United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250

APR 0 6 2010

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

Dear Mr. Gibbens:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of England's meat inspection system November 25 to December 4, 2009. Comments received from the government of England have been included as an attachment to the final report. Enclosed is a copy of the final audit report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 205-3969, by facsimile at (202) 720-0676, or electronic mail at james.adams5@fsis.usda.gov.

Sincerely,

James Adams, DVM
Director
International Audit Staff
Office of International Affairs

Enclosure

CC: List for Letters
Rodrick McSherry, Minister Counselor, US Embassy London
Oliver Griffiths, First Secretary, British Embassy, Washington DC
Wolf Maier, Counselor, Food Safety and Consumer Affairs, EC, Washington DC
Ghislain Marechal, EC, DG SANCO - Directorate General for Health and Consumers
Debra Henke, Minister-Counselor, US Mission to the EU in Brussels
Bernard Van Goethem Director, Directorate E, EC, Brussels
Alfred Almanza, Administrator, FSIS
Lisa Wallenda Picard, OA, FSIS
Ronald Jones, Assistant Administrator, OIA
Philip Derfler, Assistant Administrator, OPPD
Dan Engeljohn, Deputy Assistant Administrator, OPPD
Mary Stanley, Director, IPD, OPPD
Ann Ryan, EB, State
David Young FAS Area Director
Steve McDermott, Sr. Director, OIA
James Adams, Director, IAS, OIA
Andreas Keller, Director, IES, OIA
Rick Harries, Director, ECS, OIA
Jerry Elliott, Director, IID, OIA
Yolande Mitchell, IES, OIA
Office of Science and Technical Affairs, FAS
Country File

APR 0 6 2010

FINAL REPORT OF AN AUDIT CARRIED OUT IN ENGLAND COVERING ENGLAND'S MEAT INSPECTION SYSTEM

NOVEMBER 25 THROUGH DECEMBER 4, 2009

Food Safety and Inspection Service
United States Department of Agriculture

TABLE OF CONTENTS

1. SUMMARY
   1.1 Description/Eligibility
   1.2 Comparison of the Current Audit and the Previous Audit
   1.3 Summary Comments for the Current Audit

2. INTRODUCTION

3. OBJECTIVE OF THE AUDIT

4. PROTOCOL

5. LEGAL BASIS FOR THE AUDIT

6. SUMMARY OF PREVIOUS AUDITS

7. MAIN FINDINGS
   7.1 Government Oversight
      7.1.1 CCA Control system
      7.1.2 Ultimate Control And Supervision
      7.1.3 Assignment of Competent and Qualified Inspectors
      7.1.4 Authority and Responsibility to Enforce the Laws
      7.1.5 Adequate Administrative and Technical Support
   7.2 Headquarters and Regional Office Audit

8. ESTABLISHMENT AUDITS

9. LABORATORY AUDITS

10. SANITATION CONTROLS
   10.1 Sanitation Standard Operating Procedures (SSOP)
   10.2 Sanitation Performance Standards (SPS)
   10.3 EC Directive 64/433

11. ANIMAL DISEASE CONTROLS

12. SLAUGHTER/PROCESSING CONTROLS
   12.1 Humane Handling and Slaughter
   12.2 Hazard Analysis and Critical Control Points (HACCP) Implementation
   12.3 Testing for Generic *Escherichia coli*
   12.4 Testing for *Listeria monocytogenes*

13. RESIDUE CONTROLS
    13.1 EC Directive 96/22
    13.2 EC Directive 96/23

14. ENFORCEMENT CONTROLS
    14.1 Daily Inspection
    14.2 Testing for *Salmonella* Species
    14.3 Species Verification
    14.4 Periodic Supervisory Reviews
    14.5 Inspection System Controls

15. EXIT MEETING

16. ATTACHMENTS TO THE AUDIT REPORT

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

BM	Business Manager
CCA	Central Competent Authority (Department for the Environment, Food and Rural Affairs)
DEFRA	Department for the Environment, Food and Rural Affairs
EC	European Commission
E. coli	*Escherichia coli*
EU	European Union
FSIS	Food Safety and Inspection Service
FSA	Food Standard Agency
GB	Great Britain
HACCP	Hazard Analysis and Critical Control Points
LGC	Laboratory of Government Chemist
LV	Lead Veterinarian
MHS	Meat Hygiene Service
NOID	Notice of Intent to Delist
OV	Official Veterinarian
Salmonella	*Salmonella* species
SPS	Sanitation Performance Standards
SSOP	Sanitation Standard Operating Procedure(s)
VEA	European Community/United States Veterinary Equivalence Agreement
VMHA	Veterinary Meat Hygiene Advisor

1. SUMMARY

1.1 Description/Eligibility

This report summarizes the outcome of the audit conducted in England from November 25 through December 4, 2009. This was a routine audit. England is eligible to export raw (not ground) pork products to the United States. At the time of the audit, one slaughter/processing establishment and one cold storage facility were eligible to export to the United States. Between June 25, 2008 and November 25, 2009, England exported a total of 2,690,885 pounds of raw pork products to the United States, of which more than 1,667,351 pounds were reinspected at the US ports of entry (POE). Activities of the current audit appear in the table below.

The findings of the previous audit during June 13 through June 25, 2008, resulted in no restrictions of any England establishment's ability to export raw pork meat to the US.

1.2 Comparison of the Current Audit and the Previous Audit

		11/25-12/04, 2009	06/13-06/25, 2008
Levels of Government Oversight Audited			
	Headquarters	1	1
	Regional	1	1
	Establishment Level	2	1
Laboratories Audited			
	Microbiology	0	0
	Residue	1	1
Establishments Audited			
	Slaughter/processing	1	1
	Cold Store	1	0
Enforcement Actions Initiated			
	NOID	1	0
	Delistment	0	0
Risk Area Findings *			
	Sanitation Controls (SSOP, SPS)	2	0
	Animal Disease Controls	0	0
	Slaughter/Processing (PR/HACCP)	4	1
	Residue Controls	0	0
	Microbiology Controls	0	0
	Inspection/Enforcement Controls	6	1

* The numbers in the Risk Area Findings section reflect the individual findings noted on the establishment checklists.

1.3 Summary Comments for the Current Audit

The results of this routine audit reflected an increase in the total number of audit non-compliances over the previous audit. The increase in audit non-compliances were in Sanitation Performance Standards (SPS), Slaughter/Processing (PR/HACCP), and Inspection/Enforcement Controls risk area findings. Specific non-compliances are noted on the attached individual foreign establishment audit forms.

No establishments were delisted. One slaughter/processing establishment received a Notice of Intent to Delist (NOID) by the CCA.

All non-compliances reported during the previous FSIS audit (2008) had been addressed and corrected.

2. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) conducted an audit of England's meat inspection system from November 25 through December 4, 2009.

An entrance meeting was held on November 25, 2009, in London with the Central Competent Authority (CCA), the Department for Environment, Food and Rural Affairs (DEFRA).

At this meeting, the auditor confirmed the objective and scope of the audit, the auditor's itinerary, and requested additional information needed to complete the audit of England's meat inspection system.

The auditor was accompanied during the entire audit by representatives from the CCA, DEFRA and/or the Food Standard Agency (FSA).

3. OBJECTIVE OF THE AUDIT

This was a routine audit. The objective of the audit was to evaluate the performance of the CCA with respect to controls over establishments certified by the CCA as eligible to export meat products to the United States.

In pursuit of the objective, the following sites were visited: the headquarters of the CCA, one regional inspection office, two local inspection offices, one slaughter/processing establishment, one cold storage facility, and one laboratory performing analytical testing for the National Residue Testing Program.

4. PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records in the country's inspection headquarters, regional, and local government offices. The third part involved on-site visits to one slaughter/processing establishment and one cold storage facility. The forth part consisted of a review of a private residue laboratory.

Program effectiveness determinations of England's inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOP), (2) animal disease controls, (3) slaughter/processing controls, including the implementation and operation of Hazard Analysis and Critical Control Points/Pathogen Reduction (HACCP/PR) programs and a testing program for generic *Escherichia Coli* (*E. coli*), (4) residue controls, and (5) enforcement controls. England's inspection system was assessed by evaluating these five risk areas.

During the on-site establishment visit, the auditor evaluated the nature, extent and degree to which findings impacted on food safety and public health. The auditor also assessed how inspection services are carried out by England and determined if establishment and inspection system controls were in place to ensure the production of meat products are safe, unadulterated and properly labeled.

During the entrance meeting, the auditor explained to the CCA that their inspection system would be audited in accordance with three areas of focus. First, under provisions of the European Community/United States Veterinary Equivalence Agreement (VEA), the FSIS auditor would audit the meat inspection system against European Commission (EC) Directive 64/433/EEC of June 1964; European Commission Directive 96/22/EC of April 1996; and European Commission Directive 96/23/EC of April 1996. These directives have been declared equivalent under the VEA.

Second, in areas not covered by these directives, the auditor would audit against FSIS requirements. These include daily inspection in all certified establishments, humane handling and slaughter of animals, the handling and disposal of inedible and condemned materials, species verification, and FSIS's requirements for HACCP, SSOP, and testing for generic *E. coli/Enterobacteriaceae* and *Salmonella* species.

Third, the auditor would audit against any equivalence determinations that have been made by FSIS for England under provisions of the Sanitary/Phytosanitary Agreement. Currently, England has the same requirements as FSIS for *Salmonella* testing for pathogen reduction performance standards with the following exceptions:

- The establishment employees collect the samples for *Salmonella*;
- Private laboratories analyze samples for *Salmonella;* and

- Analytical Methods for *Salmonella* is ISO 6579:2002.

FSIS has determined that the use of *Enterobacteriaceae* and Total Viable Count in lieu of testing for generic *E. coli* is acceptable for all European Union (EU) exporting countries. However, the establishment certified to export product to the United States had decided to test for generic *E. coli.*

5. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of U.S. laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.).
- The Federal Meat Inspection Regulations (9 CFR, Parts 301 to End), which include the Pathogen Reduction/HACCP regulations.

In addition, compliance with the following European Community Directives was also assessed:

- Council Directive 64/433/EEC, of June 1964, entitled "Health Problems Affecting Intra-Community Trade in Fresh Meat"
- Council Directive 96/23/EC, of 29 April 1996, entitled "Measures to Monitor Certain Substances and Residues Thereof in Live Animals and Animal Products"
- Council Directive 96/22/EC, of 29 April 1996, entitled "Prohibition on the Use in Stock-farming of Certain Substances Having a Hormonal or Thyrostatic Action and of ß-agonists"

6. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at the following address:

http://www.fsis.usda.gov/Regulations_&_Policies/Foreign_Audit_Reports/index.asp

The last two FSIS audits of England were held May 7 through May 17, 2007, and June 13 through June 25, 2008.

The following non-compliances were identified during the FSIS audit of England's meat inspection system conducted in May 2007:

- Extensive grease from overhead structures was observed on the conveyor belt, which was transporting edible product in the cutting room, and also on many carcasses in the cooler;
- Pieces of meat scraps and fat particles were found on the "Christmas tree" hangers in the primal-cuts area during pre-operational sanitation inspection;

- The conveyor belt for pork loins was observed with deep scoring during the pre-operational sanitation inspection in the primal cuts area; and
- An employee in the export room area was observed contacting the liner of a combo bin for edible product with his boots.

The following non-compliance was identified during the FSIS audit of England's meat inspection system conducted in June 2008:

- In one establishment, synchronization of carcasses, offal, and viscera was unsatisfactory. Carcasses were moving while offal was stopped. There was no identification of detached liver, heart, and lungs to enable them to be recognized as belonging to a given carcass.

7. MAIN FINDINGS

7.1 Government Oversight

7.1.1 CCA Control system

The Department for the Environment, Food and Rural Affairs (DEFRA) is the Central Competent Authority (CCA) in England. The organizational structure of the DEFRA and the responsibilities of personnel at each level have not changed since the last FSIS audit conducted in 2008. DEFRA is responsible for trade with countries outside the European Union (EU). DEFRA carries out all communications with FSIS and communicates official instructions to establishments certified to export to the United States. The Global Animal Health Division of DEFRA has a working agreement with the Food Standards Agency (FSA). FSA carries out the practical inspections, ensures the correct application of FSIS requirements in the certified establishments, and makes recommendations to DEFRA for approval or delisting. This function is performed by the Veterinary Meat Hygiene Advisors (VMHAs). The working agreement with DEFRA states that the implementation of FSIS requirements is the responsibility of the VMHAs and therefore all communication between DEFRA Global Animal Health Division and the FSA is directed to the VMHAs. The Meat Hygiene Service (MHS) is an agency of FSA. It was first established as an executive agency of the former Ministry of Agriculture, Fisheries and Food (MAFF) in 1995, when it took over meat inspection duties from some 300 local authoroities and become a single agency responsible for the enforcement of meat hygiene legislation in the Great Britain (GB). On April 1, 2000, the MHS transferred from MAFF (now part of the DEFRA) to become part of the FSA.

7.1.2 *Ultimate Control And Supervision*

DEFRA headquarters in London has ultimate control and supervision of England's meat inspection system. DEFRA not only has the authority to approve establishments to export to the United States, but also has the responsibility for withdrawing such approval when establishments do not meet FSIS requirements.

The final decision considering the US certified establishmentsis done in cooperation with DEFRA Global Animal Health Division and FSA.

The MHS is responsible for official oversight, control, and supervision of official inspection activitiesin all approved fresh meat premises. Food control and veterinary meat inspections are handled through 12 Business Managers (BM) throughout England. Each BM manages a cluster group, which consists of three or four clusters of slaughterhouses and/or cutting establishments. There are a total of 37 clusters in GB. A Lead Veterinarian (LV) acts as a team leader in each of the 37 clusters and is responsible for ensuring technical compliance, providing advice, and directing assignments for each team in the cluster. At slaughter, establishments there are Official Veterinarians (OV) who are team leaders for Meat Hygiene Inspectors working in approved meat establishments. OVs are supported by their LV and Senior Meat Hygiene Inspectors.

Periodic supervisory reviews in the slaughter establishment are carried out by VMHA and in the cold storage facility by Local and Port Authorities.

7.1.3 Assignment of Competent and Qualified Inspectors

All inspection personnel working in England's meat producing establishments must be fully qualified in accordance with the United Kingdom (UK) and European Union (EU) legislative and instructional requirements. Inspection personnel are a mix of directly hired by CCA or staff provided by an approved contractor. The OV and some of the inspectors assigned in the only US approved slaughter/processing establishment were employed by an approved contractor. The contractor had to meet CCA and FSA requirements. At the same establishment, the majority of the line inspection personnel were directly employed by the MHS. The MHS has the authority to cancel the contracts with inspection personnel at any time if it is deemed necessary. The Official veterinarians report directly to the Lead Veterinarian (i.e. Circuit Supervisor) of the MHS.

7.1.4 Authority and Responsibility to Enforce the Laws

DEFRA has the authority for carrying out England's meat inspection program including oversight and enforcement of the FSIS regulatory requirements in establishments certified to export to the United States. Monitoring of implementation of FSIS requirements is carried out by OV in certified establishments. The Veterinary Meat Hygiene Advisor carries out periodic supervisory reviews of certified establishments as well as verifying and evaluating the implementation of the official directives, guidelines, and instructions.

7.1.5 Adequate Administrative and Technical Support

DEFRA has the resources and ability to support a third-party audit and has adequate administrative and technical support to operate England's inspection system.

7.2 Headquarters and Regional Office Audit

The auditor conducted a review of inspection system documents at the headquarters of DEFRA, located in London. The auditor also conducted a review of records and interviewed inspection officials in the MHS office located in York for the purpose of determining the level of government oversight, supervisory structure, and to review records pertinent to the US certified establishments. The record review focused primarily on food safety hazards and included the following:

- Government oversight documents, including organizational structure
- Periodic supervisory reviews
- Training programs and personnel records of training
- Requirements for employment and payment records of inspection personnel
- New laws and implementation documents such as regulations, notices, directives and guidelines
- Assignment of inspectors, staffing, and inspection coverage of the United States certified establishment
- Inspection records and enforcement actions such as withholding, suspending, or withdrawing inspection services from or delisting an establishment that is certified to export product to the United States
- Organization of the country's laboratory system
- Microbiology and residue sampling and laboratory analyses
- Export product inspection and control including export certificates
- Sanitation, slaughter and processing inspection procedures and standards
- Control of inedible and condemned materials
- Funding of England's inspection program
- Humane handling and slaughter methods

No concerns arose as a result of the examination of these documents.

8. ESTABLISHMENT AUDITS

The FSIS auditor visited one swine slaughter/processing establishment and one cold storage facility. While no establishments were delisted, one slaughter/processing establishment received a Notice of Intent to Delist (NOID) from CCA for failure to meet some of the inspection requirements.

Specific non-compliances are noted on the attached individual establishment reports.

9. LABORATORY AUDITS

During laboratory audits, emphasis is placed on the application of procedures and standards that are equivalent to U.S. requirements.

Residue laboratory audits focus on sample handling, sampling frequency, timely analysis, data reporting, analytical methodologies, tissue matrices, equipment operation and printouts, detection levels, recovery frequency, percent recoveries, and intra-laboratory check sample and quality assurance programs, including standards books and corrective actions.

The following private residue laboratory was reviewed:

The Laboratory of Government Chemist (LGC) in Middlesex was performing residue analyses on product destined for the U.S. within the scope of the England National Residue Program.

No concerns arose as a result of this review.

Microbiology laboratory audits focus on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check sample programs.

No microbiology laboratories were included in the scope of this audit.

10. SANITATION CONTROLS

As stated earlier, FSIS auditors focus on five areas of risk to assess an exporting country's meat inspection system. The first of these risk areas that FSIS auditors review is Sanitation Controls.

Based on the on-site audits of establishments, and except as noted below, England's inspection system had controls in place for SSOP programs, all aspects of facility and equipment sanitation, the prevention of actual or potential instances of product cross-contamination, good personal hygiene practices, and good product handling and storage practices.

In addition, England's inspection system had controls in place for light, back-siphonage prevention, temperature control, ante-mortem facilities, ventilation, plumbing and sewage, water supply, dressing rooms/lavatories, welfare facilities, outside premises and condemned product control.

10.1 Sanitation Standard Operating Procedures (SSOP)

One slaughter/processing establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were being met, according to the criteria employed in the U.S. domestic inspection program. The SSOP in the audited establishment was found to meet the basic FSIS regulatory requirements.

No non-compliances were noted.

10.2 Sanitation Performance Standards (SPS)

The FSIS regulations in 9 CFR 416.2 to 416.5 set forth specific sanitation performance standards that establishments must meet to prevent the creation of insanitary conditions that could cause the adulteration of meat products. The SPS in both establishments were found to meet the basic FSIS regulatory requirements.

No non-compliances were noted.

10.3 EC Directive 64/433

In one of the two establishments, the provisions of EC Directive 64/433 and/or other sanitation requirements were not effectively implemented.

Specific non-compliances are noted under section 10.2 (SPS) and in the attached individual establishment reports.

11. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviewed is Animal Disease Controls. These include ensuring adequate animal identification, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. The auditor determined that England's inspection system had adequate controls in place.

No non-compliances were noted.

There had been no outbreaks of animal diseases with public health significance since the last FSIS audit.

12. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor reviewed is Slaughter/Processing Controls. The controls include ante-mortem inspection procedures; ante-mortem dispositions; humane handling and humane slaughter; ingredients identification; control of restricted ingredients, formulations, processing schedules, equipment, and records; and processing controls of cured, dried, and cooked products.

The controls also include the implementation of HACCP systems in all establishments and implementation of a testing program for generic *E. coli* in slaughter establishments.
12.1 Humane Handling and Humane Slaughter

No non-compliances were noted.

12.2 Hazard Analysis and Critical Control Points (HACCP) Implementation

All establishments approved to export meat products to the United States are required to have developed and adequately implemented a HACCP program. Each of these programs was evaluated according to the criteria employed in the United States' domestic inspection program.

The HACCP programs were reviewed during the on-site audit of one slaughter/processing establishment. In the slaughter/process category, HACCP record keeping non-compliances for monitoring, corrective actions, and verification activities were identified as follows:

- The establishment monitoring records for CCP 3 (zero tolerance for fecal and ingesta) did not include the times when the specific events occurred;
- The establishment corrective action records for CCP 3 did not identify or document the cause of the deviation from which the critical limit was not met and the measures to be taken to prevent recurrence;
- The establishment's written HACCP plan did not address the frequency at which the calibration of process-monitoring instruments would be conducted;
- The establishment's written HACCP plan did not include the review of records as part of its ongoing verification procedures, including not addressing the frequency with which this procedure will be performed.

12.3 Testing for Generic *Escherichia. Coli (E. coli)*

England has adopted the FSIS regulatory requirements for testing for generic *E. coli.* One establishment was required to meet the basic FSIS regulatory requirements for generic *E. coli.*

Testing for generic *E. coli* was properly conducted in this establishment.

12.4 Testing for *Listeria monocytogenes*

The establishment was not producing ready-to-eat products for export to the United States and was not required to meet the FSIS requirements for *Listeria monocytogenes* testing. England currently exports only raw pork to the United States.

13. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditor reviewed was Residue Controls. These controls include sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions.

England's National Residue Control Program for 2009 was being followed as it was written.

13.1 EC Directive 96/22

In the Laboratory of Government Chemist (LGC), the provisions of EC Directive 96/22 were effectively implemented.

13.2 EC Directive 96/23

In the LGC, the provisions of EC Directive 96/23 were effectively implemented.

14. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditors reviewed is Enforcement Controls. These controls include the enforcement of inspection requirements and the testing program for *Salmonella* species.

14.1 Daily Inspection

Inspection was being conducted and documented as required by CCA.

14.2 Testing for *Salmonella* Species

England has adopted the FSIS requirements for testing for *Salmonella* with the exception of the following equivalent measures:

- The establishment is authorized to collect samples;
- A private laboratory analyzes the samples; and
- The laboratory method utilized is based on BS EN ISO 6579:2002.

Salmonella testing was properly conducted in the audited establishment.

14.3 Species Verification

Species verification testing was being conducted as required by CCA.

14.4 Periodic Supervisory Reviews

Periodic (monthly) supervisory reviews of the certified establishments were being performed and documented as required by CCA.

14.5 Inspection System Controls

The CCA had controls in place for ante-mortem, restricted product and inspection samples; disposition of dead, dying, disease or disabled animals; shipment security, including shipment between establishments, to prevent commingling of product intended for export to the United States with product intended for the domestic market.

In addition, controls were in place for the importation of only eligible livestock from other countries, i.e., only from eligible third countries and certified establishments within those countries, and the importation of only eligible meat products from other counties for further processing.

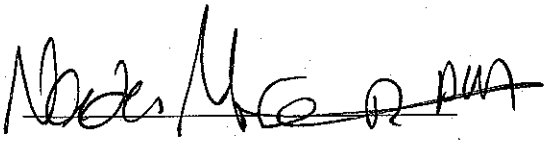
Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

15. EXIT MEETING

An exit meeting was held on December 4, 2009, in London with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the auditor.

The CCA understood and accepted the findings.

Nader Memarian, DVM
Senior Program Auditor



16. ATTACHMENTS TO THE AUDIT REPORT
Individual Foreign Establishment Audit Forms
Foreign country response to the Draft Audit Report

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Vion Group UK Hugdon Way Norton Grove Industrial Estate Malton Y017 9HG	12/01/2009	UK2060EEC	England
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment Date: 12/01/2009 Est #: UK2060EEC (Vion Group UK [S/P/CS]) (Malton, England)

14/19/22/51 A) The auditor's review of the establishment written HACCP plan for the slaughter process category did not include the review of records as part of its ongoing verification procedures, including not addressing the frequency with which this procedure will be performed. However, the establishment has generated some record review documents which were missing the times and results of verification activities. [1]
B) The auditor's review of the establishment written HACCP plan for the slaughter process category did not address the frequency at which the calibration of process-monitoring instruments would be conducted. [1]

These HACCP recordkeeping non-compliances had not been identified in the review of records by the establishment personnel or in the HACCP verifications activities performed by England inspection service for the last 90 days.

The aforementioned findings were not meeting FSIS regulatory requirement. [9 CFR § 417.2, 417.4, 417.5, and 417.8]

22/51 A) The auditor's review of the establishment monitoring records for CCP 3 (zero tolerance for fecal and ingesta) did not include the times when the specific events occurred. [1]
B) The auditor's review of the establishment corrective action records for CCP3 did not identify or document the cause of the deviation from which the critical limit was not met and the measures to be taken to prevent recurrence. [1]

These HACCP recordkeeping non-compliances had not been identified in the review of records by the establishment personnel or in the HACCP verifications activities performed by England inspection service for the last 90 days.

The aforementioned findings were not meeting FSIS regulatory requirements. [9 CFR § 417.5 and 417.8]

During the auditor's walk through of the facility the following were observation of non compliances that were address by the establishment and England's inspection service and are presented to demonstrated inspection controls:

Holes, flaking paint, loose hanging pieces of silicone sealant, and corrosion of the ceiling panels were observed over-product structures and equipment in main butchery (production area). These issues had already been identified by the veterinary service and were in the process of being corrected by the establishment.

Beaded condensate was observed on the ceiling and under the refrigeration units located over exposed product, and equipments, in several production areas of the main butchery; the middle de-boning room chiller and the swine carcass chillers. The presence of condensate had already been identified by the veterinary service and corrective measures had been implemented by the establishment. Even though product was not affected at the time of this audit, the establishment removed the product that was located under the condensate, wiped out the condensate, and tagged the product for reconditioning based on its written procedure.

58 Based on compliance history and inadequate/ineffective corrective actions taken by this establishment, DEFRA voluntarily issued a notice of intent to delist on December 17, 2009.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian, DVM	4-6-10

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Associated British Ports Corporation Road, King George Dock Hull HU9 5NF	11/30/2009	UKXA7EC	England
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

Date: 11/30/2009 Est #: UKXA7EC (Associated British Ports [CS]) (Hull, England)

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

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian, DVM	12-6-10

Food and Farming Group
5B Nobel House
17 Smith Square
London SW1P 3JR
Website www.defra.gov.uk

defra
Department for Environment
Food and Rural Affairs

Our ref: EXM1822
[Case veterinarian: Andrew Gresham
andrew.c.gresham@defra.gsi.gov.uk]

Dr James Adams
Director
International Audit Staff
Office of International Affairs
United States Department of Agriculture
Food Safety and Inspection Service
Washington, DC
20250
USA

17 March 2010

Dear Dr Adams

RESPONSE TO THE REPORT ON THE FSIS AUDIT OF ENGLAND'S MEAT INSPECTION SYSTEM

Thank you for your letter received on 23 December 2009 enclosing a copy of the draft final report on the FSIS audit of England's meat inspection system.

I would like to confirm that Defra agrees with the report and accepts its findings. Subsequent to the audit a Notification of Intention to De-list was issued to the establishment concerned on 17 December 2009, and the passage at paragraph 58, page 19 of the report could potentially be updated to reflect this timing.

The establishment notified Defra of completion of the remedial measures within 30 days of receipt the Notification, and this was confirmed by the Meat Hygiene Service during the USDA Monthly Supervisory Audit carried out on January 19 2010. As such the Notification was lifted on 29 January and this communication copied to you at the time.

I would like to thank you for the opportunity to comment on the report and apologise for the delay in responding. If there is any further information you require, please do not hesitate to contact me.

Yours sincerely

Mauricio López
Veterinary Head of Global Animal Health
Direct Line +44 (0)207 238 1720
Fax +44 (0)207 238 3087
Email Mauricio.Lopez@defra.gsi.gov.uk

cc: Steve Knight, US Embassy
Alistair Booth, VMHA, Harrogate
Jane Downes, MHS Veterinary Director, York
Ian Bolton, MHS Veterinary Auditor
Craig Kirby, Veterinary Manager, MHS
Andrew Gresham, VA, Defra