



United States Department of Agriculture

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Food Safety and
Inspection Service

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Mr. Robert Huey
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Dear Mr. Huey,

The FSIS onsite audit conducted from September 18 through September 26, 2017, supports that Northern Ireland's inspection system continues to remain equivalent to that of the United States. Enclosed is a copy of the final audit report. The comments received from the Government of Northern Ireland are included as an attachment to the report.

If you have any questions, please feel free to contact Mary Stanley in the Office of International Coordination by email at mary.stanley@fsis.usda.gov or by telephone at (202) 720-0287.

Sincerely,


Todd Furey
Acting International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

NORTHERN IRELAND

September 18 – 26, 2017

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

RAW PORK

EXPORTED TO THE UNITED STATES OF AMERICA

March 13, 2018

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from September 18-26, 2017. The purpose of the audit was to determine whether Northern Ireland's food safety system governing meat remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Northern Ireland is 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 Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditor concluded that Northern Ireland's meat inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. The CCA has implemented sanitary operating procedures and a HACCP system to ensure controls of the meat inspection system. In addition, the CCA has implemented a microbiological and chemical residue testing programs that are organized and administered by the national to verify its system. An analysis of each component did not identify any systemic findings representing an immediate threat to public health.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite audit of Northern Ireland's food safety system from September 18 – 26, 2017. The audit began with an entrance meeting held in Belfast, Northern Ireland with the participation of representatives from the Central Competent Authority (CCA), the Food Standards Agency (FSA)/Department of Agriculture, Environment, and Rural Affairs (DAERA) and the FSIS auditor.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

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

FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, point-of-entry (POE) testing results, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS over a three-year period, in addition to information obtained directly from the CCA through the self-reporting tool (SRT). In addition, the FSIS auditor conducted an onsite verification of the CCA's corrective actions in response to the audit findings reported during the previous FSIS audit in 2016. The FSIS auditor verified that the CCA has effectively implemented its proposed corrective actions.

Representatives from the CCA and local inspection offices accompanied the FSIS auditor throughout the entire audit. 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 Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditor reviewed administrative functions at the CCA headquarters, one regional office, and one local inspection office located within the audited establishment. The FSIS auditor evaluated the implementation of control systems in place that ensure the national system of meat inspection, verification, and enforcement is being implemented as intended.

FSIS audited the one certified establishment currently eligible to export raw pork products to the United States. During the establishment visit, the FSIS auditor paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that threaten food safety. The FSIS auditor examined the CCA's ability to

provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign inspection systems. These requirements are outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) §327.2, the FSIS regulations addressing equivalence determinations for foreign country inspection systems for meat products.

The FSIS auditor went to the Agri-Food and Biosciences Institute (AFBI), a government laboratory conducting microbiological and chemical residue analyses, to verify its ability to provide adequate technical support to the inspection system and assess the CCA’s oversight of laboratory functions. The FSIS auditor also visited Concept Life Sciences, a private laboratory utilized by the establishment for microbiological analysis.

Competent Authority Visits		#	Locations
Component Authority	Central	1	• FSA/DAERA, Belfast
	Regional Office	1	• Meat Inspection Branch, Newry
Laboratories		2	<ul style="list-style-type: none"> • Concept Life Sciences, Moy • AFBI, Belfast <ul style="list-style-type: none"> o Microbiological Division o Chemical Residue Division
Porcine slaughter and processing establishment		1	• Establishment UK 9052, Karro Foods Group, Cookstown

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

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

The audit standards applied during the review of Northern Ireland’s inspection system for meat included: (1) all applicable legislation originally determined by FSIS as equivalent as part of the initial review process, and (2) any subsequent equivalence determinations that have been made by FSIS under provisions of the World Trade Organization’s Sanitary/Phytosanitary Agreement.

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

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

III. BACKGROUND

From July 1, 2014, to June 30, 2017, FSIS import inspectors performed 100 percent POE re-inspection on 13,643,974 pounds of pork products exported by Northern Ireland to the United States. Of that amount, additional types of inspection were performed on 2,985,439 pounds, of which a total of 4,702 pounds were rejected for certificate issues, shipping damage, and label defects. No products were rejected for public health issues.

The FSIS final audit reports for Northern Ireland's food safety system are available on the FSIS Web site at:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishment/foreign-audit-reports>

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

The first of six equivalence components that the FSIS auditor reviewed was Government Oversight. The national government of the foreign country must design and administer an inspection system with standards equivalent to those of the United States.

The evaluation of all the components included a review and analysis of documentation previously submitted by the CCA as support for the responses provided in the SRT. The FSIS onsite audit included record reviews, interviews, and observations made by the FSIS auditor. The audited facilities included two government inspection offices, two government laboratories, and one establishment currently certified as eligible to export to the United States.

The food safety inspection system in Northern Ireland is based on collaboration between the FSA and the DAERA through the Veterinarian Service Animal Health Group (VSAHG) and the Veterinarian Public Health and Trade Program (VPHTP). The Food Standards Act of 1999 established the FSA, as the CCA for food safety. The FSA-Northern Ireland (FSA-NI) designates DAERA/VPHTP to implement inspection, verification, audit, and enforcement duties in the approved establishment, under the terms of a Service Level Agreement. The DAERA also develops animal health, animal welfare policy and verifies products shipped are meeting United States Export requirements.

The FSA has an office in Belfast and is responsible for delegated matters relating to food safety, standards, nutrition, and dietary health in Northern Ireland. The FSA is responsible for advising the Ministries, developing policy and legislation, effective response to food and feed incidences, setting standards, and auditing food and enforcement activities.

The VPHTP is a veterinary service delivery unit of the DAERA/VSAHG. The VSAHG is the integrated veterinary service providing public health, animal health, and animal welfare controls in Northern Ireland. The VPHTP has a veterinary public health (VPH) element and a trade element. The VPH element delivers official controls and activities for both the DAERA and the FSA in the slaughter establishment. The Trade Program (TP) element of the VPHTP mainly facilitates trade.

A Senior Principal Veterinary Officer (SPVO) leads the VPHTP. For the purposes of management, the VPH element of the program is split into regions, with each region being managed by a Divisional Veterinary Officer (DVO) or Supervisory Veterinary Officer (SVO). Each DVO/SVO manages a number of Official Veterinarians (OVs), who are responsible for the official controls and activities at the establishment level. The Senior Meat Inspectors (SMIs) manage and deploy the Meat Inspectors (MIs) to assist the OVs as required. Other technical and administrative colleagues support the VPH functions.

The Official Veterinary Advisor (OVA) assists the DVO/SVO by providing mainly technical support to the OVs, and the Technical Advisor, a SMI, bridges the gap between technical and administrative issues in relation to delivery to the FSA. The SMIs are responsible for staffing and utilize a computerized staff report to ensure daily inspection coverage. All permanent OVs and the MIs are employees of the DAERA. The FSIS auditor verified payment of the VPHTP salaries, by the government, for employees at the headquarters, regional offices, and establishment.

In Northern Ireland, veterinarians are recruited as government veterinary officers, and then trained as the OVs to undertake meat hygiene inspection work. To be eligible for training to become an OV, the candidate must hold a veterinary degree and be a current member of the Royal College of Veterinary Surgeons. The employment qualifications for meat inspectors are defined in the European Commission (EC) Regulation No. 854/2004.

The FSIS auditor reviewed a copy of the updated VPHTP Manual for OV Training. The manual describes the training process and requirements pursuant to EC requirements for OVs. The DAERA/VPHTP also develops a training plan each year that targets particular needs, includes regular training updates, and adds any technical training that has been identified throughout the year. Regular training events include the VPHTP annual seminars and management meetings. E-learning modules are available to the FSA officials and the DAERA officers.

The DAERA/VPHTP has a central administration team which currently coordinates dissemination of briefings, updates to new staff instruction releases, legislation, and other information to all relevant staff in the VPHTP. In addition, the VPHTP OVs assigned to the United States-eligible establishment sign up for FSIS email alerts announcing revised requirements and policies. The DAERA's Hewlett Packard Records Management system (HPRM), an electronic document management system, includes containers (folders) for VPHTP training as demonstrated at the divisional office. The DVO provided documents and explained the process for training assessors to review the candidate's OV classroom hours and scores and practical experience (portfolio of experience). The DVO provided an example Assessment of Practical Application (Annex 6) as defined in Regulation (EC) No. 854/2004.

The FSIS auditor verified through interviews with inspection personnel, and review of identification cards, that they are government employees. In addition, the FSIS auditor noted that all inspection personnel are evaluated for their competence before being assigned to the certified establishment, with the outcomes of these evaluations documented in accordance with the CCA's requirements.

The DAERA's VPHTP OV's carry two official forms of identification. The FSA-NI issues one that provides authority for enforcement actions in accordance with EC legislation, while the DAERA identification documents the authority to enforce Northern Ireland legislation. Each badge includes a photograph of the employee, an official ID number, and lists the legislative authorities for the employee. The final authorization to become an OV is provided by the FSA with the DAERA's recommendation and confers the FSA badge and authority as an official veterinarian for export purposes. The DAERA veterinarians performing other than export activities carry the separate DAERA badge, which confers authorities for domestic requirements only. The SOVs and OV's are trained on the United States requirements when assigned to the United States-eligible establishment. The FSIS auditor verified through interviews with inspection personnel and review of identification cards that they are government employees.

Currently, the DAERA has one certified pork slaughter establishment and one certified cold storage facility. The FSIS auditor verified through document reviews and interviews that the establishment only slaughters porcine that are born and raised in Ireland and Northern Ireland. In addition, the establishment is not receiving any raw materials from any other establishment.

The FSIS auditor noted that in accordance with the FSA's Meat Industry Guide Chapter 16, which is based on Regulation (EC) No. 178/2002, the establishment is required to have a written procedure for trace back and recall. The CCA will provide notification to the United States for any exported products affected by a recall through the EU Rapid Alert System for Food and Feed database. If any such product is found to have been certified for export to the United States, then the DEFRA/FSA can provide details to the United States authorities, enabling a recall. The FSIS auditor confirmed that the inspection personnel review and verify the implementation of this requirement at the United States-certified establishment in accordance with the CCA's requirements.

The DEFRA has the authority to certify and de-certify establishment that export to the United States. The DEFRA has empowered the FSA to assess compliance of an establishment with the requirements of the United States and recommend to the DEFRA whether it should be approved (certified) or, if previously approved, to be de-certified. The DAERA/VHPHT has been empowered by the DEFRA/FSA to recommend certification and decertification of establishments for export to the United States and has procedures in place to audit both operational and systems compliance. Under EU food hygiene legislation, meat plants require approval unless they benefit from specific exemptions. The FSA has published a document entitled "*Operational Policy for the Approval of Meat Establishment Undertaken by the FSA*", which outlines requirements the establishment must meet for certification. The respective reports are then completed. The approval audit focuses on establishment structures, procedures and documentation, OV oversight and verification (audit) of procedures by the establishment, and implementation of appropriate corrective action by the establishment management. In Northern Ireland, the DAERA/VPHTP OV's are responsible for initial approval and regular supervisory audits. The FSIS auditor verified certification of the establishment at the headquarters and the establishment without any noted issues.

The CCA also has the authority and responsibility to take enforcement actions in accordance with Regulation (EC) Nos. 178/2002 and 882/2004. Chapter 7 of the VPHTP Manual for Official Controls outlines how to take enforcement actions. The FSIS auditor reviewed documented enforcement actions at the CCA's headquarters and the audited establishment. This included a review of inspection-generated noncompliance reports and follow up enforcement actions. In addition, the FSIS auditor verified that the CCA has a definition for adulterated products that meets FSIS requirements. A review of the inspection-generated records did not raise any concerns regarding the enforcement of the inspection requirements or proper implementation of the establishment's corrective actions in accordance with the CCA's requirements.

The FSIS auditor verified through document reviews and interviews that the CCA has implemented a single standard of laws and regulations in the certified establishment. Supervisors conduct periodic reviews of inspection personnel conducting ante-mortem inspection; post-mortem inspection; humane handling verification; Sanitation Standard Operating Procedures (SSOP), Sanitation Performance Standards (SPS) and HACCP verification; labeling verification; official verification sampling programs; export certification; and official controls over condemned material. The DAERA and the FSA conduct audits on the establishment, in-plant inspection team, and requirements for export to the United States.

The CCA designates official laboratories for analyzing samples taken during regulatory control actions. The United Kingdom Accreditation Service (UKAS) is the official body for laboratory accreditation. The EC has created a network of European Union Reference Laboratories (EURLs) to provide technical and scientific support for the official controls framework. To complete the framework, FSA/DAERA is required to designate a National Reference Laboratory (NRL) to correspond to each EURL. NRLs collaborate with the EURLs in their particular area of expertise and disseminate information provided by the EURL, and coordinate the activities of official laboratories.

The CCA in Northern Ireland utilizes the AFBI as the NRL for the testing of official verification samples collected from products that are destined for export to the United States. The AFBI is accredited to the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025, General requirements for the competence of testing and calibration laboratories, standard by UKAS, the sole national accreditation body recognized by the government to assess, against internationally agreed standards, organizations that provide certification, testing, and inspection and calibration services.

The FSIS auditor verified that the AFBI's internal quality management system carries out annual proficiency testing on its laboratory technicians. The laboratory maintained training records supporting that each technician had been qualified for their assigned duties. The FSIS auditor also verified that the CCA's reviews of intra-lab and inter-lab proficiency testing ensure that each analyst possesses the required competencies necessary to conduct the analyses. The FSIS auditor reviewed the CCA's oversight activities including the CCA's audit reports for the AFBI. No concerns arose as the result of these reviews.

The CCA's meat inspection system has an organizational structure to provide ultimate control, supervision, and enforcement of regulatory requirements for this component.

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

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

The FSIS auditor assessed humane handling, ante-mortem, and post-mortem inspection examinations through onsite record reviews, including a review and analysis of the information provided by the CCA in the updated SRT, interviews, and observations of in-plant inspection personnel performing these examinations in the audited pork slaughter establishment.

The FSIS auditor verified that in-plant inspection personnel are required to conduct ante-mortem inspection in accordance with the CCA's requirements. The OVs conduct ante-mortem inspection on swine by observing all animals upon arrival, which includes checking records, including food chain information covering movement permits and controls of live animals intended for food from farm to slaughter during holding, and movement to slaughter. The FSIS auditor reviewed inspection records and observed execution of ante-mortem procedures that demonstrate proper implementation of the CCA's requirements.

The FSIS auditor also observed implementation of the humane handling programs in the audited pork slaughter establishment. This included the inspection personnel's hands-on verification of the maintenance and conditions of the holding pens, movement of animals, and proper stunning of animals. Additionally, the FSIS auditor reviewed the inspection-generated humane handling verification records documenting the results of their verification activities. The FSIS auditor did not identify any areas of concern during the review of humane handling records and direct observations.

The FSIS auditor verified that in-plant inspection personnel perform post-mortem inspection at the time of slaughter in accordance with the CCA's requirements. An OV provides ante-mortem and post-mortem dispositions as well as compliance verification and oversight. Inspection personnel are required to document post-mortem inspection results, including any retained or condemned carcasses. The FSIS auditor observed the implementation of the CCA's requirements by inspection personnel during post-mortem inspection presentation, identification, examination, and disposition of carcasses and parts.

The FSIS auditor also observed the performance of in-plant inspection personnel examining the heads, viscera, and carcasses to assess whether the proper incision, observation, and palpation of required organs and lymph nodes is conducted in accordance with the CCA's requirements. The FSIS auditor verified that inspection personnel are conducting carcass-by-carcass post-mortem inspection examination during all hours of operation to ensure carcasses are free from pathological conditions or any contamination prior to applying the mark of inspection. Inspection personnel also conduct inspection at least once per shift during fabrication (cut up) of all processing operations.

The CCA requires that the establishment segregates and stores inedible products in a separate area from edible products. In addition, containers used for collecting inedible products must be marked and distinguished from other containers. The FSIS auditor noted that the inspection personnel have the authority and responsibility to detain, denature, and destroy inedible products in accordance with the CCA's regulatory requirements.

The FSIS auditor reviewed both inspection-and establishment-generated records, and observed the disposal process of condemned and inedible materials at the audited establishment and found no concerns. The CCA's meat inspection system has the legal authority and a documented regulatory framework to implement the CCA's regulatory requirements for this component.

VI. COMPONENT THREE: GOVERNMENT SANITATION

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

The FSIS auditor verified that the CCA provides instructions to inspection personnel for the official controls of establishment construction, facilities, and equipment, all of which the inspection system has official control over. The CCA requires that facilities and equipment be constructed in a manner that prevents direct product contamination or creation of insanitary conditions, is maintained in good condition, is installed in such a way that product does not come into direct contact with the floor or walls, and is constructed with materials that facilitate thorough cleaning and disinfection. The CCA has the power to take formal enforcement action to direct the establishment to rectify both hygiene and structural/maintenance deficiencies. The FSIS auditor verified that the CCA provides written verification procedures to inspection personnel on how to verify that the establishment is implementing pre-operational and operational sanitation requirements.

The establishment's sanitary procedures must include the required frequency and a list of the establishment's personnel accountable for conducting sanitary procedures. The establishment is required to take necessary measures to prevent direct product contamination or creation of insanitary conditions. The OV onsite verifies that the establishment implements sanitary dressing procedures throughout the slaughter process on a daily basis in the slaughterhouse. The Manual of Controls (MOC) provides guidance on official control procedures for slaughter hygiene verification (SHV) in the red meat establishment. The inspections system incorporates

verification activities for food hygiene requirements from acceptance of the animals for slaughter, through carcass dressing/offal harvesting and chilling to carcass quartering and offal/co-product packing for dispatch. The verification objective is to provide assurance that only meat that is free from visible contamination and produced in accordance with legislative requirements is allowed to be exported.

The establishment is required to have an SPS system for non-food contact surfaces and an SSOP system for product/food contact surfaces. Continued compliance with the SSOP is part of the approval process for the establishment to be able to continue exporting to the United States. Verification activities are conducted at the time the establishment is approved to export to the United States and on a regular basis thereafter during daily inspection by the OV and the monthly/quarterly audits by the DVO/OVA.

The FSIS auditor reviewed sanitation plans and records related to the design and implementation of sanitation programs in the audited establishment. The FSIS auditor also verified the actual pre-operational inspection verification by shadowing and observing in-plant inspection personnel conducting pre-operational sanitation verification of slaughter and processing areas. The in-plant inspection personnel's hands-on verification procedures started after the establishment had conducted its pre-operational sanitation and determined that the establishment was ready for the in-plant inspector's pre-operational sanitation verification inspection. Inspection personnel conduct and document this activity daily and in accordance with the CCA's established procedures.

The FSIS auditor observed in-plant inspection verification of operational sanitation procedures in all audited establishment and compared their overall sanitary conditions to the inspection verification documentation. Inspection personnel activities included direct observation of operations and review of the establishment's records. The FSIS auditor noted that the CCA requires sanitary dressing of livestock at the slaughter establishment. As a result, the audited slaughter establishment has implemented sanitary procedures to prevent potential carcass contamination throughout the process. These sanitary procedures prevent carcass contamination; prevent direct contact between carcasses during dressing procedures; and prevent carcass contamination with gastrointestinal contents during evisceration. The audited establishment utilized sanitary dressing procedures for each step in the process and monitored their implementation daily.

The FSIS auditor's observations and record reviews including the establishment's sanitation monitoring and corrective action records, as well as those of inspection personnel documenting in-plant inspection verification results or periodic supervisory reviews, did not raise any concerns. The CCA's meat inspection system continues to maintain sanitary regulatory requirements that meet the core requirements for this component.

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

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

The CCA requires each certified establishment to develop, implement, and maintain a HACCP system. The FSIS auditor noted that Northern Ireland's meat inspection system follows EU requirements for the United States-eligible establishment, specifically Regulation (EC) Nos. 854/2004 and 852/2004, where HACCP regulatory requirements are prescribed and found equivalent to 9 CFR §417. This includes a flow diagram, hazard analysis, HACCP plan for hazards identified as likely to occur, monitoring and verification activities, corrective action, reassessment, validation, and record keeping requirements supporting the implementation of the HACCP system.

The establishment's documents must support the decisions made in the hazard analysis and HACCP plan. This supporting documentation includes the validation of the HACCP system. The FSIS auditor verified that VPHTP personnel conduct and document official verification activities related to HACCP in accordance with regulatory requirements. The inspection personnel verification procedures encompass the evaluation of written HACCP plans and verification of HACCP prerequisite programs monitoring, corrective actions, and recordkeeping in accordance with Regulation (EC) Nos. 852/2004 and 854/2004.

The FSIS auditor noted that the audited slaughter establishment has elected to conduct 100 percent monitoring of pork carcasses for the zero tolerance Critical Control Point (CCP) for presence of fecal matter, ingesta, and milk. The FSIS review of the establishment's monitoring and corrective actions records in response to the few observed deviations from the zero tolerance critical limit showed that the establishment took appropriate corrective actions addressing all four parts of the corrective action regulation. The FSIS auditor also reviewed the inspection verification records and observed the in-plant inspection personnel's hands-on verification activities for zero tolerance. The FSIS auditor noted that inspection personnel conduct daily verification of the CCPs in accordance with the CCA's requirements. The physical zero tolerance CCP monitoring and verification location for both the establishment employees and in-plant inspection personnel is before the final wash in the audited slaughter establishment.

The FSIS auditor's HACCP verification activities also included interviews with establishment and inspection personnel and review of the establishment's records that provided supporting documents as part of the decision making process for the HACCP system. The CCA's meat inspection system 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 auditor reviewed was Government Chemical Residue Testing Programs. The 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.

The EC residue regulations meet the United States' equivalence criteria for the residue control program. The EC legislation requires Member States to maintain a chemical residue control program, organized and administered by the national government, which includes random sampling of internal organs and fat of carcasses for chemical residues identified by the exporting country's meat inspection authorities or by FSIS as potential contaminants. EU Member States are responsible for the implementation of: 1) procedures to document disposition of contaminated product, 2) enforcement action against violators, and 3) measures to prevent the recurrence of the same or similar violations.

The Veterinary Medicines Directorate (VMD) is responsible for the implementation of the Residue Monitoring Plan (RMP). The RMP planning group comprises representatives from the VMD, AFBI, the Animal Health and Veterinary Laboratory Agency, FSA, the Food and Environment Research Agency, Marine Scotland Science, the Centre for Environment, Fisheries, Aquaculture Science, and the competent authority-independent Veterinary Residues Committee (VRC).

An annual Statutory Surveillance Program to analyze samples from food producing animals and their products for residues of veterinary medicines and environmental contaminants is in place in the UK. In Northern Ireland, the VSAHG carries out on-farm sampling of cattle, while the VPHTP OVs, authorized by the FSA-NI, take samples in the slaughterhouse.

In Northern Ireland, two residue testing programs outside the RMP are in place: the Meat Inspection Scheme and the Risk Scheme (RS). The Meat Inspection Scheme is analogous to FSIS "suspect" testing and the OV implements the sampling in the slaughterhouse in response to conditions identified during ante-mortem or post-mortem inspection suggesting elevated risk of veterinary drug residues. The VPHTP retains sampled suspect carcasses, pending laboratory results. Carcasses sampled under routine monitoring are not detained pending results, but a non-compliant result will trigger follow-up investigation by VSAHG. This may include follow-up sampling. The RS is similar to the meat testing scheme, but has expanded from analysis for antimicrobials to a multi-residue analytical method.

The Animals, Meat, and Meat Products (Examination for Residues and Maximum Residue Limits) Regulations (Northern Ireland) 1998 as amended implement Council Directive 96/23/EC and Council Directive 96/22/EC in Northern Ireland. These regulations cover all residues (including growth promoting hormones, beta-agonists, antimicrobial substances, and anthelmintics) and all aspects of residue sampling/testing (including primary surveillance testing, sampling/detention/testing/condemnation of suspect carcasses, on-farm investigation and

sampling, and subsequent action). The in-plant inspection team follows these regulations when dealing with animals identified as suspect at slaughter.

AFBI is a non-departmental public body sponsored by the DAERA as an amalgamation of the Science Service and the Agricultural Research Institute of Northern Ireland. The AFBI laboratory network includes the Veterinary Sciences Division (VSD), which has four branches. The Chemical and Immunodiagnostic Sciences branch is responsible for veterinary drug residues as well as pesticides, heavy metals, and mycotoxins. The Residues Action Group is comprised of the DAERA, FSA-NI, and AFBI, and meets at approximately monthly intervals. Attendees represent policy, field, and analytical positions. The purpose includes policy formulation and implementation; review of testing, results, and follow-up actions; reports on quality issues; and reports on turnaround times. The FSIS auditor reviewed examples of meeting minutes and no concerns were identified.

The AFBI VSD laboratory is in possession of multiple accreditations, including those issued by the Department of Health of the Government of the United Kingdom for Good Laboratory Practices; UKAS for ISO/IEC 17025 requirements; and the Societe Generale de Surveillance for ISO 9001, Quality management systems -- Requirements. ISO/IEC 17025 requires proficiency testing and the AFBI VSD proficiency testing sources include the Food Analysis Performance Assessment Scheme, Progetto Trieste, and Community Reference Laboratories. The FSIS auditor reviewed records related to sample handling, sample arrival temperature, sampling frequency, timely analysis, data reporting, analytical methodologies and matrices, equipment operation and detection levels, and quality assurance programs.

The FSIS auditor's review found that the laboratory conditions, records generated, and results of past UKAS audits met ISO/IEC 17025 standards. The FSIS auditor did not identify any findings or areas of concern during the audit of the official laboratory. The FSIS auditor concluded that laboratory personnel are qualified, adequately trained, subject to proficiency testing, capable of conducting analytical methods, and that the residue laboratory demonstrated the ability to produce timely and accurate data.

The FSIS auditor concluded that the CCA's meat inspection system has regulatory requirements for a chemical residue testing program that is organized and administered by the national government.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

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

Northern Ireland has adopted *Enterobacteriaceae* and Total Viable Count (TVC) in lieu of generic *E. coli* for porcine carcass testing, which FSIS has determined is acceptable for EU member states eligible to export to the United States. Sampling and testing is the responsibility

of the establishment. The VPHTP inspection personnel assigned to the slaughter establishment are responsible for verification that establishments' sampling and testing is adequate. The FSIS auditor performed an onsite visit of the private laboratory performing *Enterobacteriaceae*, TVC, and *Salmonella* sample analysis for the slaughter establishment. Concept Life Sciences is the laboratory that performs the TVC testing and is accredited by the UKAS.

The FSIS auditor observed and verified sample receipt and handling procedures, testing methodology, timely analysis of samples, data reporting, equipment operation, technical training, and intra-lab competencies. In addition, the FSIS auditor reviewed the most recent audit report issued by the UKAS. The FSIS auditor noted that Concept Life Sciences also performs its internal audits according to the Quality Assurance Manual.

Currently, the VPHTP personnel collect carcass swabs for *Salmonella* performance standards consistent with the requirements of 9 CFR §310.25. Official *Salmonella* samples are analyzed at the AFBI Sustainable Agri-Food Sciences Division (SAFSD), Food Science Branch (microbiology) laboratory, which was included in the scope of the audit. *Salmonella* samples are analyzed using FSIS testing methodology. The FSIS document audit of the AFBI SAFSD laboratory focused on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples. The FSIS auditor reviewed a sample of test results. The AFBI performs serotyping on all positive test results and includes the results in the sample report. The FSIS auditor did not identify any concerns during the audit of the AFBI SAFSD laboratory.

Additionally, the establishment is also required to collect, and have analyzed *Salmonella* carcass swabs in accordance with Regulation (EC) No. 2073/2005. During the FSIS audit, review of *Salmonella* sample results verified that the most recent 20 samples spanning four weeks' in duration were all negative. The CCA, OV, and OAs including regional supervision, demonstrated active involvement and verification of establishment corrective actions, though no enforcement actions had been taken during this period. The FSIS auditor verified sanitary dressing practices and overall sanitary procedures during the audit. The FSIS audit of the regional office verified that supervisory visits include an emphasis on microbial sampling programs and process hygiene controls at the slaughter establishment.

During the AFBI audit, the FSIS auditor observed and verified sample receipt and handling procedures, testing methodology, timely analysis of samples, data reporting, equipment operation, technical training, and intra-lab competencies. In addition, the FSIS auditor reviewed the most recent audit report issued by the UKAS. The FSIS auditor noted that AFBI also performs its internal audits according to the Quality Assurance Manual. The FSIS auditor's observation of the laboratory processes and review of the laboratory documents including the annual audit reports and corresponding follow-up reports found no concerns within the CCA's documentation of its laboratory oversight activity.

The CCA's meat inspection system has a microbiological testing program that is organized and administered by the national government. In addition, the CCA has implemented sampling and testing programs to verify its system.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on September 26, 2017, in Belfast, Northern Ireland with the CCA. The FSIS auditor concluded that Northern Ireland's meat inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. The CCA has implemented sanitary operating procedures and a HACCP system to ensure controls of the meat inspection system. In addition, the CCA has implemented a microbiological and chemical residue testing programs that are organized and administered by the national to verify its system. An analysis of each component did not identify any systemic findings representing an immediate threat to public health.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklist

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Karro Foods Group Cookstown, Northern Ireland	2. AUDIT DATE 9/19/2017	3. ESTABLISHMENT NO. UK 9052	4. NAME OF COUNTRY Northern Ireland
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
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.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

10- A belt, which is a food contact surface, utilized to transfer product during production was worn with rough edges and gouges on the surface.

15- The establishments HACCP plan for the monitoring of Nitrate critical limit did not include a calibration verification procedures for the monitoring equipment.

Appendix B: Foreign Country Response to Draft Final Audit Report

From the Chief Veterinary Officer
Robert J Huey



Department of
**Agriculture, Environment
and Rural Affairs**

www.daera-ni.gov.uk

Mary H. Stanley
United States Department of Agriculture
Food Safety and Inspection Service
The Office of International Co-ordination
Room 3143
1400 Independence Avenue, SW
Washington, D.C 20250
Email to: mary.stanley@fsis.usda.gov

Room 716, Dundonald House
Upper Newtownards Road
Ballymiscaw
Belfast BT4 3SB
Telephone: 028 9052 4643
Email: Robert.Huey@daera-ni.gov.uk

25 January 2018

Dear Mary,

FOOD SAFETY AND INSPECTION SERVICE (FSIS) ON SITE AUDIT NORTHERN IRELAND - 18-26 SEPTEMBER 2017 - DRAFT FINAL REPORT

Thank you for your letter and the accompanying draft final report, which I received on the 05 January 2018, of the FSIS audit on Northern Ireland's meat inspection system.

I am grateful for the work undertaken by the auditor during his visit and in compiling this comprehensive draft report. My officials have considered the report closely and in response please see the following;

Appendix A - which provides details on corrective actions taken to address the non-compliances as outlined in draft report at the establishment audited.

Appendix B - containing comments for consideration in relation to details contained in report relating to the Agri-Food and Biosciences Institute.

Kind regards.

Yours sincerely,

R J HUEY
Chief Veterinary Officer

If you are deaf or have a hearing difficulty you can contact the Department via the Next Generation Text Relay Service by dialling 18001 + telephone number.



Subject: Comments from DAERA regarding observation of establishment:

**Karro Food Group –UK 9052
70 Molesworth Road
Cookstown
Co Tyrone**

Extract from report: Appendix B

60. Observations of the Establishment:

10- A belt, which is a food contact surface, utilized to transfer product during production was worn with rough edges and gouges on the surface.

15- The establishments HACCP plan for the monitoring of Nitrate critical limit did not include a calibration verification procedures for the monitoring equipment.

DAERA comments regarding Corrective Actions:

Please see attached documents relevant to closure of audit non compliances;

1. **Karro Corrective action plan:** signed off by Dr W. Gilmore Official Veterinarian (OV) with responsibility for the establishment audited, verifying completion of required corrective actions for points 10 &15.



Appendix A No. 1
KARRO Corrective Ac

2. **HACCP Amendment Log:** record for HACCP updated 20/09/17 to include calibration verification to address non-compliance point 15.



Appendix A - No. 2
HACCP Amendent lo

3. **Cured Product HACCP Master Sheet dated 20/09/17:** which includes calibration verification (highlighted in yellow) to address non-compliance point 15.



Appendix A No. 3 -
Cured Products Mas

4. **Karro Belt:** Picture showing new belt installed to correct non-compliance point 10. (jpeg attached)



CORRECTIVE AND PREVENTIVE ACTION PLAN

Name of Establishment: Karro Food Ltd.	Establishment Address: 70 Molesworth Road, Cookstown, Co Tyrone
Plant number : UK 9052 EC	Audit date: 19/09/2017
Date prepared 08/11/2017	Third Country conducting Audit USDA
Prepared by: Leanne Woods QA Manager QC Supervisor / Production Supervisor / Production Manager (Name & Designation of establishment's authorized representative)	Approved by: Mary Jo McPeake Technical Manager Owner/Management Representative (Name & Designation of establishment's authorized representative)

Deficiency number (1)	Description of Deficiency (Please affix picture if possible) (2)	Corrective Action and Preventive Actions (3)	Evidence of compliance (please take a picture/photo after the institution of Corrective Action) (4)	Completion or proposed completion date dd/mm/yyyy (5)	Person Responsible (6)	Verified by the on-site OV (7)
1	Hind foot belt discoloured with chemical residual and cut marks	<p>Re-cleaned at time of audit and inspected for loose plastic.</p> <p>New belt to be installed</p> <p>As part of the preoperational integrity checks the structural integrity of the belt will be assessed.</p> <p>If damage is found the necessary links will be removed and repaired until the replacement belt is in place.</p>	<p>Ref 1: Pre-operational check sheets</p> <p>Ref 1: Photo of hind foot belt.</p>	20/10/2017 Completed on 24/10/2017	Alan Spiers	<p>Daera meat inspection team monitored the integrity of the belt through preoperative and operational checks since the audit and found no problems during this period. New belt was installed on 24/10/2017. William</p>



W. Spiers
8/11/2017

CORRECTIVE AND PREVENTIVE ACTION PLAN

Deficiency number (1)	Description of Deficiency (Please affix picture if possible) (2)	Corrective Action and Preventive Actions (3)	Evidence of compliance (please take a picture/photo after the Institution of Corrective Action) (4)	Completion or proposed completion date dd/mm/yyyy (5)	Person Responsible (6)	Verified by the on-site OV (7)
2	Master documentation of the HACCP did not detail the calibration of the Nitrite analysing equipment.	HACCP updated to include annual calibration. HACCP Annual review	Ref 2: HACCP master check sheet Ref 3: Review record of HACCP amendment	20/09/2017	MIMCP	Gilmore OV 08/11/2017 HACCP documentation has been updated to include calibration of nitrite analysing equipment. William Gilmore OV 08/11/2017



W. Gilmore
08/11/2017

Master sheet

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for Each Control Measures	Monitoring Procedures			Corrective Action	Verification	Records
			What	How	Frequency			
CCP 1	C: Chemical B: Bacteria Multiplication	As per brine matrix for salt/nitrite USDA Brines ~ 18.5-21.5% Salt 900-1300ppm Nitrite	Brine	Analysis	Every Brine	Trained Line Operative	<p>1) Technical Management verifies process control each working day by independent chemical analyses and by observation of the monitoring procedure twice per day</p> <p>In the event of a failure during the verification process the brine must be disposed off</p> <p>Management to complete an corrective action report 18/002/001 which details cause of deviation, measures taken to keep the ccp under control and prevent a reoccurrence.</p> <p>Records Daily reviewed by QA Technician</p> <p>External calibration of spectrometer minimum annually</p>	<p>Records: Brine analysis make up sheet 26/001/001</p> <p>Corrective action record 18/002/001</p> <p>Laboratory records for chemical and Micro analyses.</p> <p>Calibration records</p>
						<p>1) If a brine sample fails, the brine shall be classified as unfit and disposed of. Production Management to ensure that the failed brine is disposed of.</p> <p>2) A new brine to be made and positively released prior to production commencing</p> <p>3) The Production Management to complete an corrective action report 18/002/001 which details cause of deviation, measures taken to keep the ccp under control and prevent a reoccurrence.</p>		

Appendix B - Agri-Food Biosciences Institute - comments

Red highlighted text contains comments for consideration.

Green highlighted text indicates the section to which comments relate.

REFERENCE: IV Component One; Government Oversight –page 6.

The CCA designates official laboratories for analyzing samples taken during regulatory control actions. The United Kingdom Accreditation Service (UKAS) is the official body for laboratory accreditation. The EC has created a network of European Union Reference Laboratories (EURLs) to provide technical and scientific support for the official controls framework. To complete the framework, SA DAERA is required to designate a National Reference Laboratory (NRL) to correspond to each EURL. NRLs collaborate with the EURLs in their particular area of expertise and disseminate information provided by the EURL, and coordinate the activities of official laboratories.

Comment: NRL is appointed by VMD on behalf of DEFRA.

REFERENCE: IV Component One; Government Oversight –page 6.

The CCA in Northern Ireland utilizes the AFBI as the NRL for the testing of official certification samples collected from products that are destined for export to the United States. The AFBI is accredited to the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025, General requirements for the competence of testing and calibration laboratories, standard by UKAS, the sole national accreditation body recognized by the government to assess, against internationally agreed standards, organizations that provide certification, testing, and inspection and calibration services.

Comment: AFBI is appointed as the official controls laboratory by CCA NI. NRL function for AFBI only applies to banned veterinary drugs and this is assigned by DEFRA.

REFERENCE: VIII Component Five; Government chemical residue testing programs-page 11.

The Veterinary Medicines Directorate (VMD) is responsible for the implementation of the Residue Monitoring Plan (RMP). The RMP planning group comprises representatives from the VMD, AFBI, the Animal Health and Veterinary Laboratory Agency, FSA, the Food and Environment Research Agency, Marine Scotland Science, the Centre for Environment, Fisheries, Aquaculture Science, and the competent authority-independent Veterinary Residues Committee (VRC).

Comment: Should read "Animal and Plant Health Agency"

REFERENCE: VIII Component Five; Government chemical residue testing programs-page 12.

The AFBI VSD laboratory is in possession of multiple accreditations, including those issued by **the Department of Health of the Government of the United Kingdom for Good Laboratory Practices**, UKAS for ISO/IEC 17025 requirements; and the Societe Generale de Surveillance for ISO 9001, Quality management systems -- Requirements. ISO/IEC 17025 requires proficiency testing and the AFBI VSD proficiency testing sources include the Food Analysis Performance Assessment Scheme, Progetto Trieste, and Community Reference Laboratories. The FSIS auditor reviewed records related to sample handling, sample arrival temperature, sampling frequency, timely analysis, data reporting, analytical methodologies and matrices, equipment operation and detection levels, and quality assurance programs.

Comment: AFBI no longer holds GLP accreditation. The highlighted section can be removed

REFERENCE: Component Six; Government microbiological testing programs-page 13

Currently, the VPHTP personnel collect carcass swabs for *Salmonella* performance standards consistent with the requirements of 9 CFR §310.25. Official *Salmonella* samples are analyzed at the **AFBI Sustainable Agri-Food Sciences Division (SAFSD), Food Science Branch (microbiology) laboratory**, which was included in the scope of the audit. *Salmonella* samples are analyzed using FSIS testing methodology. The FSIS document audit of the **AFBI SAFSD laboratory** focused on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples. The FSIS auditor reviewed a sample of test results. The AFBI performs serotyping on all positive test results and includes the results in the sample report. The FSIS auditor did not identify any concerns during the audit of the AFBI SAFSD laboratory

Comment: Food micro is now part of bacteriology branch, VSD, albeit located on the Newforge Lane AFBI site. Text needs to be revised to reflect this.