



United States Department of Agriculture

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Food Safety and
Inspection Service

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Washington, D.C.
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Mr. Robert Huey
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Dear Mr. Huey,

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Northern Ireland's meat inspection system from June 5 through June 13, 2014. 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 regarding the FSIS audit or need additional information, please contact me at telephone number (202) 720-8609, by facsimile at (202) 720-0676, or electronic mail at international.audit@fsis.usda.gov

Sincerely,

A handwritten signature in blue ink, appearing to read "Shaukat H. Syed".

Dr. Shaukat H. Syed
Director
International Audit Staff
Office of Investigation, Enforcement, and Audit

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN
NORTHERN IRELAND

June 5 – 13, 2014

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING
THE PRODUCTION OF MEAT
PRODUCTS INTENDED FOR EXPORT TO
THE UNITED STATES OF AMERICA

April 3, 2015
Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from June 5 – 13, 2014, to determine whether Northern Ireland's food safety system governing the production of meat and meat products remains equivalent to that of the United States with the ability to produce products that are safe, wholesome, unadulterated, and properly labeled. Northern Ireland exports only pork products to the United States. The scope of the current onsite audit included the following audit sectors: the CCA's Headquarter Office; Newry Divisional Veterinary Office, one public microbiological laboratory, one private microbiological laboratory, and one chemical residue laboratory.

The audit was designed to determine the equivalence of Northern Ireland's meat inspection system and focused on six main system components: (1) Government Oversight; (2) Statutory Authority and Food-Safety Regulations; (3) Sanitation; (4) Hazard Analysis and Critical Control Points (HACCP) Systems; (5) Chemical Residue Control Programs; and (6) Microbiological Testing Programs. FSIS last audited Northern Ireland in 2009, and as a result of that audit, no establishments were delisted or received a notice of intent to delist (NOID). Northern Ireland did take corrective actions in response to the deficiencies that FSIS found in the 2009 audit, and the auditor in the June 2014 audit verified those corrective actions. In preparation for the audit, the auditor examined the FSIS Point-of-Entry (POE) findings since January 2013 and found that no product refused entry for food safety reasons.

The 2014 audit results indicate that the Northern Ireland's food safety inspection system is performing at an "adequate" level meeting most of the core criteria for all six equivalence components. FSIS identified operational (or procedural) weaknesses related to sanitation verification, laboratory recordkeeping, and the CCA's verification control over a private laboratory conducting microbiological testing on product destined for the United States export. However, none of these findings were significant enough as to raise a question about Northern Ireland's on-going equivalence.

The FSIS auditor discussed these issues with the CCA at the exit meeting on June 13, 2014, in Belfast, Northern Ireland. The CCA understood and accepted the nature of the audit findings and had already begun to address the audit findings identified in the sanitation component by implementing immediate corrective actions. For the findings related to CCA's oversight over the private laboratory, FSIS needs a response from the CCA within 60 days to evaluate the CCA's proposed corrective actions.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an equivalence verification audit of Northern Ireland's meat inspection system from June 5 – 13, 2014. Northern Ireland is eligible to export raw and processed pork products to the United States.

Between January 1, 2013 and March 31, 2014, Northern Ireland exported 2,580,777 pounds of raw intact pork cuts. An analysis of POE findings between January 1, 2013 and March 31, 2014, show that a total of 477 pounds of exported product to the United States was rejected at point-of-entry but for reasons other than public health concerns.

This audit was conducted pursuant to the specific provisions of the United States laws (United States Code, U.S.C.) and regulations (Code of Federal Regulations, CFR), in particular:

- Federal Meat Inspection Act (21 U.S.C. 601 et seq.),
- Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901-1906), and
- Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/HACCP regulations

The audit standards that were applied included all applicable legislation and procedures originally determined by FSIS to be equivalent as part of the initial equivalence process for Northern Ireland and any subsequent equivalence determinations that have been made under provisions of the Sanitary/Phytosanitary Agreement and the European Community/United States Veterinary Equivalence Agreement were also applied.

- Regulation (EC) 852/2004
- Regulation (EC) 853/2004
- Regulation (EC) 854/2004
- Regulation (EC) 2073/2005
- Directive 96/22/EC
- Directive 96/23/EC
- Directive 2004/41/EC

II. AUDIT GOAL AND OBJECTIVES

FSIS' overall goal for the audit was to verify that Northern Ireland's food safety inspection system governing meat products continues to be equivalent to that of the United States, with the ability to produce and export products that are safe, unadulterated, wholesome, and properly labeled. To achieve this goal, the audit focused on six equivalence components to determine whether each component continues to be equivalent to that of the meat inspection system of the United States: (1) Government Oversight, (2) Statutory Authority and Food-Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Points (HACCP) Systems, (5) Chemical Residue Control Programs, and (6) Microbiological Testing Programs.

The FSIS auditor verified that the Central Competent Authority (CCA) implemented corrective actions to address deficiencies related to the HACCP and Sanitation components at the slaughter/processing facility reported by FSIS in the FY2009 audit.. During the FY2014 audit, FSIS examined the one slaughter/processing establishment that is eligible to export raw and processed pork products to the United States.

III. AUDIT METHODOLOGY

FSIS utilized its established four-phase process to conduct this equivalence verification audit - plan, execution (on-site), evaluation, and feedback. Each phase is described below.

The first phase involves document and data analysis of previous audit findings, corrective actions and other available information. The FSIS auditor examined the CCA's performance within the six equivalence components, data on exported product types and volumes, POE testing results, and other data collected since the last FSIS audit in 2009. Northern Ireland had a single slaughter/processing and a certified cold storage facility eligible to export to the United States and the 2009 audit covered both facilities. The issues identified during the audit conducted 2009 were related to HACCP and Sanitation components and limited to the slaughter/processing facility. In addition, the FSIS auditor reviewed information obtained directly from the CCA, through the Self-Reporting Tool (SRT), outlining the structure of the inspection system and identifying any significant changes that have occurred since the last FSIS audit.

The second phase was the on-site verification audit. FSIS verified the CCA's oversight activities as they relate to each equivalence component. The FSIS auditor gathered data on all six components through document reviews, interviews, observations made during the onsite visits to all audit locations. The FSIS auditor was accompanied throughout the audit by representatives from the CCA, Department of Agriculture and Rural Development (DARD).

Management, supervision, and administrative functions were reviewed at the CCA headquarters, one divisional veterinary office and at the one pork slaughter/processing establishment eligible to export to the United States to determine whether the national system of inspection, verification, and enforcement was being implemented as required to maintain equivalence. During the establishment visit, particular attention was paid to the extent in which the CCA ensured the control of hazards and prevented non-compliances that threatened food safety, with an emphasis on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with 9 CFR Part 327.2.

The FSIS auditor assessed the CCA's oversight activities for approved chemical residue and microbiology laboratories during the planning phase and this execution phase. FSIS reviewed laboratory related data collected prior to the 2014 audit through an analysis of information in the SRT and the submitted documents. Second, at the CCA's headquarters, FSIS conducted interviews of government officials and reviewed the CCA's documents related to oversight of laboratories involved in analytical testing of export products to the United States. In addition, FSIS audited the Microbiological Division of the Agri-Food and Bioscience Institute, a non-departmental public laboratory, which conduct testing under their HACCP/Pathogen Reduction system on fresh pork products intended for export to the United States. The audit also included a

visit to Elite Technical Laboratories Ltd, a private laboratory to evaluate its analytical testing program for *Enterobacteriaceae* and Aerobic Colony Count used to assess sanitary dressing of swine carcasses.

In preparation for the on-site visit to the Chemical Residue Laboratory (a branch of Agri-Food and Bioscience Institute), the FSIS auditor reviewed the results of chemical residue testing plan for 2013 and then reviewed the chemical residue plan for year 2014. Although, there is one single Chemical Residue plan for the United Kingdom¹, the samples for testing for residues are analyzed in a laboratory in Northern Ireland.

The third phase of the audit is evaluation. FSIS conducted an evaluation of all data collected during the on-site audit through direct observations, record review, and interviews to determine whether the CCA's performance is consistent with the information provided to FSIS in the SRT and other submitted documents. FSIS conducted an exit meeting with the CCA representatives to convey all audit findings and discuss next steps.

The final phase of the audit is feedback, which begins with this draft audit report providing the CCA with an opportunity for comment. After reviewing the CCA's comments and responses to all findings, FSIS prepares a final report. The CCA develops an action plan to address any issues raised by the audit, and FSIS monitors resolution of all issues.

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT

The first of the six equivalence components reviewed was Government Oversight. The FSIS import eligibility requirements state that an equivalent foreign inspection system must be designed and administered by the national government of the foreign country with standards equivalent to those of the United States' meat inspection system. The evaluation of this component included a review of the documentation submitted by the CCA as support for the responses and corrective actions, as well as on-site record reviews, interviews, and observations made by the FSIS auditor at government offices and in the audited establishment.

The food safety inspection system in Northern Ireland is based on collaboration between the Food Standards Agency (FSA) and the Department of Agriculture and Rural Development (DARD). The FSA is the CCA for food safety and standards. It has an office in Belfast and works closely with DARD. The FSA was established in calendar year 2000 as non-ministerial government department in the United Kingdom. In Northern Ireland, the FSA is responsible for matters relating to food safety, standards, nutrition and dietary health. Other notable areas where FSA plays crucial roles which interest FSIS include:

- Set standards and auditing meat hygiene in Northern Ireland,
- Set standards and auditing district councils' food enforcement activities,
- Develop policy,
- Propose legislation, and
- Issue Food Alerts.

¹ England, Northern Ireland, Scotland, and Wales are parts of United Kingdom. Currently England and Northern Ireland are eligible to export meat product to the United States.

A staff of senior managers supports the FSA directorate in Belfast, Northern Ireland. For the delivery of food safety related affairs, the duties are distributed among Operational Policy & Delivery, Local Authority Policy & Delivery and Consumer Protection teams.

Under a Service Level Agreement (SLA) between the FSA and DARD, the latter is responsible for the delivery of meat inspection in the Northern Ireland on behalf of the FSA. As such, the Veterinary Public Health Program (VPH) an agency within Veterinary Service (VS) in DARD primarily administers the meat inspection system in Northern Ireland. Under the terms of SLA DARD-VPH and FSA-Northern Ireland officials meet every six weeks to discuss issues of mutual interest surrounding meat inspection in Northern Ireland.

While VPH carries out the official controls in the United States-eligible slaughter/processing establishment, VS provides a team of trained enforcement officers. According to the Annual Establishment Certification for 2014, Northern Ireland continues to have one slaughter/processing establishment and one cold storage facility receiving raw intact pork from the aforementioned establishment eligible to export to the United States.

According to the information gathered during the audit of the VPH at DARD's Headquarters in Belfast, the FSIS auditor learned that since the last FSIS audit in 2009, there has not been any significant changes in the manner the inspection system operates, except that at the CCA level, the deputy chief veterinary (CVO) officer has replaced the retired CVO. The deputy CVO's position is vacant and assigned temporarily to a senior staff member. As noted in the CCA's response to this audit report (Appendix B), the Deputy CVO is no longer a temporary appointment.

In the United Kingdom, FSA has published a manual outlining the responsibilities of the CCA in verifying the compliance of industry with all applicable laws and regulations, and of the industry in meeting its regulatory obligations. This manual in Northern Ireland is known as VPH- Manual for Official Control (VPH-MOC). The manual has been developed to meet the regulatory requirements contained in article 8 of (EC) Regulation 882/2004 pertaining to enforcement of official controls in approved slaughter/processing and standalone-cutting plants in the United Kingdom and in Northern Ireland by officials of VPH and DARD.

During interviews conducted at DARD's HQ in Belfast, the FSIS auditor determined that the department's employed veterinarians and inspectors carry out the practical inspections and ensures the correct application of FSIS requirements in the certified establishments. At the time of the audit, the inspection staff in VPH comprised of 30 Official Veterinary Surgeons (OVS), 10 Senior Meat Inspectors (SMI) and 82 Meat Inspectors (MI) and 10 Poultry Inspectors to oversee the compliance of meat businesses including establishments eligible to export to the United States. The above staffing is organized into 20 Meat Inspection Teams (MIT). Each MIT is led by an Official Veterinarian (OV) and consist of SMIs, MIs and poultry inspectors. The entire inspection structure in Northern Ireland is geographically based and for inspection purposes is comprised of four divisions. A Divisional Veterinary Officer (DVO) supervises each division. The United States-eligible slaughter/processing establishment and cold storage facility in Northern Ireland are located in Meat Inspection Branch South East..

In order to verify the VPHP's authority and ability to require corrective actions when a deviation from a critical limit or noncompliance occurs that may jeopardize the product safety, the FSIS auditor reviewed examples of the establishment's records for HACCP and Sanitation. The FSIS auditor reviewed the supervisory reviews conducted at the establishment by the DVO and interviewed the VPHP inspection team assigned to the establishment. The FSIS auditor correlated the daily inspection verification records with those of the establishment for the same period. The FSIS auditor concluded that the VPHP inspection team exercised its authority to require corrective actions and verified the implementation and effectiveness of the corrective actions taken by the establishment. The OV ensured that the establishment meets the requirements of importing countries outside the EU in accordance with article 12 of Regulation (EC) Regulation 178/2002.

The review of the SLA between the FSA and DARD-VPHP indicates the latter as the responsible entity to verify compliance of establishment for approval or dismissal of a noncompliant approved establishment. As such all meat hygiene official controls in approved slaughter/processing plants in Northern Ireland are carried out by DARD-VPHP on behalf of the FSA under the terms of the agreement mentioned above.

The FSIS auditor verified that all DARD-VPHP's OVs and MIs working in the certified establishment in Northern Ireland were appropriately qualified. The procedures reviewed for employment and training confirmed that new entrants satisfy the recruitment process and receive appropriate training, as required in Regulation (EC) 854/2004, Annex I, section III, chapter IV, before being recommended by DARD for the final appointment to the FSA. With regard to the training of new hires, the FSIS auditor reviewed documentation on the Probationary Official Veterinarian-Attendance Log and Portfolio of Experience and DARD-VPHU Manual for OV training.

The FSIS auditor verified that the OV and his team assigned to the establishment are full time employees of DARD and are paid by the government. The inspection team led by OV maintains daily inspection in the slaughter/processing establishment which exports raw pork meat products to the United States.

The SLA identifies DARD-VPHP as the responsible entity to recruit qualified and competent veterinarians and inspectors to be assigned at the United States-eligible establishment. The veterinary program has written policy defining the academic, skills, and experience requirements for all types of positions in the VPHP. To be qualified to work as an OV veterinarian the individual must possess a membership from Royal College Veterinary Surgeons (MRCVS).

Prior to an appointment to a position, an OV must complete a three weeks course offered at either Glasgow or Bristol University or complete the training requirement through an on-line course. The pre-appointment training requirement can also be satisfied by attending a course arranged by DARD VPHU. The OVs involved in auditing a business' compliance including United States requirements receive additional training on audit skills. In addition to the training requirements detailed above, the DARD VPHP has an on-going training program. Under the program, a United States-based HACCP consulting group was contracted to deliver the training

on food safety programs. The DARD-VPHP has also been actively participating in FSIS held international seminars for foreign meat poultry and egg products inspection system officials. The FSIS auditor reviewed these programs, which included the DARD VPHP Manual for OV training; the syllabus for the training; and documents pertaining to the probationary requirement of new hires and concluded the inspection system meets the FSIS criteria for the assignment of competent qualified inspectors.

From a review of the information contained in the SRT, the pertinent sections of the VPHP-MOC, and the observations made during the OV led establishment audit, the FSIS auditor determined that the CCA verifies the establishment's compliance with the regulatory requirements pertaining to handling of condemned materials, establishment construction, facilities, and equipment.

In order to verify daily inspection implementation, the FSIS auditor reviewed selected documents from the establishment's food safety programs and the inspection system records of daily verification activities. These documents included records for daily ante-mortem and post-mortem inspection, carcass and part condemnation, noncompliance records, HACCP, SSOPs, and pre-shipment reviews. The documents reviewed covered the same time period for both establishment and inspection staff. All formal enforcement actions taken by the OV are recorded on VPH11 titled "enforcement record" with informal enforcement recorded on form VPH01. All corrective actions (the remedial action request) are recorded on official form VPH13. No concerns arose as a result of FSIS auditor's review of this component.

The FSIS auditor examined the supervisory review records and the protocols followed to conduct reviews in the establishments eligible to produce product for export to the United States. The DVO from Newry Divisional Office conducts quarterly reviews at this establishment. The reviews are documented on official form, titled "USDA approved establishment-Audit Report." The reviews covered the following major areas of the establishments' food safety system including but not limited to:

- SSOP (Basic and Ongoing Requirements),
- HACCP (Basic and Ongoing Requirements),
- Sampling (Aerobic colony count and *Enterobacteriaceae* and *Salmonella* Performance Standards), and
- Other Requirements (Sanitation Performance Standards and labeling Economic sampling including, labeling, net weight, and residue testing etc.).

The overall condition of the audited establishment is the same as documented in the supervisory periodic review reports except some concerns were identified in the sanitation component. During the onsite audit of the slaughter/processing establishment, it was noted that supervisory reviews failed to capture concerns pertinent to the requirements for sanitation and sanitary handling of the product. This failure indicates a weakness in the reviews and a need for improvement in delivering oversight at the United States-eligible establishment over the official activities conducted by inspection personnel.

To facilitate the understanding of national and EU regulations and correct implementation by the meat industry, the Food Standard Agency (FSA) in December 2006 published "Meat Industry

Guide (MIG).” The MIG targets meat preparation businesses that slaughter animals for human consumption, dress carcasses, and cut or process meat, as well as those establishments that are subject to approval for Veterinary Inspection control. The guide is compiled in three parts covering a wide range of topics including sanitation, HACCP principals, food traceability, and microbiological criteria. The guide is periodically updated to include emerging issues or changes in regulations or third country import requirements. The last update of the guide was published in April 2014.

In order to verify the CCA’s ability to provide adequate administrative and technical support to operate the inspection system, the FSIS auditor evaluated the documentation submitted by the CCA as support for the responses in the SRT. The verification also included on-site record reviews, interviews, and observations made by the FSIS auditor at the government offices and laboratories conducting chemical residues and microbiological testing, and in the audited establishment. The further assessments of the chemical residue and microbiological testing program including the outcome of the on-site laboratories audit have been discussed in their respective components.

Based on FSIS’ on-site document reviews, interviews, and the audit observations in conjunction with the SRT review and document analysis of the CCA’s control measures, FSIS concludes that the CCA continues to maintain equivalence and is operating at an “adequate” level for this component.

V. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS

The second of the six equivalence components that the FSIS auditor reviewed was statutory authority and food safety regulations. The inspection system must provide an appropriate regulatory framework to demonstrate equivalence with FSIS’s requirements, including but not limited to HACCP, sanitation, chemical residue and microbiological sampling, humane handling, slaughter, ante-mortem inspection, post-mortem inspection, establishment construction, facilities, equipment, daily inspection, and periodic supervisory visits to the establishments certified eligible to export to the United States. The evaluation of this component included an analysis of information provided by the CCA, the SRT, interviews, and observations during the on-site portion of the audit.

The FSIS auditor reviewed the following national laws that provide the CCA with the legal authority to operate the inspection system and enforce FSIS requirements and the following National and European laws and regulations:

- Food Hygiene Regulation (NI) 2006 (FHR),
- The Official Feed and Food Controls (NI) Regulations 2006 (OFFGR),
- The General Food Regulations (NI) 2004 (GFR), and
- The Food Safety (NI) Order 1991 as amended (FSO).

The FHR of 2006 empowers Northern Ireland to enforce the requirements of (EC) regulations 852/2004 and (EC) 853/2004. The intent of OFFGR is to empower Northern Ireland to apply the requirements of (EC) Regulations 882/2004. The third regulation mentioned above is to enable compliance with the article 14 “the food safety regulations” and article 19 “recall, withdrawal

and notification requirements” of (EC) Regulation 178/2002. The main intent of the Food Safety (NI) Order 1991 is to align the definition of “food” in Northern Ireland with that in the (EC) Regulation 178/2002.

The FSIS auditor verified that the CCA maintains its regulatory authority as outlined in official laws and regulations, and in accordance with applicable EU Regulations. The legislative and enforcement power exercised by the CCA are drawn from “Food Law Code of Practice”, regulation 22 of “Food Hygiene Regulation (NI) 2006” and regulation 6 of “The Official Feed and Food Controls (NI) Regulations 2006.”

In order to verify that the inspection system continues to meet the requirement of the criteria for this equivalence component, the FSIS auditor interviewed government inspection officials at three levels, the CCA, regional, and local inspection, about statutory implementation. The auditor also reviewed monitoring documents at all three of these levels to correlate the information gathered at various locations. The following areas of the system and the procedures associated with them were examined:

- Humane handling and slaughtering 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 establishments.

The EU regulatory requirements pertaining to the Protection of Animals at the Time of Killing have been slated to transpose into all countries in the United Kingdom including Northern Ireland in 2014. The volume 1 chapter 2.3 VPHP-Manual for Official Controls (VPHP-MOC) titled “Animal Welfare” has set the guidance for the industry and inspection for the implementation of article 3(1) of Council Regulation (EC) 1099/2009. During the verification of humane handling and humane slaughter, the FSIS auditor walked around the premises of the audited establishment to observe the unloading of the livestock, pens, driveways, ramps, stunning equipment, and stunning procedures. The FSIS auditor verified that the establishment complied with the CCA’s requirements for humane handling and slaughter of livestock.

Section 1 of chapter 2.2 of the VPHP-MOC requires industry to apply correct standards to facilitate proper ante-mortem examination by the OV. The procedures to conduct an ante-mortem examination follows the provisions specified in annex III, section I, chapter IV, of Regulation (EC) 853/2004. Instructions to the OV on conducting a post-mortem examination are detailed in chapter 2.4 of VPHP-MOC titled “Post-Mortem, Health and Identification. Procedures and decisions for disposition of meat by either OV or by inspectors under the supervision of OV must conform to the relevant provisions of Regulations (EC) 854/2004. The regulation also outlines the requirements a slaughter establishment’s management must meet pertaining to their responsibilities to facilitate post-mortem inspection.

On June 1, 2014, the specific requirements for post-mortem inspection of domestic swine was implemented in accordance with the amendment of annex 1 of Regulations (EC) 854/2004 and

promulgated in Commission Regulation (EU) 219/2014. The FSIS auditor observed and verified that proper presentation, identification, examination, and disposition of carcasses and parts were being implemented. The FSIS auditor concluded that OV and his team had adequate knowledge, skill, and training to conduct post-mortem inspection duties. The design of the post-mortem inspection stations, including proper lighting, meets FSIS-equivalent requirements.

Northern Ireland's meat inspection system has legal authority and a regulatory framework to implement requirements equivalent to those governing the FSIS system of meat inspection in the United States. The analysis of documents and verification of inspection related activities indicate that the CCA continues to maintain equivalence and is operating at an "average" level for this component.

VI. COMPONENT THREE: SANITATION

The third of the six equivalence components that the FSIS auditor reviewed was Sanitation. An equivalent inspection system must provide requirements for all areas of sanitation, sanitary handling of products and Standard Sanitation Operating Procedures (Sanitation SOP). The FSIS auditor reviewed documents provided by the CCA concerning sanitation in the SRT, including EU regulations and pertinent chapters of Veterinary Public Health Program-Manual for Official Controls (VPHP-MOC) on sanitation requirement. VPHP-MOC provides instructions to the official inspection personnel to conduct a daily rigorous assessment of inspection activities during routine verification of sanitation issues. In addition to a review of the documents and procedures, the FSIS auditor:

- Conducted interviews with the CCA-Belfast, Divisional Veterinary Officer (DVO) at Newry Divisional Office, and Official Veterinarian (OV) assigned to a slaughter/processing establishment exporting raw pork product to United States.
- Interviewed Environmental Health Officers (EHO) employed by the local governmental authorities who oversee food business other than slaughter/processing establishments. In this capacity, the EHO is responsible to conduct supervisory reviews in cold storages including one cold storage certified to export to the United States.
- Reviewed the implementation and monitoring documents maintained at the establishment to meet sanitation requirements.
- Reviewed the daily inspection verification records maintained at the local inspection office.
- Reviewed the Quarterly Supervisory (audits) Reviews conducted by the DVO covering establishment's food safety program and the evaluation of performance of the inspection staff.
- Reviewed samples of VPH11-Enforcement record and VPH13-Remedial action requests,
- Reviewed the documentation from periodic audits conducted by DARD VPHP on behalf of Food Standard Agency (FSA) covering establishment's food safety program.
- Observed pre-operational and operational Sanitation during OV led visit of the establishment.

The evaluation of the inspection related record showed that the OV verifies the implementation of SSOP procedures and their efficacy in preventing events that may jeopardize product safety.

Establishments seeking eligibility to export to the United States are required to develop and implement SSOP as condition for approval.

The FSIS auditor verified that sanitation plans and records related to the design and implementation of sanitation programs at the audited establishment complied with EU hygiene standards, national regulations, and FSIS requirements. In the event that a noncompliance is observed during verification activities, the OV has the authority to take immediate enforcement action, the severity of which ranges from a verbal warning to the suspension and withdrawal of establishment's approval operating.

The FSIS auditor verified the actual pre-operational and operational inspection by shadowing and observing the OV conducting pre-operational and operational sanitation verification inspection. The FSIS auditor noted that the OV's hands-on verification procedures began after the establishment had completed its pre-operational sanitation and determined that the facility was ready for the in-plant inspector's pre-operational sanitation verification activities. The FSIS auditor followed the OV and observed in-plant inspection verification of operational sanitation procedures. These verification activities included direct observation of operations and a review of the establishment's associated records.

Except as noted below, the FSIS auditor concludes that the establishment maintained sanitation records sufficient to document the implementation and monitoring of the SSOPs and any corrective actions taken. The establishment employee responsible for the implementation and monitoring of the SSOP procedures correctly authenticated these records with initials or signatures and the date.

The following sanitation inadequacies were noted by the FSIS auditor, but were not noted by the OV or the establishment employee:

- During the pre-operational verification, the FSIS auditor observed that in the red offal room, multiple ready to use racks were not cleaned and had some fat or meat particles from the previous day's work.
- The truck receiving vestibule on receiving/shipping docks were damaged and rubber flaps lining on them were deteriorating needing replacement.
- One location of the outer premises of the establishment where truck wheels are washed had shallow pool of standing water obstructing free passage to worker or moving vehicles creating insanitary conditions.

The findings identified above were corrected immediately. The FSIS auditor reviewed evidence of the completed actions. These findings represent occasional occurrences and not a breakdown of the plant's sanitation system.

An analysis of the documents in conjunction with the observation made during the on-site visit indicate that the CCA's inspection system provides requirements equivalent to those of the FSIS system for sanitary handling of products, as well as in the development and implementation of SSOP. The FSIS auditor concluded that the CCA continues to maintain equivalence and is operating at an "adequate" level for this component.

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

The fourth of the six equivalence components that the FSIS auditor reviewed was HACCP. The inspection system needs to require a HACCP plan or similar type of preventive control plan to maintain equivalence. The evaluation of this component included a review and analysis of the information provided by the CCA in the SRT and observations made during the on-site audit.

The requirement to develop and implement a HACCP system is outlined in chapter 4, part 2 sections 1 of the Veterinary Public Health Program-Manual for Official Controls (VPH-P-MOC). The aforementioned manual instruct establishments that they need to implement, and maintain HACCP procedures as required within the meaning of chapter II, article 5 of Regulation (EC) 852-2004. The section 3 of chapter 4, part 1 outlines the procedures drawn from the seven principals of HACCP including:

- Identification of hazards that must be prevented, eliminated, or reduced to acceptable levels,
- Identification of critical control points and establishing critical limits,
- Implementation of monitoring and verification procedures, and
- Maintenance of the recordkeeping and documents related to HACCP, including the monitoring of critical control points, corrective actions, validation verification, re-assessments and official reviews.

In order to verify the correct application of the HACCP principles at the establishment level, among other verification activities for this component, the FSIS auditor reviewed the Hazard Analysis and HACCP plan for the audited establishment and confirmed that the establishment had taken into consideration all hazards that are likely to occur in its slaughter/processing operations. The establishment identified the presence of visible fecal material/ingesta on the carcass and parts and addressed the hazard as a critical control point with a critical limit of zero tolerance as defined in the HACCP program. The FSIS auditor verified through a review of the daily inspection record that the OV and his team assigned to the United States-eligible establishment were verifying the compliance of provisions in annex III, section I, chapter IV of Regulation (EC) 853/2004 (as amended) and annex I, chapter V, (1), (s) Regulation (EC) 854/2004 (as amended).

The FSIS auditor noted that DARD VPH staff conducts audits on behalf of FSA to verify the establishment's HACCP Based Procedures and compliance with EU regulations, national laws, and FSIS requirements. Chapter 4 (amendment 63) VPH-P-MOC provides guidance to the OV. The frequency determinations of these audits follow the audit risk assessment scheme as detailed in Article 4 of Regulation (EC) 854/2004.

The FSIS auditor reviewed the last two quarterly supervisory reviews conducted at the slaughter/processing establishment eligible to export raw pork products to the United States. The HACCP portion of the review consists of two sections namely, Basic Requirements and Ongoing Requirements. Both sections mirror regulatory features of 9 CFR Part 417. Divisional Veterinary Officer (DVO) conducts the reviews by conducting direct observations of monitoring,

hands-on verification of HACCP procedures and document reviews. Another notable feature of the review is evaluation of the OV and Meat Inspectors (MI). The performance is documented on the form titled “DVO Audit of OV/MI USDA Checks.” The performance is evaluated in 20 different areas including HACCP verification. The FSIS auditor identified no concerns.

The FSIS auditor verified the implementation of corrective actions for the findings pertaining to HACCP components identified in the 2009 FSIS audit. The following findings were reported in 2009 under HACCP documentation in this establishment:

- The establishment monitoring records for CCP 1 (zero tolerance for fecal and ingesta) did not include the times when the specific events occurred.
- The establishment monitoring records for CCP 1 (zero tolerance for fecal and ingesta) did not include the initials of the responsible establishment employee(s) making the entries.

The FSIS auditor verified these findings were corrected and adequate measures to prevent recurrence were in place.

The FSIS auditor verified that the certified establishment had developed, implemented, and maintained an equivalent HACCP system in accordance with the aforementioned laws, regulations, and procedures. There were no HACCP deviations identified during the audit. The OV and the DVO monitor, verify, and enforce the implementation of the HACCP regulatory requirements in the audited establishment. The analysis and on-site audit verification indicate that the CCA’s meat inspection system continues to maintain equivalence and is operating at an “average” level for this component.

VIII. COMPONENT FIVE: CHEMICAL RESIDUES CONTROL PROGRAM

The FSIS auditor reviewed Chemical Residue Control Programs as the fifth of the six equivalence components. The FSIS criterion for this component includes the design and implementation of a program managed by the CCA that conducts effective regulatory activities to prevent chemical residue contamination of food products. To be equivalent, the program needs to include random sampling of the internal organs, muscle, and fat of carcasses for chemical residues identified by the exporting countries and FSIS as potential contaminants. The inspection system must identify the laws, regulations, or other decrees that serve as the legal authority for the implementation of this program. The CCA must provide a description of its residue plan and the process used to design the plan; a description of the actions taken to address unsafe residues as they occur; and oversight of laboratory capabilities and analytical methodologies to ensure the validity and reliability of test data.

The statutory authority to operate a veterinary residue surveillance schemes in the United Kingdom is drawn from the Council Directives 96/22/EC and the provisions specified in annex I, chapter II, F of (EC) 854/2004. In the case of pesticides, in United Kingdom, the Chemicals Regulation Directorate (CRD), a directorate within Health & Safety Executive (HSE) is responsible for developing policies and proposes regulation on biocides, pesticides, detergents and chemicals control. However, the responsibility of monitoring the exposure of industrial and environmental chemicals, including plant pesticides in the human food chain, remains with DARD in Northern Ireland. The Food and Environment Protection Act 1985 authorizes DARD to enforce laws pertaining to pesticides and

environmental contaminants. Under the monitoring program, heavy metals (cadmium and lead), mycotoxins, organochlorides, and organophosphates are monitored.

While the CRD is responsible in the United Kingdom to implementing policies on pesticides and authorizes monitoring of such chemicals, the EU Commission Regulation 1881/2006 establishes Maximum Permitted Levels (MPL) of contaminants, including environmental contaminants, in food. These limits are monitored through individual countries in the United Kingdom.

Northern Ireland National Residue Program is an integral part of the broader United Kingdom based National Surveillance Scheme (NSS) for monitoring chemical residues. The residue plan in United Kingdom complies with Council Directive 96/23/EC. Volume 1, chapter 5 of Manual for Official Controls (VPHP-MOC) further describes the requirements pertaining to chemical residues monitoring, establishment's compliance, and Official Veterinarians (OV) verification activities. The Veterinary Medicines Directorate (VMD) draws up the NSS sampling plan for each year using the previous year's livestock and production figures. Northern Ireland tests a portion of the United Kingdom's total, based on its percentage contribution to the United Kingdom livestock and production figures. Animals sampled under the NSS are not detained for laboratory results. The DARD's Veterinary Service (VS), in collaboration with the laboratory, investigate any noncompliant results. The VS staff investigates the source of residue, and may take additional samples at all stages of production in order to ascertain a probable cause. All results are reported to VMD to be registered in NSS.

In Northern Ireland a multi-disciplinary group known as Residue Action Group (RAG) oversees the country's National Residue Program. The RAG meets on a monthly basis to review test results and work on follow up actions that may be required. The RAG is chaired by the head of DARD's food policy branch and includes representatives from the Food Standard Agency (FSA) Northern Ireland, DARD-VS, Agri-Food Inspection Branch (AFIB), and the officials from chemical laboratory of Agri-Food & Biosciences Institute. The National Residue Surveillance Scheme is executed in compliance with Directive 96/23/EC. As such the National Residue Plan relies on either statistically based random sampling for each compound/slaughter class pair, or targeted based upon sampling frequencies similar to those found in Council Directive mentioned above.

For the year 2014 a total of 4,876 samples drawn from porcine class were being targeted. In Northern Ireland under a "Pigs Testing Scheme" a rapid analysis of pigs for a range of antimicrobial substances are conducted. Four pigs are sampled from each producer, five times per year. The turnaround time for Phase 1 is to report 95% of samples within 20 working days. Non-compliant producers are placed onto Phase 2 of the scheme. In Phase 2, at least 5 pigs are sampled and retained at the slaughter establishment. The retained carcasses if tested positive are excluded from the food chain. The producers of noncompliant pigs remain on the intensive sampling regime of Phase 2 until 3 successive Phase 2 sampling rounds produce no non-complaint results. The turn-around for Phase 2 testing is to report 95% of samples within 5 working days.

The type of analyte to be tested is decided in the monthly RAG meetings. The quarterly analytical reports are presented to RAG. This report also contains an inventory of samples expected versus sample received, noncompliant results, and follow-up investigatory testing. The FSIS auditor reviewed a sample of quarterly reports including one for the current quarter and

determined that the program was running as expected. In addition to reviewing the aforementioned document, the FSIS auditor reviewed the procedure that dealt with noncompliant results and examples of investigations invoked because of a positive test. The procedure requires the laboratory to directly report a positive result to DARD.

The DARD's VS field staff collect field samples, while the Veterinary Public Health Program (VHPU) unit of DARD' inspectors collect samples at slaughter establishments, and both submit these samples directly to Chemical Residue Laboratory of AFBI for analysis .

The AFBI is a non-departmental government body and is credited for a wide variety of scientific activities in Northern Ireland and for DARD. AFBI operates in adherence to a sampling and analysis plan drawn up by DARD. Analysis of residues is conducted using accredited methods for each analyte/matrix combinations in the residues program. All the analytical methods employed also meet the requirements of Commission Decision 2002/657.115.

FSIS included a site visit to AFBI's chemical residue Laboratory to evaluate its role in testing chemical residues, the contribution it makes to RAG meetings, and the results reporting to DARD-VPHP. The Chemical Residue Laboratory of the Agri-Food Biosciences Institute receives the results of internal audits of veterinary residue testing by its Veterinary Sciences Division (VSD). Each method is audited once every four years which results in a minimum of 20-25 analytical methods being audited each year. The CCA ensures that the Chemical Residue Laboratory maintains its accreditation from UKAS on an annual basis, and that the laboratory implements corrections for deficiencies identified by the UKAS on ISO 17025 audits to maintain their accreditation.

The visit to the laboratory was comprised of interviews with the laboratory management and the analysts. The FSIS auditor observed analysts conducting tests on the residue samples and logging data electronically and on hard copies as a backup. The document review segment of the audit focused on laboratory standard operating procedures that included the procedures for sample receipt, samples identification, verification of sample integrity and security, and results reporting. The document review also included a review of the United Kingdom Accreditation Service's (UKAS) annual ISO 17025 accreditation audit report. The FSIS auditor verified that internal audits by VSD were being conducted at the frequency indicated, and that the ISO 17025 certification was current.

The FSIS auditor found no concerns with the CCA's chemical residue control program. The analysis and on-site audit verification indicated that the CCA's meat inspection system continues to maintain equivalence and is operating at an "average" level for the residue control programs component.

IX. COMPONENT SIX: MICROBIOLOGICAL TESTING PROGRAMS

The last of the six equivalence components that the FSIS auditor reviewed was the Microbiological Testing Programs. This component pertains to the microbiological testing programs organized and administered by the CCA to verify that products destined for export to the United States are safe, wholesome, and meet all equivalence criteria.

The evaluation of this component included a review and analysis of information provided in the Self Reporting Tool (SRT), during interviews with inspection officials and document review at the CCA' office in Belfast, Regional office at Newry, at the inspection office located in the audited establishment, and at site visits to two microbiology laboratories. Of the two laboratories audited, one was an approved private laboratory receiving samples from the United States eligible-establishment and conducting analytical testing on samples collected for Aerobic Colony Count (ACC) and *Enterobacteriaceae* on the product destined for the export. The other laboratory audited was a public laboratory conducting official testing on products destined for the United States.

Specific rules for testing and minimum sampling are written in EU Regulation 2073/2005. The FSIS auditor noted that Northern Ireland has implemented EU Regulation 2073/2005 on Microbiological Criteria for Foodstuffs and requires the slaughter/processing establishment to implement requirements in the regulations applicable to the slaughter operation. The Food Standard Agency (FSA) has provided information on the correct implementation of sanitary dressing procedure and their testing program in part 3 of chapter 2 of Meat Industry Guide (MIG). The MIG is a guidance document that benefits industry and inspection equally. The industry is not required to comply with the MIG as long as equivalent procedure can satisfy mandatory requirements in the above-cited regulation.

During the audit of the slaughter/processing establishment, the FSIS auditor reviewed the written program for testing carcass surfaces for ACC and *Enterobacteriaceae* testing program and determined it was being followed in accordance with the provisions contained in chapter 2 of annex I of EC directive 2073/2005. The samples are analyzed using the ISO 21528-2:2004 analytical method for testing porcine carcasses for *Enterobacteriaceae*.

Private laboratories interested in conducting testing to detect *Enterobacteriaceae* and total aerobic plate counts for establishments eligible to export to the United States are to apply to the CCA. Upon review of the laboratory's ISO 17025 accreditation certification, the laboratory is notified by the CCA of approval of the laboratory for analytical testing. The DARD approves or rejects private laboratories, and the list of such laboratories is maintained at the official DARD website with a link directly connecting the visitor to the approved laboratories site. The FSIS auditor reviewed the procedure of official notification to the laboratory and concluded that the CCA adheres to the standard in approving private laboratories.

The fundamental criteria for the laboratory to be on the approved list is to meet United Kingdom Accreditation Service (UKAS) certification for ISO 17025 standards. The DARD accesses the accreditation certification for laboratories wishing to be approved for microbiological testing by accessing the UKAS' web portal for accreditation for its review. The applying laboratories are notified of the outcome of approval process. The DARD routinely assesses the laboratories compliance with the accreditation criteria. The FSIS auditor reviewed the recent accreditation certification for the audited private laboratory, the Elite Technical Laboratories, Ltd., which conducts FSIS required testing for verification of sanitary dressing on the products for export to the United States.

In Northern Ireland, laboratories, whether public or private, are audited annually by the UKAS for ISO 17025 accreditation. The audit reports can be accessed from the UKAS website. The CCA routinely accesses audit reports for its review to confirm that private laboratories are maintaining their accreditation and implementing any suggestions or corrections as identified in the report. The FSIS auditor interviewed management and analysts in conjunction with the review of selected Standard Operating Procedures (SOP) related to analytical methods. The FSIS auditors identified the following concerns regarding the implementation of some of the audited laboratory's SOP standards:

- In the audited microbiology laboratory, some batches of solid and liquid media were not identified in a manner to ensure their identity or their traceability until the completion of intended testing.
- Hand-written laboratory records were observed with frequent strike out entries or overwritten values, making it difficult to interpret.

FSIS expects that the CCA to maintain oversight of private laboratories testing for verification of sanitary dressing on products destined to be exported to the United States. Additionally, FSIS expects that all laboratories comply with the general criteria for testing laboratories provided in the ISO/IEC Guide 17025. The Guide includes requirements for laboratories to establish quality control procedures and ensure that these procedures are followed as intended.

Under the HACCP/Pathogen Reduction regulation, FSIS criteria for the Microbiological Testing Programs require that the inspection system provide for a sampling and testing program for *Salmonella* in raw meat. The CCA requires that establishments eligible to export product to the United States implement the provisions of annex I, chapter 2 of (EC) 2073/2005. Through interviews of government officials at the HQ and the review of the official records maintained at the local inspection office, the FSIS auditor verified the implementation of the microbiological testing programs criteria for *Salmonella* and found the testing was in accordance with the aforementioned provisions of EU regulations.

The samples for *Salmonella* testing are collected by the OV or his team in accordance with procedures covered in the relevant chapter of Veterinary Public Health Program-Manual for Official Controls (VPHP-MOC). The *Salmonella* program of an establishment is audited periodically as a part of overall audit of HACCP based procedures in accordance with the methods described in chapter 4, part 3, and section 3 of the VPHP-MOC.

The samples for *Salmonella* are analyzed at Microbiological Division of AFBI using EN/ISO 6579 analytical methods. The latter facility was included in the scope of the audit. The document audit of the laboratory focused on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples. The FSIS auditor verified a sample of test results. Results are noted as *Salmonella* detected/not detected in the area tested per carcass. Positive test are further analyzed for serotyping and the resulting serovars are reported on the report. No concern arose as a result of the audit of the laboratory.

FSIS concludes that based on the results of the overall microbiological component assessment, the CCA continues to meet the core equivalence requirements for this component. FSIS finds that the CCA operates at an “average” level of performance.

X. CONCLUSIONS AND NEXT STEPS

The 2014 audit results indicate that the Northern Ireland’s food safety inspection system is performing at an “adequate” level meeting the core criteria for all six equivalence components. FSIS identified operational (or procedural) weaknesses related to sanitation verification, laboratory recordkeeping, and the CCA’s verification control over a private laboratory conducting microbiological testing on product destined for the United States export.

The FSIS auditor discussed these issues with the CCA at the exit meeting on June 13, 2014, in Belfast, Northern Ireland. The CCA understood and accepted the nature of the audit findings and had already begun to address the audit findings identified in the sanitation component by implementing immediate corrective actions. For the laboratory and microbiological testing findings, FSIS needs a response from the CCA within 60 days to evaluate the CCA’s proposed corrective actions.

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 Cookstown 70 Molesworth Road Cookstown County Tyrone BT80 8PJ	2. AUDIT DATE 06/9/2014	3. ESTABLISHMENT NO. UK9052 EC	4. NAME OF COUNTRY Northern Ireland
	5. NAME OF AUDITOR(S) Alam Khan, DVM		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	X
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
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	X
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

Date: 06/9/2014 Est #: UK9052 EC a slaughter/processing establishment

10/51 During the pre-operational verification, the auditor observed that in the red offal room multiple ready to use racks were not cleaned and had some fat or meat particles from the previous day's work.

38/51a) The truck receiving vestibule on receiving/shipping docks were damaged and rubber flaps lining on them were deteriorating needed replacement.

b) One location of the outer premises of the establishment where truck wheels are washed had shallow pool of standing water obstructing free passage to worker or moving vehicles creating insanitary conditions.

Immediate corrective actions were taken by plant for SSOP noncompliance. For other SPS related noncompliance commitment was provided to official veterinarian.

61. NAME OF AUDITOR

AlamKhan, DVM

62. AUDITOR SIGNATURE AND DATE

Handwritten signature of Alam Khan, DVM, dated 6/9/2014.

APPENDIX B: Foreign Country Response to Draft Audit Report

From: Robert Huey
Chief Veterinary Officer
Veterinary Service
Room 718, Dundonald House
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Rural Development**

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AN ROINN

**Talmhaíochta agus
Forbartha Tuaithe**

MÁNYSTRÍE O

**Fairms an
Kintra Fordèrin**

Dr Shaukat H Syed
Director
Internal Audit Staff
Office of Investigation, Enforcement & Audit
Food Safety & Inspection Service
1400 Independence Avenue, SW
Washington, DC
20250

2 April 2015

Dear Dr Syed

Northern Ireland FY14 Draft Final Audit Report

Once again thank you for your report and the courteous and professional manner in which you carried through your audit process.

With reference to your letter dated 2 February 2015 and the draft final report of the audit of Northern Ireland's meat inspection system in June 2014, please see my comments below.

Factual errors

Page	Paragraph	Comment
4	4	DCVO is no longer temporary appointment
4	6	Newry Division should read - Meat Inspection Branch South East
6	3	All enforcement actions should read - All formal enforcement actions.... with informal enforcement recorded on form VPH01. VPH12 should read VPH11
9	bullet 6	VPH12 should read VPH11
9	bullet 7	Audits are conducted by DARD VPHP staff on behalf of FSA
11	4	Audits are conducted by DARD VPHP staff on behalf of FSA
15	5	DARD do not review the accreditation criteria for certification but do make an assessment of compliance with the accreditation criteria

If you have a hearing difficulty you can contact the Department via Text Relay. Dial 18002 + number



INVESTOR IN PEOPLE

Comments on findings

Sanitation verification - immediate corrective actions taken during audit by inspection personnel to ensure continuing compliance with FSIS requirements.

Laboratory and microbiological testing findings

In the audited microbiology laboratory, some batches of solid and liquid media were not identified in a manner to ensure their identity or their traceability until completion of intended testing

Action taken

All batches of media are labelled throughout the process, to allow traceability until the end of testing.

Handwritten laboratory records were observed with frequent strike out entries or overwritten values, making it difficult to interpret.

Action taken

Handwritten records are now completed in a manner which allows straightforward interpretation. Strike out entries and overwritten entries are discouraged. Staff retrained in completion of records.

Note, scanned copies of handwritten records demonstrating corrective action and compliance were sent by DARD to Dr Khan on 02/09/14, with explanation of lab's corrective actions.

Yours sincerely



ROBERT HUEY
Chief Veterinary Officer

