



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

MAY 9 2003

Dr. Isabelle Chmitelin
Chief Veterinary Officer
Ministry of Agriculture
251 Rue de Vaugirard
75732 Paris
Cedex 15, France

Dear Dr. Chmitelin:

The Food Safety and Inspection Service (FSIS) has completed an on-site audit of France's meat and poultry inspection system. The audit was conducted from October 9 – November 14, 2002. Enclosed is a copy of the final audit report. France did not provide any comments in response to the draft final audit report. FSIS appreciates the corrective actions taken by the Government of France to address the audit findings.

If you have questions regarding the audit or need additional information, please contact me by telephone at 202-720-3781, by facsimile at 202-690-4040 and by email at sally.stratmoen@fsis.usda.gov.

Sincerely,

Sally Stratmoen
Acting Director
International Equivalence Staff
Office of International Affairs

Enclosure

cc:

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FINAL

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

OCTOBER 9 THROUGH NOVEMBER 14, 2002

Food Safety and Inspection Service
United States Department of Agriculture

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority [<i>Direction Générale de l'Alimentacion</i> , or General Food Directorate]
DGAL	<i>Direction Générale de l'Alimentacion</i> , or General Food Directorate
DSV	<i>Départementale Service Veterinaire</i> , Veterinary Service of the <i>Département</i> , equivalent to a Regional Office
DDSV	Director of the DSV
<i>E. coli</i>	<i>Escherichia coli</i>
FSIS	Food Safety and Inspection Service
PR/HACCP	Pathogen Reduction / Hazard Analysis and Critical Control Point Systems
OIA	Office of International Affairs
SSOP	Sanitation Standard Operating Procedures
VEA	European Community/United States Veterinary Equivalence Agreement

1. INTRODUCTION

The audit took place in France from October 9 through November 14, 2002.

An opening meeting was held on October 9, 2002 in Paris with the Central Competent Authority (CCA), the *Direction Générale de l'Alimentation* (DGAL), or General Food Directorate. 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 and/or representatives from the regional and local inspection offices.

2. OBJECTIVE OF THE AUDIT

The objective of this audit was twofold. This was a routine annual audit to evaluate the performance of the CCA with respect to controls over the slaughter and processing establishments certified by the CCA as eligible to export meat products to the United States. It was also a follow-up audit to assess the status of corrective actions taken as a result of deficiencies identified during the previous FSIS audit of France's meat and poultry inspection system, conducted in April 2002.

In pursuit of the objective, the following sites were visited: the headquarters of the CCA, three *Départementale Services Veterinaires* (DSV) inspection offices (equivalent to Regional Offices), three laboratories performing analytical testing on United States-destined product, one swine slaughter and cutting establishment, one poultry slaughter and processing establishment, and seven other meat and/or poultry processing establishments.

Competent Authority Visits			Comments
Competent Authority	Central	2	
	<i>Département</i>	3	
	Local	9	Establishment level
Laboratories		3	
Meat Slaughter and Processing Establishments		1	
Meat and Poultry Processing Establishments		2	
Poultry Slaughter and Processing Establishments		1	
Poultry Processing Establishments		5	

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 France's inspection headquarters or regional offices. The third part involved on-site visits to nine establishments: two slaughter and processing establishments and seven processing establishments. The fourth part involved visits to one government laboratory, one public microbiology laboratory, and one private microbiology laboratory. The *Laboratoire Départemental d' Analyses du Morbihan* was conducting analyses of field samples for the presence of *Salmonella* species. The laboratory in Establishment 56-091-01 (Olympig) was conducting analyses of field samples for the presence of generic *Escherichia coli* (*E. coli*). The *Laboratoire Départemental Vétérinaire du Finistère* was conducting analyses of field samples for France's national residue control program.

Program effectiveness determinations of France's inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures, (2) animal disease controls, (3) slaughter/processing controls, including the implementation and operation of HACCP programs and the testing program for generic *E. coli*, (4) residue controls, and (5) enforcement controls, including the testing program for *Salmonella* species. 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 also determined if establishment and inspection system controls were in place to ensure the production of meat products that are safe, unadulterated and properly labeled.

During 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. These include daily inspection in all certified establishments when U.S.-eligible production is conducted, humane handling and slaughter of animals, the handling and disposal of inedible and condemned materials, species verification, and FSIS' requirements for HACCP, SSOP's, and testing for generic *E. coli* and *Salmonella* species.

Third, the auditor would audit against any equivalence determinations that have been made by FSIS for France under provisions of the Sanitary/Phytosanitary Agreement. Currently, the following equivalence determinations have been made for France:

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

4. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of United States laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.).
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/HACCP regulations.
- The Poultry Products Inspection Act (21 U.S.C. 451 et seq.) and
- The Poultry Products Inspection Regulations (9 CFR Part 381)

In addition, compliance with the following European Community Directives was also assessed:

- Council Directive 64/433/EEC, of June 1964, entitled "Health Problems Affecting Intra-Community Trade in Fresh Meat"
- Council Directive 96/23/EC, of 29 April 1996, entitled "Measures to Monitor Certain Substances and Residues Thereof in Live Animals and Animal Products"
- Council Directive 96/22/EC, of 29 April 1996, entitled "Prohibition on the Use in Stockfarming of Certain Substances Having a Hormonal or Thyrostatic Action and of B-agonists"

5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at www.fsis.usda.gov/ofotsc.

The following concerns arose as a result of the FSIS audit of France's inspection system conducted in May 2001:

- ◆ Daily inspection coverage was not provided in processing establishments.
- ◆ Boneless meat re-inspection and associated record keeping was not carried out in those establishments where it was required.
- ◆ HACCP implementation deficiencies were found in six of the 18 establishments whose records were reviewed.
- ◆ SSOP implementation deficiencies were found in six of the 18 establishments whose records were reviewed.

- ◆ Documented supervisory visits were not performed in some establishments during months when U.S.-eligible product was produced, as required.

The following concerns arose as a result of the FSIS audit of France's inspection system conducted in April 2002:

- ◆ HACCP implementation deficiencies were found in 16 of the 18 establishments whose records were audited. This was a repeat finding.
- ◆ SSOP implementation was deficient in eight of the 18 establishments whose records were audited. This was a repeat finding.
- ◆ Lighting was inadequate at post-mortem inspection stations in three of the four slaughter establishments audited.
- ◆ Pest control was inadequate in four establishments.
- ◆ Maintenance and cleaning of over-product equipment was neglected in eight establishments.
- ◆ Pre-operational cleaning of product-contact equipment was inadequate in five establishments.
- ◆ Product-contact equipment was stored under insanitary conditions in four establishments.
- ◆ In two of the three swine slaughter establishments whose *E. coli* testing programs were evaluated, statistical process control methods had not been developed, as required, to evaluate the results (both had been selected for document audits only).
- ◆ Alternate laboratory methodologies were being used on U.S.-eligible product for testing for generic *E. coli* and *Salmonella* species that had not been submitted to the Office of International Affairs (OIA) in advance for equivalence determination.
- ◆ Some field inspection personnel in positions of responsibility for U.S.-listed establishments had not had formal HACCP training.

Regarding the daily inspection coverage deficiency, although considerable misunderstanding regarding this requirement had persisted after the 2001 audit, it was resolved by teleconference shortly before the April 2002 audit began, and the FSIS auditor found, during the April 2002 audit, that (nearly) all the field personnel now understood the requirement, and it was being implemented.

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

Mainland France is divided into 22 Regions, and these Regions are in turn divided into 96 *Départements* (there are also four overseas *Départements*). Each has a Director of Veterinary Services (*Directeur du Départementale Services Veterinaires*, or DDSV). Each of these Directors is a veterinarian, employed by the government, and is a sworn-in officer (as are all inspection staff); his/her testimonies have high value in court proceedings. Each Director has two deputies, one in charge of animal health and welfare, and the other in charge of food safety procedures from farm to table. The latter coordinates the inspection programs within the *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.

There are six Interregional Inspectors General (IIG's), each of whom oversees several of the 22 Regions. These individuals form an intermediate step in the chain of command between DGAL headquarters and the *Départements*. A monthly coordination meeting between the IIG's and the DGAL Director General is held in Paris. The IIG's also organize meetings with the DDSV's in their assigned regions. A new Directive has recently been signed that will promote the DDSV in the capital city of each Region to the position of Regional Coordinator, with responsibility to coordinate the activities of the DDSV's in the Region.

Within France's Department of Agriculture there is a special Standing Committee for Inspection Coordination that can dispatch a team of specialists consisting of members of the two General Councils, including Veterinary Public Health Inspectors and, if needed, economists and/or Public Works officials, into any Region or *Département* for special inspections and/or investigations.

6.2.2 Ultimate Control And Supervision

The process for initial establishment certification is as follows: when the management officials of an establishment wish to be certified by DGAL as eligible to export to the United States, the first step is to approach the DDSV for instructions on how to achieve compliance with the requirements. The DDSV then sends special inspectors to explain the requirements in detail and to assess the establishment's capability for achieving compliance. The management officials then work to implement the requirements. When they feel confident the process is complete, they notify the DDSV. (If this is to be the first establishment within a *Département* to request certification for U.S. eligibility, the DDSV will consult experienced experts from DGAL headquarters and the Regional Coordinator, who is an authority on FSIS requirements.) The DDSV or his/her deputy in

charge of food hygiene then conducts an in-depth, on-site audit of all aspects of the facilities, operations, and controls, and submits a complete report to DGAL headquarters. The report is thoroughly reviewed by the Head Veterinary Inspector in Charge of Meat Establishments and, if all aspects of the contents of the report are in compliance with FSIS requirements, the establishment is granted certification for eligibility for access to the U.S. market, and FSIS is notified of the new certification.

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

Reviews of local level programs are performed by the Chief Veterinary Inspector from the DSV office and the Chief of the Subdivision (*Circumscription*) for the Département. The FSIS auditor verified that one of the latest of the reports generated from these reviews included documented review of the HACCP and SSOP programs in the U.S.-listed establishment.

In the event that a supervisor notes a deficiency in an inspector's performance, it is documented with a *Fiche d'Anomalie* (Anomaly Form). One copy goes to the inspection official whose performance was deficient; one form stays with the DSV Quality Assurance Manager in the regional office.

With two exceptions, all DGAL officials in positions of authority in U.S.-eligible establishments are full-time employees of DGAL. It is possible, in the current French system, for veterinarians in large-animal private practice to be hired for part-time work in export slaughter facilities, including ante-and post-mortem inspection. This is the case in two establishments certified for U.S. export:

- In one swine slaughter establishment, the Veterinary Inspector-In-Charge works approximately half the time in the establishment, and the rest of the time in private large-animal practice, although not involving swine.
- In one other swine slaughter establishment, the Veterinary Inspector-In-Charge works approximately half the time in the establishment, and the rest of the time in private large-animal practice, which does involve swine, although he reported that it would be rare that an animal that he had seen professionally in the course of his practice would be presented for slaughter at this facility.

In both establishments, while these veterinarians are performing inspection-related duties in the U.S.-eligible establishments, their services are reimbursed totally by DGAL, and their training and responsibilities are identical with those of all full-time DGAL employees.

6.2.3 Assignment of Competent, Qualified Inspectors

Allocation of full-time personnel to work in establishments in which inspection is not permanent (processing facilities, cold stores) is the responsibility of the Deputy Director in charge of Food Safety; the assignment of inspection personnel to those facilities requiring full-time coverage is performed by DDSV in the *Département*.

The performance of field veterinarians and inspectors is evaluated by their supervisors, who, in establishments eligible to export to the U.S., are the internal reviewers. Their evaluations are reported orally to the respective DDSV, who files his notes on their remarks. Field employees are rated annually by the DDSV in the *Départements*, based upon recommendations by the employees' direct supervisors, except in those (smaller) *Départements* in which they are supervised directly by the Director.

6.2.4. Authority and Responsibility to Enforce the Laws

DGAL has the authority and the responsibility to enforce U.S. requirements. A copy of the PR/HACCP regulations is present at each establishment certified for U.S. export. The internal reviewer uses this to evaluate the establishments' programs.

6.2.5. Adequate Administrative and Technical Support

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

6.3 Headquarters Audit

The auditor conducted a review of inspection system documents at the headquarters of the inspection service and in two DSV offices. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- Training records for inspectors and laboratory personnel.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses for residues.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of products from livestock with conditions such as tuberculosis, cysticercosis, etc., and of inedible and condemned materials.
- Export product inspection and control including export certificates.
- Enforcement records, including examples of criminal prosecution, consumer complaints, recalls, seizure and control of noncompliant product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

No concerns arose as a result of the examination of these documents.

7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of nine establishments—two slaughter-and-processing establishments and seven processing establishments. None were delisted by France. Three received notification in writing from DGAL that corrective actions must be implemented within 30 days because of deficiencies in the implementation of requirements for PR/HACCP programs and/or SSOP. These establishments may retain their certification for export to the United States provided that they correct all deficiencies noted during the audit within 30 days of the date the establishment was audited.

At the time this audit was planned, there were 23 establishments certified as eligible to export to the United States. Eleven of these were selected at random for on-site reviews and one more was added because of a re-review evaluation during the previous FSIS audit. After France was notified of the impending audit by FSIS, and before the audit was scheduled to begin, the management officials of five of these (Establishments 22-093-01, 24-520-05, 29-027-01, 29-097-01, and 32-147-23) voluntarily requested their removal from the list of certified establishments, and FSIS was notified of their delistment (one of these was the establishment included because of the previous re-review evaluation). Other establishments were added to the list to be audited. Also, France requested that another establishment that had been delisted as a result of the FSIS audit in April 2002, be included in the audit schedule; FSIS agreed. While the audit of France was in progress, the management of one other establishment that was scheduled for audit (Est. 47-157-03) also requested delistment for U.S. eligibility.

8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

During laboratory audits, emphasis is placed on the application of procedures and standards that are equivalent to United States 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 United States samples, the auditor evaluates compliance with the criteria established for the use of private laboratories under the FSIS Pathogen Reduction/HACCP requirements.

The following laboratories were audited:

- The *Laboratoire Départemental d'Analyses du Morbihan*, a public laboratory, was conducting analyses of field samples for the presence of *Salmonella* species.
- The private laboratory in Establishment 56-091-01 (Olympig) was conducting analyses of field samples for the presence of generic *Escherichia coli* (*E. coli*).

- The *Laboratoire Départemental Vétérinaire du Finistère*, in Quimper, a public laboratory owned by the Conseil Général of the Département, was conducting analyses of field samples for France's national residue control program.

The findings in these laboratories will be discussed in Section 11.3 (Testing for generic *E. coli*), 12 (Residue Controls), and 13.2 (Testing for *Salmonella* species) of this report.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditor focuses on five areas of risk to assess France's meat and poultry inspection system. The first of these risk areas that the FSIS auditor reviews is Sanitation Controls.

Based on the on-site audits of establishments, and except as noted below, France's inspection system had controls in place for SSOP programs, all aspects of facility and equipment sanitation, the prevention of actual or potential instances of product cross-contamination, good personal hygiene practices, and good product handling and storage practices.

In addition, and except as noted below, France's inspection system had controls in place for water potability records, chlorination procedures, back-siphonage prevention, separation of operations, temperature control, work space, ventilation, ante-mortem facilities, welfare facilities, and outside premises.

9.1 SSOP

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

- ◆ In one establishment, there was complete documentation of both pre-operational and operational sanitation activities, and preventive measures only on days during which U.S.-eligible production was conducted (about twice per month). During other production days, pre-operational problems and corrections were documented, but documentation of routine operational sanitation activities was minimal, unless major problems were identified. The establishment management personnel gave assurances that the daily documentation would be improved, and DGAL officials gave assurances that they would verify this.
- ◆ In one establishment, the dropped-meat reconditioning procedure was not part of the written SSOP. The manager gave assurances this would be corrected promptly.

9.2 EC Directive 64/433

In five establishments, the provisions of EC Directive 64/433 were effectively implemented. In the four establishments with deficiencies, the 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 reviews is 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. The auditor determined that France's inspection system had adequate controls in place. No deficiencies were noted.

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

11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor reviews is Slaughter/Processing Controls. The controls include the following areas: ante-mortem inspection procedures, ante-mortem disposition, humane handling and humane slaughter, post-mortem inspection procedures, post-mortem disposition, ingredients identification, control of restricted ingredients, formulations, processing schedules, equipment and records, and processing controls of cured, dried, and cooked products.

The controls also include the implementation of HACCP systems in all establishments and implementation of a testing program for generic *E. coli* in slaughter establishments.

11.1 Humane Handling and Humane Slaughter

The following deficiency was noted:

- ◆ In the swine slaughter establishment, the drover was observed to make excessive use of the electric prod. The audit leader (the DGAL internal reviewer) identified the problem immediately and ordered that he be replaced by another drover, and stayed in the area to verify that this was done before stunning operations were allowed to continue.

11.2 HACCP Implementation

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

The HACCP programs were reviewed during the on-site audits of the nine establishments. Six establishments had adequately implemented the PR/HACCP requirements. In the other establishments, the following deficiencies were identified:

- ◆ In one establishment, some hazards had not been considered at all steps when developing the HACCP plan. This oversight had already been identified by the establishment management, and correction was programmed within the next two months.
- ◆ In one establishment, there were written procedures for the foreman to check compliance with the requirement for absence of fecal contamination, but there was not a written procedure for monitoring the effectiveness of the CCP. The establishment management gave assurances this would be included in the written HACCP plan before any U.S.-eligible production is resumed.
- ◆ In the establishment audited for adequacy of corrective actions after having been found unacceptable during the April 2002 audit, corrective actions were not adequately described in the HACCP plan, although preventive measures were described thoroughly. Also, there were written procedures for the foreman to check compliance with the requirement for absence of fecal contamination, but there was not a written procedure for monitoring the effectiveness of the CCP. The establishment management gave assurances that this would be included in the written HACCP plan and implemented before any U.S.-eligible production is resumed.

11.3 Testing for Generic *E. coli*

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

Two of the nine 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.

Testing for generic *E. coli* was properly conducted in both of the slaughter establishments; however, the methods used for analyzing the results of the testing were not those required by FSIS:

- ◆ In the swine slaughter establishment, statistical process control methods had not been developed, as required when the sponge-sampling method is used, to evaluate the results of testing for generic *E. coli*. Instead, the criteria developed only for the excision method had been adopted. The auditor explained how a statistical process control may be developed, and provided an example. The establishment management officials gave assurances this would be corrected immediately, and the DGAL officials gave assurances that they would verify compliance.
- ◆ In the poultry slaughter-and-processing establishment audited for adequacy of corrective actions after having been found unacceptable during the April 2002 audit, the criteria being used for evaluating the results of the *E. coli* testing in ducks were

those reserved for chickens; the DGAL officials explained that this was a result of a misunderstanding of information (as a result, this was not seen as a deficiency for the purposes of this audit for compliance for re-certification for U.S.-eligibility). The FSIS auditor of this current audit corrected the misinformation, and the establishment management gave assurances that a statistical process control procedure would be developed and implemented before U.S.-eligible production will begin.

11.4 Other FSIS Requirements

In the three establishments producing ready-to-eat products, testing programs for the control of *Listeria monocytogenes* had been developed and implemented.

11.5 EC Directive 64/433

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

12. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditor reviews is Residue Controls.

DGAL headquarters notifies the Director in each Département how many samples for each residue category are to be collected over the course of the year. Each Director then is responsible for requesting samples from each slaughter establishment to fulfill the sampling plan, including directions for the weeks during which samples should be taken. The Veterinary Inspector in charge of each slaughter establishment formulates a plan for the actual days on which the samples are to be collected.

The Laboratoire Départemental Vétérinaire du Finistère, in Quimper, was audited. This is a public laboratory owned by the Conseil Général of the Département. Field samples are analyzed for chlorinated hydrocarbons (including PCBs), antibiotics, chloramphenicol, organophosphates, heavy metals, and hormones. Screening testing is done at this laboratory. Only qualitative analysis (presence/absence) is done for chloramphenicol and hormones; any samples showing positive results are sent to other laboratories for confirmatory testing. Quantitative analysis is done on the other compounds. Results that are less than half the maximum (acceptable) residue limit (MRL) are considered negative. Samples that yield results that are greater than half the MRL are submitted to other laboratories for confirmation. Confirmation of pesticides and heavy metals is performed at the AFSSA laboratory in Paris, antibiotics and chloramphenicol at the AFSSA laboratory in Fougères, and hormones at the Laberca laboratory at the veterinary university in Nantes.

12.1 EC Directive 96/22

In the Laboratoire Départemental Vétérinaire du Finistère, in Quimper, the provisions of EC Directive 96/22 were effectively implemented.

12.2 EC Directive 96/23

In the Laboratoire Départemental Vétérinaire du Finistère, in Quimper, the provisions of EC Directive 96/23 were effectively implemented.

12.3 Other FSIS Requirements

The following deviations from the usual FSIS expectations were noted:

- ◆ DGAL requires turnaround times of not more than two months. In practice, according to information provided during the laboratory audit, turnaround times for antibiotics are less than one month and for pesticides, heavy metals, and hormones, between one and two months. This meets the expectations of the European Commission. During the audit of the regional office of the Département the same afternoon as the audit of the residue laboratory, however, records for analyses completed since January 2002 were examined. No results had yet been noted for samples collected 12 weeks previously for heavy metals and 13 weeks previously for hormones. (The samples, it was noted, had been taken according to the schedule.)

However, since turnaround times for residue testing are not covered under the VEA, FSIS requirements apply: FSIS expects turnaround times of 30 days from sample receipt in the laboratory to completion of analysis.

13. ENFORCEMENT CONTROLS

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

Inspectors-In-Charge have the authority to place on hold any products produced under conditions that are out of compliance with U.S. requirements. They report their findings to the Director of Veterinary Services in the *Départements*, who, in turn, has the authority to suspend production. On the basis of information provided by the Director of Veterinary Services, export certification can be withdrawn (an establishment delisted) by the Head of DGAL's Food Safety Subdirectorate. The following enforcement actions have been taken by DGAL since the last FSIS audit in April 2002:

- Subsequent to the FSIS audit of documents from Est. 32-147-23, in April 2002, compliance with requirements was closely followed by DGAL. It was determined that corrections in response to deficiencies identified were not adequate, and the establishment was delisted by DGAL on October 1, 2002.
- Est. 53-097-01, a swine slaughter establishment, was suspended in March 2002 due to one failure to meet *Salmonella* performance standards. Three subsequent tests resulted in three failures; the establishment was delisted by DGAL on September 17, 2002.

- Est. 46-102-04 was suspended before the scheduled FSIS audit in April 2002 for lack of controls in separation of U.S.-eligible and non-U.S.-eligible product received from other establishments, and was audited as scheduled at the request of DGAL. The audit went well, but DGAL followed up on deficiencies for which they had imposed deadlines; these deadlines were not met, and the plant was delisted by DGAL as a result of a report sent by the DSV on September 16, 2002. FSIS was notified on September 19.

All batches and lots of products eligible to enter the U.S.-export chain are checked by the inspection personnel, all documents pertaining to these products are reviewed, and no export certificates are signed during periods of an establishment's ineligibility for U.S. export. Also, all other establishments are informed immediately when eligibility of a supplying establishment is revoked or suspended. The auditor confirmed in the field that this system was in place.

Noncompliance in establishments certified for U.S. export is reported directly to the Director of the *Département*. All products in transit will be recalled through a well-developed alert system that may involve the press. If criminal activities are involved, the findings are reported to the Director of the *Département*. As soon as DGAL headquarters in Paris receives notification from the Director of a *Département* that an establishment has been found to fail to meet U.S. requirements, delisting of the noncompliant establishments is ordered by the CVO, and a letter to FSIS is sent by the CVO to the Counselor for Agriculture in the French Embassy in Washington, DC, who then informs FSIS. A copy is also sent to the Agricultural Minister-Counselor in the American Embassy in Paris. This may take from a few days up to a maximum of two weeks; in the meantime all product produced by the establishment is excluded from any possibility of entering the U.S.-eligible export chain.

All DGAL veterinarians and inspectors have the authority to seize any product they deem may be potentially harmful to human health. Establishments may appeal the seizure, but, in the memory of those participating in the interview at DGAL headquarters, no such appeal has ever resulted in release of the product. The affected product is destroyed under DGAL supervision.

Consumer complaints regarding food usually go directly to the Quality Control services in the establishments of origin, but occasionally some may go to the Veterinary Services Director of the *Département* and/or to DGAL headquarters. If product recall actions are necessary, they are initiated by the establishment and, if indicated, by DGAL in concert with the Department of Health and, if necessary, also by the Agency for Fraud Operations. If the plant is unable to prove it can recall all affected product or if the product is contaminated heavily or with an organism of serious public-health concern or widely dispersed, the DGAL administration takes control, informs all *Département* and field inspection personnel, and will involve the national and local news media.

13.1 Daily Inspection in Establishments

FSIS requires inspection coverage in all slaughter and processing establishments on days when U.S.-eligible production is conducted.

- ◆ In one establishment, the DGAL inspection staff was not informed in advance of production for U.S.-export on August 7 and 8, 2002. The internal reviewer (the Director of Veterinary Services [DSV] in the *Département*), during his next visit to the establishment, provided the establishment management with a reiteration, in writing, of the requirement for daily inspection coverage whenever U.S.-eligible product is produced. The DGAL headquarters officials learned, on the day that the exit meeting for this audit was held in Brussels (November 14, 2002), that two shipments of product that had been produced on the days when there was no inspection coverage, were shipped to the U.S., one (85 kg) on August 21, 2002, and another (60 kg) on October 3. DGAL proposed initiating a recall of all affected product and informing FSIS in writing of the results of the recall procedure, as soon as they are available.

13.2 Testing for *Salmonella* Species

France has adopted the FSIS regulatory requirements for testing for *Salmonella* species with the exception of the following equivalent measure(s):

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

One of the eight establishments audited was required to meet the basic FSIS regulatory requirements for *Salmonella* testing and was evaluated according to the criteria employed in the United States' domestic inspection program.

- ◆ Testing for *Salmonella* species was properly conducted in the establishment; however, the laboratory audited for *Salmonella* testing compliance was using a different (recently updated) method, NF-EN-12824, that had not been submitted to OIA in advance for an equivalence determination. During the exit meeting in Paris, the DGAL officials gave assurances that they would ensure that the ISO 6579 method will be used until the new method has been recognized as equivalent.

13.3 Species Verification

At the time of this audit, France was required to test product for species verification. Species verification is being performed, although not at the establishment level, and not by DGAL. Extensive testing is done at the retail level by the agency that investigates fraud in commerce. DGAL agreed to provide all necessary information regarding the species verification program to OIA for equivalence determination.

13.4 Monthly Reviews

FSIS requires documented supervisory visits by a representative of the foreign inspection system, no less frequently than one such visit per month to each establishment certified, during periods when the establishment is engaged in producing products for exportation to the United States.

A yearly review is conducted of all the *Départements*, usually by the Directors of the *Départements*. In the U.S.-certified establishments, monthly reviews are conducted by the supervisors of the in-plant inspection personnel. Performance of field inspection personnel is also evaluated, but the results are not part of the routine monthly reports, and are not routinely documented.

If non-compliances are identified during the course of a routine monthly review, the inspection official responsible for the establishment have the primary responsibility for ensuring that corrective actions are effective within a defined period of time, according to the severity of the noncompliance; the monthly reviewers also follow up on the corrections. In serious cases, the central authority also would conduct follow-up procedures.

A copy of the PR/HACCP regulations is present at each establishment certified for U.S. export. This document is used to evaluate the establishments' programs.

Copies of the monthly reports are distributed to the Veterinary Inspector-In-Charge and to the establishment manager, and a copy is filed in the *Département* office.

Until the FSIS audit of France in April 2002, the DGAL officials had understood (incorrectly) that FSIS requirements were met if the DGAL official assigned to a cutting or processing establishment visited that establishment at least once per month. All field personnel were informed of the requirement for monthly supervisory reviews in May 2002.

During this audit it was found that, as of June 2002, monthly supervisory reviews of certified establishments were being performed and documented as required, during months in which U.S.-eligible production was conducted, with the following exceptions:

- In each of two establishments, one required monthly review had not been performed. In both establishments, the Veterinary Inspectors-In-Charge had been present on U.S.-eligible production days.

Copies of the records of audited plants are kept in the establishments and in the departmental headquarters; all are archived indefinitely.

13.5 Inspection System Controls

The CCA had controls in place for ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; disposition of dead, dying, diseased or disabled animals; shipment security, including shipment between establishments; and prevention of commingling of product intended for export to the U.S. with product intended for the domestic market.

In addition, controls were in place for 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.

14. CLOSING MEETING

A closing meeting was held on November 14 in Paris with the CCA and, by teleconference, with a member of the European Community in Brussels. At this meeting, the primary findings, conclusions, and recommendations from the audit were presented by the auditor.

The CCA understood and accepted the findings.

15. ATTACHMENTS

The individual Foreign Establishment Audit Forms are attached on the following pages.

Gary D. Bolstad, DVM
International Audit Staff Officer

GB

Donald C. Smart

REVIEW DATE
 10/28-02

NAME OF FOREIGN LABORATORY
Att. A-1a
 Laboratoire Départemental Vétérinaire du Finistère

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOV'T AGENCY
 Public laboratory, owned by the Conseil
 Général of the Département

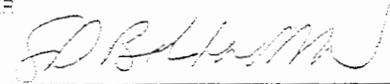
CITY & COUNTRY
 Quimper, France

ADDRESS OF LABORATORY
 ZA de Créac'h Gwen - 22, Avenue de la Plage des
 Gueux, 29334 Quimper

NAME OF REVIEWER
 Dr. Gary D. Bolstad

NAME OF FOREIGN OFFICIAL
 Dr. Lilian Puech, DGAL Veterinary Official; Dr. Henri Pelleton-Granier, Vet. Off.

Residue Code/Name			chc	pcb	abc	cap	op	hm	des						
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #													
	Sample Handling	01	A	A	A	A	A	A	A						
	Sampling Frequency	02	A	A	A	A	A	A	A						
	Timely Analyses	03	C	C	A	A	C	C	C						
	Compositing Procedure	04	O	O	O	O	O	O	O						
	Interpret Comp Data	05	O	O	O	O	O	O	O						
Data Reporting	06	A	A	A	A	A	A	A							
ANALYTICAL PROCEDURES	Acceptable Method	07	A	A	A	A	A	A	A						
	Correct Tissue(s)	08	A	A	A	A	A	A	Urine						
	Equipment Operation	09	A	A	O	A	A	A	A						
	Instrument Printouts	10	A	A	O	A	A	A	A						
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	A	A	O	O	A	A	A						
	Recovery Frequency	12	A	A	A	A	A	A	A						
	Percent Recovery	13	A	A	O	A	A	A	O						
	Check Sample Frequency	14	A	A	A	A	A	A	A						
	All analyst w/Check Samples	15	A	A	A	A	A	A	A						
	Corrective Actions	16	A	A	A	A	A	A	A						
	International Check Samples	17	A	A	A	A	A	A	A						
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	A	A	A	A	A	A	A						
OTHER REVIEW		19													
		20													

SIGNATURE OF REVIEWER


DATE
 10/28/02

FOREIGN COUNTRY LABORATORY REVIEW

(Comment Sheet)

REVIEW DATE

10/28-02

NAME OF FOREIGN LABORATORY

Laboratoire Départemental Vétérinaire du Finistère *A-16*

FOREIGN GOV'T AGENCY

Public laboratory, owned by the Conseil Général of the Département

CITY & COUNTRY

Quimper, France

ADDRESS OF LABORATORY

ZA de Créac'h Gwen - 22, Avenue de la Plage des Gueux, 29334 Quimper

NAME OF REVIEWER

Dr. Gary D. Bolstad

NAME OF FOREIGN OFFICIAL

Dr. Lilian Puech, DGAL Veterinary Official; Dr. Henri Peleton-Granier, Vet. Off.

RESIDUE	ITEM	COMMENTS
		Abbreviations: CHC = chlorinated hydrocarbons; PCB = polychlorinated biphenyls; ABC = antibiotics; CAP = chloramphenicol; OP = organophosphates; HM = heavy metals; DES = diethylstilbestrol.
chc,pcb, op,hm, des	03	DGAL requires turnaround times of not more than two months. The laboratory officials stated that, in practice, turnaround times for antibiotics are less than one month and for pesticides, heavy metals, and hormones, between one and two months. This meets the expectations of the European Commission; however, since turnaround times for residue testing are not covered under the VEA, FSIS requirements apply: FSIS expects turnaround times of 30 days from sample receipt in the laboratory to completion of analysis.
hm, des	03	During the audit of the regional office of the Département the same afternoon as the audit of the residue laboratory, records for analyses completed since January 2002 were examined. No results had yet been noted for samples collected 12 weeks previously for heavy metals and 13 weeks previously for hormones. (The samples, it was noted, had been taken according to the schedule.)
abc	09, 10	Analysis for antibiotics was conducted microbiologically. There were no printouts.
abc,cap	11	Analysis for antibiotics was conducted microbiologically. Results were reported as either positive or negative.
abc,des	13	Analysis was qualitative. Results were reported as either positive or negative.
(All)	(14,15)	There was no intra-laboratory check sample program per se in this laboratory; however, since the laboratory is accredited (and, therefore, the analysts are qualified) according to the standards set under ISO 17025, the intra-laboratory check samples are not required. The FSIS auditor made it clear, though, that if many months elapse between analyses for certain classes of compounds, an analyst's supervisor is expected to check his/her proficiency (through an intra-laboratory check sample) before the analyst performs the analysis on field samples.

REVIEW DATE
 10/30/2002

NAME OF FOREIGN LABORATORY
 Olympig, Est. 56-091-01

A 2a

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOV'T AGENCY

CITY & COUNTRY

ADDRESS OF LABORATORY

Private laboratory

Josselin, France

Josselin

NAME OF REVIEWER

Dr. Gary D. Bolstad

NAME OF FOREIGN OFFICIAL

Dr. Benjamin le Chatelier, Dr. Marie-Noël Favreau, and Dr. Jean-Paul Droux

Residue Code/Name		Item #	Ecol						
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM. #							
	Sample Handling	01	A						
	Sampling Frequency	02	A						
	Timely Analyses	03	A						
	Compositing Procedure	04	O						
	Interpret Comp Data	05	O						
	Data Reporting	06	A						
ANALYTICAL PROCEDURES	Acceptable Method	07	A						
	Correct Tissue(s)	08	O						
	Equipment Operation	09	O						
	Instrument Printouts	10	O						
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	O						
	Recovery Frequency	12	O						
	Percent Recovery	13	O						
	Check Sample Frequency	14	O						
	All analyst w/Check Samples	15	O						
	Corrective Actions	16	O						
	International Check Samples	17	O						
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	O						
OTHER REVIEW	Evaluation of Results	19	C						
		20							

SIGNATURE OF REVIEWER

G. D. Bolstad

DATE

10/30/02

FOREIGN COUNTRY LABORATORY REVIEW <i>(Comment Sheet)</i>	REVIEW DATE 10/30/2002	NAME OF FOREIGN LABORATORY Olympig, Est. 56-091-01	A-2b
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FOREIGN GOV'T AGENCY Private laboratory	CITY & COUNTRY Josselin, France	ADDRESS OF LABORATORY Josselin
NAME OF REVIEWER Dr. Gary D. Bolstad	NAME OF FOREIGN OFFICIAL Dr. Benjamin le Chatelier, Dr. Marie-Noël Favreau, and Dr. Jean-Paul Droux	

RESIDUE	ITEM	COMMENTS
<i>E. coli</i>	19	<p>Statistical process control methods had not been developed, as required when sponge sampling method is used, to evaluate the results of testing for generic <i>E. coli</i>. Instead, the criteria developed only for the excision method had been adopted. The Auditor explained how a statistical process control may be developed, and provided an example. The establishment management officials gave assurances this would be corrected immediately, and the DGAL officials gave assurances that they would verify compliance.</p>

REVIEW DATE
 Oct./31/02

NAME OF FOREIGN LABORATORY *A-32*
 Laboratoire Départemental d' Analyses du Morbihan

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOV'T AGENCY
 AL

CITY & COUNTRY
 Vannes, France

ADDRESS OF LABORATORY
 6, avenue Edgar Degas

NAME OF REVIEWER
 Gary D. Boistad

NAME OF FOREIGN OFFICIAL
 Dr. Lilian Puech, Dr. Herve Knockaert (Director, Départemental Veterinary Services)

Residue Code/Name  Sal

REVIEW ITEMS	ITEM #	EVALUATION CODE	Sal																	
Sample Handling	01	A																		
Sampling Frequency	02	A																		
Timely Analyses	03	A																		
Compositing Procedure	04	O																		
Interpret Comp Data	05	O																		
Data Reporting	06	A																		
Acceptable Method	07	C																		
Correct Tissue(s)	08	A																		
Equipment Operation	09	O																		
Instrument Printouts	10	O																		
Minimum Detection Levels	11	O																		
Recovery Frequency	12	O																		
Percent Recovery	13	O																		
Check Sample Frequency	14	O																		
All analyst w/Check Samples	15	O																		
Corrective Actions	16	O																		
International Check Samples	17	O																		
Corrected Prior Deficiencies	18	O																		
	19																			
	20																			

SIGNATURE OF REVIEWER

G.D. Boistad

DATE

10/31/02

FOREIGN COUNTRY LABORATORY REVIEW

(Comment Sheet)

REVIEW DATE

Oct./31/02

NAME OF FOREIGN LABORATORY

A-3b

Laboratoire Départemental d' Analyses du Morbihan

FOREIGN GOV'T AGENCY
DGAL

CITY & COUNTRY
Vannes, France

ADDRESS OF LABORATORY
6, avenue Edgar Degas

NAME OF REVIEWER
Dr. Gary D. Bolstad

NAME OF FOREIGN OFFICIAL
Dr. Lilian Puech, Dr. Herve Knockaert (Director, Départemental Veterinary Services)

RESIDUE

ITEM

COMMENTS

Salm.

07

According to information provided by the Office of International Affairs (OIA), the ISO-6579 method was reported to FSIS as being used for testing for *Salmonella* species. In fact, however, the laboratory was using a different method, NF-EN-12824, which had not been submitted to OIA for an equivalence determination. During the exit meeting in Paris, the DGAL officials gave assurances that they would ensure that the ISO 6579 method will be used until the new method has been recognized as equivalent.

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Ets. Aromont, Montcornet	2. AUDIT DATE 11/3/2002	3. ESTABLISHMENT NO. 02-502-01	4. NAME OF COUNTRY France
5. NAME OF AUDITOR(S) Dr. Gary D. Boistad		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Fork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	X
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O	60.	
32. Written Assurance	O	61.	

60. Observation of the Establishment

B-1b

Est. 02-502-01, Ets. Aromont, Montcornet, France, 11/3/2002

39/56 Maintenance of several hand-operated fork-lift handles and several on/off switches on processing equipment had been neglected: rubber switch covers were torn or missing, and a few had old product residues. Also, The internal DGAL reviewer ordered prompt cleaning and development and implementation of an improved maintenance/cleaning schedule, as well as increased monitoring during pre-operational sanitation inspection. This deficiency was in violation of EC Directive 64/433.

45/56 Several pieces of equipment and two floor drain traps had been inadequately cleaned before being presented for pre-operational sanitation inspection. The Veterinary Inspector-In-Charge identified the problems and ordered immediate correction. This deficiency was in violation of EC Directive 64/433.

NOTE: All previously identified deficiencies had been adequately addressed and corrected.

French officials: Dr. Maryse Flamme, Dr. Emmanuelle Soubeyran, Dr. Florence Bricout (Supervising Veterinary Inspector and leader of the audit), Dr. Hervé Fouquet, and Ms. Dominique Wersinger, Veterinary Inspector-In-Charge.

61. NAME OF AUDITOR

Gary D. Boistad, DVM

62. AUDITOR SIGNATURE AND DATE



Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Ets. Rougie Bizac International, Brive	2. AUDIT DATE 10/23/2002	3. ESTABLISHMENT NO. 19-031-02	4. NAME OF COUNTRY France
5. NAME OF AUDITOR(S) Dr. Gary D. Bolstad		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	O
8. Records documenting implementation.		34. Species Testing	X
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	X
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	X
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O	60.	
32. Written Assurance	O		

60. Observation of the Establishment

B-2b

France - Est. 19-031-02, 10/23/02

13 There was complete documentation of both pre-operational and operational sanitation activities, and preventive measures only on days during which U.S.-eligible production was conducted (about twice per month). During other production days, pre-operational problems and corrections were documented, but documentation of routine operational sanitation activities was minimal, unless major problems were identified. The establishment management personnel gave assurances that the daily documentation would be improved, and DGAL officials gave assurances that they would verify this.

38/39 Many cobwebs were observed in numerous areas of the establishment, including storage areas for can lids, carton and chemical storage areas, and the room used for product smoking and (temporarily) for storage of stainless roller combo bins that were clean and ready for use (the latter were provisionally protected under a canvas roof). Corrective actions were undertaken immediately in the more product-related areas and scheduled promptly for the others.

46/56 (A) In a product freezer, plastic bags of pork meat were stored directly on a plastic pallet, and pallets of product were stored directly on cartons of product on other pallets. The DGAL official leading the audit ordered the affected cartons to be reinspected and implementation of an improved policy to avoid the problem in the future. (B) Some large plastic combos of product were stacked. Some of the coverings on the lower containers were inadequate, so that some product was exposed. DGAL ordered retention of the affected product for reinspection and implementation of an improved policy for covering the containers. These deficiencies were in violation of EC Directive 64/433.

(34 So far as the DGAL officials are aware, no products from this establishment are routinely sampled for species verification.)

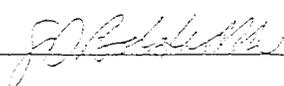
Following the audit of this establishment, DGAL issued a formal letter to the management, informing them that the deficiencies identified must be corrected within 30 days, or the establishment would be removed by DGAL from the list of establishments eligible to export products to the United States.

Accompanying DGAL officials: Dr. Maryse Flamme, Veterinary Inspector; Dr. Alain Quicroix, Regional Coordinator; Dr. Nicolas Calvagrac; Head of the Food Safety Service for the Département; Dr. Philippe Merot, Veterinarian-In-Charge

61. NAME OF AUDITOR

Gary D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE



10/23/02

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Rougie Bizac International Sarlat-la-Caneda	2. AUDIT DATE 10/22/02	3. ESTABLISHMENT NO. 24-520-02	4. NAME OF COUNTRY France
5. NAME OF AUDITOR(S) Dr. Gary D. Boistad		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

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

60. Observation of the Establishment

B-3b

France - Est. 24-520-02 - Oct. 22, 2002

57 Until the FSIS audit of France in April 2002, the DGAL officials had understood (incorrectly) that FSIS requirements were met if the DGAL official assigned to a cutting or processing establishment visited that establishment at least once per month. All field personnel were informed of the requirement for monthly supervisory reviews in May 2002. There were documented monthly reviews in this establishment beginning in June 2002.

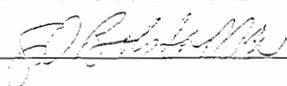
(34 So far as the DGAL officials are aware, no products from this establishment are routinely sampled for species verification.)

Accompanying French officials: Dr. Maryse Flamme; Dr. Yvan Loboit Director of Veterinary Services, Dr. Alain Laibeille, Supervising Veterinary Inspector; Dr. Jean-Claude Merigonde, Veterinarian In Charge

61. NAME OF AUDITOR

Gary D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE



10/22/02

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Roger Junca, Dax	2. AUDIT DATE 10-17-2002	3. ESTABLISHMENT NO. 40-088-03	4. NAME OF COUNTRY France
5. NAME OF AUDITOR(S) DGAL Officials: Dr. Emanuelle Souberain, Dr. Henri Viel, Dr. Marie Donguy Dr. Gary D. Bolstad		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

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

60. Observation of the Establishment

B-4b

France - Est. 40-088-03 - Oct. 17, 2002

39/56 There was no hand-washing station in the tumbling room. Prompt installation was scheduled immediately. This deficiency was in violation of EC Directive 64/433.

57 There was no supervisory review in August 2002, although there was U.S.-destined production on August 22-23. The Veterinarian-In-Charge was present on these two production days.

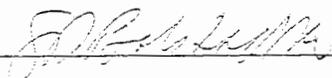
Note: All deficiencies identified during the previous FSIS audit in April 2002 had been adequately addressed and corrected.

Accompanying DGAL officials: Dr. Emanuelle Soubeyran, Head of Meat Processing Establishments; Dr. Henri Viel, Deputy Departmental Director of Veterinary Services; Dr. Marie Donguy, Veterinary Inspector (Veterinarian-In-Charge).

61. NAME OF AUDITOR

Gary D. Boistad, DVM

62. AUDITOR SIGNATURE AND DATE



10/17/02

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Ets. Castaing, Saint-Sever.	2. AUDIT DATE 10-16-2002	3. ESTABLISHMENT NO. 40-282-02	4. NAME OF COUNTRY France
5. NAME OF AUDITOR(S) Dr. Gary D. Bolstad		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

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

60. Observation of the Establishment

B-5b

France - Est. 40-282-02, October 16, 2002

38 Several cobwebs were observed in the corners of skylights in production areas and in ceiling structures in the dry-storage/carton storage area. This was identified by the audit leader and corrected immediately in production areas, and was programmed for prompt correction in the other areas.

Accompanying DGAL officials: Dr. Emanuelle Soubeyran, Head of Meat Processing Establishments; Dr. Pierre Parriaud, Departmental Director of Veterinary Services; Dr. Henri Viel, Deputy Departmental Director of Veterinary Services; Dr. Michel Castets (Veterinarian-In-Charge).

Note: all deficiencies identified during the previous FSIS audit in April 2002 had been satisfactorily addressed and corrected.

61. NAME OF AUDITOR

Gary D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE

 10/16/02

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Capel la Quercynoise, Gramat French officials: Dr. Benjamin Le Chatelier, Dr. Alain Quicroix, Dr. Francoise Garapin	2. AUDIT DATE 10/21/2002	3. ESTABLISHMENT NO. 46-128-02	4. NAME OF COUNTRY France
5. NAME OF AUDITOR(S) Dr. Gary D. Boistad		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

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

60. Observation of the Establishment

B-6b

Est. 46-128-02, France, 10/21/02

- 18 There were written procedures for the foreman to check compliance with the requirement for absence of fecal contamination, but there was not a written procedure for monitoring the effectiveness of the CCP. The establishment management gave assurances that this would be included in the written HACCP plan and implemented before any U.S.-eligible production is resumed.
- 28 The criteria being used for evaluating the results of the *E. coli* testing in ducks were those reserved for chickens; the DGAL officials explained that this was a result of a misunderstanding of information (as a result, this was not seen as a deficiency for the purposes of this audit for compliance for re-certification for U.S.-eligibility). The FSIS auditor of this current audit corrected the misinformation, and the establishment management gave assurances that a statistical process control procedure would be developed and implemented before U.S.-eligible production will begin.
- (55 On the day of the audit, post-mortem inspection was being performed by establishment employees. The DGAL officials present at the audit gave assurances that they understand that post-mortem inspection of every carcass by a full-time DGAL official is required for product to be eligible for export to the U.S.)

Note: This was not a routine audit. The establishment was found to be unacceptable during the previous FSIS audit on April 15, 2002. This was a special audit to assess the adequacy of corrective actions taken. All but one of the (15) deficiencies previously identified deficiencies (except for monitoring of critical limits—see item 18, above) had been adequately addressed and corrected.

61. NAME OF AUDITOR

Gary D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE



10/21/02

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Olympig Josselin	2. AUDIT DATE Oct. 30, 2002	3. ESTABLISHMENT NO. 56-091-01	4. NAME OF COUNTRY France
5. NAME OF AUDITOR(S) Dr. Gary D. Boistad		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

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

60. Observation of the Establishment

B-7b

Est. 56-091-01 (Olympig), Josselin, France, Oct. 30-2002

18 Monitoring of the CCP for absence of visible fecal contamination was inadequate. This was a repeat finding. The FSIS auditor explained the requirement in detail; the Quality Control manager gave assurances that this would be corrected and implemented immediately; DGAL officials gave assurances that they would verify compliance.

20 Corrective actions were not adequately described in the HACCP plan, although preventive measures were covered thoroughly. The FSIS auditor explained the requirement in detail; the Quality Control manager gave assurances that this would be corrected and implemented immediately; DGAL officials gave assurances that they would verify compliance.

28 The establishment had not developed a statistical process control to evaluate the results of testing for generic *E. coli*, but was using the criteria intended for use with the excision method of sampling. The FSIS auditor explained the requirement in detail; the Quality Control manager gave assurances that this would be corrected and implemented immediately; DGAL officials gave assurances that they would verify compliance.

39 There was no hand-washing facility for the operators performing evisceration manually when the automatic eviscerator was non-functional. DGAL ordered prompt installation of a hand-washing facility. This deficiency was in violation of EC Directive 64/433.

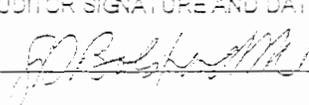
52 The drover was observed to make excessive use of the electric prod. The audit leader (the DGAL internal reviewer) identified the problem immediately and ordered that he be replaced by another drover, and stayed in the area to verify that this was done before stunning operations were allowed to continue.

Accompanying DGAL officials: Dr. Benjamin le Chatelier, Assistant Head, Office of Raw Materials; Dr. Laurence Respique, Veterinary Inspector and Export Coordinator for the eastern part of France; Dr. Marie-Noël Favreau, Veterinary Inspector for the eastern section of the Département of Morbihan and audit leader; Mr. Oliver Burel, Assistant Chief for Hygiene of the Département; and Dr. Jean-Paul Droux, Veterinary Inspector-In-Charge.

61. NAME OF AUDITOR

Gary D. Boistad, DVM

62. AUDITOR SIGNATURE AND DATE

 10/30/02

B-8a

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Feyel Artzner, Schiltigheim (Strasbourg)	2. AUDIT DATE 10/14/2002	3. ESTABLISHMENT NO. 67-447-05	4. NAME OF COUNTRY France
5. NAME OF AUDITOR(S) French officials: Dr. Maryse Flamme, Dr. L. Repiquet-Bailleul, Dr. Vincent Spony Dr. Gary D. Bolstad		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

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

60. Observation of the Establishment

B-8b

France - Est. 67-447-05, Oct. 14, 2002

- 15 Some hazards had not been considered at all steps when developing the HACCP plan. This oversight had already been identified by the establishment management, and correction was programmed within the next two months.
- 39 (A) Maintenance of over-product equipment had been neglected in several areas: rust and flaking paint were observed on motor housings, cooling units, and ceilings. Production was suspended immediately in one production area and corrective actions were undertaken; prompt correction in the other areas was scheduled. (B) Clean stainless steel combo bins were stacked after cleaning, so that water from the wheels of the stacked bins could drip into the clean ones below. The DGAL official identified the problem and ordered re-cleaning of the lower ones and an improved policy.
- 50 This establishment produces U.S.-eligible product only when special orders arrive from their American clients, which occurs about every three months. Due to a miscommunication, the DGAL inspection staff was not informed in advance of production for U.S.-export on August 7 and 8, 2002. The internal reviewer (the Director of Veterinary Services [DSV] in the *Département*), during his next visit to the establishment, provided the establishment management with a reiteration, in writing, of the requirement for daily inspection coverage whenever U.S.-eligible product is produced. Only samples, less than eleven pounds net weight, were allowed to be shipped to the U.S, on October 3, 2002. The DSV informed the establishment management that the remainder of the production, which had not yet been shipped, was ineligible for the U.S. market.

Following the audit of this establishment, DGAL issued a formal letter to the management, informing them that the deficiencies identified must be corrected within 30 days, or the establishment would be removed by DGAL from the list of establishments eligible to export products to the United States.

NOTE: One deficiency had been identified during the previous FSIS audit on 4-8-02 (condensation); it had been satisfactorily addressed and corrected.

Operations: Production of duck and goose foie gras and pork liver paté

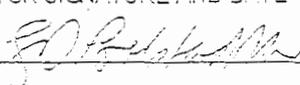
U.S. exports: duck and goose foie gras and pork liver paté.

Accompanying DGAL personnel: Dr. Maryse Flamme, , Dr. L. Repiquet-Bailleul, Coordinator for the *Département*, and Dr. Vincent Spony, Director of Veterinary Services in the *Département*

61. NAME OF AUDITOR

Gary D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE



10/14/02

B-9a

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Georges Bruck, Strasbourg.	2. AUDIT DATE 10/11/2002	3. ESTABLISHMENT NO. 67-482-21	4. NAME OF COUNTRY France
French officials: Dr. Maryse Flamme, Dr. Vincent Spony		5. NAME OF AUDITOR(S) Dr. Gary D. Boistad	6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

60. Observation of the Establishment

B-9b

Est. 67-482-21, Strasbourg, France, 10/11/02. DGAL officials: Dr. Maryse Flamme, Dr. Vincent Spony

7 The dropped-meat reconditioning procedure was not part of the written SSOP's. The manager gave assurances this would be corrected promptly.

All previously identified deficiencies had been adequately addressed and corrected.

61. NAME OF AUDITOR

Gary D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE

G. D. Bolstad 10/11/02

Country Response Not Received