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

NOV 10 2008

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 February 27 through March 11, 2008. Comments from France have been included as an attachment to the final report. Enclosed is a copy of the final audit report. We apologize for the delay in the submission of this report

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 690-5646, by facsimile at (202) 720-0676, or electronic mail at donald.smart@fsis.usda.gov.

Sincerely,

Gary D. Bolkcom (for Donald Smart)

Donald Smart
Director
International Audit Staff
Office of International Affairs

Enclosure

EQUAL OPPORTUNITY IN EMPLOYMENT AND SERVICES

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

FEBRUARY 27 THROUGH MARCH 11, 2008

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—General Food Directorate
CVO	Chief Veterinary Officer
DGAL	General Food Directorate
DDSV	Veterinary Services
EC	European Community
E. coli	*Escherichia coli*
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
Salmonella	*Salmonella* species
SSOP	Sanitation Standard Operating Procedures
VEA	European Community/United States Veterinary Equivalence Agreement

1. INTRODUCTION

The audit took place in France from February 27 through March 11, 2008.

An opening meeting was held on February 27, 2008 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 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, one *Département* office (DDSV), one *Département* microbiology laboratory, one *Département* residue laboratory, two slaughter and processing establishment, and one processing establishment.

Competent Authority Visits			Comments
Competent Authority	Central	1	Paris
	Département	1	Vannes
Microbiology Laboratory		1	Quimper, Finistère
Residue Laboratory		1	Saint Ave, Morbihan
Slaughter and Processing Establishment (Poultry)		1	Lignol
Slaughter and Processing Establishment (Swine)		1	Pouldreuzic
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 three establishments: two slaughter and processing establishment and one processing establishment. The fourth part included on-site visits and review of reports from one laboratory conducting analyses of field samples for France's national residue control program and one microbiology laboratory conducting analyses for *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 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.

The FSIS audit of France's meat and poultry inspection system conducted in March and April of 2007 identified the following deficiencies:

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

- In one establishment, the written corrective action to be taken in the event of a deviation from a critical limit did not sufficiently document how the critical limit would be judged to be under control after the corrective action was taken.

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. The auditor was also informed that the Regulation EC 852/2004 of April 29, 2004, Regulation EC 853/2004 of April 29, 2004, and Regulation 882/2004 of April 29, 2004, have superseded the EC Directive 64/433 of June, 1964 governing the production of food from animal origin.

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 *référent technique national* (hereinafter 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 oversight position works with the Director of Veterinary Services (*Directeur du Départementale Services Veterinaires*, or DDSV) to ensure that all FSIS requirements are being properly implemented and verified. These audits may be physical (on-site) audits or document

audits. Between April, 2007, and February, 2008, all of the certified establishments had been audited at least once by the ETSN.

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 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. The

most recent version of the DGAL/MCSI/N2005-8263 Memorandum concerning U.S. requirements was distributed to inspection personnel on March 5, 2007.

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 two of the 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 one *Département* office. 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 United States
- Training records for inspectors
- New laws and implementation documents such as regulations, notices, directives and guidelines
- Sanitation, slaughter and processing inspection procedures and standards
- Export product inspection and control including export certificates
- Humane handling and humane slaughter methods and documentation
- Enforcement and control actions implemented in response to non-compliances

Examination of these documents indicated that in the *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 Conscription) and the in-plant officials.

7. ESTABLISHMENT AUDITS

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

Specific deficiencies are noted on the attached individual establishment reports.

8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

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

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

The following residue laboratory was reviewed:

The *Laboratoire départemental d'analyses Morbihan (56)* in Saint Ave was performing residue analyses on product destined for the U.S. within the scope of the French National Residue Detection Program.

No concerns arose as a result of this review.

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

The following microbiology laboratory was reviewed:

The *Institut départemental d'analyses, de conseil et d'expertise en hygiene alimentaire, eau et environnement et sante animale* (IDHESA) in Quimper was performing microbiological analyses for *Salmonella* on product eligible for export to the United States.

No concerns arose as a result of this review.

During the government oversight and document reviews laboratory supervision and control procedures were evaluated 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.

Based on the document reviews in the establishment inspection offices it was found that two *Départemental* laboratories utilized to test official verification samples for *Salmonella* or *Listeria monocytogenes* were not using the FSIS MLG methodology or an analytical method for which an equivalence determination was granted.

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, 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.

No deficiencies were reported.

9.2 EC Directive 64/433

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

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.

No deficiencies were reported.

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.

- In one establishment, the condemned/inedible material was not under sufficient control of the inspection officials.

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 reported.

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.

No deficiencies were reported.

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.

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

No deficiencies were reported.

11.4 Testing of Ready-to-Eat Products

Two of the three establishments audited were producing ready-to-eat products for export to the U.S. One of these establishments produces products that are fully cooked in hermetically-sealed glass jars, and there is no post-lethality exposure to the environment, the other establishment produces canned, commercially sterile product, in both establishments the requirement to test the finished product for *Listeria monocytogenes* under FSIS Directive 10,240.4 does not apply.

However, the product that is fully cooked in hermetically-sealed glass jars is subject to non-risk-based testing for *Listeria monocytogenes* and *Salmonella*, as mandated by FSIS Directive 10,210.1 Amendment 6.

In one establishment, the analytical results for official verification samples collected for non-risk based testing of RTE product for *Listeria monocytogenes* did not identify an FSIS approved method of analysis.

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.

Specific deficiencies are noted on the attached individual establishment reports.

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 deficiencies were reported.

France's National Residue Control Program for 2008 was being followed and was on schedule.

12.1. EC Directive 96/22

No deficiencies were reported.

12.2. EC Directive 96/23

No deficiencies were reported.

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.

In one establishment, the analytical reports for the *Salmonella* testing of carcasses did not identify the FSIS method or the ISO 6579:2002 method as the method used for conducting the analysis.

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.

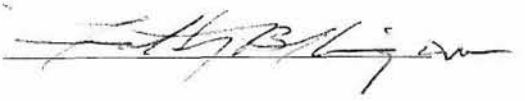
No deficiencies were noted.

14. CLOSING MEETING

A closing meeting was held on March 11, 2008, 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

ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Euralis Gastronomie, Sarlat Avenue du Perigord Zl de Madrazes Sarlat 24200	02/29/08	2452002	France
	5. NAME OF AUDITOR(S)	6. TYPE OF AUDIT	
	Timothy B. King, DVM	[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT	

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

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

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

51 During the review of analytical reports from government verification sampling of Ready-To-Eat (RTE) products for *Listeria monocytogenes* it was observed that the analytical method referenced was not the FSIS MLG 8.06 method required for this type of analysis. No equivalence determinations have been made for France to use other laboratory methods for analysis of samples for *Listeria monocytogenes*. [Regulatory reference: 9 CFR381.196(a)(2)(i)(F) and (iv)(C)]

61. NAME OF AUDITOR

Timothy B. King, DVM

62. AUDITOR SIGNATURE AND DATE

2/29/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Jean Henaff SA Ker Hastell Pouldreuzic, Finisetre 29710	03/7/08	2922501	France
	5. NAME OF AUDITOR(S) Timothy King, DVM		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

Date: 03/7/08 Est #: 2922501 (Jean Henaff SA [S/P]) (Pouldreuzic, France)

After analysis of the nature and extent of the observations made there are no findings to report for this establishment audit.

61. NAME OF AUDITOR

Timothy King, DVM

62. AUDITOR SIGNATURE AND DATE

3/7/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Euralis Gastronomie Z.A. de Kergario Lignol, Morbihan 56160	03/4/08	5611002	France
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Timothy B. King, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

48/51 The condemned/inedible materials were not under sufficient control of the inspection officials at the establishment to preclude their re-introduction into the edible products. [Regulatory references: 9 CFR 381.95 & 9 CFR 327.2(a)(2)(ii)(G)]

51 While reviewing analytical reports of the official PR/HACCP samples for *Salmonella* it was observed that the analytical method recorded on the report was not the FSIS MLG 4.04 (2008) method or the ISO 6579:2002 for which France has obtained an approval of equivalence. [9 CFR 327.2(a)(2)(iv)(C), 9 CFR 381.94(b)(1), & 9 CFR 381.196 (a)(2)(i)(F)]

61. NAME OF AUDITOR

Timothy B. King, DVM

62. AUDITOR SIGNATURE AND DATE

3/4/08

8/4/08
001/006

Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE

EMBASSY OF FRANCE IN THE UNITED STATES
ECONOMIC DEPARTMENT

Washington, July 17,2008

FAX

To :	**Mrs Sally White, Esquire** **Director, International Equivalence Staff** **Office of International Affairs**	**202 690 4040** **202 720 3781**
From	**Christian Berger** **Agriculture Division** **christian.berger@missioneco.org**	**Fax 202 944 6336** **Tel 202 944 6362**

Number of Pages : 1+5

A/s: February 27, 2008's FSIS Mission/Final Audit Report

Dear Sally

Please find attached a letter from the French Ministry of Agriculture and Fisheries pertaining to the object matter accompanied by an unofficial translation.

The original of this letter will be forwarded to you by mail.

Very sincerely

Christian Berger
Counselor, Agriculture Division

Should you have any observations or questions, Fabrice will be back to the office on July 28.

With best regards

Christian

IES
375
7/21/08

4101 Reservoir Road, NW
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membre du réseau
UBIFRANCE
ET LES
MISSIONS ÉCONOMIQUES

Unofficial Translation

Ministry of Agriculture and Fisheries
Paris, July 9 , 2008

Madam Director,

Thank you for sending me, by mail of April 16, 2008, the final draft report on the FSIS audit mission in France in February 27 to March 11th 2008.

I am pleased to address to you in the attached document our comments on this draft. In that document, you will find precisions about the measures that the professionals and our Direction Génerale de l'Alimentation (DGAL) have implemented to respond to the noted non standard (unorthodoxies?).

Sincerely

Monsieur Loïc Evain
Sous-Directeur des Affaires Sanitaires
Européennes et Internationales

RÉPUBLIQUE FRANÇAISE

MINISTERE
DE L'AGRICULTURE
ET DE LA PECHE

Direction générale de l'alimentation

Mission de Coordination sanitaire internationale

Sous-direction sécurité sanitaire des aliments

Adresse : 251, rue de Vaugirard
75 732 PARIS CEDEX 15
Dossier suivi par : S.FLAUTO
Tél. : 01.49.55.81.34
Réf.interne : N° [illegible] - 0 6 3 0

Mrs. Sally WHITE

Director of International Equivalence Staff
Office of International affairs

USDA – Food safety and inspection Service

Washington, D.C. 20250 - USA

Paris, le 09 JUIL. 2008

Objet : commentaires de la France sur le projet de rapport final d'audit du FSIS de la mission du 27 février au 11 mars 2008

Madame la Directrice,

Je vous remercie d'avoir bien voulu me transmettre, par courrier daté du 16 avril 2008, le projet de rapport final concernant la mission d'audit conduite en France par le FSIS du 27 février au 11 mars 2008.

J'ai l'honneur de vous adresser dans le document joint nos commentaires sur ce projet. Figurent également dans ce document un certain nombre de précisions sur les mesures correctives qui ont été mises en œuvre par les professionnels et la Direction générale de l'alimentation en réponse aux non conformités relevées.

Je vous prie de croire, Madame la Directrice, en l'expression de ma considération distinguée.

Monsieur Loïc EVAIN
Sous-directeur des affaires sanitaires européennes et internationales

Copie pour information :
- Ambassade des Etats-Unis à Paris
- DG-SANCO

P J : réponse projet de rapport final

Réf.	Extraits du « Draft final report » du FSIS	Commentaires et actions correctives
Page 5 para. 3	First, under provisions of the European Community / United States Veterinary 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.	Bien que la directive 64/433/CEE soit inscrite dans l'accord d'équivalence de 1998, elle a été abrogéee et les contrôles se font depuis le 1er janvier 2006 sur la base des règlements (CE) N° 178/2002, 852/2004, 853/2004 854/2004 et 882/2004.
Page 10 para. 1	A significant portion of the inspection personnel rely almost exclusively on the content of "MEGAREG" in order to perform their duties in enforcing FSIS requirements. The most recent version of the DGAL/MCSI/N2005-8263 Memorandum concerning U.S. Requirements was distributed to inspection personnel on March 5, 2007.	La note de service intitulée «application de la MEGAREG », actualisée en mars 2007, a été complétée en février 2008 par une note de service générale relative aux exportations de denrées d'origine animale. Cette instruction précise les notions de plans SPS, SSOP et HACCP et établit la correspondance entre les éléments prévus pour les dossiers d'agrément communautaire d'une part, et spécifique pour l'exportation vers les USA d'autre part.

09/07/2008 16:10 0149555580 PAGE 03/05 09/004/000

Réf.	Extraits du « Draft final report » du FSIS	Commentaires et actions correctives
Page 12 para. 2	Based on the document reviews in the etablishment inspection offices it was found that two departemental laboratories utilized to test official verification samples for salmonella and listeria monocytogenes were not using the FSIS MLG methodology or analytical method for wich an equivalence detremination was granted.	– Les recherches de salmonelles actuellement effectuées sur les oies par le Laboratoire Vétérinaire Départemental du Morbihan utilisent la méthode ISO 6579 reconnue équivalente à celle du FSIS MLG ; – Le Laboratoire départemental utilise une méthode alternative d'analyse « ALOA ONE DAY » validée AFNOR (N° attestation de validation : AES 10/3-09/00) suivant la norme NF EN ISO 16140 (référentiel de validation) par comparaison à la méthode de référence pour la recherche et dénombrement de Listeria monocytogenes NF EN ISO 11290-1 (méthode prévue par le règlement (CE) n°2073/2005). Les méthodes préconisées dans le FSIS MLG et le règlement (CE) n°2073/2005 ne sont pas comparables. Les autorités françaises souhaitent que la méthode ISO puisse être utilisée ; dans l'attente de cette confirmation, elles souhaitent disposer de la composition exacte des milieux de culture prévus par le FSIS MLG pour ces analyses.
Page 12 point 9.3	9.3 Other Sanitation Requirements […] During the audit, the following deficiencies were identified regarding these sanitation performance standards (SPS):	Le rapport ne précise pas la non-conformité.
Page 13 Point 10	10. Animal disease controls In one establishment audited, the condemned/inedible material was not undeer sufficient control of the inspection officials.	AC : La porte du local des saisies vétérinaires dispose actuellement d'un cadenas dont la clef est en possession des services de contrôles.

Réf.	Extraits du « Draft final report » du FSIS	Commentaires et actions correctives
Page 14 point 11.4	11.4 Testing of RTE products In one establishment, the analytical results for official verification samples collected for non-risk based testing for Listeria monocytogenes did not identify an FSIS approved method of analysis.	Le Laboratoire départemental utilise une méthode alternative d'analyse « ALOA ONE DAY » validée AFNOR (N° attestation de validation : AES 10/3-09/00) suivant la norme NF EN ISO 16140 (référentiel de validation) par comparaison à la méthode de référence pour la recherche et dénombrement de Listeria monocytogenes NF EN ISO 11290-1. Les méthodes préconisées dans le FSIS MLG et le règlement (CE) n°2073/2005 ne sont pas comparables. Les autorités françaises souhaitent que la méthode ISO puisse être utilisée ; dans l'attente de cette confirmation, elles souhaitent disposer de la composition exacte des milieux de culture prévus par le FSIS MLG pour ces analyses.

AC = Action(s) corrective(s)

09/07/2008 16:10 0149555690 PAGE 05/05 UUU/UUU

REPUBLIC OF FRANCE
DEPARTMENT OF AGRICULTURE AND FISHERY

General Food Office
International Health Coordination Division
Under Office of Food Safety and Security
Address: 251 rue de Vaugirard
75732 Paris Post Office 15
File tracked by: S. Flauto
Tel: 01 49 55 81 34
Ref. no.: 0530

Mrs. Sally WHITE
Director of International Equivalence Staff
Office of International Affairs
USDA – Food Safety and Inspection Office
Washington, D.C. 20250 USA

Paris, July 9, 2008

Re: Comments of France on the Draft of the final audit report of the FSIS of the division from February 27 to March 11, 2008

Dear Ms. Director:

I would like to thank you for sending me, on April 16, 2008, the draft of the final report concerning the audit conducted in France by the FSIS from February 27 to March 11, 2008.

I am pleased to send you the attached document with our comments on the draft. Also appearing in the document are several additional points on the corrective measures that were put into place by the professionals and the General Food Office in response to the points of non-compliance found.

Please accept, Ms. Director, the expression of my distinguished consideration.

Mr. Loic EVAIN
Assistant Director of European
and International Health Affairs
/signature illegible/

Copy for information purposes:
- The Ambassador of the United States in Paris
- DG – SANCO
P.J. – Response to the draft of the final report

Ref.	Excerpt from the Draft Final Report of the FSIS	Comments and Corrective Actions
Page 5 Para. 3	First, under provisions of the European Community / United States Veterinary 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.	Although Directive 64/433/CEE was inserted in the equivalence agreement of 1998, it was abrogated and the controls were done after January 1, 2006 on the basis of (EC) regulations no. 178/2002, 852/2004, 853/2004, 854/2004, and 882/2004.
Page 10 Para.1	A significant portion of the inspection personnel rely almost exclusively on the content of "MRGAREG" in order to perform their duties in enforcing FSIS requirements. The most recent version of DGAL/MCSI/N2005-8263 Memorandum concerning U.S. Requirements was distributed to inspection personnel on March 5, 2007	The service memorandum entitled "Application of the "MRGAREG", implemented in 2007, was completed in February 2008 by a general service memorandum related to exports of products of animal origin. These instructions establish the notions of SPS, SSOP, and HACCP plans and establish the correspondence between the elements stipulated for European Community files on the one hand and specifications for exports to the United States on the other hand.

Ref.	Excerpt from the Draft Final Report of the FSIS	Comments and Corrective Actions
Page 12 Para. 2	Based on the document reviews in the establishment inspection offices, it was found that two departmental laboratories utilized to test official verification samples for salmonella and listeria monocytogenes were not using the FSIS MLG methodology or analytical method for which an equivalence determination was granted.	- The tests for salmonella currently conducted on the samples by the Departmental Veterinary Laboratory of the Borbihan use the ISO 6579 method recognized as equivalent to that of the FSIS MLG; - The Departmental Laboratory uses an alternative method of analysis: "ALOA ONE DAY" with AFNOR validation (validation certificate no. AES 10/3-09/00) following the NF EN ISO 6140 regulations (validation referential) through the comparison with the reference method for the search and identification of Listeria monocytogenes NF EN ISO 1 1290-1 (the method established by the regulation) (EC) no. 2073/2005. The methods established in the FSIS MLG and the regulation (EC) no. 2073/2005 are not compatible. The French authorities believe that the ISO method may be used; in the attempt for this confirmation, they are trying to use the exact composition of the site of the culture established by FSIS MLG for this analysis.
Page 12 Point 9.3	9.3 Other Sanitation Requirements […] During the audit, the following deficiencies were identified regarding these sanitation performance standards (SPS):	The report does not specify the point of non-compliance.
Page 13 Point 10	10. Animal Disease Controls In one establishment audited, the condemned/inedible material was not under sufficient control of the inspection officials	AC: the door of the veterinary testing area currently uses a chain in which the key is in the possession of the control office.

Ref.	Excerpt from the Draft Final Report of the FSIS	Comments and Corrective Actions
Page 14 Point 11.4	11.4 Testing of RTE Products In one establishment, the analytical results for official verification samples collected for non-risk based testing for Listeria monocytogenes did not identify an FSIS approved method of analysis.	The Departmental Laboratory uses an alternative method of analysis: "ALOA ONE DAY" with AFNOR validation (validation certificate no. AES 10/3-09/00) following the NF EN ISO 6140 regulations (validation referential) through the comparison with the reference method for the search and identification of Listeria monocytogenes NF EN ISO 1 1290-1. The methods established in the FSIS MLG and the regulation (EC) no. 2073/2005 are not compatible. The French authorities believe that the ISO method may be used; in the attempt for this confirmation, they are trying to use the exact composition of the site of the culture established by FSIS MLG for this analysis.

AC = Corrective action (s)