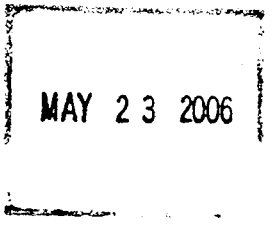
United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250



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 on November 30 to December 21, 2005. Comments from France have been included as an attachment to the final report. Enclosed is a copy of the final report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 720-3781, at (202) 690-4040 or electronic mail at sally.white@fsis.usda.gov.

Sincerely,

Sally White JP

Sally White
Director
International Equivalence Staff
Office of International Affairs

Enclosure

cc:
Elizabeth Berry, Minister Counselor, US Embassy, Paris
Christian Berger, Counselor for Agriculture, Embassy of France
Canice Nolan, First Secretary, EU Mission to US, Washington, DC
Norval Francis, Minister-Counselor, US Mission to the EU, Brussels
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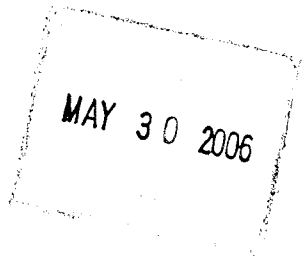

FINAL

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

NOVEMBER 30 THROUGH DECEMBER 21, 2005

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
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 November 30 through December 21, 2005.

An opening meeting was held on November 30, 2005 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 itinerary, and requested additional information needed to complete the audit of France's meat and poultry inspection system.

The auditor was accompanied during the entire audit by representatives from the CCA, the General Food Directorate, 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 meat producing/storage establishments certified by the CCA as eligible to export meat products to the United States.

In pursuit of the objective, the following sites were visited: the headquarters of the CCA, three *Département* offices (DDSV), three laboratories, three slaughter establishments, and one processing establishment.

Competent Authority Visits			Comments
Competent Authority	Central	1	Paris
	Département	3	Quimper Perigord Cahors
Laboratories		3	Quimper Vannes Cahors
Slaughter Establishments		3	Pouldreuzic Lignol Gramat
Processing Establishments		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 Department offices. The third part involved on-site visits to four establishments: three slaughter establishments and one processing establishment. The fourth part included a visit to 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)*, 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 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* 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 January of 2004 identified the following deficiencies:

- The CCA did not have ultimate control and supervision over official activities of all employees and certified establishments.
- Inspection personnel did not have sufficient knowledge of the U.S. HACCP and SSOP regulatory requirements.
- Deficiencies were identified involving the following areas of SSOP compliance:
    - Monitoring: specification of frequencies (one establishment)
    - Implementation of the SSOP (nine establishments)
    - Corrective actions: proper disposition of product (one establishment).
    - Recordkeeping: preventive measures for corrective actions were not included in the daily records (nine establishments)
- SPS deficiencies, which could result in the creation of insanitary conditions and product adulteration, were identified:
    - Equipment and utensils (five establishments)
    - Ventilation (five establishments)
    - Maintenance of grounds / facilities (three establishments)
- Noncompliances with the following regulatory requirements under HACCP were observed:
    - Completion of a supportable Hazard Analysis (6 establishments)
    - Verification activities (8 establishments)

    - Monitoring (4 establishments)
    - Corrective Actions (5 establishments)
    - Recordkeeping (5 establishments)
    - Reassessment (1 establishment)
- In two establishments, the reassessment of the HACCP plan did not properly address the hazards reasonably likely to occur associated with *Listeria monocytogenes*.
- In one establishment, daily inspection was not provided during the maturation process of fermented dry pork sausage.
- In two establishments, pre-operational sanitation was not performed in a manner consistent with US expectations.
- At one establishment, a careful post-mortem examination and inspection was not made.

During the course of this audit, three of 11 establishments were delisted for failure to meet U.S. requirements and two of 11 establishments received a Notice of Intent to Delist (NOID).

The subsequent FSIS audit was an enforcement audit conducted in December of 2004, during which the following deficiencies were identified:

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

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. In 2003, the DGAL created a new position, *référent technique national* (hereafter referred to as a national technical expert), with the role to oversee all establishments that are eligible to export products to the United States. The national technical expert brings technical support to the French inspectors, supervisors and coordinators in an advisory role.

The CCA also created a second-tier oversight position in addition to the above-mentioned national technical expert. 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 these two positions is the level at which they interact within the national inspection system. The national technical expert works directly with the establishments. The new oversight position works with the DDSV to ensure that all FSIS requirements are being properly implemented and verified.

During this FSIS audit, further clarifications were provided by the DGAL concerning the frequency at which these second-tier audits are performed. This can be summarized as follows:

1. Second-tier audits are performed prior to listing an establishment as certified for U.S. export.
2. Concerning establishments which are already certified for U.S. export, second-tier audits are performed with a target frequency of at least once per year.
3. Second-tier audits can be conducted at the request of the DDSV overseeing a particular establishment on an "as needed" basis.

Additionally, the following observations were noted concerning the actual effectuation of this position:

- The extent and nature of the noncompliances identified during this FSIS audit may be indicative of deficiencies in either the frequency or the manner in which these second-tier reviews are performed, especially with regard to newly-listed establishments.
- While this position is described as answering directly to the CVO, audits performed at the request of the associated DDSV are done at their expense (i.e., related travel and lodging expenses are covered by the DDSV's budget). Although provisions exist which allow the DDSV to procure additional funding for these expenses, this additional step is not entirely consistent with the concept of a direct line of command between the CVO and this position.
- One of the establishments visited underwent only an off-site "document audit" in the previous year. This type of audit differs from the "field audit" specified in this position's job description.

At the regional level, France is divided into 22 regions. There are two groups that work at the regional level for the DGAL. The first are the Quality Assurance Managers (QAM). The QAMs are assigned with the implementation of ISO 17020 within the

DGAL. In performing this function, the QAMs provide regional support to various *départements* in an effort to harmonize the application of US import requirements.

The second group is comprised of nine Interregional Inspectors General (IGVIRs), each of whom oversees several of the 22 Regions, functioning as one of the key components of the organization's internal audit system. A monthly coordination meeting between the IGVIRs and the DGAL Director General is held in Paris. The IGVIRs also organize meetings with the DDSVs in their assigned regions with the primary purpose of ensuring the appropriate allocation of funds and staffing.

At the local level, France's twenty-two regions are further 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). Each of these government employees holds a veterinary degree, and is a sworn-in officer (as are all inspection staff); his/her testimonies have high value in court proceedings. Each Director has at least two deputies who are assigned to either the division of animal health and welfare or the section addressing food safety. The latter coordinates the inspection programs within the *département* regarding all the approved meat and poultry slaughter and processing establishments therein. According to the volume of activity within the *département*, the deputy has other colleagues who work with him/her and report to him/her; these make up the Food Safety Service within the *département.* 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 taking place.

New official inspection guidelines are issued by DGAL headquarters in Paris. These guidelines are provided by facsimile, e-mail, and intranet to the Directors of the *Départements* and, through them, to the field personnel and, if appropriate, also to establishment and/or laboratory management officials. Under the current system, it is the responsibility of these Directors to delegate implementation instructions to the appropriate officials under their supervision, and to ensure their implementation.

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*

The following observations result from the review of this document and should be considered in association with other findings identified during the audit process:

- The section concerning hygiene synonymously equates sanitation with SSOP. This differs from the FSIS regulations outlined in 9 CFR 416, under which sanitation is divided into SPS and SSOP components.
- This document contains very few regulatory references to 9 CFR, and may need to be more specifically tailored to these specific FSIS regulations rather than providing an overview of FSIS requirements.
- A significant portion of the inspection personnel encountered during the audit rely almost exclusively on its contents in order to perform their duties in enforcing FSIS requirements. Overall, there was little familiarity among inspection personnel with regulations contained outside of 9 CFR 416, 417, and with those addressing microbial sampling.

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.

As the majority of noncompliances encountered during the audit involved a newly listed establishment, the DGAL needs to continue to ensure that knowledge of the FSIS inspection requirements, including HACCP, SSOP, and of 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 four 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 two of the three departmental offices were only minimally involved in 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 in-plant officials.

7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of four establishments: three slaughter establishments and one processing establishment. Prior to the start of the audit, two of five originally certified establishments were delisted, and one was added by the CCA. One establishment was delisted 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 the laboratory audits, emphasis was placed on the application of procedures and standards that are equivalent to U.S. requirements.

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

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

The following three laboratories were reviewed:

- Two private laboratories conducting residue and microbiological testing. These laboratories are accredited by the French Accreditation Committee (COFRAC).
  - District 29: *Laboratoire départemental d'analyses* (Quimper)
  - District 56: *Laboratoire départemental d'analyses* (Saint Ave)

- One private laboratory in Cahors, also accredited under COFRAC, and utilized by an establishment for conducting microbiological testing for generic *E. coli.*

The findings concerning the residue component of laboratory testing will be discussed in Section 12 (Residue Controls) of this report. No deficiencies were noted regarding the microbiological testing component at the visited laboratories.

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, France's inspection system had inadequate 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. For example:

- Frances's inspection system failed to identify serious deficiencies observed in establishment operations that resulted in product adulteration.

- Audit findings noted in this section include inadequate government oversight and non-compliance with Council Directive 64/433/EEC of June 1964.

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:

- In one establishment, several deficiencies were identified concerning SSOP recordkeeping requirements:
    - The pre-operational sanitation records generated on the day of the audit contained inadequate descriptions of deficiencies (e.g. "needs cleaning").
    - Preventive measures were not routinely documented as part of the establishment's corrective actions taken in response to pre-operational sanitation deficiencies.
    - The establishment's operational SSOP records focused on specific SPS elements (e.g. employee hygiene, cleanliness of work garments) and, as designed, could not be utilized to properly document instances of actual product contamination, or contamination of product-contact surfaces.

- In one establishment, a plant employee was observed placing his foot on a rack of duck carcasses, resulting in contamination of product contact surfaces.

- In one establishment, various forms of contamination (feces, unidentified foreign material, and rail dust) were identified on several hog carcasses in the carcass cooler.

9.2 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, the plastic bins used for the conveyance of boxed edible product were not clearly distinguishable from containers used for inedible product.

- In one establishment, the lighting in the carcass cooler was not of sufficient intensity to ensure that sanitary conditions were maintained and that product was not adulterated.

- In one establishment, the protective coverings on several metal bins containing product in the cooler were blown off by the air which was circulating within. One of these unprotected bins was situated under a cooling unit which presented evidence of dried condensation on the inferior surface of the drip pan.

9.3 EC Directive 64/433

In three of the four 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.

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.

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. Only two of the four establishments had fully and adequately implemented FSIS' HACCP requirements, with the following deficiencies noted at the other two establishments:

- In one establishment, fecal contamination was identified on a hog carcass in the cooler. This production step was after the Agency's established verification point for "zero tolerance" (i.e., visible feces, ingesta, and milk).

- The hazard analysis in one establishment did not specifically address each of the production steps, and the portion addressing chemical hazards was not complete.

- In one establishment, the critical limit which appeared to be related to the control of visible feces, ingesta, and milk (i.e. "zero tolerance") was not clearly defined, and was solely described as "no dirty carcasses".

- Specific on-going verification procedures and frequencies were not clearly described in one establishment's HACCP plan addressing slaughter.

- In one establishment, the prescribed monitoring frequency for a CCP, as indicated in the HACCP plan, was not always followed.

- In one establishment, the corrective actions described in the HACCP plan to be taken in response to a deviation from the critical limit were not supportable.

- In one establishment, the hazard analysis addressing the production of fully-cooked, not-shelf-stable *foie gras* did not accurately identify all the possible hazards associated with the chilling of product after cooking (e.g. *Clostridium perfringens*).

- In one establishment, the review of records indicated that all four components of corrective actions associated with a deviation from the critical limit were not always documented.

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

11.3 Testing for Generic *E. coli*

Three of the four 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, with the following result:

- In one establishment, the upper control limit associated with the implementation of process control techniques regarding generic *E. coli* testing was not statistically supportable. The method used by the establishment to determine this limit consisted in taking the average value from a series of generic *E. coli* testing results (reported in CFU/ml) and then arbitrarily multiplying this value by a factor of five. No further supporting documentation was provided by the establishment to demonstrate the statistical validity of this calculation.

11.4 Testing of Ready-to-Eat Products

One of the four establishments audited were 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 prescribed by FSIS Directive 10,210.1 Amendment 6, with regards to which the following deficiency was identified:

- The audit of this establishment revealed that testing for *Salmonella* and *Listeria monocytogenes* was not being performed. As the particular product is not post-lethality exposed, current FSIS expectations for exporting countries prescribe a testing frequency of three times per year for these pathogens.

11.5 EC Directive 64/433

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

- Review of the procedures revealed that antemortem inspection was routinely performed by a non-veterinary DGAL official, under lighting of insufficient intensity.

12. RESIDUE CONTROLS

12.1 FSIS Requirements

The fourth of the five risk areas that the FSIS auditor reviewed was Residue Controls. The following deficiency was identified:

- One laboratory was utilizing the "*primitest*" method for antibiotic screening instead of the traditional 4-plate method. At the time of the audit, no equivalence determination was in place to permit substitution of one method for the other.

12.1. EC Directive 96/22

The provisions of EC Directive 96/22 were effectively implemented at the audited laboratories which were performing residue testing.

12.2. EC Directive 96/23

The provisions of EC Directive 96/23 were effectively implemented at the audited laboratories which were performing residue testing.

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 Monthly Reviews

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

13.5 Inspection System Controls

These controls include enforcement of inspection requirements for sanitation and HACCP; 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. Not all FSIS requirements were enforced by the France's inspection system. For example:

- In one establishment, several deficiencies were identified concerning SSOP recordkeeping requirements:
    - The pre-operational sanitation records generated on the day of the audit contained inadequate descriptions of deficiencies (e.g. "needs cleaning").
    - Preventive measures were not routinely documented as part of the establishment's corrective actions taken in response to pre-operational sanitation deficiencies.
    - The establishment's operational SSOP records focused on specific SPS elements (e.g. employee hygiene, cleanliness of work garments) and, as designed, could not be utilized to properly document instances of actual product contamination, or contamination of product-contact surfaces.

- In one establishment, a plant employee was observed placing his foot on a rack of duck carcasses, resulting in contamination of product contact surfaces.

- In one establishment, various forms of contamination (feces, unidentified foreign material, and rail dust) were identified on several hog carcasses in the carcass cooler.

- In one establishment, the plastic bins used for the conveyance of boxed edible product were not clearly distinguishable from containers used for inedible product.

- In one establishment, the lighting in the carcass cooler was not of sufficient intensity to ensure that sanitary conditions were maintained and that product was not adulterated.

- In one establishment, the protective coverings on several metal bins containing product in the cooler were blown off by the air which was circulating within. One of these unprotected bins was situated under a cooling unit which presented evidence of dried condensation on the inferior surface of the drip pan.

- In one establishment, fecal contamination was identified on a hog carcass in the cooler. This production step was after the Agency's established verification point for "zero tolerance" (i.e., visible feces, ingesta, and milk).

- The hazard analysis in one establishment did not specifically address each of the production steps, and the portion addressing chemical hazards was not complete.

- In one establishment, the critical limit which appeared to be related to the control

of visible feces, ingesta, and milk (i.e. "zero tolerance") was not clearly defined, and was solely described as "no dirty carcasses".

- Specific on-going verification procedures and frequencies were not clearly described in one establishment's HACCP plan addressing slaughter.

- In one establishment, the prescribed monitoring frequency for a CCP, as indicated in the HACCP plan, was not always followed.

- In one establishment, the corrective actions described in the HACCP plan to be taken in response to a deviation from the critical limit were not supportable.

- In one establishment, the hazard analysis addressing the production of fully-cooked, not-shelf-stable *foie gras* did not accurately identify all the possible hazards associated with the chilling of product after cooking (e.g. *Clostridium perfringens*).

- In one establishment, the review of records indicated that all four components of corrective actions associated with a deviation from the critical limit were not always documented.

- In one establishment, the upper control limit associated with the implementation of process control techniques regarding generic *E. coli* testing was not statistically supportable. The method used by the establishment to determine this limit consisted in taking the average value from a series of generic *E. coli* testing results (reported in CFU/ml) and then arbitrarily multiplying this value by a factor of five. No further supporting documentation was provided by the establishment to demonstrate the statistical validity of this calculation.

- The audit of this establishment revealed that testing for *Salmonella* and *Listeria monocytogenes* was not being performed. As the particular product is not post-lethality exposed, current FSIS expectations for exporting countries prescribe a testing frequency of three times per year for these pathogens.

- The observation of post-mortem inspection of ducks in one of the establishments revealed that the thoracic cavities were not being routinely inspected by DGAL personnel.

- Review of the antemortem inspection procedures at one establishment indicated that they were not consistent with U.S. practices. These procedures were routinely performed under lighting of insufficient intensity, and were described to the auditor as involving the observation of animals from the external perimeter of the pens. On the day of the audit, the pens were filled to an extent which would not permit the sufficient movement of animals, thereby rendering the accomplishment of effective inspection difficult. Current U.S. expectations are that animals undergoing antemortem inspection are also to be viewed in motion.

- In one establishment, the inspection official instructed an employee to dispose of condemned product by placing it in a container used for edible product before

sending it to rendering.

- Several contaminated carcasses, which had been overlooked by the DGAL officials, were identified by the FSIS auditor in the carcass cooler.

14. CLOSING MEETING

A closing meeting was held on December 21, 2005, in Paris with the CCA, and by teleconference with a member of the European Community in Brussels, Belgium and with International Equivalence staff officers in Washington, D.C. At this meeting, the primary findings and conclusions from the audit were presented by the auditor.

The CCA understood and accepted the findings.

for Dr. Alexander L. Lauro
Senior Program Auditor

Margaret A. Chaudry

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	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Euralis Gastronomie Avenue di perigord ZI de Madrazes 24200 Sarlat la Caneda	Dec. 14, 2005	24-520-02	France
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Alexander L. Lauro		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
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	X
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	
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. Listeria testing – Non-Risk-Based	X
59.	

60. Observation of the Establishment

Est. #: 24-520-02
City and Country: Sarlat la Caneda
Date: 12/14/05

45 / 51: The plastic bins used for the conveyance of boxed edible product at shipping were non-distinguishable from the photograph of receptacles used for condemned materials which were indicated on posters throughout the plant. [9 CFR 416.3(c)]

15 / 51) The hazard analysis addressing the production of fully-cooked, non-shelf-stable *"foie gras"* did not accurately identify all the possible hazards associated with the chilling of product after cooking. This document did not address the possible germination and subsequent toxin production of spore forming organisms such as *Clostridium perfringens* during this production phase, nor did it reference any further documentation supporting this omission. As the product is subjected to an automated stabilization process within the pasteurizer at this step, it is unlikely that conditions would allow for toxins from these organisms to be produced. However, failure to address all possible hazards at this step does not meet the regulatory requirements of 9 CFR 417.2(a)(1).

58 / 51) The establishment was producing a ready-to-eat (RTE) product for U.S. export (*foie gras* cooked in jars), however testing for *Salmonella* and *Listeria monocytogenes* was not being performed. As this particular product is not post-lethality exposed, current FSIS expectations for exporting countries prescribe a testing frequency of three times / year for the aforementioned pathogens (i.e., non-risk-based sampling). Neither the establishment nor the inspection officials were fully aware of the specific testing requirements.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Alexander L. Lauro	Alexander L. Lauro 12/26/06

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 29710 Pouldreuzic	Dec. 5, 2005	29-225-01	France
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Alexander L. Lauro		[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.	X
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.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
16. Records documenting implementation and monitoring of the HACCP plan.	X
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	X
19. Verification and validation of HACCP plan.	
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	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	X
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58. Request by establishment to terminate audit / Delistment	X
59.	

60. Observation of the Establishment

Est.#: 29-225-01
City and Country: Pouldreuzic, France
Date: December 5, 2005

10 / 18 / 51) After observing DGAL officials performing their inspection from the doorway of this area, the auditor performed a more detailed inspection of the carcass cooler. During the auditor's inspection, several contaminated carcasses were identified, one of which presented feces around the area of the tail. This production step is after the Agency's established verification point for this hazard (i.e. just prior to the final wash). Another carcass presented unidentified foreign material on the muscles of the perineal area, and several other carcasses presented rail dust on their posterior surfaces. Both the inspection officials and establishment employees were notified of the noncompliance, and actions were taken to remove the contamination. The presence of fecal contamination is a repeat finding from the April 23, 2003 audit. [9 CFR 417.3, 310.18, 416.13] [Council Directive 64/433/EEC]

51 / 56) While observing a test of the metal detector, the plant employee performing the demonstration dropped the rod containing the metal seed on the floor, and then placed it back on the product without first washing / disinfecting it. The inspection official instructed the employee to dispose of the affected product, however these instructions consisted in removing the product from its container and placing it in a similar edible-product container before being sent away for disposal. [9 CFR 416.3] [Council Directive 64/433/EEC]

13 / 51) The review of records documenting the implementation of the establishment's SSOP identified the following noncompliances with 9 CFR 416.16:

- The pre-operational sanitation records generated on the day of the audit contained only superficial descriptions of deficiencies (e.g. "needs cleaning").
- Preventive measures were not routinely documented as part of the establishment's corrective actions taken in response to pre-operational SSOP deficiencies.
- The establishment's operational SSOP records focused on specific SPS elements (e.g. employee hygiene, cleanliness of work garments) and, as designed, could not be utilized to properly document instances of actual product contamination, or contamination of product contact surfaces.

15 / 51) The establishment's hazard analysis did not specifically address each of the production steps, and the portion addressing chemical hazards was not complete. [9 CFR 417.2]

15 / 18 / 16 / 51) The following noncompliances were identified concerning the establishment's HACCP plan addressing the control of visible feces, ingesta, and milk (i.e., "zero tolerance") on carcasses and carcass portions:

- 15 / 51) The critical limit was not clearly defined, and was solely described as "no dirty carcasses". [9 CFR 417.2]
- 15 / 51) Specific on-going verification procedures and frequencies were not clearly described in the HACCP plan, and confusion seemed to exist among plant personnel concerning differences between regulatory requirements for monitoring and verification. [9 CFR 417.2(c)(7)]
- 18 / 51) The established monitoring frequency (5 carcasses / hour) was not always followed. Further conversations revealed that both the establishment as well as inspection personnel were of the opinion that it was permissible to delay monitoring beyond the prescribed frequency if the assigned individual was performing other duties. [9 CFR 417.2(c)(4)]
- 15 / 51) Part of the corrective actions in response to a deviation from the critical limit which were specifically mentioned in the HACCP plan consisted in "going back 40 carcasses", rather than the FSIS policy of "going back to the last acceptable check". The rationale behind this determination was that these 40 carcasses would include a portion of those from the last acceptable monitoring check, based on the average line speed (30-40 carcasses per hour) and the monitoring frequency of once/hour. However, since it was previously determined that the prescribed monitoring frequency was not always followed, this rationale was not completely supportable. [9 CFR 417.3(c)(5)]
- 16 / 51) The review of records indicated that all four components of corrective actions associated with a deviation from the critical limit were not always documented, and often only trimming of the carcass was described. [9 CFR 417.5]

46 / 56) Several metal bins in the cooler containing product had their protective coverings blown off by the air which was circulating within. One of these unprotected bins was situated under a cooling unit which presented evidence of dried condensation on the inferior surface of the drip pan. [9 CFR 416.4(d)] [Council Directive 64/433/EEC]

54 / 51 / 56) Review of the antemortem inspection procedures indicated that they were not consistent with U.S. practices, or with sections of EEC Directive 64/433. These procedures were routinely performed by a non-veterinary DGAL official, under lighting of insufficient intensity, and were described to the auditor as involving the observation of animals from the external perimeter of the pens. On the day of the audit, the pens were filled to an extent which would not permit the sufficient movement of animals, thereby rendering the accomplishment of effective inspection difficult. Current U.S. expectations are that animals undergoing antemortem inspection are also to be viewed in motion. While provisions exist (i.e. "alternative antemortem") allowing only a portion of the animals to be observed in this fashion (i.e. in motion), no discussion of this provision, nor the supporting documentation to justify the current procedures were mentioned by the inspection staff. Lastly, E.U. legislation clearly states that antemortem inspection must be conducted by an official veterinarian, under suitable lighting. [9 CFR 310][Council Directive 64/433/EEC, Annex I, Chapter IV, item 10]

58) During the component of document review, the establishment asked to terminate the audit before its completion. This event, in association with discussions concerning the nature, extent, and degree of the deficiencies identified, resulted in the removal of the establishment from the list of establishments certified as eligible to export to the United States by the accompanying DGAL officials.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Alexander L. Lauro	Alexander H. Lauro 1/26/06

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
La Quercynoise Route de Figeac 46500 Gramat	Dec. 12, 2005	46-128-02	France
	5. NAME OF AUDITOR(S)	6. TYPE OF AUDIT	
	Dr. Alexander L. Lauro	[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.	X
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	X
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

60. Observation of the Establishment

Est.#: 46-128-02
City and Country: Gramat, France
Date: Dec 12, 2005

10 / 56) A plant employee was observed in the cutting room placing his foot on a rack of duck carcasses, resulting in contamination of product contact surfaces. Inspection personnel were notified of the non-compliance, and immediately then ensured that appropriate corrective actions were implemented. [9 CFR 416.13][Council Directive 64/433/EEC]

28 / 51) The upper control limit associated with the implementation of process control techniques regarding generic *E. coli* testing was not statistically supportable. The method used by the establishment to determine this limit consisted in taking the average value from a series of generic *E. coli* testing results (reported in CFU/ml) and then arbitrarily multiplying this value by a factor of five. No further supporting documentation was provided by the establishment to demonstrate the statistical validity of this calculation. [9 CFR 381.94(a)(4)(ii)]

61. NAME OF AUDITOR

Dr. Alexander L. Lauro

62. AUDITOR SIGNATURE AND DATE

Alexander L. Lauro 1/26/06

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Euralis Gastronomie ZA de Kergario 56160 Lignol	Dec. 6, 2005	56-110-02	France
	5. NAME OF AUDITOR(S)	6. TYPE OF AUDIT	
	Dr. Alexander L. Lauro	[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.	
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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	X
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	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Est.#:56-110-02
City and Country: Lignol, France
Date: Dec. 6, 2005

40 / 51 / 56) Lighting in the carcass cooler was not of sufficient intensity to ensure that sanitary conditions were maintained and that product was not adulterated. [9 CFR 416.2 (c)][Council Directive 64/433/EEC]

55 / 51) Observation of post-mortem inspection practices revealed that only specific organs of the abdominal cavity were being routinely inspected by DGAL personnel. The most notable of the organs which were omitted from routine inspection included air-sacs of the thoracic cavity, the heart, and the spleen. As certain air-sacs of the thoracic cavity communicate directly with the pneumatic bones of the wing, which in turn are in direct contact with the muscle tissue of the breast, it is important that these air-sacs be inspected in order to ensure that the breast tissue does not contain inflammatory exudate, or other pathological material. In addition, it is only through inspection of the available "noble organs" (e.g. heart, spleen, liver) contained in both the abdominal and thoracic cavities that a complete assessment of the health of the animal can be attained. [9 CFR 381.76(a)]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr Alexander L. Lauro	Margaret H. Chaudry 1/26/06

COUNTRY'S COMMENT TO DRAFT FINAL AUDIT REPORT

Ref.	Extracts of the "Draft final report" of the FSIS	Comments and corrective action
Page 8 para. 1	In 2004, the DGAL created a new position, *référent technique national* (hereafter referred to as a national technical expert), with the role to oversee all establishments that are eligible to export products to the United States. The national technical expert brings technical support to the French inspectors, supervisors and coordinators in an advisory role.	The position of national technical expert (RTN) on USDA matters was created in 2003. From the outset, the task of the national technical expert was to visit all establishments applying to export meat products to the USA. The training received in Omaha allows the expert to provide the necessary information to the inspection services. This role was strengthened by a new document stating that the national technical expert shall perform an audit before the departmental veterinary services examine any application for certification.
Page 8 Para. 4	During this FSIS audit, further clarifications were provided by the DGAL concerning the frequency at which these second-tier audits are performed. This can be summarized as follows: 1. Second-tier audits are performed prior to listing an establishment as certified for U.S. export. 2. Concerning establishments which are already certified to U.S. export, second-tier audits are performed with a target frequency of at least once per year. 3. Second-tier audits can be conducted at the request of the DDSV overseeing a particular establishment on an "as needed" basis.	Regarding point 2, second-tier audits of establishments that are already USDA certified are systematically programmed whenever any significant changes take place within the DDSV (e.g. a new inspector) or the USDA certified company. In all other cases, the DGAL decides whether an audit is necessary, on the basis of written reports on the monitoring of the establishment provided by the Director of the Departmental Veterinary Services. In 2006, these second-tier audits will be performed on all companies put forward for the FSIS audit.
Page 10 para. 1	The following observations result from the review of this document and should be considered in association with other findings identified during the audit process : • The section concerning hygiene synonymously equates sanitation with SSOP. This differs from the FSIS regulations outlined in 9 CFR 416, under which sanitation is divided into SPS and SSOP components. • This document contains very few regulatory references to 9 CFR, and may need to be more specifically tailored to theses specific FSIS regulations rather than providing an overview of FSIS requirements.	In France, the SPS plan corresponds to the prerequisites (training, staff hygiene and garments, water quality, pest control program, compliance of premises and equipment etc.). Professionals are aware that if they address a point from the SPS plan in the SSOP plan, they are obliged to keep records of all controls relating to this point. Indeed, there are few references to 9 CFR in the memo entitled "Application of MEGAREG", updated at the end of November 2005, but the inspectors were given other

	• A significant portion of the inspection personnel encountered during the audit rely almost exclusively on its content in order to perform their duties in enforcing FSIS requirements. Overall, there was little familiarity among inspection personnel with regulations contained outside of 9 CFR 416, 417, and those addressing microbial sampling.	documents (slideshows on the SSOP and HACCP plans presented at training sessions in July and December 2004, list of non compliances identified by FSIS auditors in 2003 and 2004 etc.). Moreover, in each of the 4 *départements* audited, 2 to 3 veterinary inspectors had attended one of the two training sessions on FSIS inspection requirements. We will send a reminder on this point to our departments.
Page 10 para. 3	As the majority of non compliances encountered during the audit involved a newly listed establishment, the DGAL needs to continue to ensure that knowledge of the FSIS inspection requirements, including HACCP, SSOP, end the other regulations found in 9 CFR is consistent throughout of its inspection force.	The French translation of directive 5000. 1 has been on-line on the web site of the Office de l'Elevage (National Agency for Meat and Dairy Products) for several months. The 9 CFR 416 (SSOP plan) has also been on-line since March 23rd 2006, and the 9 CFR 417 (HACCP plan) since March 31st 2006. Three agents from the veterinary services of the Finistère *département* responsible for inspecting this establishment received training on the FSIS inspection requirements in 2004. **CA**: These fundamental notions of monitoring, verification and supervision will be stressed at the next training sessions, and in a memo, accompanied by examples, which will supplement the "application of MEGAREG" memo. Furthermore, at least one agent from the DDSV Finistère will again attend a training session on the FSIS inspection requirements, to be organized by the Office de l'Elevage in June 2006. The DDSV agents will be closely involved in the work done in the companies by the national technical expert.
Page 11 point 7.	One establishment was delisted for failure to meet U.S. requirements during the course of the audit.	The establishment was delisted because the professional in question interrupted the audit. It is therefore impossible to judge what the conclusions of the audit would have been if it had been completed (NOID, delisting).

Page 12 point 9.	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, France's inspection system had inadequate 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. For example: • France's inspection system failed to identify serious deficiencies observed in establishment operations that resulted in product adulteration. • Audit findings noted in this section include inadequate government oversight and non-compliance with Council Directive 64/433/EEC of June 1964. 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, and outside premises.	This comment appears to be too general, given that the main deficiencies mentioned only concerned one establishment.
Page 12 point 9.1	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: • In one establishment, several deficiencies were identified concerning SSOP recordkeeping requirements: o The pre-operational sanitation records generated on the day of the audit contained inadequate descriptions of deficiencies (e.g. "needs cleaning").	**CA** : The professional has adopted more appropriate expressions to describe corrective and preventive action taken. For the example given here, the expression will be "has been cleaned" plus the time and the monitor's signature.
	o Preventive measures were not routinely documented as part of the establishment's corrective actions taken in response to pre-operational sanitation deficiencies.	**CA** : The preventive measures taken when non-compliance is observed will be more explicit: reminder of the instructions, awareness raising among staff, or even revision of the operating mode.
	o The establishment's operational SSOP records focused on specific SPS elements (e.g. employee hygiene, cleanliness of work garments) and, as designed, could not be utilized to properly document instances of actual product contamination, or contamination of product-contact surfaces.	**CA** : The professional has taken measures to render his SSOP plan more compact and legible, in order to allow easier and faster understanding by the FSIS auditor. It did nevertheless contain all the required information. The national technical expert provided the professional with further explanations, during a support visit in January 2006 focusing in particular on the distinction between the SPS plan and the SSOP plan . As a result, the records system has been duly modified. .

	• In one establishment, a plant employee was observed placing his foot on a rack of duck carcasses, resulting in contamination of product contact surfaces.	**CA :** As soon as this non-compliance was observed, the veterinary services agents demanded the immediate application of corrective measures (carcasses liable to have been contaminated were withdrawn from consumption) and preventive measures (the employee was made aware of his mistake).
	• In one establishment, various forms of contamination (feces, unidenitified foreign material, and rail dust) were identified on several hog carcasses in the carcass cooler.	**CA** : The carcasses concerned were treated in accordance with the HACCP plan and the overhead rail suspected of causing the contamination was galvanized.
Page 13 point 9.2	9.2 Other Sanitation Requirements The FSIS regulations in 9 CFR 416.2 to 416.5 set forth specific sanitation performance standard 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, the plastic bins used for the conveyance of boxed edible product were not clearly distinguishable from containers used for inedible product.	**CA** : From now on, the color red will be reserved exclusively for bins used for seized products, and bins of a different color will be used for edible products.

	• In one establishment, the lighting in the carcass cooler was not of sufficient intensity to ensure that sanitary conditions were maintained and that product was not adulterated.	**CA** : In the days following the audit, 4 additional light sources were added, ensuring that this carcass cooler now has excellent lighting.
	• In one establishment, the protective coverings on several metal bins containing product in the cooler were blown off by the air which was circulating within. One of the unprotected bins was situated under a cooling unit which presented evidence of dried condensation on the inferior surface of the drip pan.	**CA** : The company has bought rigid coverings in order to provide better protection for the content of bins exposed to circulating air. Instructions were also given to avoid placing bins under the cooling units.
Page 14 point 11.2	11.2 HACCP Implementation All establishment 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. Only two of the four establishments had fully and adequately implemented	

	FSIS' HACCP requirements, with the following deficiencies noted at the other two establishments:	
	• In one establishment, fecal contamination was identified on a hog carcass in the cooler. This production step was after the Agency's established verification point for "zero tolerance" (i.e., visible feces, ingesta, and milk).	**CA** : The contaminated carcass was tagged and contaminated parts were trimmed (in the absence of the Veterinary Services and the auditor). All the other carcasses in the cooler (all slaughtered that day) were closely examined and no other contamination was found.
	• The hazard analysis in one establishment did not specifically address each of the production steps, and the portion addressing chemical hazards was not complete.	The chemical hazard analysis did exit but was not broken down into each step. **CA** : Chemical hazards are now addressed step by step.
	• In one establishment, the critical limit which appeared to be related to the control of visible feces, ingesta, and milk (i.e. "zero tolerance") was not clearly defined, and was solely described as "no dirty carcasses".	The critical limit for the "evisceration – fecal contamination" CCP is: "zero contamination" **CA** : Precise definitions with descriptions of what constitutes visible feces, ingesta, and milk will be given (which are normally irrelevant because only market hogs are slaughtered in the establishment concerned). The departmental veterinary services will assess their relevance. Moreover, the FSIS directive on fecal contamination will be translated and posted on the website of the Office de l'Elevage.
	• Specific on-going verification procedures and frequencies were not clearly described in one establishment's HACCP plan addressing	**CA** : These points were clarified during the national technical expert's recent visit to the establishment concerned.

	slaughter.	Regarding the "evisceration – fecal contamination" CCP, the control point is now located slightly further downstream from the slaughter chain, close to the quick chilling room for carcasses.
	• In one establishment, the prescribed monitoring frequency for a CCP, as indicated in the HACCP plan, was not always followed.	**CA** : The monitoring frequency for this CCP has been adapted.
	• In one establishment, the corrective actions described in the HACCP plan to be taken in response to a deviation from the critical limit were not supportable.	**CA** : The procedure has been modified to take account of the auditor's comment. Any deviation from the critical limit induces the control of all carcasses having entered the cooler since the last satisfactory control.
	• In one establishment, the hazard analysis addressing the production of fully-cooked, not-shelf-stable *foie gras* did not accurately identify all the possible hazards associated with the chilling of product after cooking (e.g. *Clostridium perfingens*).	**CA** : A new critical control point: "chilling" CCP, will be added to the establishment's HACCP plan for fully-cooked, not-shelf-stable products.

	• In one establishment, the review of records indicated that all four components of corrective actions associated with a deviation from the critical limit were not always documented. A more specific description of these deficiencies can be found in the attached individual establishment reports.	The corrective actions were indeed addressed in accordance with 9 CFR 417.3 (b), but the part concerning the products' destination was addressed in a separate document. **CA** : the 4 components of corrective actions are now recorded in a single document.
Page 15 point 11.3	11.3 Testing for Generic *E. coli* Three of the four 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, with the following result: • In one establishment, the upper control limit associated with the implementation of process control techniques regarding generic *E. coli* testing was not statistically supportable. The method used by the establishment to determine this limit consisted in taking the average value from a series of generic *E. coli* testing results (reported in CFU/ml) and then arbitrarily multiplying this value by a factor of five. No further supporting documentation was provided by the establishment to demonstrate the statistical validity of this calculation.	**CA** : A statistically supportable upper value will be used.
Page 15 point 11.4	11.4 Testing of Ready-to-Eat Products One of the four establishments audited were producing ready-to-eat products (*foie 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, with regards to which the following deficiency was identified: • The audit of this establishment revealed that testing for *Salmonella* and *Listeria monocytogenes* was being not being performed. As the particular product is not post-lethality exposed, current FSIS expectations for exporting countries prescribe a testing frequency of three times per year for these pathogens.	**CA** : Since the audit in December 2005, the 3 tests required by US regulations have been performed, with satisfactory results (absence of Lm).
	11.5 EC Directive 64/433 In one of the four establishments, the provisions of EC Directive 64/433 addressing slaughter/processing system controls were not effectively implemented. • Review of the procedures revealed that antemortem inspection was routinely performed by a non-veterinary DGAL official, under lighting of insufficient intensity.	In the event of any non-compliance or doubt as to the health of an animal, this animal is isolated by the veterinary assistant until the veterinary inspector decides what shall be done with it. The participation of these veterinary assistants who assist the Official Veterinarian in his work is provided for by the Directive (CE) 64/433. **CA** : The number of hogs per pen will be reduced in order to facilitate inspection.
	12. RESIDUE CONTROLS 12.1 FSIS Requirements	

	The fourth of the five risk areas that the FSIS auditor reviewed was Residue Controls. The following deficiency was identified: • One laboratory was utilizing the "*primitest*" method for antibiotic screening instead of the traditional 4-plate method. At the time of the audit, no equivalence determination was in place to permit substitution of one method for the other.	When asked, as is the case for tests related to the monitoring of USDA certified establishments, this laboratory does indeed use the 4-plate method.
Page 17 point 13.5	13.5 Inspection System Controls These controls include enforcement of inspection requirements for sanitation and HACCP ; 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. Not all FSIS requirements were enforced by the France's inspection system. For example: • In one establishment, several deficiencies were identified concerning SSOP recordkeeping requirements: o The pre-operational sanitation records generated on the day of the audit contained inadequate descriptions of deficiencies (e.g. "needs cleaning"). o Preventive measures were not routinely documented as part of the establishment's corrective actions taken in response to pre-operational sanitation deficiencies. o The establishment's operational SSOP records focused on specific SPS elements (e.g. employee hygiene, cleanliness of work garments) and, as designed, could not be utilized to properly document instances of actual product contamination, or contamination of product-contact surfaces.	***See comments relating to point 9.1 Page 12***

	• In one establishment, a plant employee was observed placing his foot on a rack of duck carcasses, resulting in contamination of product contact surfaces. • In one establishment, various forms of contamination (feces, unidentified foreign material, and rail dust) were identified on several hog carcasses in the carcass cooler. • In one establishment, the plastic bins used for the conveyance of boxed edible product were not clearly distinguishable from containers used for inedible product. • In one establishment, the lighting in the carcass cooler was not of sufficient intensity to ensure that sanitary conditions were maintained and that product was not adulterated. • In one establishment, the protective coverings on several metal bins containing product in the cooler were blown off by the air which was circulating within. One of these unprotected bins was situated under a cooling unit which presented evidence of dried condensation on the inferior surface of the drip pan. • In one establishment, fecal contamination was identified on a hog carcass in the cooler. This production step was after the Agency's established verification point for "zero tolerance" (i.e., visible feces, ingesta, and milk). • The hazard analysis in one establishment fid not specifically address each of the production steps, and the portion addressing chemical hazards was not complete. • In one establishment, the critical limit which appeared to be related	*See comments relating to point 9.1 Page 12* *See comments relating to page 13* *See comments relating to page 13* See comments relating to page 14

	to the control of visible feces, ingesta, and milk (i.e. "zero tolerance") was not clearly defined, and was solely described as "no dirty carcasses".	
	• Specific on-going verification procedures and frequencies were not clearly described in one establishment's HACCP plan addressing slaughter.	See comments relating to page 14
	• In one establishment, the prescribed monitoring frequency for a CCP, as indicated in the HACCP plan, was not always followed.	
	• In one establishment, the corrective actions described in the HACCP plan to be taken in responses to a deviation from the critical limit were not supportable.	
	• In one establishment, the hazard analysis addressing the production of fully-cooked, not-shelf-stable *foie gras* did not accurately identify all the possible hazards associated with the chilling of product after cooking (e.g. *Clostridium perfringens*).	See comments relating to page 14
	• In one establishment, the review of records indicated that all four components of corrective actions associated with a deviation from the critical limit were not always documented.	
	• In one establishment, the upper control limit associated with the implementation of process control techniques regarding generic *E. coli* testing was not statistically supportable. The method used by the establishment to determine this limit consisted in taking the average value from a series of generic *E. coli* testing results (reported in CFU/ml) and then arbitrarily multiplying this value by a factor of five. No further supporting documentation was provided by the establishment to demonstrate the statistical validity of this calculation.	

	• The audit of this establishment revealed that testing for *Salmonella* and *Listeria monocytogenes* was no being performed. As the particular product is not post-lethality exposed, current FSIS expectations for exporting countries prescribe a testing frequency of three times per year of these pathogens.	***See comments relating to page 15***
	• The observation of post-mortem inspection of ducks in one of the establishments revealed that the thoracic cavities were not being routinely inspected by DGAL personnel.	**CA** : The veterinary services inspection station has been moved so that the inspection takes place after removal of liver and abdominal offal, which will allow for more thorough inspection of the heart and thoracic cavities.
	• Review of the antemortem inspection procedures at one establishment indicated that they were not consistent with U.S. practices. These procedures were routinely performed under lighting of insufficient intensity, and were described to the auditor as involving the observation of animals from the external perimeter of the pens. On the day of the audit, the pens were filled to an extent which would not permit the sufficient movement of animals, thereby rendering the accomplishment of effective inspection difficult. Current U.S. expectations are that animals undergoing antemortem inspection are also to be viewed in motion.	**CA** : The conditions for inspecting the animals have been improved to take account of the auditor's remarks.

	• Several contaminated carcasses, which had been overlooked by the DGAL officials, were identified by the FSIS auditor in the carcass cooler.	} ***Comments already made on pages 12 and 17 of the report***

CA = Corrective action(s)