



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

MAR 7 2005

Mrs. Sophie Villers
Director General
DGAL
Ministry of Agriculture
251 Rue de Vaugirard
75732 Paris
Cedex 15, France

Dear Mrs. Villers:

The Food Safety and Inspection Service (FSIS) has completed a follow-up enforcement audit of France's meat and poultry inspection system. The audit was conducted from September 29 through October 14, 2004. Comments from France have been included as an attachment to the final report. Enclosed is a copy of the final audit report.

If you have questions regarding the audit or need additional information, please contact me by telephone at 202.720.3781, by facsimile at 202.690.4040 and by email at sally.white@fsis.usda.gov.

Sincerely,

Sally White
Director
International Equivalence Staff
Office of International Affairs

Enclosure

cc:

Besa Kotati, Agricultural Counselor, U.S. Embassy, Paris
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Tony van der haegen, EU Mission to the US, Washington, DC
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Country File-France—final sept04

FINAL

FEB 22 2005

FINAL REPORT OF A FOLLOW-UP ENFORCEMENT AUDIT
CARRIED OUT IN FRANCE COVERING FRANCE'S MEAT AND
POULTRY INSPECTION SYSTEM

SEPTEMBER 29 THROUGH OCTOBER 14, 2004

Food Safety and Inspection Service
United States Department of Agriculture

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority [<i>Direction Générale de l'Alimentation</i> , or General Food Directorate]
DGAL	<i>Direction Générale de l'Alimentation</i> , or General Food Directorate
DDSV	<i>Direction Départementale Services Vétérinaires</i> , Veterinary Service of the Department
<i>E. coli</i>	<i>Escherichia coli</i>
FSIS	Food Safety and Inspection Service
PR/HACCP	Pathogen Reduction / Hazard Analysis and Critical Control Point Systems
<i>Salmonella</i>	<i>Salmonella</i> species
SSOP	Sanitation Standard Operating Procedures
VEA	European Community/United States Veterinary Equivalence Agreement
CAP	Corrective Action Plan

1. INTRODUCTION

The follow-up enforcement audit took place in France from September 29 through October 14, 2004.

An opening meeting was held on September 29, 2004 in Paris, France with the Central Competent Authority (CCA). At this meeting, the auditors confirmed the objective and scope of the audit, the auditors' itineraries, and requested additional information needed to complete the audit of France's meat and poultry inspection system.

The auditors were accompanied during the entire audit by representatives from the CCA and/or representatives from the regional and local inspection offices.

2. OBJECTIVE OF THE AUDIT

This audit was a follow-up enforcement audit. There were two objectives of the audit. The first objective was to determine if France had implemented its April 2004 Corrective Action Plan (CAP). The second objective 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 and poultry products to the United States.

In pursuit of the objectives, the following sites were visited: the headquarters of the CCA, three *Direction Départementale Services Vétérinaires* (DDSV) offices, one poultry slaughter establishment, and three poultry processing establishments.

Competent Authority Visits			Comments
Competent Authority	Central	1	
	Local	3	
Poultry Slaughter Establishments		1	
Poultry Processing Establishments		3	

3. PROTOCOL

This on-site audit was conducted in three 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 four establishments: one slaughter establishment and three processing establishments.

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, (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*. 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 products that are safe, unadulterated and properly labeled.

At the opening meeting, the auditor explained that the headquarters of the CCA and the DDSV offices responsible for the certified establishments would be audited against France's CAP, which was submitted to FSIS in April 2004. The CAP was developed by France to address deficiencies in its meat and poultry inspection program that led to the February 2004 suspension of France from eligibility to export meat and poultry products to the United States.

Basic elements of the CAP included: (1) the creation of a new position reporting directly to the Chief Veterinary Officer with direct responsibility for establishments certified for export to the United States, (2) participation of the official selected for the above position in FSIS' indepth review of the practical aspects of verification and enforcement of FSIS' PR/HACCP requirements, (3) a commitment to hold at least one training session per year for French inspection officials with a focus on general sanitation principles and SSOP and HACCP requirements, (4) a commitment to continue daily inspection in processing establishments.

In addition, the lead auditor explained that France's inspection system would also be audited against three standards. 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 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 auditors 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. France has two equivalence determinations.

- France suspends an establishment's eligibility to export the first time it fails to meet a performance standard.
- France uses ISO 6579:2000 to analyze for *Salmonella*.

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.
- 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 96/23/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:
http://www.fsis.usda.gov/regulations/foreign_audit_reports/index.asp

The following concerns arose as a result of the FSIS audit of France's inspection system conducted in January/February 2004:

- The CCA did not ensure that United States' requirements were being met by the establishments.
- The CCA did not have ultimate control and supervision over official activities of all employees and certified establishments.
- At all levels, adequate training of inspection personnel in HACCP still has not been completed. Similar findings in many of the establishments indicate that the national training program was insufficient.

- Inspection personnel had not been adequately trained in SSOP and sanitation principles.
- In one establishment, the SSOP did not describe all of the procedures used to monitor the daily operational sanitation activities.
 - The SSOP did not describe a procedure for the reconditioning of product dropped onto the floor.
 - The SSOP did not describe a procedure for monitoring the temperature of 82 degree centigrade water equipment sanitizers.
- In nine establishments, SSOP were not effectively implemented.
 - Pre-operational sanitary conditions were inadequate.
 - Fat particles from the previous day's production were identified on a plastic interlock conveyor in the grinding/blending room. The conveyor was ready for use for the day's production of food products.
 - Plastic tubs used to transport finished product were not cleaned and sanitized daily to removed product residue from the previous day's production.
 - In the ready-to-eat slicing room, grey watery material was identified on the product surface of a slicing machine belt, 25 to 30 black unidentified particles were identified on the surface of a product table, product residue from the previous day's production was identified on cooling racks, the cooling oven and scale supports which were in contact with the surface of a product table. All equipment was presented for use for the day's production of food products.
 - Black unidentified material was identified in a yellow product tub previously cleaned and ready for use for the day's production of food products.
 - Operational sanitary conditions were inadequate.
 - Condensation was dripping onto defeathered and partially de-paraffined ducks between the cold paraffin tank and the paraffin removal cabinet in the defeathering room.
 - A copious amount of condensation was identified dripping onto employees and their work stations in the evisceration room. Duck meat that had been dropped onto the floor was accumulated in bulk and shipped to a further processing establishment without reconditioning. This was an ongoing process described in the SSOP. Local Veterinary Services and the Department of Veterinary Services were aware of and approved this procedure. The auditor was informed that product accumulated in bulk and shipped to a further processing establishment without reconditioning was acceptable because the floor was clean and the product was cooked.
 - Sausage hangers and the container which held the sausage hangers were contaminated with multiple fat scraps. This was observed while operations were being conducted in the sausage stuffing

room. The sausage hangers were round hollow tubes and were not sealed at each end.

- In one establishment, corrective actions were insufficient to restore sanitary conditions and did not ensure proper disposition of contaminated product.
 - In reference to the sausage hangers, hangers contaminated with fat particles from the previous day's production, were placed onto the sausage hanging table, contaminating the surface of the table where sausage products were produced and therefore contaminating the sausage product. The establishment did not take immediate corrective actions to restore sanitary conditions and did not ensure proper disposition of contaminated product.
- In nine establishments, preventive measures for corrective actions were not included in the daily records for sanitation noncompliances.
- In nine establishments, adequate sanitary conditions were not present. Condensation was dripping from the vents of a refrigeration unit in the liver packaging room.
 - An establishment employee was observed touching a water hose that had been on the floor and then returned to work without washing their hands.
 - Evidence of rodents inside an establishment was observed.
 - Unidentified black particles were found on packages of ingredients stored in the ingredient storage room.
- In five establishments, equipment and utensils used for processing or otherwise handling edible product or ingredients were not adequate to maintain sanitary conditions.
 - Identity of grey, yellow and red plastic tubs used for edible product was not maintained. The tubs were used for edible, inedible and non-product storage purposes. This posed a substantial potential for inedible product to be used for edible purposes.
 - A company employee contaminated the top of a product transportation cart with the sole of their boot and then placed an edible product tub onto the same cart. The cart would normally be placed on a product table, therefore causing contamination of the product table with residue from the sole of the boot.
 - Cones from the whole bird cutup line were coming into contact with product that had piled up on the floor at the end of the line. This posed a potential for contamination of edible product from the product accumulated on the floor.
 - The dropped meat reconditioning station was not identified or equipped to maintain sanitary conditions. This posed a substantial risk for the station to be used for purposes other than dropped product and reconditioned product to be recontaminated from a surface that was not cleaned and sanitized properly between each use.

- In five establishments, equipment and utensils were not maintained in sanitary condition so as not to adulterate product.
 - A partially covered gondola of spices was stored under an unprotected wooden pallet in the spice room. This posed a substantial risk for contamination of the gondola and spices with particles and wood splinters from the pallet.
 - Product tubs located close to the floor were cross contaminated with tops of employees boots. This posed a substantial risk for contamination of edible product contained in the tubs by residue from the boots.
 - After cleaning, product carts were stacked with the wheels in contact with the top surface. The wheels were constructed of materials that could not be cleaned and sanitized adequately. Plastic product tubs used for edible product were stacked on the top surface of the carts and then placed on edible product tables.

- In five establishments, product was not protected from adulteration during processing, handling, storage, loading, and unloading at and during transportation from official establishments.
 - An overhead door for unloading trucks remained open providing direct access to exposed raw product.
 - Packaging material and box flats were stored against the walls of the storage room.
 - Black unidentified material was identified on the ceiling around the refrigerator unit in the red offal cooler.
 - Cartons of raw meat products were covered with ice and frost.

- In five establishments, ventilation adequate to control odors, vapors, and condensation to the extent necessary to prevent adulteration of product and the creation of insanitary conditions was not provided.
 - Excessive amount of frost was identified on the ceiling and walls of the liver and scallion storage freezer.
 - Condensation was identified over product in the carcass cooler and the red offal cooler, and workers and personnel traffic areas in the Dutch cutting room, GMS room, shipping dock and carcass load out.
 - Condensation was observed on pipes next to the hydro-flaking machine in the raw product processing room.

- In three establishments, the grounds around the establishment were not maintained to prevent conditions that could lead to insanitary conditions or adulteration of product.
 - The filled can storage room was not cleaned at a frequency sufficient to prevent insanitary conditions.
 - A rodent dropping was found on two separate pallets in the filled can storage room.
 - Dust, cobwebs and damp floors were identified in the annex used to store finished products.

- In two establishments, establishment buildings were not kept in good repair.

- The overhead of the white offal room was rusty and equipment was maintained in poor condition.
- Miscellaneous debris was identified behind the storage racks along the floor-wall junction.
- In six establishments, the hazard analysis and HACCP plans were insufficient.
 - Rework and returned product were not included in the flow chart or considered in the hazard analysis.
 - Two different products from different processes were controlled by one CCP in the HACCP plan. There were two separate and distinct critical limits for the one CCP.
 - Biological, chemical and physical hazards were not considered for each processing step in the hazard analysis.
 - The intended use, special labeling instructions and ingredients were not included in the HACCP plan.
- In eight establishments, ongoing verification activities were not adequately described in the HACCP plan.
- In four establishments, monitoring activities were not adequately described in the HACCP plan.
- In one establishment, monitoring activities were performed for zero-tolerance, but the written procedure in the HACCP plan described two levels of monitoring.
- In five establishments, the written HACCP plan did not include measures to prevent recurrence after a corrective action was implemented.
- In five establishments, the establishment did not maintain all of the required records documenting their HACCP plan.
 - Records were maintained that documented food safety hazards that were reasonably likely to occur, but biological, chemical and physical hazards were not considered in the hazard analysis for all processing steps described in the flow chart.
 - Calibration of equipment was performed, but the establishment did not maintain a written procedure for the calibration of equipment used to measure critical limits.
 - Preventive measures for a deviation from a critical limit were not described in the records documenting corrective actions for the deviation.
- In one establishment, the establishment did not reassess the adequacy of the HACCP plan annually.
- In two establishments, the reassessment of the HACCP plan did not adequately address the presence of *Listeria monocytogenes*.
- In one establishment, daily inspection was not provided for the maturation process of fermented dry pork sausage.

- In two establishments, pre-operational sanitation was not performed in an adequate manner.
 - French Veterinary Services did not schedule the sausage hang area containing sausage trees, sausage hangers and containers which held the sausage hangers for pre-operational sanitation. French Veterinary Services have never scheduled this area for pre-operational sanitation. The establishment has been in operation for three years.
 - Pre-operational sanitation verification was performed by French Veterinary Services five times in the last 12 months. Many pre-operational sanitation noncompliances were identified during this audit; therefore the frequency was not adequate to verify the effectiveness of the establishment's pre-operational sanitation program.

- In one establishment, a careful post-mortem examination and inspection was not made of the parts of all livestock slaughtered.
 - Viscera dropped from carcasses into the bleeding trough did not receive post-mortem inspection from the French Veterinary Service. All viscera were not inspected to determine the wholesomeness of each carcass.

6. MAIN FINDINGS

6.1 Legislation

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

6.2 Government Oversight

6.2.1 CCA Control Systems

The food safety system in France is based on collaboration between three independent ministries: the Ministry of Agriculture, Food, Fishery and Rural Affairs; the Ministry of Trade and Commerce; and the Ministry of Public Health. This inter-Ministry working group is charged with coordinating and arbitrating the national position in the international community. The Ministry of Agriculture, Food, Fishery and Rural Affairs serves as the lead component in this working group. Further, the *Direction Generale de l'Alimentation* (DGAL) is the lead agency within France for the development and implementation of food safety policy.

The DGAL is based upon a single chain of command. All direction to each of the individual departments is given from the Headquarters in Paris. Earlier this year, the DGAL created a new position, *réfèrent technique national* (now referred to as a national technical expert), the role of this individual is to oversee all establishments that are eligible to export product to the United States. The national technical expert brings technical support to the French inspectors, supervisors and coordinators in an advisory role.

In addition to the national technical expert created this year, the CCA created a second-tier oversight position. The new position reports directly to the CVO. The duties of this position include carrying out field audits and preparing reports for the CVO with recommendations.

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

At the regional level, France is divided into 22 regions. There are two groups that work at the regional level for the DGAL. The first are the Quality Assurance Managers (QAM). The QAMs are working on the implementation of ISO 17020 within the DGAL. As part of the implementation requirements, the QAMs provide regional support to various departments in an effort to harmonize the application of US import requirements.

The second group is nine Interregional Inspectors General (IIG's), each of whom oversees several of the 22 Regions. These individuals form an intermediate step in the chain of command between DGAL headquarters and the departments. A monthly coordination meeting between the IIG's and the DGAL Director General is held in Paris. The IIG's also organize meetings with the DDSVs in their assigned region. These individuals are typically former Directors of Veterinary Services in the departments. The IIGs usually provide administrative support to DGAL and the DDSV.

At the local level, France is divided into 96 departments (there are 4 overseas departments.) Each has a Director of Veterinary Services (*Directeur du Départementale Services Veterinaires*, or DDSV). Each of these Directors is a veterinarian, employed by the government, and is a sworn-in officer (as are all inspection staff); his/her testimonies have high value in court proceedings. Each Director has two deputies, one in charge of animal health and welfare, and the other in charge of food safety procedures from farm to table. The latter coordinates the inspection programs within the department regarding all the approved meat and poultry slaughter and processing establishments therein. According to the volume of activity within the department, the deputy has other colleagues who work with him/her and report to him/her; these make up the Food Safety Service within the department. These are either veterinary officers or technical assistants with specific public health training. Larger departments are divided into districts, each of which is under the supervision of a Veterinary Officer.

6.2.2 Ultimate Control and Supervision

France has one standard of inspection in all red meat slaughter and poultry facilities, both domestic and export. DGAL headquarters in Paris has the ultimate control and supervision of France's meat and poultry inspection system.

New official inspection guidelines are issued by DGAL headquarters in Paris. These are provided by fax, e-mail, and intranet to the Directors of the regional offices (departments) and, through them, to the interested field personnel and, if appropriate, also to establishment and/or laboratory management officials. 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.

6.2.3 Assignment of Competent, Qualified Inspectors

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.

During July 2004, DGAL headquarters provided training for those inspection personnel, both DGAL headquarters and the field, that are or will be responsible for certified establishments. This training session focused on development and maintenance of SSOP programs, development and maintenance of HACCP systems, and general sanitation principles. This training activity was successful as evidenced by the lack of deficiencies found during the on-site audits of the four establishments proposed for certification.

In addition, the individual selected for the new position within DGAL with direct responsibility for certified establishments attended FSIS' September 2004 training course, which provided indepth, practical information about FSIS' SSOP and HACCP requirements.

6.2.4 Authority and Responsibility to Enforce the Laws

DGAL has the authority and the responsibility to enforce all U.S. requirements.

6.2.5 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.

6.3 Audit of Headquarters and Local Offices

The auditor conducted a review of inspection system documents at the headquarters of the inspection service and in three DDSV offices. 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.

7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of four establishments. One was a poultry slaughter establishment and three were poultry processing establishments.

Specific deficiencies are noted on the attached individual establishment reports.

8. 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, France'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, 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.

8.1 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.

No deficiencies were noted.

8.2 EC Directive 64/433

In one establishment, the provisions of EC Directive 64/433 were not effectively implemented. Specific deficiencies are noted in the attached individual establishment reports.

8.3 Sanitation Performance Standards

- In one establishment, ventilation adequate to control condensation to the extent necessary to prevent adulteration of product and the creation of insanitary conditions was not provided.

9. 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.

No deficiencies were noted.

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

10. 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.

10.1 Humane Handling and Humane Slaughter

No deficiencies were noted.

10.2 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 four establishments. These four establishments had adequately implemented the HACCP requirements. However, there was one deficiency:

- One establishment did not identify the intended use or the consumers of the finished product in their written HACCP plan.

10.3 Testing for Generic *E. coli*

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

One of the four 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.

10.4 Testing for *Listeria monocytogenes*

Testing for *Listeria monocytogenes* was not evaluated during this audit.

10.5 EC Directive 64/433

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

11. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditor would normally review was Residue Controls. However, during this audit, no residue laboratories were reviewed.

12. 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*.

12.1 Daily Inspection

- Inspection was being conducted daily in all establishments.

12.2 Testing for *Salmonella*

Salmonella testing of ducks and geese is not required because FSIS has not established *Salmonella* performance standards for ducks and geese.

12.3 Species Verification

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

12.4 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.

12.5 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 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.

13. CLOSING MEETING

A closing meeting was held on October 14, 2004 in Paris, France with the CCA. At this meeting, the primary findings, conclusions, and recommendations from the audit were presented by the auditor.

The CCA understood and accepted the findings.

for 

Todd M. Furey
Lead Auditor

14. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Forms

Foreign Country Response to Draft Final Audit Report

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Ets Rougie Bizac Sarlat, France	2. AUDIT DATE 10/06/2004	3. ESTABLISHMENT NO. 24-520-02	4. NAME OF COUNTRY France
5. NAME OF AUDITOR(S) Dr. Don Carlson		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

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

60. Observation of the Establishment

France. Est. 24-520-02 : Ets Rougie Bizac, Sarlat, October 06, 2004.

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

61. NAME OF AUDITOR

Dr. Don Carlson

62. AUDITOR SIGNATURE AND DATE

Dr. Don Carlson /s/ 10/06/2004

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Capel la Quercynoise Le Perie 46500, Gramat	2. AUDIT DATE 10/08/2004	3. ESTABLISHMENT NO. 46-128-02	4. NAME OF COUNTRY France
5. NAME OF AUDITOR(S) Dr. Don Carlson		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

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

60. Observation of the Establishment

France. Est. 46-102-04: Capel la Quercynoise Le Perie 46500, Gramat, October 08, 2004.

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

61. NAME OF AUDITOR

Dr. Don Carlson

62. AUDITOR SIGNATURE AND DATE

Dr. Don Carlson /s/ 10/08/2004

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Feyel Artzner Schiltigheim, France	2. AUDIT DATE 10/04/04	3. ESTABLISHMENT NO. 67-447-05	4. NAME OF COUNTRY France
5. NAME OF AUDITOR(S) Dr. Don Carlson		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

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

60. Observation of the Establishment

France. Est. 67-447-05 : Ets Feyel-Artzner, Schiltigheim, October 4, 2004.

- 41/56 Ventilation adequate to control condensation to the extent necessary to prevent adulteration of product and the creation of insanitary conditions was not provided by the establishment. The formation of two to three condensate droplets was observed on the drainage pipes located under four refrigeration units in the Ready-to-Eat Magret slicing room. The four areas of condensation were located over employee walk ways and product transportation areas. Immediate and appropriate corrective action was implemented by the establishment and veterinary services.
[9CFR 416.2 (d)] [[EC Directive 64/433]]

61. NAME OF AUDITOR

Dr. Don Carlson

62. AUDITOR SIGNATURE AND DATE

Dr. Don Carlson /s/ 10/04/2004

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Ets Georges Bruck Strasbourg, France	2. AUDIT DATE 10/01/2004	3. ESTABLISHMENT NO. 67-482-21	4. NAME OF COUNTRY France
5. NAME OF AUDITOR(S) Dr. Don Carlson		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

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

60. Observation of the Establishment

France. Est. 67-482-2: Ets Georges Bruck, Strasbourg, October 1, 2004.

15/51 The establishment did not identify the intended use or the consumers of the finished product in their written HACCP plan. [9CFR 417.2 (a) (2) and 417.8]

61. NAME OF AUDITOR

Dr. Don Carlson

62. AUDITOR SIGNATURE AND DATE

Dr. Don Carlson /s/10/01/2004

Translation

Dear Ms White,

On November 22, 2004, you sent me the draft report of the two FSIS experts audit that took place in France from September 29 to October 14, 2004.

I thank you for this transmission.

I would like to make a few comments.

I regret that the auditors expanded part 5: "Summary of previous audits" so much. Indeed 5 full pages out of 13 are devoted to the previous audit, when only 3 pages are related to the present audit. Furthermore, this "summary" does not reflect the final report of the January/February 2004 audit; the comments sent by the French authorities are not shown, nor are the conclusions of the audit of the veterinary services made by Mr Todd Furey.

As far as the other chapters of the draft report are concerned, I shall add some straightforward remarks :

- Page 5, paragraph 4 (1) : the responsibilities of the project manager is not limited to the second level of the technical assessment regarding export to the USA. As underlined in annex 3 of the April 19, 2004 letter, it covers export to foreign countries and particularly to the USA;
- Page 5, paragraph 4 (3) : I shall emphasize that the annual training for the control of sanitary risks (good hygiene practice, SSOP, HACCP...) will take place according to the need expressed by the inspectors and second level technical inspector;
- Page 5 paragraph 4 (4) : In its action plan, France did not "commit" itself in maintaining a daily inspection in some of the producing plants (like for example drying pork products plants). For these types of plants, France is planning to officially ask your office for a waiver in order to depart from the obligation of daily inspections;
- Page 6 1st item : the sentence should be completed by : "France suspends an establishment's eligibility to export to the USA if it fails to meet a permanent standard and until it doesn't take corrective actions";
- Page 11 : since the action plan developed in 2004, the task of the national technical referent is focused on the technical assistance to the USDA certified establishments. This national technical referent does not have a mission toward French inspectors;
- Page 12 : because of his thorough training to the American requirements, the second level technical inspector can participate in the training of inspectors, supervisors and coordinators;
- Page 12, paragraph 5, 3rd line : all the veterinary services directors are not veterinarians. Some are agricultural engineers, others are agricultural works engineers. However, all of the officials involved in the veterinary certification for export hold a diploma of doctor of veterinary medicine.
Line 4 : each director has at least 2 deputies.

In addition to taking into account the above remarks, I shall appreciate that part 5 "Summary of previous audit" of the final report, is really the summary of the main non compliances that had been noted down in the final report of the January/February 2004 audit.

I remain,
Sincerely yours

Jean-Jacques Soula