of premises and equipment, with particular emphasis on rust
2. Ventilation, with particular emphasis on condensation

DAFM are required to verify that FBOs comply fully with their obligations under EU Regulations in respect of, *inter alia*, the above two issues.

#### Legal Basis

All Food Business Operators (FBOs) approved under SI 432/2009 (soon to be replaced) are obliged to comply with Regulation (EC) No 852/2004 and Regulation (EC) No 853/2004 in relation to the production of safe food. In particular, Annex II of Regulation (EC) No 852/2004 requires that:

#### Chapter I

1. Food premises are to be kept clean and **maintained in good repair and condition**.
2. The layout, design, construction, siting and size of food premises are to:
  - a. **permit adequate maintenance**.....
  - b. be such as to protect against ... the **formation of condensation** or undesirable mould on surfaces;
5. There is to be suitable and sufficient means of natural or mechanical **ventilation**. Mechanical airflow from a contaminated area to a clean area is to be avoided. Ventilation systems are to be so constructed as to enable filters and other parts requiring cleaning or replacement to be readily accessible.

#### Chapter II

1. In rooms where food is prepared, treated or processed (excluding dining areas and those premises specified in Chapter III, but including rooms contained in means of transport) the design and layout are to permit good food hygiene practices, including protection against contamination between and during operations. In particular:
  - a. .
  - b. .
  - (c) ceilings (or, where there are no ceilings, the interior surface of the roof) and overhead fixtures are to be constructed and finished so as to **prevent the accumulation of dirt and to reduce condensation**

## **FBO Obligations**

All food business must have in place effective prerequisite programmes (PRPs, HPRs). These are good hygiene practices that are the basic conditions and activities necessary to maintain a hygienic environment.

Among these prerequisite programmes the FBO is obliged to have:

1. A **Maintenance (Structures and Equipment) Programme**, and
2. A **Ventilation (control of condensation) Programme**

These must be in the form of documented procedures (SOPs) which clearly describe the FBOs procedures in developing, implementing, monitoring and verifying each HPR.

### **Maintenance (Structures and Equipment) Programme**

The HPR for maintenance must clearly describe the procedure for reactive and preventative maintenance of structures and equipment. Particular emphasis must be placed on the prevention of rust and its removal when it does occur to prevent any risk of contamination of food.

The programme must be proactive and not just reactive to findings of poor maintenance or rust. Regular inspections of all structures and equipment must be undertaken to ensure that no deterioration of maintenance standards is able to occur.

### **Ventilation (control of condensation) Programme**

It is well known that a major cause of condensation is poor ventilation. In addition, condensation is common where hot and cold air meet, for instance, at the entrance to chills. Condensation dripping onto exposed product is a food safety hazard.

The FBO must have an effective condensation prevention and control programme. Manual removal of condensation is only acceptable as an exception. The overall aim must be to prevent condensation. The FBO must have in place condensation monitoring procedures (before and during production), corrective actions where condensation is found and strategies to prevent further condensation, particularly by improving ventilation.

## **Enforcement**

DAFM is required to verify compliance with EU Regulations by inspections and audits of FBO premises and procedures. DAFM staff will be required to take stringent enforcement action in the case where HACCP Pre-requisites are not effective, resulting in maintenance failures or presence of condensation. These enforcement actions may be up to and including suspension of production in affected areas until the hazard is removed and the non-compliance corrected.

Meat Hygiene Division

January 2020

**From:** Moran, Michael <Michael.Moran@agriculture.gov.ie>  
**Sent:** Wednesday 15 January 2020 09:02  
**Subject:** FW: Trader Notice TN 01/2020 Maintenance Ventilation and Condensation

**To All VPHIS,**

The attached Trader Notice was recently circulated to industry to remind them of their obligation under EU Regulations to have effective prerequisite programmes (HPRs, Sanitation Performance Standards-USDA) in place. In this Trader Notice there is particular emphasis on two prerequisites:

- **Maintenance** (prevention of rust)
- **Ventilation** (prevention of condensation)

Recent Third Country audits have found multiple non-compliances with regard to rust and condensation.

DAFM staff are required to verify compliance of FBOs with EU Regulations and their own Food Safety Management System. VPHIS documented procedures have all of the tools required to enforce compliance with regulations and Third Country requirements.

Where poor maintenance (rust) and condensation occur, you are required to take effective, proportionate and dissuasive enforcement action in accordance with the [Enforcement SOP 2/2015](#).

Thank you for your co-operation in this.

Regards

Michael

**Michael Moran, MVB CertVPH MRCVS**  
**Superintending Veterinary Inspector**  
**Veterinary Public Health Inspection Service, Implementation**  
**Department of Agriculture, Food and the Marine**  
**T: +353 (0)86 6012377**



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

**From:** Seale, Emma  
**Sent:** 14 January 2020 10:23  
**Cc:** .....  
**Subject:** Trader Notice TN 01/2020 Maintenance Ventilation and Condensation

All,

Please see attached **Trader Notice MH 01/2020**. Reminder of Maintenance, Ventilation and Condensation

The purpose of this is to remind DAFM approved FBOs of their obligations to have effective Pre-requisite Programmes, including maintenance (prevention of rust) and ventilation (prevention of condensation).

It should be brought to the attention of any relevant personnel who do not have e-mail. It will shortly appear on the Department of Agriculture website, on which all other Trader Notices may also be viewed using this [Link](#).

Regards,

*Meat Hygiene Division,*

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

**Pailliún B, Páirc Gnó Grattan, Bóthar Átha Cliath, Port Laoise, Co Laoise, R32 KW50**  
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# Veterinary Public Health Inspection Service

DOC No. GN_USDA CCP	Title: <b>USDA~CCP_Guidance</b>	Version: 05	Issue Date: 10/01/2020
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## DAFM Verification of Plant CCPs

- All CCPs must be reviewed by the VI in charge once a week using **USDA~CCP** form.
- The CCP number must be entered (located above table).

## Establishment Monitoring of CCP

- In relation to Monitoring, the VI must either observe the plant monitor conducting this activity and/or the VI actually performs (direct measurement) the activity. The results of such observations should be compared with those of the plant monitor and previous monitoring records.
- Where monitoring is continuous, VIs must check that the CCP monitor indicates the start-time and end-time of their monitoring period. In the case of the carcass inspection CCP, the monitoring record must also show the identification of the first and last carcass checked and the initials of the monitor.
- Where CCP findings (deviations) occur, VIs must check that the CCP monitor records the time of the deviation and initials the record (if manual).
- VIs must ensure that, where deviations of the CCP occur, the FBO's corrective action includes the all of the requirements of **9CFR 417.3**, i.e.
  - The cause of the deviation is identified and eliminated;
  - The CCP will be under control after the corrective action is taken;
  - Measures to prevent recurrence are established; and
  - No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.
- In relation to record-keeping, critical limits, monitoring, verification, corrective and preventative action records to be clearly stated. They must be accurate, signed and dated by the monitor and/or verifier.
- Long term preventive measures should be clearly set out in the HACCP plan for each CCP. Examples include retraining of staff, ensuring that back-up staff are properly trained and have sufficient experience to carry out certain critical tasks during the holiday periods, review of the cold chain process.
- Long term preventive actions must be undertaken by the FBO where deficiencies in the HACCP system are identified by either their own verification procedures or by verifications procedures carried out by the VI.
- The implementation of long term preventative actions must be verified by the VI.

## Establishment Verification of CCPs

- When checking the FBO's verification of the CCP, VIs must ensure that this includes

# Veterinary Public Health Inspection Service

DOC No. GN_USDA CCP	Title: <b>USDA~CCP_Guidance</b>	Version: 05	Issue Date: 10/01/2020
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- Direct observation of the monitor by the QA verifier. This should be proven by the initials of both the monitor and QA verifier on the verification record.
  - Record Review by the QA verifier
  - Checks on calibration of process monitoring instruments
- 
- Verification Activities, Findings and Action taken by the VI must be entered clearly and concisely.
  - The VI should occasionally observe the QA Verifier performing their verification activities.
  - Comparison of DAFM verification findings should be made with those of the plant by examination of plant monitoring and verification records over a period.
  - It is recognised that it may not be possible to verify all the elements listed in **USDA~CCP each week**, especially some elements of plant verification e.g. calibration of monitoring equipment or direct observation.
  - Verification of the calibration of monitoring equipment should be carried out periodically. The frequency will depend on the frequency of calibration exercised by plant management.
  - In addition to the time and initials of the VI entered in the right hand column, it is **essential to enter the day of the week in which this activity was carried out**.
  - The VI must sign and date the completed **USDA~CCP** at the end of the week.

# Veterinary Public Health Inspection Service

DOC No. GN_USDA SSOP	Title: <b>USDA~SSOP_Verification_Guidance</b>	Version: 06	Issue Date: 10/01/2020
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## SSOP Verification by Department Officials

### Review and Observation Procedure (ROP) – FrmUSDA~SSOP (a).

- The ROP must be carried out by the VI/SAO/TAO in all USDA approved establishments on a daily basis for the Operational SSOPs and on a weekly basis for the Pre-Operational SSOPs. The selection of the day of the week for the Pre-Operational SSOP ROP must be done randomly.
- The Pre-Operational SSOP inspection carried out by DAFM Officers should target food contact surfaces in the cutting room and slaughter room. Zones without food contact surfaces should **not** be targeted for inspection.
- Using a plan or blueprint of the plant, the VI (with the assistance of other DAFM officers) must divide up the plant production areas (Operational SSOPs) into discrete areas (zones) and each area must be properly identified e.g. numerically. **The cutting room and slaughter floor divided areas will also apply to the Pre-Operational SSOP inspection described above.** The size of each area marked on the blueprint should be such that the officer carrying out the ROP can complete the work in less than 15-20 minutes.
- Once the blueprint has been divided up into suitable areas the VI can proceed with the area allocation for the week, as indicated on **FrmsUSDA~SSOP (a)**. The selection of the areas for the coming week must be done on a random basis e.g. the roll of dice or numbers out of a hat. The top table on the form can now be completed.
- There are six slots available for the insertion of random numbers in the top table. At **least one area** must be selected for the weekly Pre-Operational SSOP ROP/Inspection and at **least two areas** for the daily Operational SSOP ROP.
- The area number should be entered into the appropriate column of the main table by the officer carrying out the ROP.
- Verification Activities and Findings must be completed with respect to the note (1-5) at the bottom of the main table. The activities can be referenced using the appropriate numbers. All findings must be written clearly and accurately as seen i.e. write “organic matter including blood observed” instead of writing “dirt”.
- Explanatory table for the 5 options:

Code and Description	Guideline
1. Inspection of direct contact surfaces in one or more areas	This is generally only carried out on a Pre-op inspection
2. Observe establishment perform monitoring procedures (only where possible and if not then <u>after</u> the establishment has conducted its monitoring of the implementation of the	It may be possible to carry out this task during both pre-op and operational SSOP inspections

# Veterinary Public Health Inspection Service

DOC No. GN_USDA SSOP	Title: <b>USDA~SSOP_Verification_Guidance</b>	Version: 06	Issue Date: 10/01/2020
----------------------------	--	----------------	---------------------------

SSOP)	
3. Compare findings with what establishment has documented (see Record-Keeping Verification Form)	This is particularly important during Pre-op inspection, but should also be carried out during examination of operational SSOPs. The officer should examine the supervisor's monitoring record to ensure they are carrying out their checks at the correct frequency.
4. Observe plant Corrective Actions	This will always be possible during Pre-op inspections where the officer can observe the FBO carrying out a "mini-clean" <sup>1</sup> of contaminated surfaces. In the case of operational SSOP non-compliances, it may not always be possible to see the full corrective action implemented as it may involve retraining, etc.
5. Observe plant activities in implementing the SSOPs	This means observing the establishment staff implementing the SSOPs (pre-op and operational) in the select zone. The officer should be familiar with the SSOPs to know if the plant is carrying them out correctly.

- Follow-up action by the officer carrying out the ROP must be entered clearly and concisely. The prompts in the top row should help. Please note that a "Continuation Sheet" is provided for further elaboration if needed.
- The time and officer's initials must be entered in the right-hand column each time a ROP is carried out in a selected area.
- The VI must sign and date the completed **frmUSDA~SSOP (a)** at the end of the week.

**\*Note:** Plant Preventive Action should include a review of how the plant sanitation is conducted, including the make-up and use of sanitising chemicals e.g. are correct concentrations used in accordance with the manufacturer's instructions or correct contact time applied?

## **Review of SSOP and Related Records - FrmUSDA~SSOP(b).**

- There must be a file containing up-to-date versions of all of the SSOPs (in colour, where possible) in the Veterinary Office.
- The DAFM officer should analyse in detail at least one SSOP per week.

<sup>1</sup> "mini clean" means a cleaning procedure that is a version of the standard plant sanitation procedure. It should involve removal of the contamination using water (+/- brush), using a sanitizer and rinsing with water.

# Veterinary Public Health Inspection Service

DOC No. GN_USDA SSOP	Title: <b>USDA~SSOP_Verification_Guidance</b>	Version: 06	Issue Date: 10/01/2020
----------------------------	--	----------------	---------------------------

- As the plant is likely to have several SSOPs on file, one SSOP should be selected and the number entered on the form above the table. All available SSOPs should be examined in a systematic manner so that each is examined on a rotational basis.
- All SSOPs are dated and physically signed off by a person in authority.
- Guide to Review Questions:

Elements of Review	Guidance
Establishment is following the pre-operational/operational procedures in the SSOP	This is asking if the plant operative is following the procedure as written in the SSOP. You need to be familiar with the SSOP to answer this. There are several possibilities where implementing the procedure could be non-compliant: <ul style="list-style-type: none"> <li>• Not wearing the correct PPE</li> <li>• Not using the hygiene facilities sufficiently</li> <li>• Not following the work procedure as written</li> <li>• Causing contamination of the carcass/product.</li> </ul>
Monitoring activities are conducted at the specified frequencies	Each SSOP should clearly state the type and frequency of monitoring. For example, pre-op is done daily before production, operational SSOPs may be monitored by a supervisor twice a day.
Corrective action requirements are being met	The SSOP should clearly state the corrective action required when the SSOP fails (as per <b>9CFR 416.15</b> ) <ol style="list-style-type: none"> <li>1. appropriate disposition of product(s) that may be contaminated,</li> <li>2. restore sanitary conditions, and</li> <li>3. prevent the recurrence of direct contamination or adulteration of product(s), including appropriate re-evaluation and modification of the SSOPs.</li> </ol>
Records are being signed and dated by the plant person responsible for implementation of SSOPs	Make sure that pre-op and operational SSOP records are signed and dated by plant staff responsible for monitoring each SSOP
Does the Establishment routinely evaluate the effectiveness of the SSOPs (9CFR 416.14)	This question is all about plant verification of the SSOPs which is the responsibility of QA staff. It is not just about QA staff signing the bottom of SSOP monitoring records. It must also involve the QA independently verifying that each SSOP is working, by looking at how each SSOP is implemented and by checking if there are repeat findings of any SSOP failures. It also involves implementing preventive actions to reduce SSOP failures and reviewing SSOPs at a set frequency to ensure they continue to be effective.

# *Veterinary Public Health Inspection Service*

DOC No. GN_USDA SSOP	Title: <b>USDA~SSOP_Verification_Guidance</b>	Version: 06	Issue Date: 10/01/2020
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- The record-keeping elements are listed for review. Where there are no deficiencies found, enter "NONE".
- Any deficiencies found must be entered clearly and concisely. And follow-up action must also be clearly described.
- The footnote on SSOP Review is to remind officers of the need to be familiar with the procedures in the SSOP.
- The VI/SAO/TAO must sign and date the completed **FrmUSDA~SSOP (b)**.