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

JAN 28 2010

Dr. Jean-Luc Angot
Chief Veterinary Officer
Ministry of Agriculture
251 Rue de Vaugirard
75732 Paris,
Cedex 15, France

Dear Dr. Angot:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of France's meat/poultry inspection system September 9 to September 25, 2009. Comments received from the government of France 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

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

SEPTEMBER 9 THROUGH SEPTEMBER 25, 2009

Food Safety and Inspection Service
United States Department of Agriculture

TABLE OF CONTENTS

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority—General Food Directorate
CFR	Code of Federal Regulations
CVO	Chief Veterinary Officer
DGAL	General Food Directorate
DDSV	Department of Veterinary Services
E. coli	*Escherichia coli*
FSIS	Food Safety and Inspection Service
ISPV	Veterinary Public Health Inspector
MFAF	Ministry of Food, Agriculture, and Fishery
POE	Port of Entry
PR/HACCP	Pathogen Reduction / Hazard Analysis and Critical Control Point Systems
Salmonella	*Salmonella* species
SPS	Sanitation Performance Standards
SSOP	Sanitation Standard Operating Procedures
VEA	European Community/United States Veterinary Equivalence Agreement
VO	Veterinary Officer

1. SUMMARY

1.1 Description/Eligibility

This report summarizes the outcome of the audit conducted in France from September 9 through September 25, 2009. This was a routine audit. France exports raw (03C) and processed (03D and 03G) pork and poultry products to the United States. Between March 11, 2008 and September 25, 2009, France exported a total of 362,849 pounds of meat and poultry products to the United States, of which more than 157,690 pounds were reinspected at US ports of entry (POE). There were no rejections at POE.

The findings of the previous audit during February 27 through March 11, 2008, resulted in no restrictions of any French establishment's ability to export pork or poultry products to the United States. Activities of the current audit appear in the table below.

1.2 Comparison of the Current Audit and the Previous Audit

		02/27-03/11, 2008	09/09-09/25, 2009
Levels of Government Oversight Audited			
	Headquarters	1	1
	Regional	1	2
	Establishment Level	3	2
Laboratories Audited			
	Microbiology	1	1
	Residue	1	1
Establishments Audited			
	Slaughter/processing	2	1
	Processing	1	1
	ID Warehouses	0	0
Enforcement Actions Initiated			
	NOID	0	0
	Delistment	0	0
Risk Area Findings			
	Sanitation Controls (SSOP, SPS)	1	0
	Animal Disease Controls	0	0
	Slaughter/Processing (PR/HACCP)	0	15
	Residue Controls	0	0
	Microbiology Controls	1	1
	Inspection/Enforcement Controls	3	16
	Humane Handling / Slaughter	0	1

1.3 Summary Comments for the Current Audit

The results of this routine audit, conducted during September 9 through September 25, 2009, resulted in the following actions:

1) No establishments were delisted or received a Notice of Intent to Delist (NOID) by the CCA;

2) FSIS inspection requirements were not fully enforced in two audited establishments. The results of this audit identified an increase, from previous FSIS audit conducted during February 27 through March 11, 2008, in risk area findings in slaughter/processing (two establishments) and inspection/enforcement controls (two establishments); and
3) One slaughter establishment did not meet EU requirements in regard to humane handling of animals before the slaughter.

2. INTRODUCTION

The audit took place in France from September 9 through September 25, 2009. An entrance meeting was held on September 9, 2009, in Paris 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 France's meat and poultry inspection system.

The auditor was accompanied during the entire audit by representatives from the CCA, the General Food Directorate (DGAL), and/or representatives from the *Département* inspection offices.

3. OBJECTIVE OF THE AUDIT

This audit 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 products to the United States.

In pursuit of the objective, the following sites were visited: the headquarters of the CCA, two *Département* of veterinary service offices (DDSV), one microbiology laboratory in *Département* 24, one residue laboratory in *Département* 61, one slaughter and processing establishment, and one processing establishment.

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 or *Département* of veterinary service offices. The third part involved on-site visits to two establishments: one swine slaughter and processing establishment and one poultry processing establishment. The fourth part involved visits to two government laboratories. One *Département* laboratory located in Colounieix-Chamiers that conducts microbiology analyses for *Listeria monocytogenes* and *Salmonella* and another *Département* laboratory located in Alencon conducts residue analytical testing of field samples for the national residue testing program were audited.

Program effectiveness determinations of France'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 Point (HACCP) systems and a testing program for generic *Escherichia coli (E. coli)*, (4) residue controls, and (5) enforcement controls, including a testing program for *Salmonella*. France'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 France and determined if establishment and inspection system controls were in place to ensure the production of meat and poultry products that are safe, unadulterated and properly labeled.

At 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 and poultry 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 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, and testing for generic *E. coli*, *Listeria monocytogenes,* and *Salmonella*.

Third, the auditor would audit against any equivalence determinations that have been made by FSIS for France under provisions of the Agreement on the Application of Sanitary and Phytosanitary Measures. Currently, FSIS has determined that three alternate procedures are equivalent to U.S. requirements:

- France uses ISO 6579:2002 to analyze for *Salmonella*.
- France suspends an establishment's eligibility to export the first time it fails to meet a *Salmonella* performance standard until compliance with this standard is met.
- FSIS has now determined the use of Enterobacteriaceae and Total Viable Count in lieu of generic *E. coli* is acceptable for all EU exporting countries. However, none of the establishments audited utilize this equivalence determination, but continue to rely on generic *E. coli* as an indicator of process control.

5. 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,
- The Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and
- The Poultry Products Inspection Regulations (9 CFR Part 381).

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 96/22/EC, of 29 April 1996, entitled Prohibition on the Use in Stock farming of Certain Substances Having a Hormonal or Thyrostatic Action and of B-agonists, and
- Council Directive 96/23/EC, of 29 April 1996, entitled Measures to Monitor Certain Substances and Residues Thereof in Live Animals and Animal Products.

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 FSIS audit of France's meat and poultry inspection system conducted from March 28 through April 12, 2007, identified the following non-compliances:

- In one establishment, the corrective actions taken in response to SSOP failures did not document the measures taken to prevent recurrence.
- In one establishment, feathers and residue from a previous day's production were present on surfaces that were identified in the SSOP plan as being cleaned daily.
- In one establishment, foreign material was present on the wheels of equipment that had been cleaned and was ready for reuse.
- In one establishment, the monitoring records for the Critical Control Point (CCP) of the slaughter process did not have entries recorded at the frequency stated in the HACCP plan.
- In the same establishment, there was insufficient supporting documentation for the frequency of ongoing verification for the calibration of the process monitoring instruments.
- In one establishment, the corrective action to be taken in the event of a deviation from a critical limit did not sufficiently document how the critical limit would be judged to be under control after the corrective action was taken.

The FSIS audit of France's meat and poultry inspection system conducted from February 27 through March 11, 2008, identified the following non-compliances:

- In one establishment, the condemned/inedible material was not under sufficient control of the inspection officials.
- In one establishment, the analytical results for official verification samples collected for non-risk based testing of RTE product for *Listeria monocytogenes* did not identify an FSIS approved method of analysis.
- In one establishment, the analytical reports for the Salmonella testing of carcasses did not identify the FSIS method or the ISO 6579:2002 method, granted equivalence, as the method used in the sample analysis.

- Two *Départemental* laboratories utilized to test official verification samples for *Listeria monocytogenes* were not using the FSIS MLG methodology or a method for which an equivalence was granted.

7. MAIN FINDINGS

7.1 Legislation

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

7.2 Government Oversight

7.2.1 CCA Control Systems

The *Direction Generale de l'Alimentation* or General Food Directorate (DGAL) is the Central Competent Authority (CCA) under the Ministry of Food, Agriculture, and Fishery (MFAF). The DGAL is comparable to the Food Safety and Inspection Service (FSIS) in the United States.

The food safety system in France is based on collaboration among three independent ministries: the Ministry of Food, Agriculture, and Fishery (MFAF); the Ministry of Trade and Commerce (DGCCRF); and the Ministry of Public Health (DGS). This inter-Ministry working group is charged with coordinating and arbitrating the national position in the international community. The Ministry of Food, Agriculture, and Fishery serves as the lead component in this working group.

France is divided into 22 regions and 100 *Départements*. The DGAL is based upon a single chain of command with direction being given to each individual *Département* from the Headquarters in Paris. Working closely with the DGAL is the *référent technique national* (hereafter referred to as a national technical expert) from France AgriMer. The role of the national technical expert is to assist the establishments that are, or wish to become, eligible to export products to the United States. The national technical expert also brings technical support to the French inspectors, supervisors, and coordinators in an advisory role.

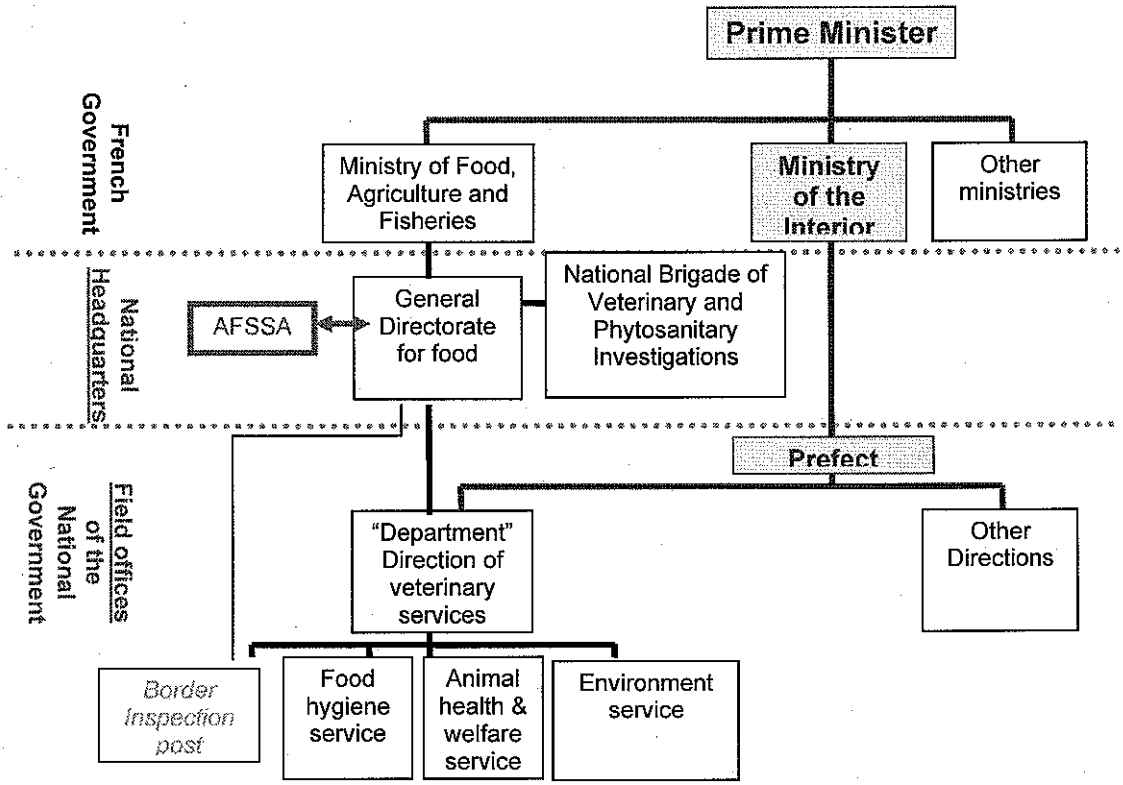
Within the DGAL there is a second-tier oversight position, the ETSN. The official in this position reports directly to the Chief Veterinary Officer (CVO), and the duties of this position include carrying out field audits, training of inspection personnel in U.S. eligible establishments, and preparing reports for the Veterinary Services Directorates Directors (DDSVs) with recommendations. There are seven ETSN auditors in France.

The key difference between the national technical expert and the second tier oversight position is the level at which they interact within the national inspection system. The national technical expert works directly with the establishments. The ETSN auditor works with the DDSV to ensure that all FSIS requirements are being properly implemented and verified.

The ETSN performs the second-tier audits as follows:

1. Prior to listing an establishment as certified for U.S. export.
2. In establishments already certified for U.S. export, whenever there is a significant change in the DDSV (e.g. new agents conducting inspections) with a target frequency of at least once per year.
3. At the request of the DDSV overseeing a particular establishment on an "as needed" basis.

At the local level, France is divided into 96 *Départements* (there are also an additional 4 overseas *Départements*). Each has a Director of Veterinary Services responsible for enforcement, control, and surveillance regarding animal health and food laws. Each Director has at least two Chiefs of Service who are assigned to either the Service of Animal Health and Welfare or the Service of Food Safety. The latter coordinates the inspection programs within the *Département* regarding all the approved meat and poultry slaughter and processing establishments. Depending on the volume and type of activities within the *Département*, the Chief of Service may also have other technical experts and assistants performing key functions in the Food Safety Service. These are either veterinary public health inspectors (ISPV) or technical assistants with specific public health training. Larger *Départements* are divided into districts, each of which is under the supervision of a Veterinary Officer (VO).



7.2.2 Ultimate Control and Supervision

The DGAL headquarters in Paris has the ultimate control and supervision of France's meat and poultry inspection system. Although France's inspection system is supervised by individual DDSVs, the DGAL develops and distributes official legislations or official inspection guidelines to the DDSVs. These legislations or guidelines are generally provided by e-mail or intranet, utilizing the Ministry database systems called GALATEE and NOCIA, to the Directors of the *Départements*. Under the current system, it is the responsibility of these Directors to delegate implementation instructions to the appropriate officials under their supervision, and to ensure their implementation.

The preponderance of information issued by the DGAL to the field is contained in a document referred to as the "MEGAREG", which is regularly updated and consolidates elements of the following FSIS requirements into one location:

1. Sanitation
2. HACCP
3. Generic *E. coli* sampling
4. *Salmonella* testing
5. Testing for *Listeria monocytogenes*

A significant portion of the inspection personnel rely almost exclusively on the content of the "MEGAREG" in order to perform their duties in enforcing FSIS requirements. The most recent version of the DGAL/MCSI/L2008-0164 Memorandum concerning certificate conditions for export of fresh meat to the third countries was distributed to inspection personnel on February 19, 2008.

7.2.3 Assignment of Competent, Qualified Inspectors

The DGAL is responsible for the initial hiring, training, and payment of veterinarians and non-veterinary technicians. Veterinary public health inspectors (ISPV) are officials who have received specific training in the national veterinary services school in Lyon. Contract veterinary inspectors (VIV) are qualified veterinarians who are not statutory civil servants. They are trained to assume responsibilities as official veterinarians. Veterinary technicians are civil servants who carry out controls under the authority of the ISPVs in relation to animal health, animal welfare, and food and feed safety.
No full- or part-time DGAL employees are permitted to perform any private, establishment-paid tasks at an establishment in which they perform official duties.

The CCA and the DDSVs provided several training courses in 2007/2008 in regard to SSOP, SPS, and HACCP to increase the level of knowledge of the official inspectors concerning U.S. inspection requirements.

7.2.4 Authority and Responsibility to Enforce the Laws

The DGAL has the authority for carrying out France's meat and poultry inspection program including oversight and enforcement of the FSIS regulatory requirements in establishments certified to export to the United States. The DGLA not only has the

authority to approve establishments for export to the United States, but also has the responsibility for withdrawing such approval when establishments do not meet FSIS requirements.

The DGLA has the legislative authority and the responsibility to enforce all FSIS requirements, but not all FSIS requirements were enforced. Specific non-compliances are noted on the attached individual establishment reports.

7.2.5 Adequate Administrative and Technical Support

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

7.3 Audit of Headquarters and *Département* Offices

The auditor conducted a review of inspection system documents at the headquarters of the DGAL, located in Paris. The auditor also conducted a review of records and interviewed inspection officials in the DDSV offices located in Perigueux (*Département* 24) and Quimper (*Département* 29) for the purpose of determining the level of government oversight, supervisory structure, and to review records pertinent to the U.S. certified establishments. The record review focused primarily on food safety hazards and included the following:

- Government oversight documents, including organizational structure
- Periodic supervisory visits
- 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 France's inspection program
- Humane handling and slaughter methods

Examination of these documents indicated that in the D*épartements* in which certified establishments are located, the assignment of the daily inspection tasks related to pre-operational sanitation and HACCP verification, and the frequency at which these tasks are performed is largely at the discretion of the district supervisor for the establishment (Chief of Conscription) and the in-plant inspection officials.

8. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of two establishments: one slaughter and processing establishments and one processing establishment. No establishments were delisted or received a Notice of Intent to Delist (NOID) for failure to meet U.S. requirements during the course of the audit.

Specific deficiencies are noted on the attached individual establishment reports.

9. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

During laboratory audits, emphasis was placed on the application of procedures and standards that are equivalent to United States requirements.

The residue laboratory audit focused 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, international check samples, and quality assurance programs, including standards books and corrective actions.

The following residue laboratory was reviewed:

The Laboratoire Départemental de l'Orne (*Département* 61) in Alencon was performing residue analyses on product destined for the U.S. within the scope of the French National Residue Program.

No concerns arose as a result of this review.

The microbiology laboratory audit focused on the following parameters: the role of the laboratory relative to other laboratories involved in U.S. export testing; which U.S. export establishments and products were being tested; the U.S. export testing activities; the receipt of samples from all the establishments the laboratory says it services; the testing of samples for the relevant pathogens and at the relevant frequencies; the receipt of the correct type of sample; and the testing of the correct amount of product sample for the analysis.

The following microbiology laboratory was reviewed:

The Laboratoire Départemental d' Analyse et de Recherché (*Département* 24) in Perigueux was performing microbiological analyses for *Salmonella* and *Listeria monocytogenes* on ready-to-eat products eligible for export to the U.S.

The following finding was noted:

- This laboratory was not using the FSIS MLG methodology or an analytical method for which an equivalence determination was granted. Therefore, it was not meeting FSIS requirements.

Both laboratories were ISO certified by COFRAC. COFRAC is the France national body for accreditation which was established in 1994 and governed by the 1901 law.

10. SANITATION CONTROLS

As stated earlier, the FSIS auditor focused on five areas of risk to assess France's meat inspection system. The first of these risk areas that the auditor reviewed was Sanitation Controls.

Based on the on-site audits of establishments, France's inspection system had controls in place for SSOP programs, 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, France'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.

10.1 Sanitation Standard Operating Procedures (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 both audited establishments were found to meet FSIS regulatory requirements.

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 and poultry products.

The SPS in both audited establishments were found to meet FSIS regulatory requirements.

10.3 EC Directive 64/433

In the establishments audited, the provisions of EC Directive 64/433 concerning sanitation controls were effectively implemented.

11. 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.

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 was Slaughter/Processing Controls. The controls include the following areas: 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 testing programs for generic *E. coli* in slaughter establishments.

12.1 Humane Handling and Slaughter

In one slaughter establishment, animals which have been held for more than 12 hours after their arrival in the establishment were not fed. Council Directive 93/119/EC (protection of animals at the time of slaughter) states, "animals which are kept for 12 hours or more at a slaughterhouse must be fed and must subsequently be given moderate amounts of food at appropriate intervals".

This finding is not a FSIS requirement. Code of Federal Regulations (CFR) in part 313.2 (e) states, "animals shall have access to feed if held longer than 24 hours".

12.2 Hazard Analysis and Critical Control Point (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 two establishments. The HACCP plans in these establishments were found to meet basic FSIS requirements with the following exceptions.

In one establishment, HACCP record keeping non-compliances for fully cooked HACCP plan were identified as follows:

- The establishment HACCP flow chart for *fois gras* did not include the following processing steps and food safety hazards for these processing steps were not identified in the hazard analysis:
    - Receipt and storage of packaging materials
    - Receipt and storage of ingredients (spices and vegetables)
    - Reworked/returned products
- The establishment monitoring records for CCP2 (cooking) did not document the times when monitoring activities occurred;

- The establishment monitoring records (CCP2) did not include the initials of the responsible establishment employee(s) making the entries;
- The establishment verification records for CCP1 (closure of cans) did not follow its verification frequency as prescribed in the establishment written HACCP plan;
- The establishment verification records for all CCPs did not document the record review component of on-going verification activities;
- The establishment verification records for all CCPs did not document the type (direct observations of monitoring activities or calibration of process-monitoring instruments) of the verification activities;
- The establishment verification records for all CCPs did not document the results of the verification activities;
- The establishment verification records for the calibration of process-monitoring instruments did not document the times when the specific events occurred;
- The establishment verification records for the calibration of process-monitoring instruments did not include the initials of the responsible establishment employee(s) making the entries; and

In another establishment, monitoring records for thermally processed HACCP plan did not include:

- The dates of monitoring activities (CCP 9B retort);
- The initials of the responsible establishment employee(s) making the entries (CCP 9B); and
- The quantifiable values, the times, or the initials of the responsible establishment employee(s) making the entries (CCP 1 zero tolerance for fecal and ingesta).

12.3 Testing for Generic *Escherichia. coli*

France has adopted the FSIS regulatory requirements for testing for generic E. coli with the exception of the following equivalent measure:

- FSIS has now determined the use of *Enterobacteriaceae* and Total Viable Count in lieu of generic *E. coli* is acceptable for all EU exporting countries. However, the only certified slaughter establishment continues to rely on generic *E. coli* as an indicator of process control.

One of the two establishments audited was required to meet the basic FSIS regulatory requirements for testing for generic *E. coli.*

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

12.4 Testing of *Listeria monocytogenes*

Both of the establishments audited were producing ready-to-eat products for export to the U.S. One of the two establishments produces products that are fully cooked in hermetically-sealed container, and there is no post-lethality exposure to the environment, the other establishment produces canned, commercially sterile product.

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.

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

13.1. EC Directive 96/22

In the Laboratoire Départemental de l'Orne, the provisions of EC Directive 96/22 were effectively implemented.

13.2. EC Directive 96/23

In the Laboratoire Départemental de l'Orne, the provisions of EC Directive 96/22 were effectively implemented.

14. 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.*

14.1 Daily Inspection in Establishments

Inspection was conducted on each U.S. production day in both certified establishments.

14.2 Testing for *Salmonella* Species

France had adopted the FSIS requirements for testing for *Salmonella* with the exception of the following equivalent measures:

- Analytical Methods—France uses ISO 6579:2002 to analyze samples for *Salmonella.*
- Enforcement Strategy— France suspends an establishment's eligibility to export the first time it fails to meet a *Salmonella* performance standard until compliance with this standard is met.

14.3 Species Verification

Species verification was being conducted for those establishments in which it was required.

14.4 Periodic Supervisory Reviews

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

14.5 Inspection System Controls

These controls include ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; shipment security, including shipment between establishments; and prevention of commingling of product intended for export to the U.S. 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 countries for further processing.

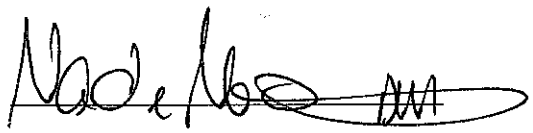
Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

15. EXIT MEETING

An exit meeting was held on September 29, 2009, in Paris with the CCA. At this meeting, the preliminary findings and conclusions from the audit were presented by the auditor.

The CCA understood and accepted the findings.

Dr. Nader Memarian
Senior Program Auditor



16. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Forms

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
Euralis Gastronomie, Sarlat Avenue du Perigord ZI de Madrazes Sarlat 24200	09/16/2009	2452002	France
	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 .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
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.	X
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	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	
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	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: 09/16/2009 Est. #: 2452002 (Euralis Gastronomie, Sarlat [P/CS]) (Sarlat, France)

15/51 The establishment flow chart for fois gras did not include the following processing steps and food safety hazards for these processing steps were not identified in the hazard analysis.
A) Receipt and storage of packaging materials.
B) Receipt and storage of ingredients (spices and vegetables).
C) Reworked/returned products.

15/51 The HACCP plan for fois gras did not include review of the records and its frequency as part of its on-going verification activities.

The aforementioned findings (15/51) were not meeting FSIS regulatory requirements. [9 CFR §417.2(c) and 417.8]
The last reassessment of the HACCP plan conducted by the establishment was August 25, 2009. Establishments' records for June, July, and August, 2009, documenting the HACCP plan and its verification were reviewed. The establishment did not identify these non-compliances. French Veterinary Service did not adequately verify the adequacy of the establishment's HACCP plan. Inspection records did not identify these non-compliances for the last 90 days.

HACCP record keeping non-compliances for monitoring and verification activities were identified as follows:

18/22/51 A) The establishment monitoring records for CCP2 (cooking) did not document the times when monitoring activities occurred.
B) The establishment monitoring records (CCP2) did not include the initials of the responsible establishment employee(s) making the entries.

19/22/51 A) The establishment verification records for all CCPs did not document the record review component of on-going verification activities.
B) The establishment verification records for all CCPs did not document the type of the verification activities.
C) The establishment verification records for all CCPs did not document the results of the verification activities.
D) The establishment verification records for the calibration of process-monitoring instruments did not document the times when the specific events occurred.
E) The establishment verification records for the calibration of process-monitoring instruments did not include the initials of the responsible establishment employee(s) making the entries.
F) The establishment verification records for CCP1 (closure of cans) did not follow its verification frequency as prescribed in the establishment written HACCP plan.

The aforementioned findings (18/19/22/51) were not meeting FSIS regulatory requirements. [9 CFR §417.4, 417.5, and 417.8]
These HACCP record keeping non-compliances had not been identified in the review of records by the establishment personnel or in the HACCP verifications activities performed by French inspection service for the last 90 days.

The auditor was assured by the inspection officials and/or establishment personnel that all deficiencies found in this audit would be corrected immediately.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian, DVM	09/16/2009

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
Jean Henaff SA Ker Hastell Pouldreuzic, Finistere 29710	09/21/2009	2922501	France
	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 .	
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.	
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	X
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment Date: 09/21/2009 Est #: 2922501 (Jean Henaff SA [S/P]) (Pouldreuzic, France)

22/51 A) The establishment monitoring records for CCP 9B (retort) did not include the dates of monitoring activities.
B) The establishment monitoring records for CCP 9B did not include the initials of the responsible establishment employee(s) making the entries.
C) The establishment monitoring records for CCP 1 (zero tolerance for fecal and ingesta) did not include the quantifiable values, the times, or the initials of the responsible establishment employee(s) making the entries.

The aforementioned findings (22/51) were not meeting FSIS regulatory requirements. [9 CFR § 417.5, and 417.8]
These HACCP record keeping non-compliances had not been identified in the review of records by the establishment personnel or in the HACCP verifications activities performed by French inspection service for the last 90 days.

52/51 Animals which have been held for more than 12 hours after their arrival in the establishment were not fed. Council Directive 93/119/EC (protection of animals at the time of slaughter) states, "animals which are kept for 12 hours or more at a slaughterhouse must be fed and must subsequently be given moderate amounts of food at appropriate intervals".
This issue had not been addressed in humane handling/animal welfare verification activities / records either by establishment personnel or veterinary inspection service. This is not a FSIS requirement.

The auditor was assured by the inspection officials and/or establishment personnel that all deficiencies found in this audit would be corrected immediately.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian, DVM	09-21-2009