United States Department of Agriculture

Food Safety and
Inspection Service

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MAR 0 6 2020

Ms. Christine Middlemiss
Chief Veterinary Officer
Department for Environment, Food and Rural Affairs (DEFRA)
Area 5 B, Nobel House
17 Smith Square
London SW1P 3JR, United Kingdom

Dear Ms. Middlemiss,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted an on-site verification audit of the United Kingdom's inspection system from July 15 through August 2, 2019. Enclosed is a copy of the final audit report. The comments received from the Government of the United Kingdom are included as an attachment to the report.

Sincerely,

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN THE UNITED KINGDOM JULY 15 THROUGH AUGUST 2, 2019

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING MEAT EXPORTED TO THE UNITED STATES OF AMERICA

February 26, 2020

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site equivalence verification and reinstatement audit conducted by the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) from July 15 through August 2, 2019. The first purpose of the audit was to determine whether the United Kingdom's food safety inspection system governing 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. The second purpose of the audit was to assess the regulatory oversight that the government provides for beef and small ruminants in preparation to grant the reinstatement of beef and small ruminants for export to the United States. The third purpose of the audit was to determine if the United Kingdom implements one food safety inspection system that encompasses the four countries (England, Northern Ireland, Scotland, and Wales) of the United Kingdom with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Currently only Northern Ireland and England are eligible to export 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 on-site audit observations within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors concluded that the United Kingdom's meat inspection system governing raw pork, raw beef, and small ruminants' function in a manner equivalent to that of the United States. In addition, the FSIS auditors verified that the CCA implements a single food safety inspection system by applying the same set of laws, regulations, and policies to all establishments certified to export to the United States.

Although there were no systemic findings, during the audit exit meeting, the CCA committed to addressing the preliminary isolated 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.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of the United Kingdom's (UK) food safety system from July 15 through August 2, 2019. The audit began with an entrance meeting held on July 15, 2019, in London, England, during which the FSIS auditors discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – Department of Environment Food and Rural Affairs (DEFRA). Representatives from the CCA accompanied the FSIS auditors throughout the entire audit.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a three-part audit which encompassed a routine ongoing (pork) equivalence verification audit, a reinstatement audit of beef and small ruminants equivalence verification and an initial audit for the United Kingdom to be recognized as a single food safety inspection system. The first audit objective was to determine whether the food safety system governing 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. The second audit objective was to assess the regulatory oversight that the government provides for beef and small ruminants, in preparation to grant the reinstatement of beef and small ruminants. The third audit objective was to determine if the United Kingdom has implemented one food safety inspection system that encompasses the four countries (i.e., England, Northern Ireland, Scotland, and Wales) that comprise the United Kingdom.

Currently, England, Wales, Northern Ireland, and Scotland are listed in Title 9 of the United States Code of Federal Regulations (9 CFR) 327.2 as having meat food safety inspection systems equivalent to that of the United States. During previous ongoing verification audits, FSIS only audited raw pork product produced at the certified establishments located in England and Northern Ireland. During those audits, Scotland and Wales did not have any certified establishments as eligible to export to the United States. In response to the CCA's request to reinstate its eligibility to export beef and small ruminants, the current FSIS audit's scope included an on-site audit of raw beef and small ruminates products in establishments seeking the CCA certification. In order to achieve a systematic approach concerning reinstatement, FSIS selected a sample of beef and small ruminant establishments presented by the CCA in all four countries. Currently, only England and Northern Ireland actively export raw pork products to the United States[1] and there has not been any export of raw beef or small ruminants to the United States.

Process Category	Product Category	Eligible Products
Raw - Non-Intact	Raw ground, comminuted, or otherwise non-intact pork	Pork- Ground product, sausage, and other non-intact products, except Mechanically Separated and Advance Meat Recovery Product (AMR)
Raw - Intact	Raw intact pork	Pork- Boneless manufacturing trimmings, carcass (including carcass halves or quarters), cuts, edible offal, other intact, and primals and subprimals

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

The USDA's Animal and Plant Health Inspection Service (APHIS), which regulates importation of animals and animal products into the United States, recognizes the United Kingdom as subject to the following restrictions. Beef imported from the United Kingdom is subjected to foot-and-mouth disease requirements specified in 9 CFR 94.11, and bovine spongiform encephalopathy requirements specified in 9 CFR 94.18 and/or 9 CFR 94.19.

England, Scotland, and Wales are considered controlled risk status for bovine spongiform encephalopathy. Northern Ireland is considered to have a negligible risk status for bovine spongiform encephalopathy.

Pork imported from the United Kingdom is subjected to African swine fever requirements specified in 9 CFR 94.8, classical swine fever requirements specified in 9 CFR 94.31, swine vesicular disease requirements specified in 9 CFR 94.13, and foot-and-mouth disease requirements specified in 9 CFR 94.11.

The United Kingdom is considered affected with scrapie for small ruminants. Currently, APHIS has restrictions in place regarding the importation of small ruminant products as specified in 9 CFR 94.24. The United Kingdom will not be eligible to export small ruminant products to the United States until these restrictions are lifted.

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.

The FSIS auditors reviewed administrative functions at CCA headquarters, three regional offices, and 11 local inspection offices located in audited establishments. The FSIS auditors evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

Currently, the United Kingdom has 11certified establishments that produce and export raw pork products to the United States. Prior to the on-site audit, the CCA provided FSIS with 10 additional establishments intending, but not yet certified, to export raw beef or small ruminants (sheep) to the United States. The FSIS auditors selected a sample of 11 establishments from the total of 21 establishments presented by the CCA. This included four pork slaughter and raw processing, four beef

slaughter and raw processing, one beef slaughter, one sheep slaughter and raw processing, and one cold storage facility.

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 impacts 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, the FSIS regulations addressing equivalence determinations for foreign country inspection systems for meat.

Additionally, two microbiological and one chemical residue laboratories were audited to verify their ability to provide adequate technical support to the food safety inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• DEFRA, London, England
	Regional	3	• Northern Ireland Regional Authority, Ballykelly, Northern Ireland • Scotland Regional Authority, Food Standards Scotland, Aberdeen, Scotland • Food Standards Agency Headquarters, direct authority for England and Wales, York, England
Laboratories		2	• Agri-Food and Bioscience Institute (AFBI), Government Chemical and Microbiological analysis laboratories, Belfast, Northern Ireland • ALS Chatteris Private Microbiological laboratory, Medcalfe, England
Beef slaughter		1	• Establishment No. 1541, AK Stoddart Ayr, Ayr, Scotland
Beef slaughter and raw processing		3	• Establishment No. 2536, Pickstock Telford Limited, Telford, England • Establishment No. 7176, Kepak Food Group Limited, Merthyr Tydfil, Wales • Establishment No. 9016, Foyle Food Group, Foyle Campsie, County Londonderry Derry, Northern Ireland
Beef raw processing		1	• Establishment No. 1626, AK Stoddard Broxburn, Broxburn, Scotland
Lamb and mutton slaughter and raw processing		1	• Establishment No. 7015, Dunbia Llanybydder, Lampeter, Wales
Pork slaughter and raw processing		4	• Establishment No. 2060, Karro Food Limited, North Yorkshire, England • Establishment No.2093, Cranswick Country Foods PLC, North Humberside, England • Establishment No. 4085, Tulip Ltd, Dunkinfield, England • Establishment No. 8061, Tulip Ltd, Bristol, England
Cold storage facility		1	• Establishment No. 7158, Norish Ltd., Wrexham, England

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 Meat Inspection Regulations (9 CFR 301 to the end).

The audit standards applied during the review of the United Kingdom's inspection system for meat included: (1) all applicable legislation originally determined by FSIS as equivalent as part of the initial review process, and (2) any subsequent equivalence determinations that have been made by FSIS under provisions of the World Trade Organization's *Agreement on the Application of Sanitary and Phytosanitary Measures*; and includes the following:

- *Salmonella* Sample Collection equivalent determination; align Northern Ireland's *Salmonella* sampling procedures with the other countries of the United Kingdom (England, Scotland, and Wales) where establishment employees collect the samples for *Salmonella*;
- European Commission Regulation (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 (EC) No. 142/2011;
- EC Directive No. 93/119/EC;
- EC Directive No. 96/22/EC; and
- EC Directive No. 96/23/EC.

III. BACKGROUND

From April 1, 2016 through March 31, 2019, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 65,410,568 pounds of raw pork exported by England and Northern Ireland to the United States. FSIS also performed reinspection on 6,979,852 pounds at POE for additional types of inspection, including testing for chemical residues and *Salmonella*, for which no products were rejected for issues related to public health.

The previous FSIS audit in 2017 identified the following findings:

GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)

- The Central Competent Authority (CCA) used contract employees to conduct inspection (e.g., ante-mortem inspection, final carcass disposition during post-mortem inspection, and sanitation and HACCP verification activities) during the production of pork product to export to the United States.

GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (e.g., INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)

- At two of the four audited pork slaughter establishments, inspection personnel did not take appropriate regulatory control actions when carcasses were not presented with their organs or viscera, when carcasses were presented with the wrong organs, or when carcasses were presented with punctured viscera.

Prior to this 2019 on-site equivalence verification audit, FSIS reviewed and analyzed the United Kingdom's SRT responses and supporting documentation. During the audit, the FSIS auditors conducted interviews, reviewed records, and made observations to determine whether the United Kingdom's food safety inspection system governing meat is being implemented as documented in the country's SRT responses and supporting documentation. The FSIS auditors verified that the corrective actions for the previously reported findings were implemented.

The FSIS final audit reports 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 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.

At the time of the audit, the United Kingdom was a member of the European Union (EU) and drawing its authority to enforce inspection laws from Regulation (EC) No. 178/2002, which establishes the general principles and requirements of food law, defines the European Food Safety Authority, and procedures in matters of food safety. The United Kingdom implements the requirements of the *EC Food Hygiene Regulations,* which are the primary overarching laws for regulating meat inspection and have been found to be equivalent to that of the United States.

Food safety and standards are devolved matters in the United Kingdom, whereas foreign policy and trade remain reserved matters. Devolved matters are those areas of government authority for which the United kingdom Parliament has delegated decision making institutions such as the Scottish Parliament, the Assemblies of Wales, Northern Ireland, and London, or to local authorities. Reserved matters are areas of government authority for which decisions taken by the United Kingdom Parliament have effect in Scotland, Wales, Northern Ireland, or the regions of England.

DEFRA is the central United Kingdom ministerial government department, and therefore the CCA for the whole of the United Kingdom for international trade negotiations on all sanitary and phytosanitary matters and international trade of food of animal origin. DEFRA is also the CCA for animal health and

animal welfare for the whole of the United Kingdom, on behalf of the Devolved Administrations in Wales, Scotland, and Northern Ireland.

DEFRA as the United Kingdom's CCA has overall responsibility for policy development and implementation of policy in relation to certification of foods for export to non-EU countries, in carrying out its duty to ensure that requirements are met. DEFRA delegates responsibility to several agencies for ensuring that products intended for export comply with importing country requirements. DEFRA works closely with the Food Standards Agency (FSA) United Kingdom Exports Branch, London when negotiating market access for food, and DEFRA delegates to the FSA regulatory authority for compliance with food hygiene requirements for the whole of the United Kingdom.

The FSA is responsible for the government inspection activities in approved slaughterhouses and non-slaughter processing establishments in England and Wales. Food Standards Scotland (FSS) is responsible for government inspection activities in Scotland. The Department for Agriculture Environment and Rural Affairs, Veterinary Public Health Program (DAERA VPHP) carries out food safety-related official controls in Northern Ireland on behalf of the FSA under the terms of a service level agreement. Devolved Administrations are the Competent Authorities (CA) for their countries regarding food legislation, animal health, and animal welfare.

The Veterinary Medicines Directorate (VMD) is an agency of DEFRA which oversees the veterinary and chemical residues surveillance program for the United Kingdom. The Animal and Plant Health Agency (APHA), another agency of DEFRA, oversees the operational delivery of animal health and welfare as well as the international trade policy for England, Wales, and Scotland, while in Northern Ireland this is the responsibility of DAERA VPHP.

The FSA, FSS, and DAERA VPHP assign Official Veterinarians (OVs) and Official Auxiliaries (OAs) to certified meat establishments. The FSIS auditors verified that the FSA, FSS, and DAERA VPHP staffing programs were enough to ensure that an effective level of oversight is maintained as described in the SRT. At slaughter establishments, government inspections are required throughout the entire shift, and for processing, government inspection is required once every shift at establishments exporting to the United States. EC regulations require the continuous presence of an OV during slaughter operations. The FSIS auditors verified that FSA, FSS, and DAERA VPHP government inspection personnel (GIP), which include contracted personnel, conduct inspection activities at least once per shift for processing establishments and continually for slaughter.

The FSIS auditors' review of the oversight activities carried out at DEFRA headquarters, regional offices, and government offices at establishments demonstrate that DEFRA: has a single set of rules; has legal authority and responsibility to enforce inspection regulations; and enforces requirements that ensure adulterated or misbranded products are not exported to the United States.

OVs and OAs are contracted employees or licensees paid by the government either directly or through a third-party contractor who has been contracted to conduct official controls on behalf of the government in England, Scotland, and Wales. Prior to the audit, FSIS determined that the use in the United Kingdom of inspectors who are not under direct government supervision meets equivalence criteria. The CCA has formally delegated to contract employees the authority to conduct government inspection activities and to take enforcement measures when necessary to stop violations of food safety measures.

The CCA maintains ultimate control and supervision of all contract employees or licensees by means of ongoing monitoring and formal assessment of the contract employees. The CCA maintains controls, including an effective enforcement program, to remove contract employees or licensees who do not meet the written performance standards or who violate codes of conduct. The CCA maintains controls on conflicts of interest to ensure that contract employees or licensees act in the public interest. The contract employees are not paid directly by the establishment.

Quarterly supervisory audits are conducted by DEFRA employees to verify the effectiveness of government controls at establishments. Additionally, the performance of the contract OVs and OAs is evaluated against the key performance indicators included in the contracts monthly by FSA and FSS management. The FSIS auditors conducted direct observation of the implementation of government controls, interviewed GIP, and reviewed audit reports without any concerns with the utilization of third-party contractors.

The government recovers the costs of inspection by collecting inspection fees from establishments. The charges are reviewed every year and are implemented according to EU guidelines. The FSIS auditors verified through interviews and records review that all GIP are paid directly by the government or indirectly through a third-party contactor.

DEFRA ensures that OVs and OAs have appropriate educational credentials and appropriate training and experience to carry out their inspection tasks. All OVs and OAs are required to meet the professional qualifications specified in Regulation (EC) No. 854/2004. There is a standard training for all inspection personnel regardless of whether they are directly employed by the government or contracted. The government approves course content and training. Only those persons that have undergone training and passed an examination are eligible for employment as inspectors. The performance of officials is actively assessed during the documented monthly or quarterly supervisory visits performed at all certified establishments. The FSIS auditors did not have any concerns with the GIP's knowledge and implementation of regulatory requirements.

To be appointed as an OV in the United Kingdom, applicants must have a recognized veterinary degree. In addition, the GIP must undergo training specific to their jobs which includes training on export requirements specific to countries such as the United States. Competency is assessed through regular audits. The FSIS auditors confirmed through interviews and records review that GIP have the required education and appropriate training required by DEFRA.

The FSIS auditors verified that meat intended to be exported to the United States must be certified by an OV and must comply with EU and additional FSIS requirements. If the meat is not produced, stored, and transported in compliance with the United States requirements, the certifying OV will not issue and sign the *Internal Movement Certificates* (IMC), *Support Health Attestations* (SHA), or the final *Export Health Certificate*. The IMCs and SHAs are utilized to facilitate the export of meat products from the United Kingdom to countries outside the EU by providing the necessary chain of evidence and custody that the meat products satisfy the specific requirements of the destination country, which go beyond EU requirements, when they move between establishments within the United Kingdom. The certifying OVs are required to ensure that all establishments involved in the chain of production for the product are eligible for export to the United States.

Certification of all products for export does not occur until microbiological test results of the establishment or official government testing are received as acceptable. Furthermore, if an OV suspects or chooses to sample an animal for any chemical residues under the targeted program based on observations during ante-mortem or post-mortem inspections, that carcass is held pending acceptable test results. The FSIS auditors verified through interviews and records review that carcasses that have been sampled for routine chemical residue testing during the production of product intended for export to the United States must either be held pending acceptable test results or must be diverted from the United States production.

The United Kingdom General Food and Feed law requires food business operators to immediately inform the CAs if they consider or have reasons to believe that a food which they placed on the market may be injurious to human health or non-compliant with the receiving country requirements. The FSA and FSS have the authority to withdraw exported food and feed from the market. Furthermore, FSA, FSS, and DAERA VPHP can take enforcement actions if a certified establishment does not meet the requirements of DEFRA. The FSIS auditors verified through records review and interviews that FSA, FSS, and DAERA VPHP have procedures in place to notify FSIS of the shipment of adulterated products.

DEFRA has the authority to certify and de-certify establishments for export to the United States. FSA/FSS/DAERA VPHP are empowered by DEFRA by means of a memoranda of understanding (MOU), to recommend certification and de-certification of establishments for export to the United States. The MOU establishes the roles and responsibilities for the export of products of animal origin amongst DEFRA, APHA, FSA, FSS, and DAERA VPHP. FSA, FSS, and DAERA VPHP have procedures in place to audit both operational and systems compliance against the requirements of the United States. The FSIS auditors reviewed certification documentation that includes initial and ongoing audits without any concerns with the certification process.

DEFRA has the authority to approve and disapprove laboratories under Regulation (EC) No. 882/2004 to carry out the analysis of samples taken during official controls. DEFRA has a written procedure for the laboratory approval process which requires that the analytical test used is accredited to International Organization for Standardization (ISO)/ International Electrotechnical Commission (IEC) 17025, *General requirements for the competence of testing and calibration laboratories*, and this is verified by the United Kingdom Accreditation Service (UKAS). UKAS carries out periodic audits of the laboratories performing official and private testing according to the requirements of the standards outlined in the MOU between United Kingdom Department for Business, Energy and Industrial Strategy and UKAS. This forms part of the laboratories' ongoing accreditation procedures. The principle of this is outlined in the accreditation standards.

The National Reference Laboratories and UKAS carry out periodic audits of the official control laboratories (OCL) to ensure the terms of accreditation continue to be met. The OCLs must demonstrate continued compliance with the ISO/IEC 17025 standard. The OCLs test the product destined for export to the United States. The FSIS auditors reviewed the most recent accreditation report available at each visited laboratory and confirmed that any identified findings were addressed in a timely manner.

During the on-site visit to a private microbiology laboratory, the FSIS auditors identified an isolated finding that the laboratory technicians do not wear gloves while analyzing samples, including during

start-up, media preparation, screening, or culture confirmation steps. This is contrary to good laboratory practices and may result in cross-contamination of sterile media or samples, thereby rendering the results inaccurate and most likely to result in a false positive.

During the on-site visit to a government microbiology laboratory, the FSIS auditors identified an isolated finding that several documents were missing reviews, signatures, dates, and other pertinent information. Results should be reviewed and authorized before the final results are sent out to ensure that erroneous results are not reported.

The FSIS analysis and on-site verification activities indicated that DEFRA's meat products inspection system has an organizational structure to provide control, supervision, and enforcement of regulatory requirements. However, the FSIS auditors identified the above-mentioned isolated laboratory findings during the on-site visits to the laboratories.

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; at least once per shift inspection during processing operations; and periodic supervisory visits to official establishments.

The FSIS auditors verified by review of supervisory records and interviews that supervisors from DEFRA implement supervisory reviews at certain frequencies. The frequencies are once per month for the first three months of export to the United States and quarterly thereafter. In addition, the FSIS auditors verified that the supervisors possessed the knowledge of EC requirements along with United States export requirements to be competent in conducting supervisory and establishment audits. The United States requirements are specified in the *Required Methods of Operation Procedures* (RMOP) *for USDA FSIS Certified Establishments: Compliance with Special Conditions.* The FSIS auditors did not identify any concerns with DEFRA's ability to conduct supervisory audits of employees and establishments.

DEFRA implements a Food Chain Information System as described in the *Manual for Official Controls* (MOC) for each DEFRA-delegated regional authority. This system uses a combination of pre-slaughter data, including animal passports, and post-mortem inspection information. The information included in this system allows for full traceability and provides health information. The Food Chain Information System ensures that animals arriving at the slaughter facilities can be traced back to the farms they originate from and have the appropriate health certificates. This ensures that the OV can confirm any requirements for disease statuses outlined by APHIS.

The FSIS auditors verified that establishments can trace products forward in the event of a recall. The FSIS auditors determined through interviews and records review that the GIP verify at least ten percent of animals for identification, animal passport information, and dentition. If an animal is missing an ear tag, the information is referred to the local authorities for follow up and enforcement.

The FSIS auditors also observed implementation of the humane handling programs at the audited slaughter establishments. This included directly observing GIP performing hands-on verification of the maintenance and conditions of the holding pens, movement of animals, access to water or feed, and proper stunning of animals. The written requirements ensure that animals present within the facility are handled humanely prior to slaughter in a manner consistent with 9 CFR 313.2, as required by Chapter II, Article 3.1 of Regulation (EC) No. 1099/2009, and in accordance with the MOCs. The FSIS auditors observed OVs and GIP conducting daily humane handling verification activities. Additionally, the FSIS auditors reviewed the GIP-generated humane handling verification records, which are recorded in an electronic recordkeeping system documenting the results of their verification activities. The FSIS auditors did not identify any areas of concern with humane handling requirements during the direct observations and review of records.

DEFRA requires ante-mortem inspection on every shipment of animals within 24 hours of slaughter by GIP. The FSIS auditors observed that the audited slaughter establishments provided an isolation holding pen designated for observation and further examination of suspect animals. The OV performs a detailed ante-mortem inspection on suspect animals to determine if they are fit for slaughter and can be used to produce human food. Any pathological conditions that would affect fitness for human consumption are reflected in the food chain information and ante-mortem inspection records.

The FSIS auditors reviewed inspection records, including pen cards, and observed execution of ante-mortem procedures that demonstrate GIP implement the DEFRA requirements. Through interviews and review of written programs, the FSIS auditors verified that DEFRA follows EU requirements which would permit the harvest of non-ambulatory animals for human consumption. However, the FSIS auditors verified through interviews and records review that harvested non-ambulatory animals are not certified for export to the United States and are separated from carcasses certified for export to the United States.

The FSIS auditors verified that GIP perform post-mortem inspection at the time of slaughter on each and every carcass in accordance with the requirements. The FSIS auditors directly observed the implementation of DEFRA's requirements by GIP during post-mortem inspection presentation, identification, examination, and disposition of carcasses and parts. All carcasses railed out during post-mortem inspection must be re-inspected by the GIP prior to being released back into the process. The FSIS auditors also directly observed the actions of GIP performing on-line post-mortem inspection following DEFRA inspection methods for bovine, porcine, and ovine carcasses. Post-mortem inspection results are recorded daily in an electronic recordkeeping system. The FSIS auditors' review of the verification records confirmed that the OVs are conducting these activities daily as required by DEFRA.

DEFRA requires establishments to have a critical control point (CCP) that ensures that carcasses are free of contamination by fecal material, ingesta, or milk. Any visible contamination must be removed immediately by trimming. The OV verifies the effectiveness of the CCP by direct observations and review of records daily. The FSIS auditors verified that the slaughter establishments control contamination by ingesta, fecal material, or milk through a CCP in their HACCP plan with a critical limit of zero tolerance. These verifications by the FSIS auditors included directly observing the establishments' implementation and the OV's verification activities including zero tolerance CCP record

review and observation. The FSIS auditors did not have any concerns with the implementation of the zero tolerance CCP but observed isolated findings with recordkeeping.

DEFRA follows Regulation (EC) No. 999/2001, which describes requirements for the removal of specified risk materials (SRM) in cattle. This regulation requires that tonsils and distal ileum of all cattle regardless of age must be removed. The FSIS auditors directly observed the implementation of SRMs removal and disposal during slaughter operations. DEFRA verifies establishments' compliance with requirements for the identification, removal, segregation, and disposal of SRMs. DEFRA's MOCs for each regional authority outline the government inspection and verification activities for SRMs controls.

The FSIS auditors observed that GIP verify the removal of SRMs from every carcass and verify the separation of SRMs from edible product daily as per the MOCs. The FSIS auditors reviewed government verification records and the establishments' monitoring records concerning control and disposal of SRMs. The FSIS auditors also observed that the establishments use dedicated equipment for removal of SRMs and ensure the segregation and control of inedible materials. No issues were identified regarding the implementation of SRM controls at the establishments during the audit.

DEFRA requires the establishments to segregate and store inedible products in a separate area from edible products in accordance with the MOCs, Regulation (EC) No. 1069/2009, and Regulation (EC) No. 142/2011. In addition, containers used for collecting inedible products must be conspicuously marked and distinguished from other containers. The FSIS auditors noted that the GIP have the authority and responsibility to detain, denature, and destroy inedible products in accordance with DEFRA's requirements. The FSIS auditors reviewed both government and establishment-generated records and observed the disposal process of condemned and inedible materials at the audited establishments and found no concerns.

Isolated findings related to zero tolerance recordkeeping requirements are noted in the individual establishment checklists provided in Appendix A of this report. The FSIS auditors concluded that the United Kingdom's food safety inspection system maintains the legal authority and a regulatory framework that 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.

The FSIS auditors verified that the United Kingdom inspection system enforces overarching EC sanitary regulations, including Regulation (EC) Nos. 852/2004, 853/2004, and 854/2004. The FSIS auditors verified that each audited establishment maintains a written sanitation program to prevent direct product contamination or adulteration. Each establishment's program included maintenance and improvement of sanitary conditions through routine assessment of the establishment's hygienic practices.

The FSIS auditors verified that GIP carried out government inspection and verification activities as outlined in the official instructions, including verifying that establishment construction, facilities and equipment meet DEFRA's requirements. The FSIS auditors observed localized facilities deficiencies at three establishments.

The FSIS auditors verified that DEFRA requires establishment operators to adhere to DEFRA requirements and ensure that their premises are properly built and maintained in good repair to prevent the creation of insanitary conditions. Government officials regularly evaluate the conditions of the different areas of the establishments, document their findings, and require that establishments implement adequate corrective actions when sanitary deficiencies are identified. Documents reviewed by the FSIS auditors show that establishments and government officials interact to ensure that noncompliances related to maintenance of the facilities are identified and addressed to comply with the regulations of the program.

The FSIS auditors confirmed that GIP at establishments certified to export to the United States conduct verification activities of sanitary conditions which include monitoring and implementation of sanitation procedures, records review, and hands-on verification inspection of both pre-operational and operational sanitation procedures. The frequency of sanitation SOP verification tasks is set as daily for GIP in establishments certified for export to the United States.

The FSIS auditors assessed the adequacy of the pre-operational inspection verification by observing GIP conducting pre-operational sanitation verification inspection. The GIP's verification procedures started after the establishment had conducted its pre-operational sanitation and determined that the facility was ready for the GIP's pre-operational sanitation verification inspection. The FSIS auditors determined that GIP conduct pre-operational sanitation verification in accordance with DEFRA's established procedures.

The FSIS auditors observed GIP performing operational sanitation verification in all the audited establishments. The FSIS auditors noted that the government inspection verification activities included direct observation of the actual operations and review of the establishments' associated records. The FSIS auditors compared their overall observation of the sanitary conditions of the establishments with the government inspection verification records. The FSIS auditors' records review included both the establishments' sanitation monitoring and corrective action records; the government inspection records documenting government inspection verification results, and noncompliances; and periodic supervisory reviews of establishments. The FSIS auditors' review of records generated by GIP showed that in-plant GIP have identified and documented sanitation findings in accordance with DEFRA's requirements.

The FSIS auditors verified that DEFRA requires sanitary dressing of livestock at slaughter establishments. As a result, each audited slaughter establishment has implemented sanitary procedures to prevent potential carcass contamination throughout the process. These include sanitary procedures to prevent carcass contamination among carcasses during dressing procedures and prevent carcass contamination with gastrointestinal contents during evisceration. The FSIS auditors conducted direct observations, interviewed OVs, and reviewed government inspection records without concern for the ability of DEFRA to enforce requirements for sanitary dressing.

The FSIS auditors verified that the audited establishments maintain sanitation records sufficient to document the implementation and monitoring of the sanitation SOPs and any corrective actions taken. Establishment personnel responsible for the implementation and monitoring of the sanitation SOPs correctly authenticated these records with initials or signatures and the date.

Isolated findings related to the verification of sanitation requirements are noted in the individual establishment checklists provided in Appendix A of this report. The FSIS auditors' analysis and on-site verification activities indicate that DEFRA requires operators of official establishments to develop, implement, and maintain sanitation programs. The FSIS auditors concluded that DEFRA continues to meet the core requirements for this component.

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

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

The FSIS auditors noted that DEFRA requires establishments exporting to the United States to develop and implement a HACCP program. The FSIS auditors verified that establishments' HACCP programs include written hazard analysis, flow charts, and HACCP plans to identify, evaluate, and prevent or control food safety hazards in their production processes. The HACCP plans included monitoring and verification procedures and records to document the results of monitoring and verification activities as well as implementation of corrective actions if needed. In addition, the establishments maintain documents for validation of the HACCP system. OVs at certified establishments are to verify all the aspects related with the requirements of 9 CFR 417.

The GIP's daily verification methodology includes such activities as the evaluation of the establishment's written HACCP programs and observing the establishment personnel perform monitoring, verification, corrective actions, and recordkeeping activities. The official daily HACCP verification activities also include direct observation or records review of CCPs for all production shifts, with results of verification being entered in the associated government inspection records. The FSIS auditors conducted an on-site observation and document review of CCPs in all the audited establishments which included zero tolerance CCPs at all slaughter establishments.

The FSIS auditors noted in the audited beef slaughter establishments the sampling and testing for Shiga toxin-producing *Escherichia coli* (STEC) that is required for export to the United States has yet to be implemented, as the United Kingdom has not certified any beef establishments. In one establishment the FSIS auditors were able to observe sampling for *E. coli* O157:H7 following the N60 methodology for sampling required by another country without any concerns. DEFRA will require that all establishments intending to ship raw beef products intended for non-intact use to have a sampling and testing program meeting FSIS requirements. Establishments must follow the N60 sampling methods consistent with *FSIS Directive 10.000.1 Sampling Verification Activities for Shiga Toxin-Producing Escherichia Coli (STEC) in Raw Beef Products (Aug 20, 2015; 88 pp)*. DEFRA will require N60 samples to be tested for the presence of STECs (*E. coli* O157:H7 and other six STECs (O26, O103,

O111, O121, O45, O145) referred to as the Top 7 STECs) at UKAS-accredited laboratories. At the time of the audit none of the beef establishments had initiated a Top 7 STECs sampling and testing program.

Isolated findings related to the requirements for the HACCP plan and HACCP recordkeeping requirements are noted in the individual establishment checklist provided in Appendix A of this report. The FSIS analysis and on-site verification activities indicate that DEFRA requires operators of official establishments to develop, implement, and maintain a HACCP system for each processing category. The FSIS auditors concluded that DEFRA continues to meet the core requirements for this component.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

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

Prior to the on-site visit, FSIS residue experts reviewed the United Kingdom's Residue Surveillance Program (RSP) previous testing results, associated methods of analysis, and additional SRT responses outlining the structure of the United Kingdom's chemical residue testing program. It was noted that as of the time of the audit, there have not been any POE violations related to this component since the last FSIS audit.

The VMD is the Competent Authority for the RSP which monitors the use of authorized and unauthorized substances in the United Kingdom's products. There are two types of schemes, a surveillance scheme and a suspect sampling scheme. The residues surveillance program is implemented by the VMD. The GIP collects samples at establishments.

DEFRA has the authority and resources to remove violative product from the human food chain, to take regulatory action against violative meat products, and to take regulatory action against individuals who introduce violative meat products into the human food chain. For the suspect sampling scheme, government veterinarians have the authority to detain, sample, and test suspect animals and carcasses. If the results are unsatisfactory, the animals and carcasses are deemed unfit for human consumption and disposed of as animal by-products.

The residue program provides for enforcement actions to be taken when positive or violative results occur. An investigation is undertaken for all non-compliant samples, and in most of the cases advice is provided to the farmer to avoid a re-occurrence in the future. If a farmer has used a prohibited substance or is in breach of a maximum residue limits (MRL), they can be financially penalized. In more serious cases, the animals can be destroyed without any compensation to the farmer, usually when an unauthorized or prohibited substance is found. In the most severe cases, enforcement notices can be issued which can lead to prosecution. The FSIS auditors verified that DEFRA has an enforcement policy in place for samples that originate from establishments exceeding MRLs.

The FSIS auditors verified that official GIP collect routine residue samples and the GIP may choose to collect additional targeted residue samples based on dispositions made during ante-mortem or post-

mortem inspections. Sampling integrity procedures are in place to address packaging of the tissue samples to prevent contamination and deterioration during shipment to the laboratory. Samples are sent for analysis to either the Food and Environment Research Agency or Agri-Food & Biosciences Institute, both of which are National Reference Laboratories. Receipt of samples, tracking of samples, handling and analysis, and reporting of results were reviewed by the FSIS auditors, without concern, at AFBI.

The FSIS analysis and on-site verification activities indicated that DEFRA continues to maintain the legal authority to regulate, plan, and execute activities of the government inspection system that are aimed at preventing and ensuring controls of the presence of residues of veterinary drugs and contaminants in meat destined for human consumption.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

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

Prior to the on-site visit, FSIS microbiologists reviewed the United Kingdom's national microbiological sampling and testing programs, laboratory methods of analysis, and additional SRT responses outlining the structure of DEFRA's microbiological verification sampling and testing programs. Since the last FSIS audit, DEFRA has designed a government STEC testing program for beef products and requires establishments seeking certification for the export of raw beef products to develop a STEC testing program for beef intended for non-intact use.

DEFRA requires samples for *Salmonella*, *Enterobacteriaceae,* and total viable count (TVC) be taken and packaged under the supervision of an OV. DEFRA requires establishments to have a written sampling plan describing the microbiological criteria to be met, sampling methods, place and frequency of sampling, trained employees responsible, storage and dispatch of the sample, laboratory and test methods. It must also include the actions to be taken when results are not satisfactory. The GIP taking samples, must be trained in procedures and techniques for taking samples (sites, number, and frequency) for the relevant target (*Salmonella*, *Enterobacteriaceae*, and TVCs).

The FSIS auditors verified that DEFRA ensures establishments follow Regulation (EC) No. 2073/2005 regarding process hygiene criteria testing and analysis for carcasses. Establishments are required to conduct indicator organism testing on carcasses for TVC and *Enterobacteriaceae,* then analyze the data. The FSIS auditors verified that establishments adhere to the sampling frequencies as per the DEFRA requirements and take any required actions of individual test results, or when a trend is determined. In addition, the FSIS auditors observed the establishments conducting its sampling procedure prior to chilling, reviewed test results, and observed OVs verifying the establishments sampling programs without any concerns.

DEFRA has developed *Salmonella* official sampling and testing programs for carcasses prior to chilling following the criteria outlined in Regulation (EC) No. 2073/2005. Routine testing is performed according to the DEFRA guidelines with testing conducted initially each week for 30 weeks on five

carcasses. If satisfactory results are obtained for 30 consecutive weeks of sampling, sampling may be reduced to one sampling event of five carcasses every two weeks. The FSIS auditors did not identify any concerns regarding sample collection procedures or the DEFRA testing methods regarding the *Salmonella* sampling programs.

The FSIS auditors noted that in the audited beef slaughter establishments the government sampling and testing for STEC has yet to be implemented. DEFRA will require that all establishments intending to export raw beef products intended for non-intact use will have a sampling and testing program that complies with FSIS requirements. DEFRA will implement a government STEC sampling verification procedure following the N60 method and analyzed at the AFBI UKAS accredited laboratory. The OV will collect samples from one to four batches or production lots per month depending on the daily production volume. Microbiological independence and randomization need to be respected. If any sample tests positive, follow-up testing occurs on a set of either eight or 16 (depending on daily throughput) batches or production lots. If the follow-up tests results are consecutively negative, testing reverts to the normal frequency.

There have not been any POE violations related to this component since the last FSIS audit. The FSIS analysis and on-site verification activities indicated that DEFRA continues to maintain and implement its microbiological sampling and testing programs to ensure that meat is safe and wholesome. The FSIS auditors concluded that DEFRA meets the core requirements for this component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on August 2, 2019, in London, England, with DEFRA. At this meeting, the FSIS auditors presented the preliminary findings from the audit.

An analysis of the on-site audit observations within each component did not identify any deficiencies that represented an immediate threat to public health, nor any systemic findings. The FSIS auditors concluded that the United Kingdom's meat inspection system governing raw pork, raw beef, and small ruminants' functions in a manner equivalent to that of the United States. In addition, the FSIS auditors verified that the CCA implements a single food safety inspection system by applying the same set of laws, regulations, and policies to all establishments certified to export to the United States.

Although there were no systemic findings, during the audit exit meeting, the CCA committed to address the preliminary isolated 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

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
AK Stoddart Ayr Old Farm Rd, Ayr KA8 9ST	07/22/2019	UK 1541 EC	United Kingdom
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

40: The lighting at the head/viscera post-mortem inspection station was below DEFRA's lighting requirement.

41: FSIS auditors observed beaded condensate on the overhead structures above exposed beef carcasses in the expedition and a carcass cooler. The auditors did not observe any direct product contamination.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	07/22/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
AK Stoddard Broxburn . 16 Dunnet Way East Mains Industrial Estate Broxburn EH52 5NN	07/23/2019	UK 1626 EC	United Kingdom
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

22: The establishment's HACCP verification records for CCP1 (metal detector) did not include the time or result of verification activities.

22: The establishment’s HACCP monitoring records did not include time of monitoring activities.

38: The packaging supplies were kept in a manner that prevented proper inspection of the dry storage area for the presence of pest.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	07/23/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Karro Food Ltd Hugden Way, Norton Grove Industrial Estate, Malton, North Yorkshire YO17 9HG	07/30/19	UK 2060 EC	United Kingdom
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	0
34. Species Testing	0
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57.	
58.	
59.	

60. Observation of the Establishment

22 - The establishments HACCP plan monitoring records for zero tolerance did not include the result of the monitoring procedure at the time the monitoring took place

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	07/30/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Cranswick Country Foods PLC Staithes Road Hull North Humberside	07/30/2019	UK 2093 EC	United Kingdom
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

No findings identified during the audit.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	07/30/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Pickstock Telford Limited 45 Hortonwood Industrial Estate Hortonwood Telford	07/26/19	UK 2536 EC	United Kingdom
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
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8. Records documenting implementation.	
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Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
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Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

60. Observation of the Establishment

No findings identified during the audit.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	07/26/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Tulip Ltd Bow Street Dukinfield Cheshire	07/29/2019	UK 4085 EC	United Kingdom
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

No findings identified during the audit.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	07/29/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Dunbia Llanybydder Llanybydder Lampeter SA40 9QE	07/25/2019	UK 7015 EC	United Kingdom
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	O
8. Records documenting implementation.		34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. 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	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

39 - The lamb skinning and start of the evisceration area had loose wall and ceiling panels, rusted and flaking paint, silicone caulking was hanging and loose, and holes in the ceiling where patching had come apart. No product was observed contaminated.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	07/25/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Norish Ltd Ash Road South Wrexham Industrial Estate Wrexham LL13 9UG	07/26/2019	UK 7158 EC	United Kingdom
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

No findings identified during the audit.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	07/26/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Kepak Food Group Limited Pengarnddu Industrial Estate Dowlais Top Merthyr Tydfil CF48 2TA	07/23/19	UK 7176 EC	United Kingdom
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	0
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	X
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57.	
58.	
59.	

60. Observation of the Establishment

41- Beaded condensation was observed on the ceiling over the offal line prior to entering the offal processing area, beaded condensate was also observed on the ceiling around the zero tolerance monitoring area. no product contamination was observed.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	07/23/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Tulip Lid Oakleigh Green Westerleigh Bristol BS37 8QZ	07/24/19	UK 8061 EC	United Kingdom
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	0
34. Species Testing	0
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57.	
58.	
59.	

60. Observation of the Establishment

22 - The establishments HACCP plan did not list the verification procedures and frequencies

22 - The establishments CCP verification monitoring records did not include the time or result on all records

22 - The establishments HACCP plan monitoring records for zero tolerance did not include the result of the monitoring procedure at the time the monitoring took place

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	07/24/19

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Foyle Food Group, Foyle Campsie Lisahally, Campsie County Londonderry BT47 6TJ	07/18/19	UK 9016 EC	United Kingdom
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

22: The establishment's HACCP verification records for CCP1 (zero tolerance) did not include the time, result, or the type (direct observation or record review) of verification activities.

39: FSIS auditors observed numerous gaps between the ceiling and protruding metal bars holding attached structures in the ceiling above exposed products and food contact surfaces in the production areas. The auditors did not observe any direct product contamination.

41: FSIS auditors observed beaded condensate on the overhead structures above exposed beef carcasses in two carcass coolers. The auditors did not observe any direct product contamination.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	07/18/2019

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

Department
for Environment
Food & Rural Affairs

Nobel House
17 Smith Square
London SW1P 3JR

T: 03459 335577
helpline@defra.gsi.gov.uk
www.gov.uk/defra

Dr Michelle Catlin PhD
International Coordination Executive
Office of International Coordination
1400 Independence Avenue SW
Washington D.C. 20250
United States of America

9 December 2019

Dear Michelle

UNITED KINGDOM (UK) RESPONSE TO THE DRAFT FINAL AUDIT REPORT EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING MEAT EXPORTED TO THE UNITED STATES OF AMERICA FROM THE UK

Thank you for your letter and accompanying draft final audit report received on 16 October 2019, regarding the FSIS audit for the reinstatement of UK beef and lamb production systems, and the audit of approved pork establishments.

I would like to thank all of the inspectors and FSIS for their work undertaken prior to, during and after the visit, and for developing the comprehensive draft audit report so swiftly.

I am delighted that the audit reported only isolated findings, and that FSIS has confirmed that the United Kingdom's meat inspection system governing raw pork, raw beef and small ruminants functions in a manner equivalent to that of the United States. Following the evidence included within this response, I trust that FSIS will now be able to reinstate equivalence for UK beef and lamb systems, as well as to continue equivalence for pork.

My officials have studied the draft FSIS audit report closely to address the audit findings. Information describing this further is summarised as follows below.

Annex A to this letter outlines all of the actions and supporting evidence to correct the isolated deficiencies identified at the Food Business Operators (FBOs) that were inspected. For each FBO this is based an individual Corrective and Preventative Action (CAPA) plan that details and verifies the steps taken to address the deficiencies described in the draft FSIS audit report.

Annex B outlines the corrective actions relating to the isolated audit findings at the two microbiology laboratories that were visited.

I trust that this satisfactorily addresses all of the findings raised at the specific establishments. If you have any further questions or concerns, please do not hesitate to contact my officials, who will be happy to help.

Once again, I would like to thank all of the inspectors and FSIS for their time, effort and professionalism in all aspects of the work related to this audit. I look forward to your response, and keenly await publication of the final FSIS audit report.

Yours sincerely

PROFESSOR CHRISTINE MIDDLEMISS
UK CHIEF VETERINARY OFFICER

T: +44 (020) 7238 6495
Christine.Middlemiss@defra.gov.uk

Annex A

Deficiencies identified at specific FBO plants during the inspection audit

The table below provides an overview of the isolated deficiencies identified at the establishments throughout the visit:

FBO Establishment & unique Approval number	FSIS Code and Deficiencies identified	FBO Actions taken and supporting evidence	Annex A page number
AKS Ayr 1541	40 – Lighting 41 – Condensation	CAPA form Supporting evidence	4
AKS Broxburn 1626	22 – Records documenting 38 – Grounds and pest control	CAPA form Supporting evidence	5
Dunbia Llanybydder 7015	39 – Construction/ Maintenance	CAPA form Supporting evidence	6
Foyle Food Group Campsie 9016	22 – Records documenting 39 – Construction /Maintenance 41 – Ventilation	CAPA form Supporting evidence	7
Karro Food Ltd 2060	22 – Records Documenting	CAPA form Supporting evidence	8
Kepak Food Group Ltd 7176	41 – Ventilation	CAPA form Supporting evidence	9
Tulip Ltd Westerleigh 8061	22 – Records documenting	CAPA form Supporting evidence	10

i) Establishment number: 1541 - AK Stoddart Ayr

Deficiencies identified:

a) 40: The lighting at the head/viscera post-mortem inspection station was below DEFRA's lighting requirement.

b) 41: FSIS auditors observed beaded condensate on the overhead structures above exposed beef carcasses in the expedition and a carcass cooler. The auditors did not observe any direct product contamination.

Corrective and Preventative Action Plan verified by the on-site Official Veterinarian:


1541 CAPA 151119.pdf

Supporting evidence for the correction of deficiency a):


1541 NCa Lighting report.pdf


1541 NCa Lighting Photos.pdf

Supporting evidence for the correction of deficiency b):


1541 NCb pre-op hygiene report 2210


1541 NCb pre-op hygiene template 14


1541 NCb SH chill check report 091019


1541 NCb SH chill check template 1311


1541 NCb brief 151119.pdf


1541 NCb additional ventilatic

ii) Establishment number: 1626 - AK Stoddart Broxburn

Deficiencies identified:

a) 22: The establishment's HACCP verification records for CCP1 (metal detector) did not include the time or result of verification activities.

b) 22: The establishment's HACCP monitoring records did not include time of monitoring activities.

c) 38: The packaging supplies were kept in a manner that prevented proper inspection of the dry storage area for the presence of pests.

Corrective and Preventative Action Plan verified by the on-site Official Veterinarian:

1626 CAPA 151119.pdf

Supporting evidence for the correction of deficiencies a) and b):

1626 NCab CP checks 041119.pdf

Supporting evidence for the correction of deficiency c):

1626 NCc photo.pdf

iii) Establishment number: 7015 - Dunbia Llanybydder

Deficiency identified:

a) 39: The lamb skinning and start of the evisce silicone caulking was hanging and loose, and observed to be contaminated.

Corrective and Preventative Action Plan verified by the on-site Official Veterinarian:

7015 CAPA 210819.pdf

Supporting evidence for the correction of deficiency a):

7015 NCa checks template.pdf

7015 NCa maintenance order.p

7015 NCa photos.pdf

iv) Establishment number: 9016 - Foyle Food Group, Foyle Campsie

Deficiencies identified:

a) 22: The establishment's HACCP verification records for CCP1 (zero tolerance) did not include the time, result, or the type (direct observation or record review) of verification activities.

b) 39: FSIS auditors observed numerous gaps between the ceiling and protruding metal bars holding attached structures in the ceiling above exposed products and food contact surfaces in the production areas. The auditors did not observe any direct product contamination.

c) 41: FSIS auditors observed beaded condensate on the overhead structures above exposed beef carcasses in two carcass coolers. The auditors did not observe any direct product contamination.

Corrective and Preventative Action Plan verified by the on-site Official Veterinarian:


9016 CAPA 180719.pdf

Supporting evidence for the correction of deficiency a):


9016 NCa CCP1 Electronic record.pd

Supporting evidence for the correction of deficiency b):


9016 NCb GMP daily audit.pdf


9016 NCb panelling photos.pdf

Supporting evidence for the correction of deficiency c):


9016 NCc GMP daily audit.pdf


9016 NCc chill rail photos.pdf


9016 NCc carcase rail photo.pdf


9016 NCc roof photo.pdf

v) Establishment number: 2060 - Karro Food Ltd

Deficiencies identified:

a) 22 - The establishments HACCP plan monitoring records for zero tolerance did not include the result of the monitoring procedure at the time the monitoring took place.

Corrective and Preventative Action Plan verified by the on-site Official Veterinarian:

2060 CAPA 121119.pdf

Supporting evidence for the correction of deficiency a):

2060 NCa CCP1 procedure.pdf

2060 NCa inspection records.p

2060 NCa upgrade system.pdf

Confirmation of project to monitor and record CCP results:

2060 monitoring project.pdf

vi) Establishment number: 7176 - Kepak Food Group Limited

Deficiencies identified:

a) 41 - Beaded condensation was observed on the ceiling over the offal line prior to entering the offal processing area, beaded condensate was also observed on the ceiling around the zero tolerance monitoring area. No product contamination was observed.

Corrective and Preventative Action Plan verified by the on-site Official Veterinarian:

7176 CAPA 191119.pdf

Supporting evidence for the correction of deficiency a):

7176 NCa photos.pdf

7176 NCa condensation check

7176 NCa ventilation control.p

7176 NCa warm air quotation.pdf

7176 NCa air extraction quotatior

vii) Establishment number: 8061 - Tulip Limited (Westerleigh)

Deficiencies identified:

a) 22 - The establishments HACCP plan did not list the verification procedures and frequencies.

22 - The establishments CCP verification monitoring records did not include the time or result on all records.

22 - The establishments HACCP plan monitoring records for zero tolerance did not include the result of the monitoring procedure at the time the monitoring took place.

Corrective and Preventative Action Plan verified by the on-site Official Veterinarian:

8061 CAPA 261119.pdf

Supporting evidence for the correction of deficiency a):

8061 NCa evidence.pdf

Annex B

Observations by FSIS Officials at the Official Government and Private Microbiology Laboratories

Observations at the Official Government Laboratory: Agri-Food and Biosciences Institute (AFBI)

During the on-site visit to a government microbiology laboratory, the FSIS auditors identified an isolated finding that several documents were missing reviews, signatures, dates, and other pertinent information. Results should be reviewed and authorized before the final results are sent out to ensure that erroneous results are not reported.

Response to FSIS auditor comments

We note the finding identified by the FSIS auditors, and would like to highlight the following points that we trust will provide sufficient clarification to address this funding.

During the visit by FSIS audit officials, any 'white paper' copy Standard Operating Procedure (SOP) documents that were printed out for the auditors were marked as uncontrolled copies – for use only on the day of printing.

Document control such as issue date, approval signature or review history is managed on our laboratory IT system and will not appear on printed copies.

We also recognise that some of the forms presented to the FSIS auditors were for demonstration purposes as "example documents", and therefore would not be functional, nor subject to the same scrutiny, and would be disposed of immediately following the completion of the audit. We apologise that these approaches may not have been made sufficiently clear during the auditors visit.

We can also confirm that in line with AFBI policies and procedures, all laboratory test results and reports are reviewed and signed by the laboratory manager or their deputy before being issued.

In addition the AFBI laboratory is accredited to ISO 17025 for this procedure by UKAS (with the certificate being recently renewed), and our policies and procedures, as well as independent third-party audit by UKAS would not tolerate reports going out without proper scrutiny and authorisation.

If the FSIS auditors have any further specific concerns, or if any further supporting evidence is required, please let us know and we will be happy to respond further.

Observations at the Private Microbiology Laboratory: ALS Chatteris

During the on-site visit to a private microbiology laboratory, the FSIS auditors identified an isolated finding that the laboratory technicians do not wear gloves while analyzing samples, including during start-up, media preparation, screening, or culture confirmation steps. This is contrary to good laboratory practices and may result in cross-contamination of sterile media or samples, thereby rendering the results inaccurate and most likely to result in a false positive.

Response to FSIS auditor comments

Defra have explored this isolated audit finding with ALS Chatteris, and we understand that the site policy is that the use of gloves is not currently required during sample preparation or inoculation of media. This policy is also applied at the stage of reading of plates, which is considered to pose a reduced sample contamination risk, and use of gloves at this stage is also based on assessment of risk to employees.

ALS Chatteris have advised that their site policy decision has been taken following consideration of cross-contamination risks. This is based on the laboratory's understanding that where analysts wear gloves over a prolonged period of time, they may become complacent with regards to preventing hand contact. Therefore, staff may have a lowered awareness of the contaminants that may be present on their hands, which can lead to a higher risk of contamination from sample to sample.

In order to mitigate this risk, ALS Chatteris cite that technicians follow aseptic practices, which protect both the sample and technicians from cross contamination. The laboratory managers are confident that, through techniques honed by training, technicians' hands do not come into contact with the sample at any point.

Handwashing is also required on entry and exit from each of the different laboratory areas, and environmental monitoring is carried out. The laboratory communicated that their performance is routinely assessed by internal, supplier and independent audits (including against ISO 17025), and the use of gloves has not been raised as an issue.