



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

Ms. Monique Eloit
Chief Veterinary Officer
Ministry of Agriculture
251 Rue de Vaugirard
75732 Paris,
Cedex 15, France

Dear Ms. Eloit:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of France's meat and poultry inspection system March 28 to April 12, 2007. 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 (402) 344-5100, by facsimile at (402) 344-5169, or electronic mail at donald.smart@fsis.usda.gov.

Sincerely,

A handwritten signature in cursive script, appearing to read "Donald Smart".

Donald Smart
Director
International Audit Staff
Office of International Affairs

Enclosure

FINAL

NOV 21 2007

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

MARCH 28 THROUGH APRIL 12, 2007

Food Safety and Inspection Service
United States Department of Agriculture

TABLE OF CONTENTS

1. INTRODUCTION
2. OBJECTIVE OF THE AUDIT
3. PROTOCOL
4. LEGAL BASIS FOR THE AUDIT
5. SUMMARY OF PREVIOUS AUDITS
6. MAIN FINDINGS
 - 6.1 Legislation
 - 6.2 Government Oversight
 - 6.3 Headquarters and Department Audits
7. ESTABLISHMENT AUDITS
8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS
9. SANITATION CONTROLS
 - 9.1 SSOP
 - 9.2 EC Directive 64/433
 - 9.3 Other Sanitation requirements
10. ANIMAL DISEASE CONTROLS
11. SLAUGHTER/PROCESSING CONTROLS
 - 11.1 Humane Handling and Slaughter
 - 11.2 HACCP Implementation
 - 11.3 Testing for Generic *Escherichia coli*
 - 11.4 Testing of Ready-to Eat Products
 - 11.5 EC Directive 64/433
12. RESIDUE CONTROLS
 - 12.1 FSIS Requirements
 - 12.2 EC Directive 96/22
 - 12.3 EC Directive 96/23
13. ENFORCEMENT CONTROLS
 - 13.1 Daily Inspection
 - 13.2 Testing for *Salmonella*
 - 13.3 Species Verification
 - 13.4 Periodic Reviews
 - 13.5 Inspection System Controls
14. CLOSING MEETING
15. ATTACHMENTS TO THE AUDIT REPORT

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority—General Food Directorate
CVO	Chief Veterinary Officer
DGAL	General Food Directorate
DDSV	Veterinary Services
<i>E. coli</i>	<i>Escherichia coli</i>
FSIS	Food Safety and Inspection Service
IGVIR	Interregional Inspectors General
QAM	Quality Assurance Manager
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

1. INTRODUCTION

The audit took place in France from March 28 through April 12, 2007.

An opening meeting was held on March 28, 2007 in Paris, France, with the Central Competent Authority (CCA). At this meeting, the auditor confirmed the objective and scope of the audit, the auditor's itineraries, 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, and/or representatives from the *Département* inspection offices.

2. OBJECTIVE OF THE AUDIT

This audit was a routine annual audit. The objective of the audit was to evaluate the performance of the CCA with respect to controls over 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, three *Département* offices (DDSV), one slaughter and processing establishment, and one processing establishment.

Competent Authority Visits			Comments
Competent Authority	Central	1	Paris
	<i>Département</i>	3	Vannes Perigueux Cahors
Slaughter and Processing Establishment		1	Lignol
Processing Establishment		1	Sarlat

3. PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records in the country's inspection headquarters or *Département* offices. The third part involved on-site visits to two establishments: one slaughter and processing establishment and one processing establishment. The fourth part included the review of reports from the laboratories conducting analyses of field samples for France's national residue control program, as well as some microbiological sampling for generic *Escherichia coli* (*E. coli*), *Listeria monocytogenes* and *Salmonella*.

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 opening meeting, the auditor explained to the CCA that their inspection system would be audited in accordance with three areas of focus. First, under provisions of the European Community/United States Veterinary Equivalence Agreement (VEA), the FSIS auditor would audit the meat 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.

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 96/22/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, 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.

5. 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 in December of 2004 identified the following deficiencies:

- In one establishment, adequate ventilation was not provided to control condensation to the extent necessary to prevent adulteration of product and the creation of insanitary conditions.
- In one establishment, the intended use or the consumers of the finished product were not included in their written HACCP plan.

The FSIS audit of France's meat and poultry inspection system conducted in November and December of 2005 identified the following deficiencies:

- In two of the three *Départements*, the assignment of pre-operational and HACCP verification activities to inspection personnel was minimal.
- The second tier audits of the establishments certified to export to the U.S. were conducted only at the request of the *Départements* and at a frequency that failed to provide useful information to the CVO.
- Improvement in the inspection personnel's knowledge of U.S. HACCP, SSOP, and other requirements in part nine of the Code of Federal Regulations (CFR) was needed.
- One laboratory was utilizing the "primitest" method for antibiotic screening instead of the traditional four plate method.
- In one establishment producing ready-to-eat, non-shelf stable product for export to the U.S., the required testing of product for *Salmonella* and *Listeria monocytogenes* was not being performed.

- In one establishment, the pre-operational sanitation records contained inadequate descriptions of the sanitation deficiencies observed.
- In one establishment, the preventive measures were not included in the corrective action documents related to pre-operational sanitation deficiencies.
- Operational sanitation (SSOP) records documented sanitation performance standards and could not be used to document the monitoring of product contact surfaces or product for contamination.
- In one establishment, an employee was observed placing his foot on a rack of duck carcasses causing contamination of the product contact surface.
- In one establishment, carcasses in a cooler were found contaminated with feces, rail dust, and unidentified foreign material.
- The lighting in one carcass cooler was not of sufficient intensity to ensure that sanitary conditions were maintained and product was not adulterated.
- In one establishment, the protective coverings on bins of product in a cooler had been blown off and resulted in the potential for contamination of product.
- The hazard analysis of one establishment did not address each of the process steps and the portion addressing chemical hazards was not complete.
- In one establishment, the Critical Limit which was associated with the control of visible feces, ingesta, and milk was not clearly defined.
- In one establishment, the specific ongoing verification procedures were not clearly stated.
- In one establishment, the monitoring activities were not consistently performed at the frequency stated in the HACCP plan.
- In one establishment, the corrective actions taken in response to a deviation from a Critical Limit were not supportable.
- One establishment's hazard analysis did not accurately identify all possible hazards associated with chilling of product.
- In one establishment, the Upper Control Limit of the generic *E. coli* testing process control chart was not a statistically supportable value.
- Inspection personnel in one establishment were not routinely inspecting the thoracic cavities of carcasses.
- Inspection officials instructed establishment employees to place condemned materials in a container used for movement of edible product.

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 among 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 with direction being given to each individual *Département* from the Headquarters in Paris. Working closely with the DGAL is the *réfèrent technique national* (hereafter referred to as a national technical expert) from the Office De L'Elevage. 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 CCA 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, and preparing reports for the CVO with recommendations.

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 new oversight position works with the DDSV to ensure that all FSIS requirements are being properly implemented and verified. These audits may be physical (on-site) audits or document audits. During 2007, both certified establishments were audited.

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 (*Directeur du Départementale Services Veterinaires*, or DDSV) 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 officers 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.

6.2.2 Ultimate Control and Supervision

DGAL headquarters in Paris has the ultimate control and supervision of France's meat and poultry inspection system and has the authority to add or remove establishments from the list of establishments certified to export to the U.S., or to refuse the issuance of veterinary health certificates in order to prohibit exports from occurring.

New official inspection guidelines are issued by DGAL headquarters in Paris. These guidelines are generally provided by e-mail or intranet, utilizing the Ministry database systems called GALAT@E 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.

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.

The DGAL needs to continue to ensure that knowledge of the FSIS inspection requirements, including HACCP, SSOP, and the other regulations found in 9 CFR is consistent throughout of its inspection force.

6.2.4 Authority and Responsibility to Enforce the Laws

DGAL has the authority and the responsibility to enforce all U.S. requirements. However, deficiencies involving the enforcement of U.S. requirements were identified at the two establishments audited.

Specific deficiencies are noted on the attached individual establishment reports.

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 *Département* Offices

The auditor conducted reviews of inspection system documents at the headquarters of the inspection service and in three *Département* offices. This 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,
- New laws and implementation documents such as regulations, notices, directives and guidelines,
- Sanitation, slaughter and processing inspection procedures and standards, and
- Export product inspection and control including export certificates.

Examination of these documents indicated that in the two *départements* 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 Conscripton) and the in-plant officials.

7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of two establishments: one slaughter and processing establishment 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.

8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

No residue or microbiology laboratory audits were performed.

During the government oversight and document reviews laboratory supervision and control procedures were reviewed along with analytical reports generated by the laboratories. The focus of the review was on the submission of appropriate samples, the assessment of analytical reports at the various administrative levels, documentation of methodology used in performing the analysis, and the response to positive laboratory results. No deficiencies were noted regarding the microbiological testing component of the documents reviewed.

9. 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, and except as noted below, 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, 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.

9.1 SSOP

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

- During pre-operational sanitation inspection, feathers and residue from a previous production period were observed on equipment that was identified in the establishment's SSOP as scheduled for daily cleaning.
- Daily records of the establishment documenting corrective actions taken in response to a SSOP failure did not record procedures to prevent recurrence.

9.2 EC Directive 64/433

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

9.3 Other Sanitation Requirements

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.

During the audit, the following deficiencies were identified regarding these sanitation performance standards (SPS):

- In one establishment, foreign material was observed on the wheels of a cart that was clean and ready for reuse.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product.

No deficiencies were noted.

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

11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor reviewed was Slaughter/Processing Controls. The controls include the following areas: 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.

11.1 Humane Handling and Humane Slaughter

No deficiencies were noted.

11.2 HACCP Implementation

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

The HACCP programs were reviewed during the on-site audits. One of the two establishments had not fully and adequately implemented FSIS HACCP requirements, with the following deficiencies noted:

- In one establishment, a review of the Critical Control Point (CCP) monitoring records revealed that on several days the monitoring of the slaughter CCP for visible feces on carcasses was not being performed at the frequency stated in the HACCP plan.
- In one establishment, the HACCP plan for slaughter of poultry did not sufficiently describe or document that the CCP will be under control after the corrective action is taken in response to a deviation from a critical limit.
- In one establishment, there was insufficient supporting documentation for the selection of the frequency for the ongoing verification activity, calibration of process monitoring equipment, in several of the processing HACCP plans.

A more specific description of these deficiencies can be found in the attached individual establishment reports.

11.3 Testing for Generic *E. 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, none of the establishments audited utilize this equivalence determination, but continue 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* and was evaluated according to the criteria employed in the United States' domestic inspection program.

No deficiency was noted.

11.4 Testing of Ready-to-Eat Products

One of the two establishments audited was producing ready-to-eat products (*fois gras*) for export to the U.S. As this particular product is fully cooked in hermetically-sealed glass jars, and there is no post-lethality exposure to the environment, the requirement to test the finished product for *Listeria monocytogenes* under FSIS Directive 10,240.4 does not apply.

However, this product is subject to non-risk-based testing for *Listeria monocytogenes* and *Salmonella*, as mandated by FSIS Directive 10,210.1 Amendment 6.

No deficiencies were noted.

11.5 EC Directive 64/433

In one of the two establishments, the provisions of EC Directive 64/433 addressing slaughter/processing system controls were not effectively implemented.

- The equipment used for working on meat had not been carefully cleaned at the end of the day and before being re-used when they had been soiled.

12. RESIDUE CONTROLS

12.1 FSIS Requirements

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.

No residue laboratories were audited.

During the document audits of the CCA and Départements a review of laboratory records and sample analyses for the National Residue Program in France was conducted.

No deficiencies were noted.

France's National Residue Control Program for 2007 was being followed and was on schedule.

12.1. EC Directive 96/22

No residue laboratory was audited.

12.2. EC Directive 96/23

No residue laboratory was audited.

13. ENFORCEMENT CONTROLS

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

13.1 Daily Inspection in Establishments

Inspection was conducted on each U.S. production day in all slaughter and processing establishments.

13.2 Testing for *Salmonella*

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.

No deficiencies were noted.

13.3 Species Verification

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

13.4 Periodic Reviews

The audit determined that, in all establishments visited, periodic supervisory reviews of certified establishments were being performed and documented as required.

13.5 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.

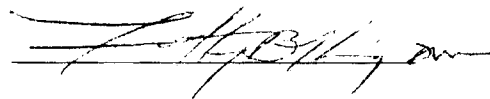
No deficiencies were noted.

14. CLOSING MEETING

A closing meeting was held on April 12, 2007, 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. Timothy B. King
Senior Program Auditor



15. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Forms
Foreign Country Response to Draft Final Audit Report

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Euralis Gastronomie Sarlat Avenue du Perigord Z1 de Madrazes Sarlat 24200	2. AUDIT DATE 5 April, 2007	3. ESTABLISHMENT NO. 24 520 02	4. NAME OF COUNTRY France
	5. NAME OF AUDITOR(S) Timothy B. King, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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	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.	X	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	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQU/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.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

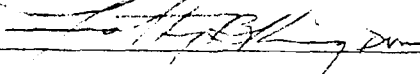
Date: 04/05/07 Est #: 2452002 (Euralis Gastronomie Sarlat [P/CS]) (Sarlat, France)

- 13/51 The daily records of the establishment documenting corrective actions in response to Sanitation Standard Operating Procedures (SSOP) failures did not record the procedures to prevent recurrence. [Regulatory references: 9CFR416.15(b) and 9CFR416.17]

61. NAME OF AUDITOR

Timothy B. King, DVM

62. AUDITOR SIGNATURE AND DATE



5 APR, 2007

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Euralis Gastronomie Z.A. de Kergario Lignol 56160	2. AUDIT DATE 2 April, 2007	3. ESTABLISHMENT NO. 56 110 02	4. NAME OF COUNTRY France
	5. NAME OF AUDITOR(S) Timothy B. King, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
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.	X	46. Sanitary Operations	X
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.	X	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	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork 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	X
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

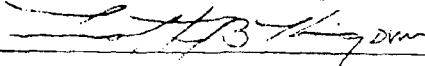
Date: 2 April 2007 Est #: 5611002 (Euralis Gastronomie [S/P/CS]) (Lignol, France)

- 10/56 Feathers and residue from the previous operational activities were observed, during pre-operational sanitation inspection, on the grills of fans in the live bird receiving area and on the sprockets and guide wheels of the slaughter chain in the evisceration room. This equipment was specifically identified for daily cleaning in the establishment's Sanitation Standard Operating Procedures (SSOP). Immediate corrective action was implemented by the establishment personnel. [Regulatory references: 9CFR416.13(c) and EC Directive 64/433(V)(18)(c)]
- 18/51 Review of the establishment's Critical Control Point (CCP) monitoring records revealed that on several days the monitoring of the slaughter CCP for observable fecal contamination was not being performed at the frequency stated in the Hazard Analysis Critical Control Point (HACCP) plan. [9CFR417.5(a)(3) and 9CFR417.8]
- 22/51 A) The review of the HACCP plan for the slaughter of poultry revealed that the description of corrective actions to be taken in the event of a deviation from a critical limit did not sufficiently document that the CCP will be under control after the corrective action is taken. [9CFR417.2(c)(5) and 9CFR417.8]
- B) The establishment did not have supporting documentation for the choice of the frequency for the ongoing verification for the calibration of instruments used to monitor the CCPs, in several processing HACCP plans. [9CFR417.5(a)(2) and 9CFR417.8]
- 46/56 An accumulation of foreign material was observed on the wheels of carts used in the poultry receiving area that were clean and ready for reuse. Immediate corrective action was implemented by establishment personnel. [9CFR416.4(b) and EC Directive 64/433(V)(18)(c)]

61. NAME OF AUDITOR

Timothy B. King, DVM

62. AUDITOR SIGNATURE AND DATE

 2 APR, 2007

Ministry of Agriculture and Fishing

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Mrs. Sally WHITE
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Washington, D.C. 20250 – USA

Paris; [stamp:] SEPT. 13, 2007

Subject: Commentaries submitted by France regarding the final draft of the FSIS audit report completed between March 28 and April 12, 2007.

Dear Madam Director:

I would like to thank you for having sent me, in a letter dated June 14, 2007, the final draft of the audit report completed in France by the FSIS from March 28 to April 12, 2007.

Please find in the attached document our comments on the draft. Included in this document are also a number of comments on the corrective actions added by the professional staff and the Department of Food in response to the non-compliance issues that were listed.

Sincerely,

Monique ELOIT
[signature]

Associate Director

Ref.	Excerpts from the FSIS "Draft Final Report"	Comments and Corrective Actions
Pages 5-6		Although Directive 64/433/EEC is included in the 1998 equivalence agreement, it was annulled and the inspections, henceforth and since January 1, 2006, are performed on the basis of regulations (EC) N° 178/2002, 852/2004, 853/2004, 854/2004 and 882/2004.
Page 8 Sect. 5		<p>With regard to point 2, there is a systematic second-tier technical audit of establishments already USDA certified. They are conducted whenever there has been a significant change in the DDSV (e.g., a new agent conducting the inspections) or in an establishment that is USDA certified. In other cases, the DGAL evaluates the written record of the establishment's surveillance provided by the Director of Veterinary Services of the <i>Département</i>.</p> <p>In 2007, these evaluative second-tier technical audits were carried out for the two companies to be audited for FSIS.</p>
Page 9 Sect. 4		There are very few references to 9 CFR in the internal memorandum entitled "application of MEGAREG", updated in March 2007, but other documents were forwarded to the inspectors (slides on the SSOP and HACCP plans that were shown during the training sessions, the non-compliance list compiled by the FSIS auditors in previous years...). Furthermore, in the 2 departments that were audited, veterinary services inspectors had attended at least one of the two training sessions on FSIS held in 2006.
Page 9 Sect. 6		The French translation of directive 5000. 1, 9 CFR 416, 9 CFR 417, and 9 CFR 430 were progressively posted to the website of the Office of Livestock during the year 2006. Furthermore, three training sessions were held in June 2006, September 2006 and June 2007.
Page 9 Sect. 9.1		<p>Corrective Actions (CA): the hot-air heaters in the live poultry entry ramp were withdrawn from the SSOP plan in order to redesign the process of cleaning them in proportion to the accumulation of feathers and residues on them.</p> <p>CA:</p> <ul style="list-style-type: none"> • The parameters for non-compliance of SPS and SSOP were brought to the attention of those in charge of recording the pre-operating and operating hygiene inspection for all sectors of production during the COMUSDA (USDA Committee) discussion of the establishment of April 30, 2007 and recorded. • Strengthening the recording inspections for all levels (by the Supervisors and Quality Control).
Page 11 Sect. 9.2		CA: The cleaning time the delivery carts for live poultry was extended and the orientation of the cleaning nozzles was changed to improve wheel cleaning.
Page 11 Sect. 9.3		CA: With regard to condensation, the problem was solved by installing an air-heating system.
Page 12 Sect. 11.2		<p>CA: The frequency of the inspection for fecal contamination of the carcasses shall henceforth be the same as in the HACCP plan and the results of this inspection shall be duly recorded.</p> <p>CA: The procedures have been revised and it may be noted that fecal contamination is inspected after supervised control failure and as a</p>

		consequence it was necessary to establish corrective measures in order to be sure that the critical limit was once again under control. CA: The calibration process for thermometers is currently being modified.
Page 13 Sect. 11.5		CA: The conveyor belt was replaced in the waxing room.