



United States Department of Agriculture

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Food Safety and  
Inspection Service

FEB 01 2016

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Washington, D.C.  
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Mr. Nigel Gibbens  
Department for Environment Food & Rural Affairs (DEFRA)  
Area 5B, Nobel House  
17 Smith Square  
London SW1P 3JR, United Kingdom

Dear Mr. Gibbens,

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of England's meat inspection system from May 20 through June 4, 2014. Enclosed is a copy of the final audit report. The comments received from the Government of England are included as an attachment to the report.

For technical questions regarding the FSIS audit report, please contact Dr. Shaukat H. Syed, Director of the International Audit Staff with the Office of Investigation, Enforcement and Audit (OIEA) at telephone number (202) 720-8609, by facsimile at (202) 720-0676, or by electronic mail at [international.audit@fsis.usda.gov](mailto:international.audit@fsis.usda.gov).

If you have any other questions, please feel free to contact me directly.

Sincerely,

A handwritten signature in blue ink that reads "Jane H. Doherty". The signature is fluid and cursive, with the first letters of each word being capitalized and prominent.

Jane H. Doherty  
International Coordination Executive  
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN  
ENGLAND

May 20 – June 4, 2014

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

January 29, 2016  
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) on from May 20 through June 4, 2014, to determine whether England's food safety inspection system governing the production of meat products remains equivalent to that of the United States with the ability to produce products that are safe, wholesome, unadulterated, and properly labeled. England is eligible to export raw and processed pork products to the United States.

The audit focused on six main system equivalence components: (1) Government Oversight (Organization & Administration), (2) Statutory Authority and Food-Safety Regulations, (3) Sanitation, (4) HACCP Systems, (5) Government Chemical Residue Control Programs, and (6) Government Microbiological Testing Programs. In addition, the auditor verified that the corrective actions proffered by the Central Competent Authority (CCA) in response to November 2009 FSIS audit findings had been implemented.

The FSIS auditor reviewed management, supervision, and administrative functions at the CCA headquarters; two slaughter/processing establishments; and one ready-to-eat (RTE) processing establishment. The audit scope also included one government chemical residue laboratory and one private microbiological laboratory performing official analyses for presence of *Salmonella spp.* The auditor assessed whether the national system of inspection, verification, and enforcement are being implemented as required to maintain equivalence.

The 2014 audit results show that the CCA did not ensure that all the requirements pertaining to post-lethality exposed (PLE) RTE products identified in FSIS regulations were addressed, nor did the CCA demonstrate how it would conduct microbiological testing on PLE-RTE product destined for export to the United States. The CCA has clarified to FSIS that no PLE-RTE product is being exported to the United States. FSIS is not in the position to assess the level of performance at which England produces RTE products until England submits its request for an equivalency determination on the process by which RTE products are produced. FSIS requests that England clarify within 60 days how the CCA will follow up on its request for an equivalence determination for RTE products. FSIS will update the Public Health Information System (PHIS) to restrict eligibility of products from England to raw pork products only.

The 2014 audit further raises concerns regarding the assignment of the contracted inspection personnel at the United States certified slaughter/processing establishments, as it contradicts the United States statutes which require that inspection personnel be government employees.

During the exit meeting on June 4, 2014, the CCA noted that it has already begun to address the audit findings by implementing immediate corrective actions for the short-term and long-term effective resolution of on-site audit findings. FSIS will evaluate any information provided by the CCA, including should it submit proposed corrective actions in response to the audit findings. FSIS expects the CCA response within 60 days of the issuance of this report.

In regard to England's reinstatement of beef equivalence, FSIS is reviewing the information provided in the Self Reporting Tool as an overarching United Kingdom meat equivalence request. The equivalence determinations for reinstatement beef eligibility to export beef to the United States will include a review of England, Scotland, Wales, and Northern Ireland's meat inspection system.

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## **I. INTRODUCTION**

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site equivalence verification audit of England's meat inspection system from May 20 – June 4, 2014. England is eligible to export raw and processed pork products to the United States.

Between January 1, 2013 and March 31, 2014, England has exported 2,700,830 pounds of raw intact pork cuts; of this volume 621,668 pounds of the product received types of inspection beyond certification and labeling verification at the FSIS' United States Point-of-Entry (POE). Of this volume of product imported to the United States, a total of 862 pounds were rejected due to either a missing shipping mark or shipping damages to cartons.

This audit was conducted pursuant to the specific provisions of the United States laws and regulations, 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 England 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.

### **Core EU Regulations and /Directives**

- Regulation (EC) 852/2004,
- Regulation (EC) 853/2004,
- Regulation (EC) 854/2004,
- Regulation (EC) 2073/2005,
- Directive 96/22/EC,
- Directive 96/23/EC, and
- EU Regulation 1099/2009.

### **Main National Legislations, Rules, Regulation, Procedures and Policies**

- Food Standards Act of 1999,
- The Official Feed and Food Controls (England) Regulations 2009,
- Food Safety and Hygiene Regulations (FSHR-2013), and
- Welfare of Animals (Slaughter or Killing) Regulations of 1995.

## **II. AUDIT GOAL AND OBJECTIVES**

FSIS' overall goal for the audit was to assess whether England's food safety inspection system governing pork 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 United States: (1) Government Oversight (Organization & Administration), (2) Statutory Authority and Food-Safety Regulations, (3) Sanitation, (4) HACCP Systems, (5) Government Chemical Residue Control Programs, and (6) Government Microbiological Testing Programs.

The FSIS auditor verified that the corrective actions proffered by the Central Competent Authority (CCA) in response to the November 2009 FSIS audit had been implemented. All of the November 2009 audit deficiencies were corrected. In the 2014 audit, two slaughter/processing establishments and the RTE processing establishment that were eligible to export raw and processed pork products to the United States were audited.

### **III. AUDIT METHODOLOGY**

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

The first phase is document and data analysis of previous audit findings and other available information. Therefore, prior to conducting the May/June 2014 on-site audit, FSIS 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 November 2009. 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.

Since the last audit in November 2009, England has certified two slaughter/processing establishments, one RTE processing establishment, and one cold storage facility as eligible to export to the United States. At the time of FSIS' on-site audit of 2009, England had a slaughter/processing and a cold storage facility certified to export to the United States, and both were audited. The audit raised concerns about the HACCP and Sanitation components in the slaughter/processing facility. As a result of the audit, the CCA issued the audited slaughter/processing establishment a Notice of Intent to Delist (NOID). The establishments implemented corrective actions which were verified by the CCA. The Department for Environment, Food and Rural Affairs (DEFRA) submitted the establishment's corrective actions and its recommendations for FSIS review prior to removing the NOID. As part of review process, FSIS reviewed the corrective actions and included the establishment for the on-site audit.

The second phase is the on-site audit or execution phase. FSIS conducted this on-site audit to verify the CCA's oversight activities as they relate to each of the six equivalence components mentioned above. The auditor gathered data on all six components through document reviews, interviews, observations made during site visits. Accompanying the FSIS auditor throughout the audit were representatives from, the DEFRA, the Food Standard Agency (FSA) and the Animal Health and Veterinary Laboratories Agency (AHVLA).

Management, supervision, and administrative functions were reviewed at the CCA's headquarters, at two pork slaughter/processing establishments, and at one RTE-processing establishment eligible to export meat and meat products to the United States to determine whether the national system of inspection, verification, and enforcement is being implemented as intended. During the establishment visits, particular attention was paid to the extent to which the CCA verified that the establishments ensure the control of hazards and prevent product adulteration. The audit also verified the corrective actions implemented by the establishment that had received a NOID during the November 2009 audit. The 2014 audit found that the corrective actions were in place. The FSIS auditor also verified that the CCA provided oversight through supervisory reviews conducted in accordance with requirements equivalent to 9 Code of Federal Regulations (CFR) Part 327.

The FSIS auditor assessed the CCA's oversight activities for approved chemical residue and microbiology laboratories during the planning phase and this execution phase. The auditor reviewed information related to laboratory's quality management system through analysis of documents in the SRT. Second, the auditor conducted on-site interviews of inspection personnel in conjunction with reviews of reports of the audits of laboratories conducted by the CCA. In addition, the FSIS auditor visited a chemical residue laboratory and a microbiology laboratory. The auditor visited the Food and Environmental Research Agency (FERA), a government operated laboratory, to assess its chemical residues analysis program. He also visited the Exova, a private microbiology laboratory, to assess its *Salmonella* testing program.

The third phase of the audit was evaluation. The evaluation phase of the equivalence verification audit takes place throughout the entire audit. The FSIS auditors evaluated information throughout audit verification process. The auditor, as well as FSIS management at FSIS headquarters, assessed the results of the evaluations to determine whether the CCA's performance is consistent with the information provided to FSIS, and thereby, whether England remained equivalent to the United States' meat and poultry inspection system. The results of the evaluation are discussed in the corresponding sections of this report for each of the system's components.

The final phase of the audit process is feedback, which begins with FSIS providing a draft audit report to the CCA and giving them an opportunity to comment on the contents of the report. After reviewing the CCA comments and responses to all findings, FSIS finalizes the report. The CCA develops an action plan to address any issues raised by the audit, and FSIS monitors the resolution of all issues

#### **IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (ORGANIZATION & ADMINISTRATION)**

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 documentation submitted by the CCA as support for the responses; corrective actions taken in response to the findings of the last on-site audit, as well as

on-site record reviews, interviews, and observations made by the FSIS auditor at the CCA's offices and the government offices in the audited establishments.

The audit of the CCA's headquarters in London confirmed that in England, the delivery of inspection over food operating businesses, including the United States-eligible establishments, is achieved under a Memorandum of Understanding (MOU) between the three governmental agencies at the central level. The signatories to this MOU are DEFRA, AHVLA, and the FSA.

The review of the MOU indicates that the DEFRA holds the authority as the CCA and is responsible to enforce requirements for Animal Health and Animal Welfare and represents United Kingdom (UK)<sup>1</sup> in international trade negotiations. In deliverance of the meat inspection system the DEFRA is supported by AHVLA and the Veterinary Medicines Directorate (VMD). The AHVLA, a sub-agency within DEFRA, oversees the international trade operational delivery for England and other parts of the Great Britain (GB) among many other vital functions related to food safety. The VMD, another sub-agency of the DEFRA, oversees the veterinary/chemical residues surveillance program for the UK. The DEFRA also oversees pesticide residues surveillance for which the CCA liaisons with another central authority outside the DEFRA. As will be discussed later in the chemical residue component of this report, the CCA relies on the Chemicals Regulations Directorate (CRD), an agency of the Health and Safety Executive (HSE), for regulatory and enforcement functions with respect to pesticide and other environmental contaminants.

While for FSIS purposes the DEFRA is the central competent authority, the FSA, an autonomous governmental department in the UK, is mainly concerned with enforcing food law pertaining to hygiene, contaminants, additives, labelling, imports, and food contact materials and to oversee food safety and public health matters. The FSA was established in 2001 under the authority of the Food Standards Act of 1999.

During the audit of the DEFRA's headquarters in London and the interviews conducted at the FSA's headquarters in York, the FSIS auditor confirmed that the latter agency carries out the practical inspections, ensures the correct application of FSIS requirements in the United States-certified establishments, and makes recommendations to the DEFRA for approval of new establishments or removal of an establishment found not to be in compliance with FSIS requirements.

The auditor noted that there have not been any changes in the manner in which the inspection systems are funded. However, a significant shift was noted in the way supervisory reviews and the staffing needs are met at the establishments eligible to export to the United States. The supervision in these establishments, which was formerly the responsibility of the Meat Hygiene Service, an executive agency of the former Ministry of Agriculture, Fisheries and Food, is now directly provided by the lead veterinarian (LV) of the FSA. The supervisory oversight at the establishments other than slaughter operations, which may include cold storage facilities meat cutting and meat processing establishments, is provided by the Local Health Authorities

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<sup>1</sup> While England, Scotland, Wales, and Northern Ireland are parts of the United Kingdom, England, Scotland, and Wales make up Great Britain. Currently, each part of the UK or GB has their respective meat inspection system, and are eligible to export pork product to the United States.

(autonomous local governmental entities) in England and in other parts of GB. An exception to this setup pertaining to the supervisory oversight was noted at the United States-eligible processing establishment. The FSIS auditor verified that at the RTE processing establishment additional supervisory reviews are also conducted by FSA's appointed LV.

Prior to June 1, 2014, for the purpose of supervision in the United States-eligible slaughter establishments, the responsibility of conducting periodic supervisory reviews within FSA had been distributed among Operations Assurance and Field Operations offices of the Agency. Now, supervisory periodic visits at the United States-eligible establishments are conducted by the LV from the Operations Assurance office, while the Field Operation office is responsible for the audits of the establishments exporting to countries other than the United States. The reviews cover all aspects of the United States-certified establishment's food safety system and focus any specific requirements not covered in the EU regulations. The reviews further evaluate the performance of Official Veterinarians (OV) assigned to these establishments.

The FSIS auditor reviewed a sample of supervisory reviews conducted at the two slaughter establishments and one meat processing establishment producing RTE products. At the slaughter establishments, these reviews, which are also referred to as audits, are conducted with a frequency based on assessed risk and compliance history associated with each establishment. Although the supervisory reviews at the meat processing establishments are mainly a responsibility of the Local Government Health Authorities, the meat processing establishment eligible to export to the United States also receives reviews from the FSA's appointed LV.

During the on-site audit of the United States-eligible RTE-processing establishment, the FSIS auditor reviewed samples of the audit reports for the audits conducted by both the Local Health Authority and the FSA's appointed LV. The auditor noted that while the Local Health Authority appointed Environmental Health Officials (EHOs) to conduct these reviews annually, the frequency of the FSA's audit varies based on risk assessment score assigned to the establishment. EHOs are employed with the local government such as borough, city, or district councils and are skilled inspectors in food safety oversight. EHOs are authorized to enforce the EU hygiene regulations in food operating business including any processing establishments eligible to export to the United States.

However, the FSIS auditor determined that the EHO lack knowledge about FSIS' criteria of food safety applicable to RTE product or *Listeria* as specified in 9 CFR Part 430, based on a review of the audit conducted by the EHO who has jurisdiction over the RTE processing establishment. Additionally, the RTE processing establishment's Hazard Analysis did not consider all microbiologically known hazards associated with its product. For example, *Listeria monocytogenes*, a known pathogen associated with post-lethality exposed (PLE) RTE product, was not taken into consideration as a hazard reasonably likely to occur in PLE-RTE product by the audited establishment. Neither the supervisory review nor EHO's audit identified this concern in advance of the current FSIS audit.

The FSIS auditor reviewed the inspection generated documents at two slaughter establishments to assess the CCA's ability to maintain daily inspection in the United States-eligible establishments. The following documents covering a period of 90 days were reviewed:

- Establishment Day book,
- Time sheets of the inspection staff,
- Ante-mortem and Post mortem data (slaughter establishments only),
- Daily data report for contamination on carcasses (slaughter establishment only),
- Non-compliance report, and
- Supervisory Audit Reports.

During the audit of the RTE-processing establishment, the FSIS auditor noted that apart from the supervisory audit report by the FSA's Lead Veterinarian/advisor and audit report for the audit conducted by a Local Authority appointed EHO, no other inspector generated data, for example routine SSOP/HACCP verification documents, were provided for FSIS to review. The review of the United States-POE data revealed that no product from this establishment has ever been exported to the United States since the certification of the establishment by the CCA.

The interviews conducted with officials from the DEFRA, the AHVLA, and the FSA present during the audit indicated that the RTE processing establishment was ready to export to the United States but waiting for the internal administrative process "not related to certification requirements" to be completed by the above mentioned agencies. While the CCA met the criteria for the supervisory review and the daily inspections at the slaughter establishments, neither the DEFRA nor the FSA demonstrate how England would meet daily inspection requirement at the processing establishment during the days when production for the United States would occur. Therefore, auditor concluded that the CCA currently did not meet the requirements for the daily inspection requirements, at the meat processing establishment.

In assessing England's ability to acquire and maintain competent and qualified personnel who are employed by the CCA, the auditor noted that the England's inspection system relies on contracting companies that specialize in recruiting veterinarians and inspectors. The auditor noted that in two slaughter establishments eligible to export to the United States the contracted veterinarians and inspectors were conducting inspection related activities.

- Based on the information gathered and interviews conducted during the on-site audits of the CCA, FSIS concludes that, although England's inspection system employs competent and qualified inspectors to supervise the product destined for the United States export, they are not government employees. This type of inspection arrangement is not consistent with the United States statues and regulations pertaining to the employment of inspectors in meat, poultry, and egg inspection system domestically.

The FSIS auditor interviewed inspection personnel and reviewed their training records. The auditor reviewed the training agenda and syllabus of training designed for new veterinarians entering into Novice Official Veterinarian status. The training is provided to the new entrants in pursuant to provisions of annex 1 of chapter IV of regulation (EC) 854/2004. In the UK, the University of Glasgow and University of Bristol have designed the training for applicants who hold a Doctor of Veterinary Medicine (DVM) degree and wish to pursue a career as meat and poultry inspectors. A three week training course is offered to the novice veterinarians as condition of employment. Trainees at the conclusion of training are required to take an assessment test and must obtain a minimum of 70 percent in order to continue employment with

the firm. The hands-on segment of the training consisting of 200 hours of supervised on the job training in an establishment. The training documents reviewed was from a training offered by the University of Bristol from March 3-21, 2014.

During the on-site audit of two slaughter plants, the FSIS auditor verified that the FSA's contracted OVs are assigned to conduct ante-mortem examination and verification activities to ensure pigs for slaughter are being handled and killed humanely in accordance with the domestic and the EU regulations mentioned above. The inspection personnel observed all animals at rest and in motion in designated holding pens prior to slaughter in order to determine whether they are fit for slaughter and thereby fit for human consumption. The designated holding pens for sick or suspect animals were maintained for further examination of these animals as needed. The FSIS auditor concluded that the implementation of the ante-mortem inspection and humane handling of livestock met FSIS requirements.

The FSIS auditor assessed post-mortem inspection through on-site record reviews, interviews, and observations of personnel performing post-mortem examinations. The FSIS auditor observed and verified that proper presentation, identification, examination, and disposition of carcasses and parts were occurring and concluded that the in-plant inspection personnel were adequately trained in performing their on-line post-mortem inspection duties. The design of the post-mortem inspection stations, including proper lighting, met the equivalent requirements.

The FSIS analysis and on-site verification activities indicated that England's meat inspection system has the legal authority and a documented regulatory framework to implement regulatory requirements. However, FSIS observed that at the United States-eligible meat processing establishment, the CCA did not ensure that all the requirements pertaining to PLE-RTE products identified in FSIS regulations were identified in CCA documentation. Additionally, the CCA did not demonstrate how it would conduct microbiological testing on RTE product destined for export to the United States. The CCA has clarified to FSIS that no PLE-RTE product is being exported to the United States. FSIS is not in the position to assess the level of performance at which England produces RTE products until England submits its request for an equivalency determination on the process by which RTE products are produced.

FSIS requests that England address within 60 days how the CCA will provide for the use of government inspection personnel at the United States-eligible slaughter establishments and address the absence of inspection once per shift at the establishments processing RTE products. Once FSIS has received the requested information on the use of government inspection personnel and England's RTE program, FSIS will analyze whether the system is still equivalent and eligible to export product to the United States.

## **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' 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 at slaughter and meat cutting establishments, 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 in the (SRT), interviews, and observations during the on-site portion of the audit.

In order to determine the CCA's legal authority to enforce the appropriate laws and FSIS' requirements, the auditor interviewed inspection officials at the CCA's office and local inspection offices of each establishment audited and reviewed selected sections of the following UK Legislation and European Union (EU) regulations:

- The Official Feed and Food Controls (England) Regulations 2009,
- The Food Safety Act 1990,
- The General Food Regulations 2004,
- The Food Hygiene Regulations 2006,
- Relevant sections of the EU hygiene regulations, and
- The Food Safety and Hygiene Regulations (FSHR-2013).

All United States-eligible establishments, in addition to compliance with the EU regulations, must also comply with FSIS requirements. The FSA and the DEFRA provide the necessary guidance to establishments eligible to export to the United States, as to which applicable regulations of Title 9 of Code of Federal Regulations shall be met.

Until the enactment of Food Safety and Hygiene Regulations (FSHR-2013) in December 2013, England's meat inspection system relied on "The Official Feed and Food Controls (England) Regulations 2009" and "The General Food Regulations 2004" to enforce EU and United States import requirements. The two legislative instruments were combined into one unified regulation as FSHR-2013. This latter regulation provides the CCA with legal authority to enforce inspection requirements. To facilitate the understanding of national, EU regulations, and correct implementation thereof by the meat industry, the FSA in December 2006 published "Meat Industry Guide (MIG)."

Regarding the implementation of FSIS' criteria for humane handling and slaughter of livestock and ante-mortem and post-mortem examination, the auditor reviewed the information provided in the SRT. The DEFRA is responsible in the UK for providing oversight of animal health and animal welfare. It achieves this objective by enforcing the EU Regulation 1099/2009 concerning the protection of animals at the time of killing in the slaughter establishments. Additional legislation with which slaughter establishments need to comply comes from domestic legislation on the "Welfare of Animals (Slaughter or Killing) Regulations" of 1995. The hygiene and welfare regulations referenced above require establishments to have procedures in place to guarantee that the welfare of animals destined for slaughter are not compromised on farm, during transport, or on arrival at the slaughterhouse, and the OV or his/her designee is required to verify compliance.

During the review of information provided in the SRT concerning ante-mortem inspection, the auditor learned that the FSA has legal authority to enforce regulations on ante-mortem examinations. Section 1 of Chapter 2.2 of the Manual for Official Controls (MOC) requires

slaughter establishments to meet the ante-mortem standards as specified in Regulation (EC) 853/2004, annex III, section I, chapter IV, and paragraph 5.

The instructions to the OVs on conducting post-mortem examination are detailed in chapter 2.4 of the MOC, titled "Post-Mortem, Health and Identification Procedures," and decisions made about disposition of carcasses or parts by either the OVs or the MHIs under the supervision of the OV must conform to the relevant provisions of Regulations (EC) 854/2004. The regulation also outlines the requirements pertaining to post-mortem inspection that a slaughter establishment's management must meet. The FSIS auditor determined that, in establishments certified to export to the United States, a team of contracted Meat Hygiene Inspectors was conducting post-mortem inspection under the direct supervision of a contracted OV on all swine carcasses and parts in accordance with the procedures outlined in Section 2 of Chapter 2.4 of FSA's administered MOC.

Regarding presence of inspection at the meat slaughter establishments, the auditor verified that the CCA has implemented the provisions as stipulated in annex I, section III, chapter II of Regulation (EC) 854/2004. These provisions require that the competent authority must ensure that at least one OV is present at slaughterhouse to conduct ante-mortem and post-mortem inspection. The Veterinary Field Manager or Lead Veterinarian use their discretion in assessing staffing needs and may consider deployment of additional OV or MHI on an as needed basis. The FSIS auditor noted that at the two United States-eligible slaughter establishments, the contract official veterinary and contract meat hygiene inspectors were conducting inspection activities in accordance with the FSA administered MOC to ensure that the establishments are complying with the EU, United Kingdom's requirements and third country import requirements. However, the auditor concluded that FSIS statutory and regulatory requirements "that inspection personnel be government employees" were not being met at United States- eligible establishments.

The inspection arrangements observed in the slaughter establishments were different in the cold storage, meat, and meat processing establishments. The FSA relies on Local Health Authority to provide oversight to these types of facilities. The FSA contracted OVs and MHIs are responsible for the delivery of oversight at the slaughter establishments while all other meat-processing establishments including cold storages are supervised by Local Health Authority employed EHOs. In United Kingdom, Local health Authorities is autonomous governmental entities that have legal authority to enforce food safety laws and regulation. They work with DEFRA, FSA and other food safety authorities to oversee and ensure safety of the food including food of animal origin.

- The FSIS auditor noted that the CCA is not meeting the criterion for the daily official inspection at the United States-eligible meat-processing establishment preparing RTE product. FSIS criterion states that the inspection system must provide for daily official supervision of processing activities for when meat, poultry, and egg products are produced for export to the United States.

The United States requires inspection during each shift of production at all processing establishments, when producing product eligible for export to the United States. FSIS expects the CCA to provide its complete RTE program for FSIS review and equivalence determination,

including how daily (once per shift) inspection will be documented prior to exporting RTE product from any processing establishment. FSIS will evaluate any information provided by the CCA including the submittal of the CCA's proposed corrective actions. FSIS expects the CCA response within 60 days of the issuance of this report.

## **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 SSOP. Prior to the on-site portion of the audit, the auditor reviewed documentation provided by the CCA concerning sanitation component in the SRT. In addition, the auditor reviewed the chapter 4 of the FSA's Manual for Official Controls (MOC) pertaining to the Sanitation component.

The FSIS auditor reviewed records related to the design and implementation of establishment sanitation programs in the audited establishments. In one of the audited slaughter establishments, the FSIS auditor verified the actual pre-operational inspection by shadowing and observing the OV conducting pre-operational sanitation verification of slaughter and meat processing areas. The OV's hands-on verification procedures began after the establishment personnel had conducted its pre-operational sanitation and determined that the facility was ready for in-plant inspector pre-operational sanitation verification activities. The FSIS auditor determined that the OV conducts this activity in accordance with the CCA's established procedures. The OV documents daily verification activity on the FSA's issued official Day book.

The auditor also observed operational sanitation verification procedures conducted by the OV. The verification activities included direct observation of operations and review of the establishments' associated records. The FSIS auditor also reviewed the establishment's sanitation monitoring and corresponding inspection verification records for the same time period.

The following daily records relating to the inspection verification activities were maintained at the local inspection offices audited:

- Establishment Day book,
- Time sheet,
- Non-compliance report, and
- Supervisory Audit Reports.

The FSIS auditor reviewed a sample of supervisory reviews conducted at the United States-eligible establishments. These reviews are conducted by the LV at all slaughter or standalone cutting plants with frequencies based on risks that are noted in the previous supervisory reviews. The SSOP is covered in part A of the report, and the HACCP procedures are in part B. The results of the verification activities are recorded as acceptable, marginal, or unacceptable. The auditor concluded that these reviews conducted by the FSA's appointed LV at the two slaughter establishments and one processing establishment were being conducted with specified frequencies and followed-up on any past issues.

Except as noted below, the FSIS auditor determined that the CCA's inspection system provides requirements equivalent to those of the FSIS system for sanitary handling of products, as well as development and implementation of SSOPs. As a result of the audit of this component, the auditor made the following observations:

- In one of the three establishments audited, in one of the fresh product cutting rooms, condensate from an overhead steel pipe was observed dripping on the product being processed. Cracked or broken meat storage containers, in some cases lined with torn plastic liners, were in use in different food processing compartments.
- In one establishment, porcine carcasses were rubbing against a steel frame where a plant employee was monitoring zero tolerance for fecal contamination just prior to the carcasses entering the chiller.
- In one establishment, at the kidney harvest location, tubs containing unwashed and unchilled porcine kidneys were stacked on top of each other creating insanitary conditions.
- In one establishment, a wooden pallet of combo bins used for product storage was placed in the outer premises of the establishment. The protective plastic sheet around the pallet and the bins was torn at places that would expose the stack of bins to dirt and extraneous material causing insanitary conditions.

Based on the observations made on-site in conjunction with the analysis of objective evidence gathered during the audit, FSIS expects that the CCA appropriately address these audit findings within 60 days of issuance of the draft final audit report.

## **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 requirements to develop and implement the HACCP system is outlined in Chapter 4, Part 2, section 1 of the Manual for Official Controls (MOC). The previously mentioned MOC instructs 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. Section 3 of chapter 4, part 1 of the MOC outlines the procedures drawn from the seven principles 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 documents related to HACCP, Record Keeping of Monitoring, Corrective Action, Verification, and Reviews.

The routine daily inspection activities to verify the establishment's compliance with the EU regulations and FSIS requirements at the United States-eligible establishments are conducted by a team of inspectors led by the OVs. In addition to daily inspection activities, an OV is required to conduct comprehensive periodical audits of the HACCP system as a part of the establishment's overall food safety system. The audits described here and in the sanitation

component are conducted to meet the audit requirements as set forth by Regulation (EC) 854/2004. The audit frequency is based on the following risk criteria as set out in that regulation:

- Public health risks,
- Animal health risks and animal welfare risks (where appropriate),
- Type of process, and
- Establishment's record of compliance with food law.

The establishments are required to maintain documents in accordance with the seven principles of HACCP including pre-requisite programs when the latter are used as control measures in the HACCP plan. For record keeping, establishments can use the FSA's Food Safety Management Diary (FSMD), a log book that has many desirable features to warehouse information on the plant's food safety program and records it all in one place that is in FSMD.

At the two slaughter establishments audited, the FSIS auditor verified through observations and record review that the OVs at the establishments conduct verification of hazard analysis and review of HACCP and pre-requisite programs in accordance with the procedures described in the above referenced of MOC. In addition, trained OVs conduct HACCP audits as required under the EU regulations.

The auditor further evaluated the written HACCP programs, monitoring, verification, corrective actions, recordkeeping, and hands-on verification inspection at the only United States-eligible processing establishment producing post lethality exposed RTE pork product. The in-plant daily inspection verification included Critical Control Point (CCP) verification with results entered in in-plant inspection records.

The FSIS auditor reviewed the HACCP records at the two slaughter establishments and verified that the corrective actions taken following the November 2009 FSIS audit had been successfully implemented and maintained.

The FSIS auditor verified that the certified establishments had developed, implemented, and maintained an equivalent HACCP system in accordance with the aforementioned regulations. The OV and the lead veterinarians verify and enforce the implementation of the HACCP regulatory requirements in the audited establishments.

The analysis and on-site audit verification indicate that the CCA's meat inspection system continues to maintain equivalence and is operating at an adequate level for this component.

## **VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE CONTROL PROGRAM**

The FSIS auditor reviewed Chemical Residue Control Programs as the fifth of the six equivalence components. The FSIS criteria for this component include 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 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 residue as they occur; and oversight of laboratory capabilities and analytical methodologies to ensure the validity and reliability of test data.

The audit of the chemical residues control program consisted of:

- The CCA's audit which included interviews with governments officials at central and local level, and document review of selected record, and
- A visit to a chemical laboratory.

While the Department for the Environment, Food and Rural Affairs (DEFRA) has overall responsibility for the National Residues Control Plan (NRCP) at the UK level, the Veterinary Medicine Directorate (VMD), an agency of DEFRA, is the Competent Authority for veterinary medicines controls and residues surveillance programs. In addition to operating NRCP, the VMD is also responsible to approve and inspect animal feed additives and feed medicates. In this capacity, the VMD has authority to conduct routine audits of manufacturers and distributors of animal feed and collect samples of feed for quantitative analysis. The frequency of the VMD's future audits and the selection of establishments are risk based.

The VMD, as the competent authority for the implementation and monitoring of the "Residues Surveillance Program," implements the requirements specified in Council Directive 96/23/EC. Each year the VMD holds an annual planning meeting for the selection of specific species and substances to be included in the annual residue plan for the subsequent year. The list of the participants in the annual planning meeting include experts from the Food Standard Agency (FSA), the Food and Environmental Agency (FEA), the Animal Health and Veterinary Laboratories Agency (AHVLA), the Veterinary Residue Committee (VRC), and the VMD. Samples for red meat, poultry and eggs, milk, honey, and fish are collected by the representatives from FSA and AHVLA. All samples under the Residue Surveillance Program are tested at the FERA, a laboratory that has been contracted since 2011 to analyze samples received under the Residues Surveillance Program.

The interviews conducted with the VMD, the DEFRA, and the FSA's representative and the OVs at local inspection offices confirmed that if a sample under Residues Surveillance Program tested higher than Maximum Residue Level (MRL), the product may not be recalled, but a veterinary officer from AHVLA will investigate the farm from which the livestock was offered for slaughter. The FSA has legal authority to sample and test suspect animals or carcasses in accordance with the provisions of section 3, chapter 5 of the Manual for Official Controls (MOC), and, if found implicated with a violative level of medicinal or environment contaminant, the product is disposed of according to applicable EU regulations. In instances where the same producer or food business operator is found repeatedly implicated in the residue violation, targeted sampling is initiated either at the farm or at the slaughterhouse involved.

While the VMD is the main entity in overseeing and executing the Residues Surveillance Program, it does not play any role in regulatory control of industrial or environmental

contaminants. The Chemicals Regulation Directorate (CRD), a directorate within Health & Safety Executive (HSE), is responsible for the regulation of biocides, pesticides, detergents, and chemicals. The CRD closely works with the DEFRA and provides its expertise on regulatory aspects or the MRL on environmental contaminants. However, the responsibility for monitoring the exposure of food of animal origin to these environmental contaminants and pesticides chemicals, and the product derived therefrom, remains the responsibility of the VMD.

The FSIS auditor reviewed the FERA laboratory for its chemical residue testing program. This laboratory is accredited by the United Kingdom Accreditation Service (UKAS) for ISO 17025 in the specific areas of residues of pesticides and organic contaminants, anabolic steroids, metals, and residues from veterinary medications.

The auditor interviewed the analysts to assess their technical competency, training, and knowledge of the analytical methods used on the samples to detect chemical residues. The document review included an evaluation of management system documents, internal audit reports; the UKAS audit reports, and corrective action reports. The auditor confirmed that the FERA had implemented the recommendations made to the laboratory during the last accreditation audit of the facility by the UKAS. The review of proficiency testing record revealed that all results reviewed were acceptable. During the visit to the facility, the auditor observed the laboratory personnel at the sample receipt area who were receiving samples, checking sample integrity and security, assigning the identification, and storing the samples in accordance with the laboratory's standard operating procedure.

Based on review of the FSIS' POE records for the past three years, England has had no residue violations. 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 of performance.

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

The last of the six equivalence components that the FSIS auditor reviewed was 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 EU Regulation (EC) 2073/2005 on "Microbiological Criteria for Food For Certain Microorganisms and rules" to be complied with by establishments. The articles 4(3) and (4) of Regulation 852/2004 provide the legal basis for implementation of Regulation in (EC) 2073/2005. The CCA has facilitated the application of the requirements in the regulation in its Meat Industry Guide (MIG). The chapter 2 of part 3 of the guide document describes how industry can achieve specific requirements in the EU regulations on microbiological criteria.

England requires all slaughter establishments to develop and implement sampling and testing program for the indicators of fecal contamination in order to assess the effectiveness of its

slaughter and dressing process control during the production of raw meat. England allows the slaughter establishments to choose a fecal indicator as *Escherichia coli* (Biotype 1) or test for *Enterobacteriaceae* and Total Viable Count (TVC) in accordance with provision in the EU Regulation (EC) 2073/2005.

The FSIS auditor verified that at the two slaughter establishments audited, the establishments were conducting testing on carcasses for *Escherichia coli* (*E. coli*) in accordance with FSIS' criteria for verifying process control as specified in 9 CFR 310.25 (a). The establishments were also sampling and testing the carcasses in accordance with the provisions outlined in chapter 2 of annex I of (EC) 2073/2005. The auditor reviewed the establishment's in-plant program and records and except for what is noted below had no concerns as a result of this review.

- In one slaughter establishment, the establishment was using FSIS' criteria established for the excision method rather than employing statistical process control technique for evaluation of its swab samples for *Escherichia coli* (Biotype 1) tests.

Through interviews of the government officials at the headquarters and the review of the official record maintained at the local inspection office, the auditor verified that the implementation of the microbiological testing programs for *Salmonella* was in accordance with the provisions of Annex I, Chapter 2 of (EC) 2073/2005. The FSA's published MIG document provides step-by-step instructions to establishments on how to achieve the compliance with the set provisions. Additionally, the document is also resourced by OV's and his staff on how to verify establishment's compliance.

FSIS has made the following equivalence determinations for England for official testing for *Salmonella* in raw product:

- Private laboratories analyze samples for *Salmonella* using ISO 6579:2002 analytical methods to analyze the detection of *Salmonella* on raw product, and
- Establishment employees collect samples for *Salmonella*.

The OV monitors the sampling, integrity and security of samples, analytical methods used, and verification of results. As part of the monitoring of results in swine carcasses, the OV keeps the record of number of samples taken and the number of positive samples. Thus, if warranted, an enforcement action can be invoked in accordance with procedures provided in the Manual for Official Controls (MOC), volume 1, chapter 4, and part 3.

The auditor's verification of the *Salmonella* testing program at the CCA's headquarters government offices and at the audited slaughter establishments raised no concerns.

FSIS is pleased to update England on agency's new initiatives and strategies for pathogen reduction in raw meat products. FSIS is implementing exploratory sampling of raw pork products for pathogens of public health concern, as well as for indicator organisms. In this regard, FSIS has provided instruction to in-plant personnel at establishments that produce raw pork products through FSIS Notice 23-15 on how to sample for *Salmonella* as part of the nationwide raw pork products exploratory sampling project. The notice can be accessed at the [FSIS Website](#).

The auditor included an audit of the private laboratory in the scope of this audit. The selected laboratory conducts official microbiological testing on raw pork product for *Salmonella* performance standard. The Laboratory conducts these tests under a signed agreement between the establishment and the laboratory. Concerning the oversight of laboratory, the CCA requires that any laboratory conducting official testing must be accredited by the UKAS for ISO 17025 standards, and must maintain accreditation standards at all time. The audit of the laboratory included interviews with the officials, document review, and concluded with a site visit to the microbiological portion of the laboratory. The laboratory is audited annually by the UKAS for ISO 17025 standards.

As a part of the document review, the FSIS auditor reviewed the last ISO accreditation audit report for the audit conducted by the UKAS to cover all microbiological analyses conducted on the samples received from the United States-certified establishments. The method of analysis to detect *Salmonella* on the product destined for the export is ISO 6579. This method has been found to be equivalent by FSIS. The FSIS auditor reviewed the training materials, records, and the results of proficiency testing of analysts. The review of document was correlated with the interviews of analysts to assess their competency, skill, and knowledge of FSIS requirement pertaining to analytical method used on samples.

The following concerns arose as a result of the audit of the microbiological laboratory:

- On the incubation control form, at multiple occasions analyst did not sign and or enter timings when a procedure completed,
- On the incubation control form the auditor noted that at multiple occasions the laboratory instead of creating separate entries for new methods, it modifies or overwrites the existing methods making interpretation difficult,
- The laboratory's web application was not updated as auditor noted that some completed work on analytical methods was still showing not completed.

Based on analysis of information provided in the SRT, in conjunction with the evaluation of objective evidence gathered during the on-site audit, FSIS concludes that the CCA meets the equivalence core criteria at an adequate level of performance. FSIS expects that the CCA appropriately address these audit findings within 60 days of issuance of the draft final audit report.

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

The 2014 audit results found that the CCA's food safety inspection system that the CCA did not ensure that all the requirements pertaining to post-lethality exposed (PLE) RTE products identified in FSIS regulations were addressed, nor did CCA demonstrate how it would conduct microbiological testing on PLE-RTE product destined for export to the United States. The CCA has clarified to FSIS that no PLE-RTE product is being exported to the United States. FSIS is not in the position to assess the level of performance at which England produces RTE products until England submits its request for an equivalency determination on the process by which RTE products are produced.

The 2014 audit further found that the CCA is assigning contracted inspection personnel at the United States certified slaughter/processing establishments. Its failure to adhere to FSIS statutory and regulatory requirements “that inspection personnel be government employees” raises significant concerns as to whether England’s system is still equivalent to that of the United States.

During the exit meeting on June 4, 2014, the CCA noted that it has already begun to address the audit findings by implementing immediate corrective actions for the short-term and long-term effective resolution of on-site audit findings. FSIS will evaluate any information provided by the CCA including the submission of the CCA’s proposed corrective actions in response to the audit findings to assess the effectiveness of the corrective actions. FSIS expects the CCA response within 60 days of the issuance of this report.

In regard to England’s reinstatement of beef equivalence, FSIS is reviewing the information provided in the Self Reporting tool as an overarching United Kingdom meat equivalence request. The equivalence determinations for reinstatement beef eligibility to export beef to the United States will include a review of England, Scotland, Wales, and Northern Ireland’s meat inspection system.

## **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<br>TMI Foods,<br>Lodge Farm Industrial Estate<br>Lodge Way<br>Northampton, NN5 7US<br>England | 2. AUDIT DATE<br>05/22/2014             | 3. ESTABLISHMENT NO.<br>UK NM 007 P | 4. NAME OF COUNTRY<br>England   |
|  | 5. NAME OF AUDITOR(S)<br>Alam Khan, DVM |                                     | 6. TYPE OF AUDIT<br><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)<br>Basic Requirements   | Audit Results | Part D - Continued Economic Sampling             | Audit Results |
|--|---------------|--|---------------|
| 7. Written SSOP  |               | 33. Scheduled Sample                             | X             |
| 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)<br>Ongoing Requirements  |               | Part E - Other Requirements                      |               |
| 10. Implementation of SSOP's, including monitoring of implementation.  |               | 36. Export                                       |               |
| 11. Maintenance and evaluation of the effectiveness of SSOP's.   |               | 37. Import                                       |               |
| 12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.                                 |               | 38. Establishment Grounds and Pest Control       |               |
| 13. Daily records document item 10, 11 and 12 above.   |               | 39. Establishment Construction/Maintenance       |               |
| 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                    | X             |
| 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<br>Generic <i>E. coli</i> 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: 05/22/2014 Est #: UK 007 TMI foods (IP) ,(Northampton, England)

50/51 Criteria for daily inspection (once per shift) is not being met.

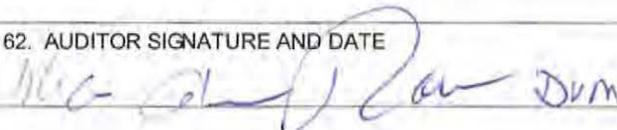
51 The CCA has not initiated any verification sampling to test Ready-to-Eat (post-lethality exposed) products, food contact surfaces, or the sampling and testing of the production environment ((non-product contact surfaces) to ensure that the establishments' *Listeria* control measures are effective.

The CCA's officials present during the audit stated that product intended for export to the United States would be produced under the supervision of an Official Veterinarian (OV) to be assigned at the establishment in future. The OV will be responsible for collecting verification samples of both non post-lethality and post-lethality exposed product, including food contact surfaces and the environment in accordance with the recommendation in (Chapter 4, Part 3, Section 3, Page 3-10) FSA's Manual of Controls. These requirements will be immediately effective once establishment complies with the labeling requirements for the United States destined product.

61. NAME OF AUDITOR

AlamKhan, DVM

62. AUDITOR SIGNATURE AND DATE

 Alam Khan, DVM 5/22/2014

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

|   |   |                                 |   |
|---|---|---------------------------------|---|
| 1. ESTABLISHMENT NAME AND LOCATION<br>Karro<br>Hugden Way<br>Norton<br>Malton, North Yorkshire, YO17 9HG<br>England | 2. AUDIT DATE<br>05/28/2014             | 3. ESTABLISHMENT NO.<br>UK 2060 | 4. NAME OF COUNTRY<br>England   |
|   | 5. NAME OF AUDITOR(S)<br>Alam Khan, DVM |                                 | 6. TYPE OF AUDIT<br><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)<br>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)<br>Ongoing Requirements  |               | Part E - Other Requirements                      |               |
| 10. Implementation of SSOP's, including monitoring of implementation.  |               | 36. Export                                       |               |
| 11. Maintenance and evaluation of the effectiveness of SSOP's.   |               | 37. Import                                       |               |
| 12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.                                 |               | 38. Establishment Grounds and Pest Control       |               |
| 13. Daily records document item 10, 11 and 12 above.   |               | 39. Establishment Construction/Maintenance       |               |
| 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                                  |               |
| 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<br>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                | O             |
| 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

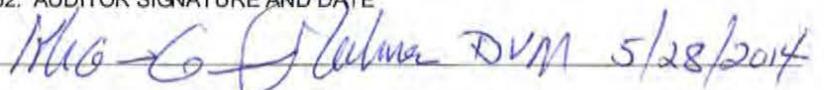
Date: 05/28/2014 Est #: UK 2060 ((S/P)) ,(North Yorkshire, England)

There were no significant findings to report after consideration of the nature, extent, and degree of all observations.

61. NAME OF AUDITOR

AlamKhan, DVM

62. AUDITOR SIGNATURE AND DATE

Handwritten signature of Alam Khan, DVM, dated 5/28/2014.

### Foreign Establishment Audit Checklist

|  |   |                                    |   |
|--|---|------------------------------------|---|
| 1. ESTABLISHMENT NAME AND LOCATION<br>Tulip<br>Bow Street<br>Dukinfield Cheshire SK16 4HY<br>England | 2. AUDIT DATE<br>05/30/2014             | 3. ESTABLISHMENT NO.<br>UK 4085 EC | 4. NAME OF COUNTRY<br>England   |
|  | 5. NAME OF AUDITOR(S)<br>Alam Khan, DVM |                                    | 6. TYPE OF AUDIT<br><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)<br>Basic Requirements   | Audit Results | Part D - Continued Economic Sampling                    | Audit Results |
|--|---------------|---|---------------|
| 7. Written SSOP  |               | 33. Scheduled Sample                                    |               |
| 8. Records documenting implementation.   |               | 34. Species Testing                                     |               |
| 9. Signed and dated SSOP, by on-site or overall authority.   |               | 35. Residue   |               |
| <b>Sanitation Standard Operating Procedures (SSOP)<br/>Ongoing Requirements</b>  |               | <b>Part E - Other Requirements</b>                      |               |
| 10. Implementation of SSOP's, including monitoring of implementation.  | X             | 36. Export  |               |
| 11. Maintenance and evaluation of the effectiveness of SSOP's.   |               | 37. Import  |               |
| 12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.                                 |               | 38. Establishment Grounds and Pest Control              |               |
| 13. Daily records document item 10, 11 and 12 above.   |               | 39. Establishment Construction/Maintenance              |               |
| <b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>  |               | 40. Light   |               |
| 14. Developed and implemented a written HACCP plan.  |               | 41. Ventilation   |               |
| 15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.          |               | 42. Plumbing and Sewage                                 |               |
| 16. Records documenting implementation and monitoring of the HACCP plan.   |               | 43. Water Supply  |               |
| 17. The HACCP plan is signed and dated by the responsible establishment individual.  |               | 44. Dressing Rooms/Lavatories                           |               |
| <b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>   |               | 45. Equipment and Utensils                              | X             |
| 18. Monitoring of HACCP plan.  |               | 46. Sanitary Operations                                 |               |
| 19. Verification and validation of HACCP plan.   |               | 47. Employee Hygiene                                    |               |
| 20. Corrective action written in HACCP plan.   |               | 48. Condemned Product Control                           |               |
| 21. Reassessed adequacy of the HACCP plan.   |               | <b>Part F - Inspection Requirements</b>                 |               |
| 22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences. |               | 49. Government Staffing                                 |               |
| <b>Part C - Economic / Wholesomeness</b>   |               | 50. Daily Inspection Coverage                           |               |
| 23. Labeling - Product Standards   |               | 51. Enforcement   | X             |
| 24. Labeling - Net Weights   |               | 52. Humane Handling                                     |               |
| 25. General Labeling   |               | 53. Animal Identification                               |               |
| 26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)  |               | 54. Ante Mortem Inspection                              |               |
| <b>Part D - Sampling<br/>Generic E. coli Testing</b>   |               | 55. Post Mortem Inspection                              |               |
| 27. Written Procedures   |               | <b>Part G - Other Regulatory Oversight Requirements</b> |               |
| 28. Sample Collection/Analysis   | X             | 56. European Community Directives                       | X             |
| 29. Records  |               | 57. Monthly Review                                      |               |
| <b>Salmonella Performance Standards - Basic Requirements</b>   |               | 58.   |               |
| 30. Corrective Actions   |               | 59.   |               |
| 31. Reassessment   |               |   |               |
| 32. Written Assurance  |               |   |               |

60. Observation of the Establishment

Date: 05/30/2014 Est #: UK 4085 ((S/P)) Cheshire, England

- 10/51 1) In one of the fresh product cutting rooms, condensate from an overhead steel pipe was dripping on the product being processed.
- 2) Cracked or broken meat storage containers (dolavs), in some cases lined with torn plastic liners were in use in different food processing compartments.
- 3) Porcine carcasses were rubbing against a steel frame where a plant employee was monitoring zero tolerance for fecal contamination prior to carcasses entering the chiller.
- 4) At the kidney harvest location tubs of unwashed, un-chilled porcine kidneys were stacked on top of each other.
- 28/51 The establishment was using FSIS' criteria established for the excision method rather than employing statistical process control technique for evaluation of its swab samples for Escherichia coli (Biotype 1) tests.
- 45/51 A wooden pallet of combo bins was stored in the outer premises of the establishment. The plastic sheet wrapped around the combo bins were torn at place would expose the stack of bins to dirt and extraneous material.

Immediate corrective actions were initiated either by official veterinarians or by the plant management for the immediately correctable non-compliances. The CCA provided commitments to correct those non-compliance which were not corrected immediately and needed additional time to finish the task.

61. NAME OF AUDITOR

AlamKhan. DVM

62. AUDITOR SIGNATURE AND DATE

 Alam Khan DVM 5/30/2014

**APPENDIX B: England's Response to Draft Final Audit Report**



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for Environment  
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United States Department of Agriculture  
Food Safety and Inspection Service  
14000 Independence Avenue SW  
Washington DC 20250

20 January 2016

**From Professor Nigel Gibbens CBE**  
Chief Veterinary Officer and Director General

Dear Dr Syed

**FSIS AUDIT OF ENGLAND'S FOOD SAFETY SYSTEM FOR PRODUCTION OF PORK  
MAY 20 – JUNE 2014**

Following receipt of the draft report of this inspection under cover of a letter from Jane Doherty of FSIS Office of International Coordination dated 16 July 2015, please find in the attached Annex our comments on the factual detail. I apologise for the belated response.

I also have some general comments to make, including on the conclusions in the report:

1. The names and structures of some CCAs mentioned on the report have since changed e.g. AHVLA is now the Animal and Plant Health Agency (APHA) and the operations division of FSA has been restructured extensively to separate initial approvals from on-going audits and boost the latter. These will be explained in the updated SRT when re-submitted.
2. As acknowledged in the report's conclusion, the UK does not at this time intend to seek equivalence for Ready to Eat (RTE) meat products. This will be reflected in updated SRT when resubmitted.
3. Regarding the employment of "contracted inspection personnel" as Official Veterinarians trained and appointed by the UK Central Competent Authority (CCA) in the supervision of official controls of meat production by Food Business Operators, this practice is permitted under EU legislation. The justification for this being equivalent to the US requirements will be explained in the updated SRT when resubmitted. The work carried out by the 'contracted inspection personnel' is audited on a regular basis by veterinary auditors who are full-time salaried employees of the CCA responsible for the official controls on meat hygiene (FSA). Arrangements are also in place to ensure any 'conflict of interest' concerns are addressed.

4. All corrective actions as identified have been taken. The RTE establishment has been de-listed. The meat plant was delisted but, after the corrective actions were taken, was subsequently re-listed.

Please let me know if you require any more information.

Kind regards.

Yours sincerely

A handwritten signature in dark ink, appearing to read 'Nigel Gibbens', with a long horizontal flourish extending to the right.

**PROFESSOR NIGEL GIBBENS CBE  
CHIEF VETERINARY OFFICER AND DIRECTOR GENERAL**

Cc: Steve Knight, FAS, US Embassy, London ([Steve.Knight@fas.usda.gov](mailto:Steve.Knight@fas.usda.gov))

Enclosed: Draft audit report with UK CCA comments

**COMMENTS ON DRAFT REPORT OF AN AUDIT CONDUCTED IN ENGLAND: May 20 – June 4, 2014**

**1. Page 5: 1<sup>st</sup> paragraph, 1<sup>st</sup> line**

An exception to this setup pertaining to the supervisory oversight was noted at the United State-eligible processing establishment.

For clarity, the following amendment is proposed:

An exception to this setup pertaining to the supervisory oversight was noted at the United State-eligible processing establishment and this would apply to any other such establishments (including cold stores) which are under Local Authority supervision.

Additional information: Template of letter that is sent to such establishments is embedded below



USDA APPROVAL by  
FSA in LA establishme

**2. Page 6: 3<sup>rd</sup> paragraph, final sentence**

Therefore, auditor concluded that the CCA currently did not meet the requirements for the daily inspection requirements, at the meat processing establishment.

For clarity, the following amendment is proposed:

Therefore, auditor concluded that the CCA currently did not meet the requirements for the daily inspection requirements, at the RTE establishment.

Additional information: The cutting plants audited were co-located with slaughterhouses and the 'daily inspection' requirement will be met by the supervising OV. For all other establishments, the daily inspection requirement has been clarified in the letter sent to establishments expressing interest in exporting to the US (see section 7 in the letter embedded at point 1 above).

**3. Page 9: 2<sup>nd</sup> paragraph, last line**

.....FAS's administered MOC.

Typo, to be corrected as below:

.....FSA's administered MOC.

**4. Page 9: final paragraph**

The FSA contracted OVs and MHIs are responsible for the delivery of oversight at the slaughter establishments while all other meat-processing establishments including cold storages are supervised by Local Health Authority employed EHOs

For clarity, the following amendment is proposed:

The FSA contracted OVs and MHIs are responsible for the delivery of oversight at the slaughter/cutting establishments while all other stand-alone meat-processing establishments including cold storages are supervised by Local Health Authority employed EHOs.

Additional information: Cutting plants whether co-located with slaughterhouse or standalone are supervised by FSA contracted OVs and MHIs. Also, any meat preparation or other meat processing plants co-located with the slaughterhouse are also supervised by the FSA contracted OVs and MHIs.

**5. Page 11: 3<sup>rd</sup> bullet under VI**

In one establishment, at the kidney harvest location, tubs containing unwashed and un-chilled porcine kidneys were stacked on top of each other creating insanitary conditions.

The following correction is proposed:

In one establishment, at the kidney harvest location, tubs containing washed and unwashed and also un-chilled porcine kidneys were stacked on top of each other creating insanitary conditions.

**6. Page 15: 1<sup>st</sup> paragraph**

England allows the slaughter establishments to choose a fecal indicator as *Escherichia coli* (Biotype 1) or test for *Enterobacteriaceae* and Total Viable Count (TVC) in accordance with provision in the EU Regulation (EC) 2073/2005.

For accuracy, the following amendment is proposed:

England allows the slaughter establishments to choose a fecal indicator as *Escherichia coli* (Biotype 1) or test for *Enterobacteriaceae* and Total Viable Count (TVC) in accordance with provision in the EU Regulation (EC) 2073/2005, but the latter is required to ensure compliance with EU requirements if the former option is chosen for exports to the US.

Date:

Ref:

Address

Dear xxx

## **FSA RECOMMENDATION PROCESS FOR APPROVAL TO EXPORT PIG MEAT PRODUCTS TO THE USA**

The Food Standards Agency (FSA) has been informed that you are interested in exporting **Pig Meat Products to USA**. These products are **meat preparations and meat products** (not ready to eat) under the EU Regulations and definitions: sausages, bacon, gammon, etc

This letter provides you with **information** on the approval process, timescales and likely costs involved to gain approval for exporting beef to USA.

### **Introduction**

This document is intended as a preliminary guide for meat plant operators considering applying for USA export approval. It identifies the essential requirements that will have to be complied with in order to obtain approval to export to the United States. Any establishment approved for export to the USA must, as a prerequisite, be licensed for intra-Community trade and must meet **fully the requirements of the EU and UK legislation**. Any enforcement action taken in respect of intra-Community trade would apply equally to the production for export to the USA.

These items below are US Department of Agriculture (USDA) Food Safety Inspection Service's (FSIS) requirements and can be found mainly in the **USA Code of Federal Regulations on Animals and Animal Products (9 CFR)** and they are in addition to the requirements set out in Regulation (EC) 852/2004 and Regulation (EC) 853/2004. Most of the other USDA requirements can be met by full compliance with the EC Regulations and the standards and procedures set out in the FSA Operations Manual.

It is important to emphasise that the establishment operator is **responsible for compliance with the USDA requirements** which are mainly based on the adequate application and implementation of the

**HACCP and SSOP principles.** The UK competent authority will verify compliance of the USDA standards in accordance with the USDA inspection and supervisory conditions

## **USDA Requirements**

### **1. Plans approval procedures**

- A copy of plans will be necessary to enable the company to demonstrate the suitability of the site and the layout. Therefore the company must have available at least one copy of the following **plans and documentation**:
  - ✓ Site layout
  - ✓ Floor plan of all buildings
  - ✓ Position of major items of equipment
  - ✓ Flow of operation and approximate rates of production
  - ✓ Layout of drains
  - ✓ Layout of water supply showing off-take points and capacity
  - ✓ Specifications of rooms (eg materials used, heights of ceilings)

### **2. Equipment and materials approval procedures**

- A major feature of the USDA requirements is the need for all machinery, equipment, materials and substances used in the plant to be suitable and acceptable for their intended use. A complete list of all equipment and materials used in those areas of the plant where meat and meat products are present must be provided by the operator. The following categories are involved:
  - ✓ materials such as paints, pesticides, detergents, lubricants, sealants etc
  - ✓ ingredients used in preparation of the product
  - ✓ packaging and wrapping materials
  - ✓ plant equipment and machinery
  - ✓ plant utensils (eg knives, scabbards, protective clothing)

It is the operator's responsibility to obtain evidence of the suitability of all these materials and have this documentary evidence available.

### **3. Sanitation Performance Standards:**

- Part 416.1 to 416.6 of the Code of Federal Regulations (9-CFR). These are procedures that control the operational conditions within a food establishment allowing **for environmental conditions** that are

favourable to the production of safe food. These are also known as Prerequisite Programs, GMPs, SOPs.

- Each establishment must be operated and maintained in a manner sufficient to **prevent** unsanitary conditions and to ensure that product is not adulterated. It must also allow for the verification duties of the Competent Authorities to take place unhindered.
- These SPS have to be **documented and implemented** accordingly. These SPS are related to:
  - ❖ Establishment Grounds and facilities: These include the requirements and standards of:
    - ✓ Grounds and pest control
    - ✓ Construction
    - ✓ Light
    - ✓ Ventilation
    - ✓ Plumbing
    - ✓ Sewage disposal
    - ✓ Water supply and water, ice and solution reuse
    - ✓ Dressing room, lavatories and toilets

The quality of construction must be to a high standard and any necessary upgrading or maintenance and repair must be carried out before granting eligibility to export to the US.

- ❖ Equipment and utensils: ensure the construction is fit for use with meat, the cleaning and maintenance conditions is adequate, handling by the staff is hygienic. Example: the containers used to store waste (ABP) must be identified and permanently labelled and must not be used to store any meat even after being cleaned and disinfected.
- ❖ Sanitary Operations: cleaning of the food-contact surfaces, non-food contact surfaces, use and storage of the cleaning chemicals and protection from adulteration of the product.
- ❖ Employee hygiene: the staff cleanliness, clothing use and management and disease control.

#### 4. Sanitation Standard Operating Procedures (SSOPs)

- Part 416.11 to 416.16 of the 9CFR requires the following:
  - **Development** of Sanitation SOPs
  - **Implementation** of the Sanitation SOPs
  - **Maintenance** of the Sanitation SOPs (ensuring its

- effectiveness).
  - Take **corrective actions**
  - **Record keeping**
- A SSOP must describe the specific procedures that the establishment conducts daily to **prevent direct** contamination or adulteration of product, including the frequency, and the employees responsible for implementation and maintenance of the programme. It must refer to both pre-operational and operational hygiene procedures and shall address, as a minimum, the cleaning of **food contact surfaces** of facilities, equipment and utensils. There must be daily monitoring of the SSOP by establishment employees.

##### **5. Hazard analysis and critical control points (HACCP) systems**

- This requirement is set up in Part 417 of 9 CFR. Every establishment must produce and implement a written HACCP plan covering **each product produced** when the hazard analysis reveals that one or more food safety hazards are reasonably likely to occur. Each HACCP plan must be drawn up and operated in accordance with the seven principles of HACCP. Each HACCP plan must, as a minimum:
  1. List food safety hazards which must be controlled for each process.
  2. List the critical control points (CCPs) for each of the identified food safety hazards.
  3. List the critical limits that must be met at each of the CCPs.
  4. List the procedures, and the frequency with which these procedures will be performed that will be used to monitor each of the CCPs to ensure compliance with the critical limits.
  5. Include all corrective actions to be followed in response to any deviation from a critical limit at a CCP.
  6. Provide for a record-keeping system that documents the monitoring of the CCPs. The records shall contain the actual values and observations obtained during monitoring.
  7. List the verification procedures, and the frequency with which these procedures will be performed.
- Plans must be **actively monitored and verified** by establishment employees in accordance with the requirements of sub-paragraphs 6) and 7) above. The plan shall be dated and signed by the responsible management individual upon initial acceptance, upon any modification and at least annually upon reassessment.

- It is important to be aware of the following:
  - FSIS requires a **mandatory CCP** at the processes/steps where there will be zero tolerance of **ingesta, faecal and milk** contamination. It should not be a problem as the origin of the raw material must come from USDA approved plants with this CCP being implemented
  - Monitoring records must be reviewed by someone **other than** the monitoring person and signed or initialled and dated. These document are checked at the pre-shipment review (see below)
  
- Part 417.3 requires establishments to identify **who** is responsible to take **corrective actions** and that these include:
  - Determining **the cause** of deviation
  - Bringing the **process back** under control
  - Preventing a **re-occurrence** of the deviation
  - Determining the **disposition** of any affected product
  
- Part 417.4 requires the **validation, verification, reassessment of the HACCP plan and HACCP activities**. Verification evaluates the day to day compliance of activities at each CCP and must not be confused as monitoring. For each verification task the person responsible (title), the frequency and the task must be identified:
  - ✓ There are 3 types of required CCP verification activities:
    - **Calibration** of processing and monitoring equipment.
    - **Review** of monitoring and corrective action **records**
    - **Direct observations** of the monitoring activities and corrective actions on the adequacy of control measures, critical limits, etc
  
  - ✓ Another verification activity required by FSIS is the **Pre shipment Review** (9 CFR 417.5 (c)) in which the establishment must review the records associated with the production of that product:
    - All critical limits were met
    - Appropriate corrective actions were taken, documented, and recorded
    - Proper disposition of defective product was taken.
    - Review shall be conducted, dated, and signed by an individual who did not produce the records.

- The establishment must maintain **records documenting the establishment's HACCP plan**. The content of the active records should include:
  - Form title and date
  - Production date/product code
  - Critical limits and corrective actions
  - Observations and measurements
  - Monitor's initials or signature and date
  - Reviewer's signature and date of review
  - Pre-shipment reviewer's signature and date

#### 6. Labelling and packaging:

- The USDA has laid down extensive regulations in respect of the information that must appear on a product label. All labels must conform and some may need prior **approval by the USDA Food Labelling Division** before the product can be exported to the USA. Label approval requires the submission of a 'sketch' presented as a printer's proof or equivalent, clearly showing all features, size, location and final colours.
- The establishment must obtain approval from the FSIS Food Labelling Division). However, generic labels and some other specific categories of product **do not need FSIS approval**. The content declaration must correspond to the product and the labels must be under adequate FBO and OV control
- The establishment must have documented evidence ensuring that the **packaging and wrapping material is suitable** for food contact and provides protection.

#### 7. Daily Inspection

- **FSA OV attendance** will be required **every day** during **cutting/processing** for export to the USA to ensure any operation which requires verification of a CCP under HACCP is inspected/verified to ensure compliance with FSIS requirements.
- All activities will be subject to **full veterinary control** during US production runs once the establishments are approved to export to the USA. The supervising official veterinarian will have overall responsibility for ensuring applicable USDA standards are complied with and approve the meat for export certification.

- **Veterinary control procedures for USDA compliance** will be in addition to supervisory visits required under the EU legislation as part of the delivered of the official controls by the Local Authorities Environmental Health Officers. The OV will verify compliance of the USDA export requirements –EU hygiene legislation and specific USDA: SSOP, HACCP...-
- The OV, who will be trained in USDA controls and HACCP verification will carry out a verification check of the **establishment's controls on a daily basis**. These will include:
  - Checks on one monitoring procedure of the SSOP (this should vary daily).
  - Checks on monitoring and verification of one CCP of the HACCP plan (this should vary daily).
  - Review of the required microbiological tests.
  - Checks on the pre-shipment review procedure.
- Initially a **monthly supervisory visit** will be carried out by the area **FSA Veterinary Auditor** -Veterinary Auditor (VA)/ Audit Veterinary Leader (AVL)/ Export Veterinary Leader (EVL)- at the establishment to confirm adequacy of:
  - the performance and inspection procedures of the **plant OV** and OV/ meat inspector contractor, and
  - the implementation of appropriate corrective actions taken by the **establishment operator** when necessary.
- During the three first months, after the USDA approval has been recommended by the veterinary official (FVL), the establishment will be audited on a **monthly** basis. After this period, and depending on the level of compliance, establishments will be audited **every 3 months**.
- If, at any time the **FSA auditor** considers the need to **increase the audit frequency** –typically because the plant standards have dropped- the FBO will be informed verbally and in writing. The FSA auditor will determine **when to return** to the 3 monthly frequency.

## **8. Other Requirements.**

- It is essential that the raw material that will be used for processing in your establishment is **sourced in USDA approved establishment**. The meat must be accompanied the adequate documentation including the UK **Internal Movement Document (IMD)**.
- Plants requesting approval to export meat products will be required to

demonstrate that they only use ingredients, additives and other substances that are permitted in the Code of Federal Regulations, 9-CFR Chapter III and that all products to be exported meet any regulatory **compositional** standard . This may require the establishment to carry out **analytical testing** to determine criteria such as the minimum meat Protein Fat Free percentage in cured pig meat products. They will also be required to comply with any processing requirements that are specified for the category of product intended for export.

- **Species testing** is required for establishment processing more than a single species. Separation and segregation procedures will be part of the approval assessment.
- **Pig meat products ready to eat (RTE) cannot be certified** under the current conditions and agreements to USA

### **The Process of Approval**

The first step to be taken by the FSA to consider the recommendation of approval is to assess your level of compliance **with the EU legislative requirements**.

We will contact your Local Authority and request the last audit/ inspection report and information about any outstanding situation in term of compliance

It is your responsibility to ensure that you meet the **additional requirements** required by USDA. These conditions should be documented in an establishment specific standard operational procedure (SOP), which must be trialled and implemented accordingly.

The advisory/approval visits will normally be carried out by the **Field Veterinary Leaders (FVL)** within the FSA approval veterinary team. Please be aware that **you will be charged** for the time spent by FSA officials for these visits.

The FVL will contact you to arrange the visit and will verify compliance of all the requirements and specifically **the implementation and trial of the SOP**. The FVL will inform you of the outcome of the assessment at the end of the visit and will also inform you in writing of **any deficiencies** against the export approval requirements that need to be addressed

The timescale for approval will largely depend on the initial **level of compliance** with EU regulations and the time you take to put in place the **specific procedures** required for USDA approval.

When your establishment is compliant with the approval conditions the **FSA will make the recommendation** to Defra. Defra will then communicate with the USDA and, if successful, they will forward to you a letter with the **formal notification of your approval** to export to the USA. If you required an update of your approval status after FSA recommendation of approval, please contact Animal and Plant Health Agency's (APHA) on 03000 200 301 (international trade option)

Once your establishment is approved to export to USA, APHA Centre for International Trade in Carlisle, will be able to issue the **Export Health Certificates (EHC)** to your FSA OV. This will allow you to start exporting your products to USA.

You will be required to **maintain the approval standards** in order to keep the "approved" status of your establishment. **Failure to comply with both EU and USDA** meat export requirements may result in suspension/ withdrawal of approvals and/or the OV refusal to sign the EHC.

The familiarisation of your OV with the USDA requirements will be required before the establishment can be recommended for approval. If you and your OVs require **USDA training**, this can be provided by FSA. This will usually be provided by the Export Veterinary Leader.

### **The Charging Mechanism**

All FSA time involved with **appraisal/approval visits, training, inspection visits, monthly/ three monthly audits and report writing** relating to your establishment will be charged to you at the non-regulatory Veterinary Rate of £38.00 per hour. Discount is not applicable to this work and any facilitation to the export markets by FSA is above and beyond the EU and UK legislation.

Further information on charges for official controls is available at <http://www.food.gov.uk/sites/default/files/charges-guide-mar15.pdf>

The time taken will be **coded** as HTCA for FSA employed veterinarians (FVL, AVL, VA, EVL) for appraisal/approval visits and associated report writing and as HLVI for the veterinarians (OV, AVM) carrying out associated work when the plant is approved and exporting. This should appear on your monthly invoice as a separate line.

Yours Sincerely

**Joaquim Ferré**  
Exports Veterinary Leader  
Operations Assurance Division