



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

AUG 19 2003

Mr. Nigel Gibbens
Head, International Animal Health Division
Department for Environment Food & Rural Affairs (DEFRA)
State Veterinary Service
Room 403c
1A Page Street
London
SW1P 4PQ

Dear Mr. Gibbens:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Great Britain's meat inspection system from March 5-19, 2003. Enclosed is the final audit report. We have incorporated into the final report as Attachment "G" your July 3, 2003 letter commenting on the draft final report of the same audit.

We appreciate the actions taken by the United Kingdom to correct the deficiencies identified by the FSIS auditor. If you have any questions regarding the FSIS audit, please contact me at my telephone number 202-720-3781. You may also reach me at my facsimile number 202-690-4040 or email address sally.stratmoen@fsis.usda.gov.

Sincerely,

Sally Stratmoen, Acting Director
International Equivalence Staff
Office of International Affairs

Enclosure

FINAL

AUG - 8 2003

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

MARCH 5 THROUGH MARCH 19, 2003

Food Safety and Inspection Service
United States Department of Agriculture

TABLE OF CONTENTS

1. INTRODUCTION
2. OBJECTIVE OF THE AUDIT
3. PROTOCOL
4. LEGAL BASIS FOR THE AUDIT
5. SUMMARY OF PREVIOUS AUDITS
6. MAIN FINDINGS
 - 6.1 Legislation
 - 6.2 Government Oversight
 - 6.3 Headquarters Audit
7. ESTABLISHMENT AUDITS
8. LABORATORY AUDITS
9. SANITATION CONTROLS
 - 9.1 SSOP
 - 9.2 EC Directive 64/433
10. ANIMAL DISEASE CONTROLS
11. SLAUGHTER/PROCESSING CONTROLS
 - 11.1 Humane Handling and Slaughter
 - 11.2 HACCP Implementation
 - 11.3 Testing for Generic *Escherichia coli*
 - 11.4 Testing for *Listeria monocytogenes*
 - 11.5 EC Directive 64/433
12. RESIDUE CONTROLS
 - 12.1 FSIS Requirements
 - 12.2 EC Directive 96/22
 - 12.3 EC Directive 96/23
13. ENFORCEMENT CONTROLS
 - 13.1 Daily Inspection
 - 13.2 Testing for *Salmonella*
 - 13.3 Species Verification
 - 13.4 Monthly Reviews
 - 13.5 Inspection System Controls

14. CLOSING MEETING

15. ATTACHMENTS TO THE AUDIT REPORT

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority [Department for Environment, Food and Rural Affairs]
DEFRA	Department for Environment, Food and Rural Affairs
FSA	Food Standards Agency
MHS	Meat Hygiene Service
VPHOD	Veterinary Public Health Operations Division (of the FSA)
VMHA	Veterinary Meat Hygiene Adviser
VMD	Veterinary Medicines Directorate
POVS	Principal Official Veterinary Surgeon
OVS	Official Veterinary Surgeon
FSIS	Food Safety and Inspection Service
VEA	European Community/United States Veterinary Equivalence Agreement
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
SSOP	Sanitation Standard Operating Procedures
<i>E. coli</i>	<i>Escherichia coli</i>
<i>Salmonella</i>	<i>Salmonella</i> species
<i>Listeria</i>	<i>Listeria monocytogenes</i>

1. INTRODUCTION

The audit took place in England from March 5 to March 19, 2003.

An opening meeting was held on March 5, 2003 in London with the Central Competent Authority (CCA). 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 (Department for Environment, Food and Rural Affairs) and/or representatives from the regional and district inspection offices.

2. OBJECTIVE OF THE AUDIT

This audit was a routine annual audit. The objective of the audit was to evaluate the performance of the CCA with respect to controls over the slaughter and processing 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: one regional inspection office, one district office, two laboratories performing analytical testing on United States-destined product, one swine slaughter establishment, and one cold storage facility.

Competent Authority Visits			Comments
Competent Authority	Regional	1	MHS regional office in York
Laboratories		2	
Meat Slaughter Establishments		1	
Cold Storage Facilities		1	

3. 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 or regional offices. The third part involved on-site visits to two establishments: one slaughter establishments and one cold storage facility. The fourth part involved visits to two private laboratories. The Allied Laboratory Services Limited was conducting analyses of field samples for the presence of generic *Escherichia coli* (*E. coli*) and *Salmonella*. The Laboratory of the Government Chemist was conducting analyses of field samples for England's national residue control program.

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, (2) animal disease controls, (3) slaughter/processing controls, including the implementation and operation of HACCP programs and a testing program for generic *E. coli*, (4) residue controls, and (5) enforcement controls, including a testing program for *Salmonella*. England's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, 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 that are safe, unadulterated and properly labeled.

At the opening 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 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 by FSIS under the VEA.

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

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 an equivalence determination from FSIS regarding their *Salmonella* testing program. These differences can be reviewed under section 13.2 of this report.

4. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of United States 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 Stockfarming of Certain Substances Having a Hormonal or Thyrostatic Action and of B-agonists

5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at www.fsis.usda.gov/ofotsc.

The following deficiencies were identified during the FSIS audit of England's meat inspection system conducted in May 2000.

- Inadequate prevention of contamination was found in three of the five establishments.
- Inadequate hand-washing facilities were found in two establishments.
- Inadequate light at inspection station was observed in one establishment.
- Neglected maintenance and cleaning of over product equipment was observed in one establishment.
- Swine were not observed from both sides in motion during ante-mortem inspection in one establishment.
- Monthly supervisory audits were not adequately conducted in four of the five establishments certified as eligible to export to the U.S.

The following deficiencies were identified during the FSIS audit of England's meat inspection system conducted in February 2002. Notice of Intent to Delist (NOID) for inadequate implementation of SSOP was given to one of the three establishments audited.

- The written SSOP procedures did not indicate any preventive actions in two of the three establishments.
- HACCP implementation problems were found in one establishment.
- Post-mortem inspection procedures were incomplete in one establishment.
- Condensation controls were inadequate in two establishments.
- Sanitary dressing procedures were inadequate in one establishment.
- Grease from rail and other sources was observed on several carcasses and in boxed trimmings in one of three establishments.
- Containers for condemned product were not identified in one establishment.
- One establishment was using the sponge method for sampling carcasses for generic *E. coli* but did not evaluate the test results using statistical process control techniques.

6. MAIN FINDINGS

6.1 Legislation

The auditor was informed that the relevant EC Directives, determined equivalent under the VEA, had been transposed into England's legislation.

6.2 Government Oversight

6.2.1 CCA Control Systems

The CCA, the Department for the Environment, Food and Rural Affairs (DEFRA), is responsible for trade with countries outside the EU (including the U.S.). DEFRA carries out all communications with FSIS and will communicate official instructions to establishments certified to export to the United States. The International Animal Health Division of DEFRA has a Working Agreement with the Veterinary Public Health Operations Division (VPHOD) of the Food Standards Agency (FSA). FSA carries out the practical inspections and make recommendations for approval or de-listing to DEFRA, and ensures the correct application of FSIS requirements in the establishments. This function is performed by the Veterinary Meat Hygiene Advisors (VMHAs) from the VPHOD of the FSA. There are eight VMHAs in England, each one covering a specified area of the country. The Working Agreement with DEFRA states that the implementation of FSIS requirements is the responsibility of the VMHAs and therefore all communication between DEFRA International Animal Health Division and the VPHOD of the FSA is directly to the VMHAs. The Meat Hygiene Service (MHS), an executive agency of FSA, provides the government veterinarians and inspectors for “approved” meat and poultry establishments (domestic and exporting) by either direct hiring or through contract services. All official veterinarians assigned to the two establishments currently certified to export to the United States are on contract to MHS. The Veterinarian contracts are reviewed annually and renewed every three years by FSA. The MHS has the authority to cancel the contracts with veterinarians at any time deemed necessary. The Chief Executive of the MHS reports to the FSA Director of Enforcement and it is agreed that instructions for the plant Official Veterinarian (OV) and Principal Official Veterinarian (POV) in relation to FSIS requirements will come direct from the VMHA. The official veterinarians and inspectors report directly to the POVS, which are stationed throughout Great Britain.

6.2.2 Ultimate Control and Supervision

DEFRA, as the CCA, has the authority to remove establishments from the list of establishments certified to export to the U.S., and refuse the issuance of veterinary health certificates to prohibit exports from taking place. The decision as to whether the establishment is failing to meet U.S requirements and the recommendation that de-listing should occur is the responsibility of the VMHA who would reach his/her decision after considering reports from the OV and the POV and carrying out an audit of the establishment.

6.2.3 Assignment of Competent, Qualified Inspectors

All veterinarians and meat inspectors working in England’s establishments must be fully qualified in accordance with legislative and instructional requirements. Veterinarians have to attend an intensive two-week training course as well as participate in on-the-job training with experienced veterinarians. Meat Inspectors must undergo training in accordance with the requirements of EU Directive 64/433/EEC, Annex III for veterinary auxiliaries (400 hours theoretical and 200 hours practical instructions) and must have

passed an examination before being authorized to work in meat establishments. Since the adoption of EU Commission Decision 2001/471/EC requiring the introduction of controls based on HACCP Principles, the MHS has instigated a program of HACCP training for all its employees. The following deficiency was noted:

- Inspection service employee at all levels do not fully understand the U.S. PR/HACCP requirements

6.2.4 Authority and Responsibility to Enforce the Laws

DEFRA, as the CCA, can remove establishments certified to export to the United States if FSIS requirements are not met. Monitoring of these requirements is carried out by VMHAs and POVs from the MHS under the requisite schedule of visits (annually by the VMHA and monthly by the POV when exports are taking place). Additional visits are carried out as necessary when there are adverse reports from the plant OV. De-listing would be carried out by DEFRA International Animal Health Division on a recommendation from the VMHA.

MHS has the authority and responsibility to enforce the applicable laws relevant to U.S.-certified establishments. The Principal Official Veterinary Surgeons (POVS) are in-charge of verifying and evaluating the implementation of the official directives, guidelines and instructions. The following deficiencies were noted:

- In one establishment, HACCP implementation deficiencies resulted in a Notice of Intent to Delist (NOID) if the deficiencies are not corrected within 30 days. These deficiencies should have been identified by MHS before this FSIS audit. In this establishment, the Official Veterinary Surgeon (OVS) was not verifying the adequacy of the HACCP plan by reviewing and determining the adequacy of corrective actions to be followed in response to a deviation from a critical limit at a critical control point (CCP) or direct observation or measurement at a CCP. In the same establishment, the OVS was not documenting corrective actions taken for the identified pre-operational sanitation deficiencies most of the time.

6.2.5 Adequate Administrative and Technical Support

During the audit, the auditor found that at the present, the CCA has administrative and technical support to operate England's inspection system and has the resources and ability to support a third-party audit.

Technical support to operate the inspection system to FSIS requirements is provided by the VMHAs of the FSA. They also have sufficient manpower to provide the support necessary to handle third-party audits. The audit support is part of the working agreement between the FSA and DEFRA. Adequate administrative support is available at all stages in the enforcement chain in DEFRA, FSA and the MHS.

6.3 Headquarters Audit

The auditor conducted a review of inspection system documents at the MHS regional office in York. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- Training records for inspectors and laboratory personnel.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses for residues.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of inedible and condemned materials.
- Export product inspection and control including export certificates.
- Enforcement records, including examples of criminal prosecution, consumer complaints, recalls, seizure and control of noncompliant product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

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

6.3.1 Audit of Regional Office

The auditor visited one regional Meat Hygiene Service (MHS) office in York. The purpose of the visit was to determine (1) whether the regional office had received the instructions from the DEFRA regarding EC Directives 96/22; EC Directive 96/23; EC Directive 64/433 and including FSIS PR/HACCP implementation requirements, and (2) whether the instructions were implemented by the regional office in the certified establishments.

The auditor found that the instructions had been received and implemented by the regional office visited.

7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of two establishments. One was a slaughter and processing establishment and one was a cold storage facility. No establishments were delisted by DEFRA. One establishment received a NOID for failing to adequately implement the PR/HACCP programs. This establishment may retain its certification for export to the United States provided that within 30 days of the date the establishment was reviewed that all deficiencies were corrected and the government of England has verified the corrective actions.

Specific deficiencies are noted on the attached individual establishment reports.

8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

During the laboratory audits, emphasis was placed on the application of procedures and standards that are equivalent to United States' 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, intra-laboratory check samples, and quality assurance programs, including standards books and corrective actions.

Microbiology laboratory audits focus on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples. If private laboratories are used to test United States samples, the auditor evaluated compliance with the criteria established for the use of private laboratories under the PR/HACCP requirements.

The following laboratories were reviewed:

- The Laboratory of the Government Chemist is a private laboratory, located in Middlesex, which conducts analyses of field samples for Great Britain's national residue control program.
- The Allied Laboratory Services Limited is a private laboratory, located in Grimsby, which conducts analyses of field samples for the presence of *Salmonella* species and generic *Escherichia coli* (*E.coli*)

No deficiencies were noted.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditor focuses on five areas of risk to assess an exporting country's meat and poultry inspection system. The first of these risk areas that the FSIS auditor reviewed was 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 and practices, and good product handling and storage practices.

In addition, and except as noted below, England's inspection system had controls in place for water potability records, chlorination procedures, back-siphonage prevention, separation of operations, temperature control, work space, ventilation, ante-mortem facilities, welfare facilities, and outside premises.

9.1 SSOP

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the United States' domestic inspection program. The SSOP in the both establishments were found to meet the basic FSIS regulatory requirements with the following deficiencies.

- One establishment was not adequately documenting daily operational sanitation deficiencies (records were maintained once a week only). Another establishment was not maintaining records for pre-operational sanitation.

9.2 EC Directive 64/433

In all establishments, the provisions of EC Directive 64/433 were effectively implemented, with the following deficiencies.

- One establishment did not have adequate controls in place to prevent the entry of rodents and other vermin in the dry storage room.

In both establishments, the specific deficiencies are noted in the attached individual establishment reports.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviewed was Animal Disease Controls. These controls 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 deficiencies were noted.

There had been no outbreaks of animal diseases with public health significance since the last FSIS audit. APHIS declared Great Britain free of Rinderpest and FMD effective December 17, 2002, although subject to special export conditions. APHIS also declared Great Britain free of Swine Vesicular Disease, although subject to special export conditions.

Importation of beef or beef products was not allowed into the United States from England at the time of this audit due to the presence of BSE in the United Kingdom. APHIS continues to place import restrictions on Great Britain for Hog Cholera for the counties of Essex, Norfolk, and Suffolk.

11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor reviewed was Slaughter/Processing Controls. The controls include the following areas: ante-mortem inspection procedures, ante-mortem disposition, humane handling and humane slaughter, post-mortem inspection procedures, post-mortem disposition, 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.

11.1 Humane Handling and Humane Slaughter

No deficiencies were noted.

11.2 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 audits of the two establishments. One establishment was a cold storage facility. The only establishment that was required to meet the HACCP programs requirements had not adequately implemented the HACCP requirements. The following deficiencies were identified.

- The records documenting ongoing verification such as the calibration of process-monitoring, direct observations of monitoring activities and corrective actions were not adequately met by the establishment.
- The records were not maintained at the identified critical control point for the monitoring CCP's for zero tolerance for fecal materials. The entries were not made at the time the deviation occurred, and did not include the time, signature/initials and corrective actions taken in response to a deviation of critical limits by the responsible establishment employee.

11.3 Testing for Generic *E. coli*

England has adopted the FSIS regulatory requirements for testing for generic *E. coli*.

One of the two establishments audited was required to meet the basic FSIS regulatory requirements for testing for generic *E. coli* and was evaluated according to the criteria employed in the United States' domestic inspection program.

Testing for generic *E. coli* was properly conducted in this establishment and no deficiency was noted.

11.4 Testing for *Listeria monocytogenes*

Both establishments audited were not producing ready-to-eat products for export to the United States and were not required to meet the FSIS requirements for *Listeria monocytogenes* testing. England is only exporting fresh pork ribs to the United States.

11.5 EC Directive 64/433

In the one slaughter establishment audited, the provisions of EC Directive 64/433 were effectively implemented.

12. 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.

The Laboratory of the Government Chemist, located in Middlesex (London), is a private laboratory. No deficiencies were noted.

England's National Residue Control Program for 2003 was being followed and was on schedule.

12.1 FSIS Requirements

The GOE had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals. The methods used for the analyses were acceptable. No deficiencies were noted.

12.2 EC Directive 96/22

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

12.3 EC Directive 96/23

In the Laboratory of the Government Chemist, the provisions of EC Directive 96/23 were effectively implemented.

13. ENFORCEMENT CONTROLS

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

MHS needs to strengthen its ability to enforce U.S. requirements by implementing enforcement procedures to take corrective actions, including implementation of the 30-days NOID policy for inadequate SSOP and HACCP implementation.

- In one establishment, DEFRA officials gave a Notice of Intent to Delist (NOID) regarding the inadequate implementation requirements for SSOP's and HACCP. MHS is to evaluate the adequacy of corrective actions and provide a full report to FSIS.

13.1 Daily Inspection in Establishments

Inspection was being conducted daily in all slaughter and processing establishments.

13.2 Testing for *Salmonella*

England has adopted the FSIS requirements for testing for *Salmonella* with the exception of the following equivalent measure(s).

- Establishment takes samples.
- Private laboratory analyzes samples.

One of the two establishments audited was required to meet the basic FSIS regulatory requirements for *Salmonella* testing and was evaluated according to the criteria employed in the United States' domestic inspection program.

Salmonella testing was properly conducted in this establishment and no deficiencies were noted.

13.3 Species Verification

UK is required to conduct species verification testing while FSIS evaluate UK's request for an exemption to species testing.

13.4 Monthly Reviews

During this audit it was found that in all establishments visited, monthly supervisory reviews of certified establishments were being performed and documented as required.

13.5 Inspection System Controls

The CCA had controls in place for ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; disposition of dead, dying, diseased or disabled animals; shipment security, including shipment between establishments; and prevention of 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 meat products from other countries for further processing.

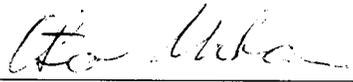
Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

14. CLOSING MEETING

A closing meeting was held on March 19, 2003 in London with the CCA and, by teleconference, with a member of the European Community in Brussels. At this meeting, the primary findings and conclusions from the audit were presented by the auditor. The CCA understood and accepted the findings.

for

Faizur R. Choudry, DVM
International Audit Staff Officer



15. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Forms

Foreign Country Laboratory Review Reports

Foreign Country Response to Draft Final Audit Report

REVIEW DATE
 03/10/03

NAME OF FOREIGN LABORATORY
 Allied Laboratory Services Ltd.

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOV'T AGENCY
 Private

CITY & COUNTRY
 Grimsby, Great Britain

ADDRESS OF LABORATORY
 The Technical Center , Wickham Road, Grimsby
 North East Lincolnshire

NAME OF REVIEWER
 Dr. Faiz R. Choudry, DVM

NAME OF FOREIGN OFFICIAL
 Alistair J. Booth BVMS, MSc. MRCVS, Veterinary Meat Hygiene Advisor

Residue Code/Name		E.co	Sal																	
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE																	
	Sample Handling	01		A	A															
	Sampling Frequency	02		A	A															
	Timely Analyses	03		A	A															
	Compositing Procedure	04		O	O															
	Interpret Comp Data	05		O	O															
	Data Reporting	06	A	A																
ANALYTICAL PROCEDURES	Acceptable Method	07	A	A																
	Correct Tissue(s)	08	A	A																
	Equipment Operation	09	O	O																
	Instrument Printouts	10	O	O																
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	O	O																
	Recovery Frequency	12	O	O																
	Percent Recovery	13	O	O																
	Check Sample Frequency	14	A	A																
	All analyst w/Check Samples	15	A	A																
	Corrective Actions	16	A	A																
	International Check Samples	17	O	O																
REVIEW	Corrected Prior Deficiencies	18	O	O																
OTHER REVIEW		19																		
		20																		

SIGNATURE OF REVIEWER

Dr. Faiz R. Choudry

DATE

3/10/03

FOREIGN COUNTRY LABORATORY REVIEW

(Comment Sheet)

REVIEW DATE

03/10/03

NAME OF FOREIGN LABORATORY

Allied Laboratory Services Ltd.

FOREIGN GOV'T AGENCY
Private

CITY & COUNTRY
Grimsby, Great Britain

ADDRESS OF LABORATORY
The Technical Center , Wickham Road, Grimsby
North East Lincolnshire

NAME OF REVIEWER
Dr. Faiz R. Choudry, DVM

NAME OF FOREIGN OFFICIAL
Alistair J. Booth BVMS, MSc. MRCVS, Veterinary Meat Hygiene Advisor

RESIDUE

ITEM NO.

COMMENTS

REVIEW DATE

03/12/03

NAME OF FOREIGN LABORATORY

Laboratory of the Government Chemist.

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOV'T AGENCY
 Private

CITY & COUNTRY
 Middlesex, Great Britain

ADDRESS OF LABORATORY
 Queens Road Teddington, Middlesex TW 11 OLY,
 UK

NAME OF REVIEWER
 Dr. Faiz R. Choudry, DVM

NAME OF FOREIGN OFFICIAL
 Mr. Simon Hall, Deputy Veterinary Head; Mr. Steve Knight, Agri. Specialist

Residue Code/Name			100	111	200	203	300	400	500	800	910	923		
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE											
	Sample Handling	01	A	A	A	A	A	A	A	A	A	A		
	Sampling Frequency	02	A	A	A	A	A	A	A	A	A	A		
	Timely Analyses	03	A	A	A	A	A	A	A	A	A	A		
	Compositing Procedure	04	O	O	O	O	O	O	O	O	O	O		
	Interpret Comp Data	05	O	O	O	O	O	O	O	O	O	O		
Data Reporting	06	A	A	A	A	A	A	A	A	A	A	A		
ANALYTICAL PROCEDURES	Acceptable Method	07	A	A	A	A	A	A	A	A	A	A		
	Correct Tissue(s)	08	A	A	A	A	A	A	A	A	A	A		
	Equipment Operation	09	A	A	A	A	A	A	A	A	A	A		
	Instrument Printouts	10	A	A	A	A	A	A	A	A	A	A		
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	A	A	A	A	A	A	A	A	A	A		
	Recovery Frequency	12	A	A	A	A	A	A	A	A	A	A		
	Percent Recovery	13	A	A	A	A	A	A	A	A	A	A		
	Check Sample Frequency	14	A	A	A	A	A	A	A	A	A	A		
	All analyst w/Check Samples	15	A	A	A	A	A	A	A	A	A	A		
	Corrective Actions	16	A	A	A	A	A	A	A	A	A	A		
	International Check Samples	17	A	A	A	A	A	A	A	A	A	A		
REVIEW	Corrected Prior Deficiencies	18	A	A	A	A	A	A	A	A	A	A		
OTHER REVIEW		19												
		20												

SIGNATURE OF REVIEWER

Dr. Faiz R. Choudry

DATE

3/12/03

FOREIGN COUNTRY LABORATORY REVIEW

(Comment Sheet)

REVIEW DATE

03/12/03

NAME OF FOREIGN LABORATORY

Laboratory of the Government Chemist.

FOREIGN GOV'T AGENCY
Private

CITY & COUNTRY
Middlesex, Great Britain

ADDRESS OF LABORATORY
Queens Road Teddington, Middlesex TW 11 OLY,
UK

NAME OF REVIEWER
Dr. Faiz R. Choudry, DVM

NAME OF FOREIGN OFFICIAL
Mr. Simon Hall, Deputy Veterinary Head; Mr. Steve Knight, Agri. Specialist

RESIDUE

ITEM NO.

COMMENTS

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Grampian Country Pork Parliament Street Norton, Malton, North Yorkshire	2. AUDIT DATE 03/07/03	3. ESTABLISHMENT NO. UK 2060	4. NAME OF COUNTRY England 6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT
5. NAME OF AUDITOR(S) Dr. Faiz R. Choudry, DVM			

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

	Audit Results		Audit Results
Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements		Part D - Continued Economic Sampling	
7. Written SSOP	O	33. Scheduled Sample	O
8. Records documenting implementation.	O	34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.	O	35. Residue	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	O	36. Export	O
11. Maintenance and evaluation of the effectiveness of SSOP's.	O	37. Import	O
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	O	38. Establishment Grounds and Pest Control	X
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	O
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	O
14. Developed and implemented a written HACCP plan .	O	41. Ventilation	O
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	O	42. Plumbing and Sewage	O
16. Records documenting implementation and monitoring of the HACCP plan.	O	43. Water Supply	O
17. The HACCP plan is signed and dated by the responsible establishment individual.	O	44. Dressing Rooms/Lavatories	O
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	O
18. Monitoring of HACCP plan.	O	46. Sanitary Operations	O
19. Verification and validation of HACCP plan.	X	47. Employee Hygiene	O
20. Corrective action written in HACCP plan.	O	48. Condemned Product Control	O
21. Reassessed adequacy of the HACCP plan.	O	Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	O
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	O
23. Labeling - Product Standards	O	51. Enforcement	X
24. Labeling - Net Weights	O	52. Humane Handling	O
25. General Labeling	O	53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O	54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	X
29. Records	O	57. Monthly Review	O
Salmonella Performance Standards - Basic Requirements		58. Intended Enforcement Actions	X
30. Corrective Actions	O	59.	O
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

Etablissement # UK 2060

Dated 03/07/03

- 13. The establishment was not adequately documenting daily operational sanitation deficiencies (records were maintained once a week only) and corrective actions for the identified deficiencies were not documented most of the time. FSIS regulatory requirement 416.16(a) were not adequately met.
- 19. The records documenting ongoing verification such as the calibration of process-monitoring instruments, direct observations of monitoring activities and corrective actions were not adequately met FSIS 417.4 (a) (2)(i)(ii) regulatory requirements by the establishment.
- 22. The records were not maintained at the identified critical control point for monitoring CCP's for zero tolerance for fecal materials. The entries were not made at the time the deviation occurred, including the time, signature or initials and corrective actions taken in response to a deviation of critical limits by the responsible establishment employee. FSIS 417.5 regulatory requirements were not adequately met.
- 38/56. Gaps at the sides and bottom of door in the main dry storage room were not sealed properly to prevent the entry of rodents and other vermin. Council Directive 64/433 EEC Annex 1 Chapter 1(v) was not adequately met.
- 51. A) The Official Veterinary Surgeon was not verifying the adequacy of the HACCP plan's such as: By reviewing and determining the adequacy of corrective actions to be followed in response to a deviation from a critical limit at a critical control point; direct observation or measurement at a CCP. FSIS 417.8(c) (f) regulatory requirements were not adequately met.

B) The Official Veterinary Surgeon was not documenting corrective actions taken for the identified pre-operational sanitation deficiencies most of the time. FSIS 416.17(c) regulatory requirements were not adequately met.
- 58. MHS officials gave a Notice of Intent to Delist (NOID) regarding the inadequate implementation requirements for SSOP's and HACCP. MHS is to evaluate the adequacy of corrective actions and provide a full report to FSIS.

61. NAME OF AUDITOR

Richard R. Chocary, DVM

62. AUDITOR SIGNATURE AND DATE

Richard R. Chocary 3/8/03

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION ABP Connect Corporation Road, King George Dock Hedon Road, HULL	2. AUDIT DATE 03/06/03	3. ESTABLISHMENT NO. UK2182	4. NAME OF COUNTRY England
5. NAME OF AUDITOR(S) Dr. Faiz R. Choudry, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

	Audit Results		Audit Results
Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements		Part D - Continued Economic Sampling	
7. Written SSOP	O	33. Scheduled Sample	O
8. Records documenting implementation.	O	34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.	O	35. Residue	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	O	36. Export	O
11. Maintenance and evaluation of the effectiveness of SSOP's.	O	37. Import	O
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	O	38. Establishment Grounds and Pest Control	O
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	O
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	O
14. Developed and implemented a written HACCP plan .	O	41. Ventilation	O
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	O	42. Plumbing and Sewage	O
16. Records documenting implementation and monitoring of the HACCP plan.	O	43. Water Supply	O
17. The HACCP plan is signed and dated by the responsible establishment individual.	O	44. Dressing Rooms/Lavatories	O
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	O
18. Monitoring of HACCP plan.	O	46. Sanitary Operations	O
19. Verification and validation of HACCP plan.	O	47. Employee Hygiene	O
20. Corrective action written in HACCP plan.	O	48. Condemned Product Control	O
21. Reassessed adequacy of the HACCP plan.	O	Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	O	49. Government Staffing	O
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	O
23. Labeling - Product Standards	O	51. Enforcement	O
24. Labeling - Net Weights	O	52. Humane Handling	O
25. General Labeling	O	53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Park Skins/Moisture)	O	54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57. Monthly Review	O
Salmonella Performance Standards - Basic Requirements		58.	O
30. Corrective Actions	O	59.	O
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

Establishment # UK2182 Audit Date 03/06/03

13. The daily pre-operational sanitation records were not maintained. FSIS 416.16(a) regulatory requirements were not met. MHS officials ordered establishment officials to take corrective actions immediately.

61. NAME OF AUDITOR

Fernando R. Chaves, DVM

62. AUDITOR SIGNATURE AND DATE

[Handwritten Signature] 3/6/03

Room 403c
1A Page Street
London
SW1P 4PQ

Tel 020 7904 6169
Fax 020 7904 6364
e-mail rdigel.gibbens@defra.gsi.gov.uk
website www.defra.gov.uk



Our reference:

Your reference: EXM 1229/
EXM 1243

Mrs Sally Stratmoen (001 202 690 4040)
Acting Director
International Equivalence Staff
Office of International Affairs
USDA FSIS
1400 Independence Avenue
Washington, DC 20250

3 July 2003

Dear Mrs Stratmoen

USDA FSIS AUDIT OF GREAT BRITAIN, 5 - 19 MARCH 2003

Thank you for your letter of 9 May enclosing the draft final report of the FSIS audit of our meat and poultry inspection system.

We have discussed the report with colleagues from the Food Standards Agency, who accompanied the FSIS auditors, and have the following comments to make concerning the draft report:

1. Names of Establishments

I note that the report makes reference to Malton Bacon Factory and Nippress Cold Store. The correct names for these establishments are Grampian Country Pork and ABP Connect respectively.

2. Section 6.2.1: CCA Control Systems - Line 6 from the end of the paragraph.

The Meat Hygiene Service (MHS) is responsible for contracts with veterinarians and any authority to cancel contracts lies with the MHS rather than with the Food Standards Agency.

3. Section 6.2.4: Authority and Response to Enforce the Laws - second line of bulleted paragraph

The report states that the deficiencies leading to the serving of the Notice of Intent to Delist (NOID) 'should have been identified by the MHS before this FSIS visit'.

It is regretted that the auditor identified deficiencies in one establishment that, in his opinion, should have resulted in the service of an NOID. However, the deficiencies identified in this case were largely in the detail of supervision and the recording of checks in relation to the HACCP plan, rather than in the sanitary outcome achieved. On the basis of your clarification of FSIS expectations, new arrangements for checks and record-keeping are now in place in line with your detailed requirements.

4. Section 9.1: SSOP - bulleted paragraph

The report states that one establishment was not adequately documenting daily operational sanitation deficiencies (records were maintained once a week only). I would like to confirm that checks are carried out daily, with arrangements in place to ensure that all operational sanitation deficiency checks are completed, but signed off weekly. This may have given the misleading impression that the checks are carried out only once a week. I can confirm that new procedures are now in place to ensure that checks will be signed off at the time they are carried out.

The report goes on to state 'Another establishment was not maintaining records for pre-operational sanitation'. Again, I am assured that a system for daily pre-operational sanitation checks is in place at the premises. However, documents were not countersigned at the time, giving the impression that the checks are not carried out correctly. I can confirm that, in future, the checks will be signed off as they are carried out.

5. Section 13: Enforcement Controls - first bulleted paragraph

The report mentions that MHS officials served the NOID on one establishment. In fact, the NOID was served by the Central Competent Authority, Defra.

6. Additional Concerns raised by the FSIS Auditor

I have noted the concerns raised by the FSIS auditor regarding inadequate implementation and documentation of the Hazard Analysis Critical Control Point (HACCP), inadequate documentation of Sanitation Standard Operating Procedures (SSOP) and also the comment regarding inadequate government oversight in the implementation of HACCP and SSOP requirements in establishments certified to export meat to the United States.

I believe that some of the criticisms raised in the Draft Final Report have been addressed in the above response. We have also obtained the most up to date



HACCP information available from FSIS and this has been distributed to the premises concerned and to our supervisory staff for their action.

SSOP

With regard to the observations regarding the SSOP documentation, I accept that the documentation did not meet with your expectations. However, I hope that the above explanations and implementation of new arrangements for signing off the relevant documents as the required checks are completed will avoid such problems in the future.

HACCP Training

I can confirm that a HACCP training course, given by an independent, United States based, HACCP Consulting Group, was arranged and held in Northern Ireland at the beginning of July this year. A two day course was held for staff working in the establishments in Northern Ireland currently approved to export to the United States. This was followed by a one day course for the regulators.

There were 15 government officials present at the regulator's session, of whom 3 were from GB (Veterinary Meat Hygiene Adviser, Meat Hygiene Service, Official Veterinary Surgeon and Circuit Supervisor), all of whom cover the two approved establishments in England.

The training consisted of an explanation of the regulatory process for SSOPs and HACCP in ss. 416 and 417 of the CFR9 and FSIS Directive 5000.1. As a result the enforcement programme implemented in GB will be altered to bring it more specifically into line with the procedures carried out in the US.

Arrangements have been made to hold a four day HACCP training course between 8 and 11 September in Great Britain. The course will consist of a two day training session for staff working in USDA approved establishments in GB, with an additional two days to carry out a comprehensive review of HACCP and SSOP documentation maintained at the establishments.

Species Testing

I can advise you that species testing has now commenced, with a sample of the American rib product intended for export to the United States being submitted to a United Kingdom Accreditation Service (UKAS) Laboratory. Tests for material of porcine, bovine, ovine and poultry origin will be carried out on the sample.

On the basis that the pig meat to be tested is in recognisable anatomical form and originates from a slaughterhouse that processes pigs only, we have recommended a six monthly species testing programme. I should be grateful if you would confirm that this will be acceptable to FSIS.

Thank you for the opportunity to comment on the draft report and I look forward to receiving a copy of the final report in due course. If you have any outstanding concerns, I should be grateful if you would contact me.

Kind regards.

Yours sincerely



NIGEL GIBBENS
Head, International Animal Health Division

cc: Steve Knight, US Embassy, London (by fax: 020 7894 0031)
James Hughes (e-mail: James.Hughes@fco.gov.uk)

