



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

Washington, D.C.  
20250

DEC - 6 2002

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 April 3 through April 29, 2002. Enclosed is a copy of the final audit report. Your comments have been included as Attachment G in the 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 at 202-720-3781. My fax number is 202-690-4040 and my email address is [sally.stratmoen@fsis.usda.gov](mailto:sally.stratmoen@fsis.usda.gov).

Sincerely,

A handwritten signature in cursive script that reads "Sally Stratmoen".

Sally Stratmoen  
Acting Director  
Equivalence Division  
Office of International Affairs

Enclosure

Dr. Isabelle Chmitelin

2

cc:

Alejandro Checchi-Lang, European Commission, Brussels, Belgium

Besa Kotati, Agricultural Counselor, U.S. Embassy, Paris

Carol Buy, Deputy Counselor for Agriculture, Embassy of France, Washington, DC

Joerg Niederberger, Agriculture and Consumer Affairs, EU Mission to the US, Wash, DC

Norval Francis, Minister/Counselor for Agricultural Affairs, USEU /Brussels

Sally Stratmoen, Acting Director, ED, OIA

Karen Stuck, Act. Deputy Asst. Administrator, OIA

Donald Smart, Director, Review Staff, PEER

John Wilson, FAS Area Officer

Amy Winton, State Department

Nancy Goodwin, ED, OIA

Country File-France Audit FY 2002—final



## AUDIT REPORT FOR FRANCE APRIL 3 THROUGH APRIL 29, 2002

### INTRODUCTION

#### Background

This report reflects information that was obtained during an audit of France's meat and poultry inspection system from April 3 through April 29, 2002. Eleven of the 24 establishments certified to export meat and poultry to the United States were audited on-site. Three of these were slaughter establishments; the other eight were conducting processing operations.

The last audit of the French meat inspection system was conducted in May 2001. Eight establishments and one *Département* residue and microbiology laboratory were audited on-site. The auditor found serious deficiencies in two establishments, which were then designated as marginal/re-review at the next audit. The following major concerns were reported at that time:

- ? Daily inspection coverage was not provided in processing establishments.
- ? 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 all establishments during months when U.S.-eligible product was produced, as required.
- ? Boneless meat re-inspection and associated record keeping was not carried out in those establishments where boneless meat re-inspection was required.

At the time of this audit, French beef was ineligible for export to the U.S. due to the presence of Bovine Spongiform Encephalopathy (BSE) in France. Pork and poultry products were eligible for U.S. export. France had been declared free of Foot-and-Mouth Disease (FMD) in November 2001, with certain restrictions since France shares borders with countries that were not FMD-free.

From January 1 through March 31, 2002, French establishments exported 238,585 pounds of pork and poultry products to the United States. Of this amount, 82,283 pounds were reinspected at U.S. ports of entry (POE): 0.07% of the reinspected product was rejected at U.S. POEs for missing shipping marks and transportation damage. During calendar year 2001, French establishments exported 598,128 pounds of pork and poultry products to the United States. Of this amount, 291,343 pounds were reinspected at U.S. POEs: rejections

were for miscellaneous defects (1.16% of the reinspected amount); unsound condition (0.06%); contamination (0.01%); and missing shipping marks, labeling defects, and transportation damage (0.11% combined).

## PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with French national meat and poultry inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of a selection of records in the meat and poultry inspection headquarters facilities preceding the on-site visits and audits of documents from seven other establishments selected at random. The third was conducted by on-site visits to eleven establishments. The fourth was a visit to two laboratories, one performing analytical testing of field samples for the national residue testing program, and the other culturing field samples for the presence of microbiological contamination with *Salmonella*. Seven of the establishments audited on-site were chosen at random. Two others (29-097-01 and 40-088-03) were added because they had been evaluated as requiring re-review during the May 2001 FSIS audit; 02-502-01 was added to assess the source of beef used for U.S.-eligible products, and 46-128-02 was added because there had been a species violation in a shipment from this establishment.

France's program effectiveness was assessed by evaluating five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials (this was the case with two establishments—see below).

## RESULTS AND DISCUSSION

### Summary

Effective inspection system controls were found to be in place in nine of the eleven establishments audited on-site. Two establishments (24-336-04 and 46-128-02) were found to be unacceptable and were delisted by the French meat inspection officials. Details of audit findings, including compliance with HACCP, SSOPs, and testing programs for *Salmonella* species and generic *E. coli*, are discussed later in this report.

As stated above, five major concerns had been reported during the May 2001 FSIS audit of France:

- ? *Daily inspection coverage had not been provided in processing establishments.* By the time this new audit took place, this had been corrected.
- ? *HACCP implementation deficiencies had been found in six of the 18 establishments whose records were reviewed.* During this new audit, HACCP implementation was found to be deficient in 16 of the 18 establishments whose records were audited.
- ? *SSOP implementation deficiencies had been found in six of the 18 establishments whose records were reviewed.* During this new audit, SSOP implementation deficiencies were identified in eight of the 18 establishments whose records were audited.
- ? *Documented supervisory visits had not been performed in all establishments during months when U.S.-eligible product was produced, as required.* Although considerable misunderstanding regarding this requirement had persisted after the 2001 audit, it was resolved by teleconference shortly before this new audit began, and the Auditor found that (nearly) all the field personnel now understood the requirement, and it was now being implemented.
- ? *Boneless meat re-inspection and associated record keeping had not been carried out in those establishments where boneless meat re-inspection was required.* This had been resolved.

In addition, the following new concerns resulted from this new audit:

- ? 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 International Policy Division's Equivalence Branch in advance for equivalence determination.
- ? Some field inspection personnel in positions of responsibility for U.S.-listed establishments had not had formal HACCP training.

### Entrance Meeting

On April 3, an entrance meeting was held in the Paris offices of the French Ministry of Agriculture's *Direction Générale de l'Alimentation*, or General Food Agency (*DGAL*), and was attended by Dr. Paul Menecier, Head, International Sanitary Coordination Division, Dr. Jean-Yves Kerveillant, Head of the Fresh Meat and Poultry Inspection Programs Unit; Dr. Olivier Faugere, Deputy Head of the Food Safety Division; Dr. Jean-Christophe Tosi, Head of the Processing Establishments Inspection Programs Unit; Dr. Emmanuelle Soubeyran, in charge of the Meat and Poultry Processing Plants Inspection Programs; Dr. Maryse Flamme, Export Assistance Department, National Interprofessional Agency for Meat, Livestock, and Poultry (a subdivision of *DGAL*); Mr. Christian Bastien, Technical Assistant, Meat and Poultry Processing Establishments Inspection Programs Unit; Ms. Dominique Malo, Technical Assistant, Fresh Meat and Poultry Programs Inspection Unit; Mr. Kurt Seifarth, Agricultural Attaché, FAS, American Embassy, Paris; and Ms. Florence Pinon, Agricultural Assistant, American Embassy, Paris. The FSIS International Audit Staff Officer (hereinafter called "the Auditor") was Dr. Gary D. Bolstad. Topics of discussion included the following:

1. The audit itinerary was finalized.
2. The Auditor explained how and when the draft audit report would be transmitted, that the French officials would have the opportunity to provide comments, how and when the audit report would be finalized, and the final audit report would be posted on the FSIS Website.
3. The Auditor provided a summary of the data regarding French products presented and reinspected at U.S. ports of entry including rejections.
4. The Auditor explained that, as a result of the Veterinary Agreement between the European Union (EU) and the United States, he would be auditing against the three EC Council Directives agreed upon, and also against certain U.S. regulations not covered in the Veterinary Agreement, in particular regarding HACCP and Pathogen Reduction programs and Sanitation Standard Operating Procedures. The three applicable European Commission Directives are:
  - ? Council Directive 64/433: Health Problems Affecting Intra-Community Trade in Fresh Meat [this EC Directive applies only to establishments processing red meat; in establishments processing only poultry, U.S. poultry regulations apply],

- ? Council Directive 96/22: Prohibition On the Use in Stockfarming of Certain Substances Having a Hormonal or Thyrostatic Action and of  $\beta$ -Agonists, and
- ? Council Directive 96/23: Measures to Monitor Certain Substances and Residues Thereof in Live Animals and Animal Products.

### Headquarters Audit

There had been changes in the organizational structure of DGAL since the last U.S. audit of France's inspection system in May 2001. On June 14, 2001, the Veterinary Services became independent under the authority of the Prefect and under the Ministry of Agriculture. The purpose of this independence was to encourage better cooperation with other government agencies. The Departmental Director of Veterinary Services was elevated to the same level as the Departmental Director of Agriculture and Forestry (DDAF) and now reports directly to the Prefect, rather than to the DDAF, and is now in charge of implementing public-health and health-safety related veterinary measures. In each *Département* at the head of the Region, the Director of the Veterinary Services is appointed by the Minister of Agriculture and is in charge of coordinating the Veterinary Service Departmental Directorates (DDSVs) of the Region, under the authority of the Prefect of the region.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications. The FSIS auditor (hereinafter called "the Auditor") observed and evaluated the process.

The Auditor conducted a review of certain inspection system documents located at the headquarters of the inspection service. This records review focused primarily on food safety hazards and included the following:

- ? A summary of internal review program,
- ? New laws/regulations/directives/ guidelines,
- ? Monthly internal review reports,
- ? Other supervisory visits to establishments that were certified to export to the U.S.,
- ? Sampling and laboratory analyses for residues,
- ? Official communications with field personnel, both in-plant and supervisory, in which U.S. requirements were conveyed, and

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

## Government Oversight

All inspection veterinarians and inspectors in establishments certified by France as eligible to export meat and poultry products to the United States were full-time DGAL employees, receiving no remuneration from either industry or establishment personnel.

The country is divided into 93 *Départements*. Each *Département* has a Director of Veterinary Services. Each of these Directors is a veterinarian, employed by the government, and is a sworn-in officer with legal prosecution rights; 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 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.

## Establishment Audits

Twenty-four establishments were certified to export meat and/or poultry products to the United States at the time this audit was conducted. Eleven establishments were visited for on-site audits. In nine of the 11 establishments visited, establishment system controls were in place to prevent, detect and control contamination and adulteration of products. The remaining two were found to be unacceptable and were delisted accordingly by DGAL.

## Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information was also collected about the risk areas of government oversight of accredited, approved, and private laboratories; intra-laboratory quality assurance procedures, including sample handling; and methodology.

The Laboratoire Départemental d'Analyses (LDA-56) in Vannes was audited on April 18, 2002. This is a public laboratory, receiving all its resources from the fees charged for the analytical and microbiological activities. It is staffed by public servants employed by the *Département*. The laboratory was accredited by COFRAC (French Accreditation Committee). Effective controls were in place for sample handling and frequency, data reporting, tissue matrices for analysis, equipment operation and instrument printouts, minimum proficiency levels, recovery frequency, and percent recoveries. The methods used for the analyses were acceptable. No compositing of samples was done (this was not a deficiency).

Turnaround times met the requirements of the European Commission and were usually in the range of two months for heavy metals, and between two and four months for the other classes of compounds. If any targeted samples were analyzed, e.g., for injection site lesions, the analyses were completed within 24-72 hours.

The check sample program met the requirements of the European Commission; the laboratory was accredited by the French Accreditation Committee and (except for the chromatography section) also under ISO-17025. Inter-laboratory check samples for organochlorines, organophosphates, PCBs, and heavy metals were provided annually by the French Agency for Food Safety AFFSA and the Interprofessional Bureau for Analytical Studies (BIPEA). Inter-laboratory check samples for chloramphenicol were expected to be provided in the near future.

One deficiency was identified:

- ? The chromatography section was not yet accredited under ISO-17025 and consequently written corrective action programs for organochlorines, organophosphates, and PCBs had not been developed, but this was expected to be completed by the end of 2002.

France's microbiological testing for *Salmonella* was being performed in public laboratories staffed by government employees. The microbiological testing for generic *E. coli* was performed in both public and private (in-plant) laboratories. One of these public laboratories, the *Laboratoire Départemental d'Analyses* in Cahors, was audited on April 12, 2002. Controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, check sample programs, and corrective actions.

One deficiency was identified:

- ? DGAL had officially informed FSIS that the FSIS regulatory requirements for testing for generic *E. coli* had been adopted. However, in this microbiology laboratory an alternate method, AFNOR (*Association Francaise de Normalisation*) V-08-053, was being used for field *E. coli* samples. This alternate methodology had not been submitted to the International Policy Staff's Equivalence Branch in advance for an equivalence determination before it was used for U.S.-eligible product. The DGAL and laboratory officials were informed that, until this has been done, the AOAC method must be used. Likewise, DGAL had officially informed FSIS that the ISO-6579 method was being used for the testing for *Salmonella* species. However, "a simplified version of" this method (AFNOR V-08-052) was being used. Again, any alternate methodology must be submitted to the International Policy Staff in advance for an equivalence determination before it may be used for U.S.-eligible product; this was not done. The DGAL and laboratory officials were informed that, until this has been done, the unmodified ISO-6579 method must be used.

## Establishment Operations by Establishment Number

The following operations were being conducted in the 11 establishments visited on-site:

- ✍ Beef, chicken, pork, turkey, duck, lamb, and veal processing, cooked in plastic pouches (shelf-stable) and (not for U.S. export) other heat-treated but not shelf-stable products – one establishment (02-502-01)
- ✍ Duck and goose processing and canning of foie gras and other duck and goose products and (not for U.S. export) a small amount partially cooked and fresh duck liver – one establishment (40-088-03)
- ✍ Duck and goose slaughter and cutting (and, not for U.S. export), canned products and fully-cooked, not shelf-stable duck and goose products – one establishment (46-128-02)
- ✍ Processing and packaging of smoked duck breast, canning of duck, goose, and pork paté – one establishment (40-282-02)
- ✍ Swine slaughter, pork cutting, and raw sausage production – one establishment (29-097-01)
- ✍ Ham, pork and duck liver paté, cooked pork sausage, head cheese – one establishment (87-085-03)
- ✍ Duck and goose liver foie gras and related products – one establishment (46-102-04)
- ✍ Duck and goose foie gras and pork liver paté – one establishment (67-447-05)
- ✍ Duck and goose slaughter and cutting –one establishment (85-109-01)
- ✍ Duck and goose slaughter – one establishment (24-336-04)
- ✍ Duck and goose foie gras – one establishment (67-482-21)

## SANITATION CONTROLS

Based on the on-site audits of establishments, France's inspection system had controls in place for water potability records and chlorination procedures, back-siphonage prevention, separation of operations, temperature control, operators' and inspectors' work space, ante-mortem facilities, outside premises, sanitary dressing procedures, product reconditioning and transportation, and waste disposal.

### Sanitation Standard Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

Evaluation of the SSOPs in the 11 establishments audited on-site and in documentation provided from the seven establishments selected for records audit revealed the following deficiencies in the development and/or implementation of the SSOP requirements:

- ? There was inadequate daily documentation of one or more of the required elements of both operational and pre-operational sanitation in eight (24-336-04, 40-282-02, 46-102-

04, 46-128-02, 67-482-21, 19-031-02, 32-147-23, and 47-157-03) of the 18 establishments whose SSOP programs were evaluated.

- ? In Est. 24-336-04, cleaning/disinfection of product-contact surfaces was not adequately addressed in the written SSOPs; furthermore, the cleaning/disinfection that was mentioned in the written plan was not followed in practice (see below).

In addition, the following sanitation deficiencies were also identified:

#### Cross-Contamination

- ? Neck flaps of split swine carcasses were observed to contact workers' boots and standing platforms on the slaughter line in Est. 29-097-01, in violation of EC Council Directive 64/433, Annex I, Chapter III. DGAL officials immediately ordered the establishment to provide a worker to trim those that were too long and would be cross-contaminated and also ordered the neck flaps from the day's previous production to be removed and condemned. Note: cross-contamination had been identified on the slaughter floor during the previous FSIS audit (this had been corrected at that location).

#### Maintenance and Cleaning

- ? Maintenance and cleaning of over-product equipment was found to have been neglected in eight establishments (02-502-01, 29-097-01, 40-088-03, 40-282-02, 46-102-04, 46-128-02, 67-482-21, and 85-109-01). DGAL officials ordered improved maintenance of the neglected structures and increased monitoring during pre-operational sanitation inspection. In the red-meat plants, this was a violation of EC Directive 64/433, Annex I, Chapter III.
- ? Pre-operational cleaning of product-contact equipment was inadequate in five establishments (24-336-04, 29-097-01, 40-282-02, 46-102-04, and 46-128-02). In the red-meat plants, this was a violation of EC Directive 64/433, Annex I, Chapter III, 3 (c). DGAL officials ordered re-cleaning of the equipment; in Est. 46-128-02, the re-cleaning was ineffective and was ordered to be repeated.
- ? Maintenance of product-contact equipment was found to be inadequate in two establishments: this was a violation of EC Directive 64/433, Annex I, Chapter III, 3 (c) in Est. 87-085-03: approximately 10% of the wheeled stainless steel combo bins and half of the large plastic combo bins were cracked and in need of repair or replacement. Replacement bins had been ordered, but several seriously deteriorated containers were in use for exposed edible product. They were rejected by DGAL. In Est. 46-102-04, buildups of rust, flaking paint, grease, and old product residues were observed on all four canning machines. The DGAL official leading the audit ordered production to be stopped until they had all been cleaned.

## Storage of Product and Product-Contact Equipment

- ? Product-contact equipment was observed to have been stored under insanitary conditions in three establishments (40-282-02, 46-128-02, and 87-085-03). In the red-meat establishments, this was a violation of EC Directive 64/433, Annex I, Chapter III, 3 (c). Corrective actions were ordered by the DGAL officials.
- ? Product had been stored under insanitary conditions in two establishments. In Est. 02-502-01, several large stacks of frozen chicken necks waiting for processing had large amounts of snow, from condensation on the ceiling above, on the coverings; some of these coverings did not offer adequate protection of the meat. (No snow was actually observed to have contacted the product). The establishment management gave assurances that the establishment of origin would be notified and required to provide better protection of the product. In 67-447-05, heavy condensation was present on a large portion of the ceiling of a freezer containing uncovered frozen smoked duck breasts, many of which had ice visible on the exposed surfaces. The DGAL personnel ordered the top layer to be discarded and microbiological testing done on the rest of the product. Although the insanitary storage involved poultry meat, this was a violation of EC Directive 64/433, Annex I, Chapter III, since both establishments also processed pork.
- ? Protective clothing was stored under insanitary conditions in two establishments. In Est. 46-128-02, white work coveralls were found to have been stored in lockers reserved for street clothes in both the male and female locker rooms. In one locker, street shoes were found on top of the white work coveralls. The DGAL official ordered the coveralls to be removed for cleaning. In Est. 24-336-04, employees' work clothes were stored in direct contact with a fieldstone wall. No immediate corrective actions were taken.

## Pest Control Programs

- ? Pest control was found to be inadequate in four establishments: rodent droppings were present in the carton storage- and preparation room in Est.46-108-02, flies were observed in production areas in Est. 02-502-01 and, cobwebs were present in storage areas in both of the above and also in the changing room and the main hand-washing station in Est. 24-336-04, and the storage area for empty cans in Est. 46-102-04. In Est. 02-502-01, which processed red meat, this was in violation of EC Council Directive 64/433, Annex I, Chapters II and III.

## Hygiene of Personnel

- ? Personal hygiene problems (failure to wash hands after handling pallets on the floor, unclean vests worn over protective clothing) were found in establishment 46-128-02. Corrective actions were immediate.

## Operational Sanitation

- ? The slaughter operations in Est. 24-336-04 were conducted under insanitary conditions. The ducks were stunned and bled in an area that had a roof but was completely open to the outside environment on two sides. The large opening between this outside area and the de-feathering area was only half-covered. De-feathering and evisceration were performed in the same small room, and there was no effective wall between this room and the post-mortem inspection area. No corrective actions were taken.
- ? In Est. 46-128-02, a breakdown in the hot-water system resulted in all the sterilizers in the establishment being well below the required temperature of 180°F (82°C). Nevertheless, operations were allowed to begin as usual. After the problem was identified in the cutting room, the operations were allowed to continue for fifteen minutes longer.

When the audit team moved to the slaughter area, the sterilizer temperatures there were also all well below the required temperature. In spite of this, the hanging, stunning, bleeding, defeathering, and evisceration were allowed to continue for more than ten minutes more before operations were stopped pending resolution of the problem.

- ? Hand-washing facilities were inadequate at the two of the entrances to the production areas of Est. 24-336-04. At the main entrance to the establishment, there was no hand-towel dispenser; the roll of hand towels was stored on an insanitary window shelf with obvious cobwebs, together with a coumarin-containing bait station. Also, at the only hand station available to workers entering the defeathering/evisceration room, the hand soap dispenser was inoperable. No corrective actions were taken.
- ? Several doors to the outside from exposed-product production areas in Est. 24-336-04 were left open during operations. Corrective actions were ineffective.

## ANIMAL DISEASE CONTROLS

With the exceptions listed below, France's inspection system had controls in place to ensure adequate animal identification, ante-mortem inspection procedures, condemned and restricted product control, and procedures for sanitary handling of returned and rework product.

The only animal disease with public-health significance in France at the time of this audit was Bovine Spongiform Encephalopathy (BSE). According to the U.S. Agricultural Minister-Counselor, France was free of hog cholera, and the French officials were expecting official APHIS recognition of this status.

- ? Lighting was inadequate at post-mortem inspection stations in three of the four slaughter establishments audited. EC Community Directives require 540 Lux, or 49 foot-candles (fc) of light at inspection stations. In the swine slaughter establishment (29-097-01), the

Auditor measured 330 Lux (30 fc) at mandibular lymph nodes at the post-mortem inspection station and at the level of forelegs and heads at the inspection station for the retained-carcass rail, and only 110 Lux (10 fc) in thoracic and abdominal cavities at the retained-carcass rail. In two of the three duck slaughter facilities (24-336-04 and 46-128-02) the light was measured at 220 Lux (20 fc) at the main post-mortem inspection stations. The issue of adequate light was discussed at the exit meeting in Paris as well as during the establishment audits, and DGAL officials agreed to ensure that adequate light would be provided promptly at all inspection stations.

- ? Post-mortem inspection was found to be inadequate in Est. 24-336-04: the inspection of the carcasses and viscera was being performed by a DGAL employee from a distance of approximately 6 feet from the inspection surfaces. No corrective action until the Auditor pointed out the deficiency.

### RESIDUE CONTROLS

France's National Residue Testing Plan for 2002 was being followed, and was on schedule. The French inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures. One deficiency was noted:

- ? Several unmarked chemicals were observed in Est. 40-282-02. This was in violation of EC Council Directive 64/433, Annex I, Chapter III. The containers were labeled promptly by the establishment officials.

### SLAUGHTER/PROCESSING CONTROLS

Except as noted below, the French inspection system had controls in place to ensure adequate control and disposition of dead, dying, diseased or disabled animals, humane handling and slaughter, ingredients identification; formulations; packaging materials; laboratory confirmation; label approvals; inspector monitoring; processing schedules, equipment and records; post-processing handling; processing defect actions by establishment personnel; and processing control by inspection personnel.

### HACCP Implementation

All establishments approved to export meat and poultry products to the U.S. are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

The following deficiencies regarding the development and/or implementation of the HACCP requirements were identified in the 18 establishments whose HACCP programs were audited:

- ? According to 9CFR §417.2, “the HACCP plan shall, at a minimum: ...(7) list the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with §417.4 of this part.” Furthermore, according to 9CFR §417.4 (a) and (a)(2), “every establishment shall... verify that the [HACCP] plan is being effectively implemented. On-going verification activities include...direct observations of monitoring activities and corrective actions.” These verification requirements were not met in 16 establishments (for details, see Attachment B).
- ? According to 9CFR §417.5 (c), “prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met, and, if appropriate, corrective actions were taken, including proper disposition of product.” This requirement for a formal pre-shipment document review was not met in 11 establishments (for details, see Attachment B).
- ? An essential component of the development of any HACCP plan is an analysis for physical, chemical, and microbiological hazards. In three establishments (24-336-04, 24-520-05, and 46-128-02), chemical hazards had not been considered when the HACCP plan was developed; in two of these (24-336-04 and 24-520-05), physical hazards had also not been considered. In Est. 47-157-03, both microbiological and physical hazards were part of the documented risk analysis; however, chemical risks—although they had been considered—were not included in the risk analysis documentation.
- ? In two establishments (24-336-04 and 46, 128-02), critical limits were not monitored as required.
- ? In Est. 46-128-02, there was no documentation of corrective actions taken when critical limits were exceeded.

### Testing for Generic *E. coli*

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

Four of the establishments audited on-site and two of those selected for document audit were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

Two deficiencies regarding the implementation of the generic *E. coli* testing requirement were noted:

- ? In the two swine slaughter establishments chosen for document review (29-027-01 and 29-225-01), statistical process control methods had not been developed, as required when sponge sampling method is used, to evaluate the results. 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 rest of the generic *E. coli* testing programs were found to meet the basic FSIS regulatory requirements, except that, as explained in the Laboratory Audits section earlier in this report, an alternate method, AFNOR V-08-053, was being used, without the Equivalence Branch having been notified in advance for an equivalence determination. The DGAL and laboratory officials were informed that, until this has been done, the unsimplified ISO-6579 method must be used.

Additionally, establishments had adequate controls in place to prevent meat and poultry products intended for French domestic consumption from being commingled with products eligible for export to the U.S.

## ENFORCEMENT CONTROLS

### Inspection System Controls

The French inspection system had effective programs in place for control of restricted product and inspection samples, boneless meat reinspection, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, the importation of only eligible meat or poultry products from other countries for further processing. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

### Testing for *Salmonella* Species

Three of the establishments audited were required to meet the basic FSIS regulatory requirements for testing for *Salmonella* species, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

France's DGAL officials had informed FSIS that they had adopted the FSIS regulatory requirements for HACCP. They had reported that *Salmonella* testing in the establishments certified as eligible to export meat and poultry products to the United States was the same with exception of the following equivalent measures:

## 1. ENFORCEMENT STRATEGY.

- ? The government suspends an establishment from export to the U.S. the first time it fails to meet a performance standard.
- ? The establishment can only be recertified after it has taken corrective actions and meets the performance standard.

## 2. ANALYTICAL METHODS: Different methods.

- ? The government laboratories were reported to use ISO 6579 to analyze for *Salmonella*. ISO 6579 is an internationally recognized method of analysis for detecting *Salmonella*.

The *Salmonella* testing programs were found to meet the basic FSIS regulatory requirements, except that, as explained in the Laboratory Audits section earlier in this report, "a simplified version of" this method (AFNOR V-08-052) was being used, without the Equivalence Branch having been notified in advance for an equivalence determination. The DGAL and laboratory officials were informed that, until this has been done, the unsimplified ISO-6579 method must be used.

### Species Verification

At the time of this audit, France was not exempt from the species verification requirement. The French officials stated, during the entrance meeting, that species verification was being performed in the field, and the Auditor requested a summary of the program to be provided at the exit meeting. During the audits in the field, however, none of the officials in any of the establishments the Auditor visited were aware of any species verification activities being performed. In the exit meeting, the Auditor again requested a summary of the species verification program, but it had not yet been prepared. The French officials stated that species verification was not the responsibility of DGAL, but rather of the Directorate General for Consumers, Competition, and Fraud Repression. They further stated that they would request a summary of whatever species verification program was in effect and provide it as soon as it became available. As of the time of the writing of this report, it had not yet been received.

### Monthly Reviews

According to 9CFR §327.2 (a) (2) (iii) (A), the foreign inspection system must maintain a program that must, among other requirements, provide for:

“Periodic supervisory visits by a representative of the foreign inspection not less than one visit per month to each establishment certified...to assure that requirements...are being met: *Provided*, that such visits are not required with respect to any

establishment during a period when the establishment is not operating or is not engaged in producing products for exportation to the United States.”

Until shortly before this audit, the French meat inspection (DGAL) officials had misunderstood the requirements for the inspection coverage provided to establishments certified by them as eligible to export to the U.S. There was daily, continuous coverage by DGAL of slaughter operations; the misunderstanding involved coverage of cutting and processing establishments. 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.

This misunderstanding was resolved during a teleconference held, some two weeks in advance of the (April 3<sup>rd</sup>) beginning of the recent on-site audit of France, with Sally Stratmoen, Chief of the Equivalence Branch of the Office of Policy, Program Development and Evaluation; Don Smart, Director, Audit Staff; Gary Bolstad, International Audit Staff Officer, and Paul Mennecier, Head of the International Sanitary Coordination Division of the French General Agency for Food. The exact nature of the coverage requirements was made clear; these requirements involve two levels of coverage of cutting and processing establishments:

1. Daily inspection coverage (a visit during the hours of operation) on any day when an establishment is producing product that is eligible for U.S. export or for use by another establishment in product that may be eligible for U.S. export, and
2. A documented monthly visit to each establishment certified by France as eligible to export to the U.S., by a supervisor of the inspection personnel assigned to the establishment, in any month during which the establishment produces product that is eligible for U.S. export or for use by another establishment in product that may be eligible for U.S. export.

According to the size of the *Département* (see the description of the organizational structure under Headquarters Audit, earlier in this report), the internal reviews were performed by either the head of the District or, in the smaller *Départements*, that were not subdivided into Districts, by the Deputy Director. A yearly review was conducted of all the *Départements*, usually by the Directors of the *Départements*. In the U.S.-certified establishments, the monthly reviews were conducted by the supervisors of the in-plant inspection personnel. Performance of field inspection personnel was also evaluated, but the results were not part of the routine monthly reports, and were not routinely documented.

The method of plant selection and internal review was applied equally to both export and non-export establishments, but export establishments were reviewed with extra requirements in mind, according to the countries for which the products were eligible for export.

Some internal reviews were unannounced and some were announced in advance. The decision was left up to the internal reviewers; they were usually unannounced to both

management and in-plant inspection personnel, and were usually conducted by a single reviewer, occasionally accompanied by another.

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

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

The internal reviewers had full authority from detention of products in one area to complete stopping of operations.

All batches and lots 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 that this system was in place in the field.

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, 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 US-eligible export chain.

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*. Delisting of noncompliant establishments is ordered by the CVO.

The following problems with the system of internal reviews were found:

- ? In Est. 32-147-23, which was not visited on-site, there was no documented supervisory visit during calendar year 2001. The (new) Deputy Director of the *Département* had visited the establishment, but did not generate a report of his activities and/or observations. The Auditor reinforced the requirement that at least one documented visit must be done annually. Note: no products had ever been exported to the U.S. from this establishment, but the management planned to begin in the foreseeable future.

- ? In Est. 40-282-02, product for the U.S. was produced during June through July 2001 and in February and March 2002. The only months when there were supervisory visits were in April and October 2001 and in March 2003.
- ? The *Département* official performing the supervisory visits of Ests. 24-336-04 and 24-550-05 (these establishments were not audited on-site) had not been informed of the U.S. requirement for monthly visits during all months when U.S.-eligible product was produced. This establishment had received such visits only once per year, although U.S.-eligible product was produced during all months of the year.
- ? There was no visit to Establishment 67-447-05 by the Veterinarian-In-Charge during the month of October 2001, although there was U.S. production in that month. Following discussions between FSIS and DGAL since that time, DGAL had informed the establishment management, prior to this audit, that DGAL must be notified in advance when U.S.-eligible production is to take place so that the Veterinarian-In-Charge may be notified in advance and can perform inspection coverage on all days when the plant is producing U.S.-eligible product.

### Enforcement Activities

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* of 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 Dept. 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. There were nearly a thousand food recalls in France in 2001, 36 of which involved products of animal origin.

Pork antigens were found in duck liver paté from Est. 46-128-02 at a U.S. port of entry in February 2001. This establishment slaughters only poultry and conducts cutting operations on the poultry, and also processes some pork. An investigation was initiated that involved the Agency for Fraud Operations, and a request for more information was sent to FSIS in July 2001; with the information provided, the French authorities were unable to determine how any species cross-contamination could have occurred in the establishment of origin. Raw duck *foie gras* (fatty liver) is readily differentiated visually from pork liver (the former is small and a yellowish-tan color and the latter much larger and dark reddish-brown). The on-site audit of this establishment revealed no laxity in controls to prevent species cross-contamination.

There was considerable concern regarding the level of awareness on the part of field inspection officials of FSIS requirements and the effectiveness of their ability to enforce implementation of those requirements in establishments certified by DGAL as eligible to

produce products that are to be eligible for the U.S. export chain, since these field inspection personnel had not adequately enforced compliance, by management personnel in the vast majority of establishments audited, with various elements of the requirements of HACCP and SSOPs. Nearly all the field inspection personnel had had at least some formal training in these requirements, but not all:

- ? The Veterinarian-In-Charge of Est. 46-102-04 had been employed by DGAL for one year and had requested HACCP training when her employment was begun. She was given notes from training sessions that others had attended, but had not yet been enrolled in a formal course herself. Until shortly before the audit of this establishment, she had been unaware of the requirement for verification procedures and pre-shipment document reviews (both were missing in the establishment).
- ? The technical assistant who was present for the audit of Est. 40-282-02 had been in her position for a year, but had not had formal HACCP training, although the Deputy Director of Veterinary Services for the *Département* had given her personal instruction in the principles and she had attended routine quarterly regional correlation meetings, and there were plans to include her in a formal training course during 2002.
- ? At least one *Département* Director, who was performing the monthly supervisory reviews of a U.S.-listed establishment, had not had any formal HACCP training.

### Exit Meetings

An exit meeting was conducted in the headquarters of the French Ministry of Agriculture in Paris on April 29, 2002. The French participants were Dr. Paul Menecier, Head, International Sanitary Coordination Division, Dr. Jean-Yves Kerveillant, Head of the Fresh Meat and Poultry Inspection Programs Unit; Dr. Emmanuelle Soubeyran, in charge of the Meat and Poultry Processing Plants Inspection Programs; Dr. Maryse Flamme, Export Assistance Department, National Interprofessional Agency for Meat, Livestock, and Poultry (a subdivision of DGAL); Dr. Lilian Puech, Bureau of Research and Laboratory Analysis; and Ms. Dominique Malo, Technical Assistant, Fresh Meat and Poultry Programs Inspection Unit. USDA was represented by Dr. Besa L. Kotati, Agricultural Minister-Counselor and Ms. Florence Pinon, Agricultural Specialist, American Embassy, Paris; and Dr. Gary D. Bolstad, International Audit Staff Officer, FSIS. The following topics were discussed:

1. The details of the audit findings were reiterated and discussed in detail. Dr. Menecier gave his assurances that:
  - ? Delistment notices for the two unacceptable establishments had been provided to FSIS and all other French establishments listed as eligible for U.S. export had also been notified.

- ? Field inspection officials would ensure that adequate light would be provided and maintained at all post-mortem and retained-rail inspection stations.
- ? Written instructions would be provided promptly to all field offices involved in the supervision of establishments listed for U.S. export that would cover all points discussed during this exit meeting and during all discussions with field officials during establishment audits and document audits.
- ? DGAL would continue to provide daily inspection coverage in all establishments whenever U.S.-eligible product was being produced, and that documented supervisory reviews would be performed monthly whenever U.S.-eligible product was being produced.
- ? Written instructions would be sent to all establishments in which HACCP and SSOP development, implementation, and/or documentation deficiencies had been identified, requiring correction within 30 days, and field inspection personnel would be instructed to verify and continue to monitor compliance.
- ? Letters had already been sent to Ests. 02-502-01, 24-520-05, 29-097-01, 31-147-23, and 40-282-02 with deadlines for completion of corrective actions in response to deficiencies identified.
- ? DGAL would ensure that all field inspection personnel in positions of responsibility for establishments listed for U.S. export are brought up to date on the details of the requirements for compliance regarding HACCP/PR and SSOP programs.
- ? Regarding the methods employed for testing of field samples for the presence of generic *E. coli* and *Salmonella* species, all microbiology laboratories handling samples from U.S.-listed establishments had been contacted, and it had been determined that (1) most of them were using the methods that had been reported to FSIS, and (2) the methods used in the laboratory in Cahors were those used in the French national surveillance program. The alternate methods would be provided to FSIS promptly for equivalence determination; in the meantime, the laboratory officials would be instructed to use the methods reported to FSIS for field samples from U.S.-listed establishments.
- ? A summary of the species verification program would be provided to FSIS as soon as it is available.

Following the exit meeting with the French officials, a teleconference was held with the same participants mentioned above and, in addition, Dr. Nicolas Guth, DG, Health and Consumer Protection Directorate General (SANCO), European Commission; Ms. Caroline Hommez, Agricultural Specialist, United States Mission to the European Union, Brussels; and Ms. Sally Stratmoen, Chief, International Policy Staff. The content was identical to that of the exit meeting with the French officials.

## CONCLUSION

In nine of the 11 establishments audited on-site, the inspection system of France was found to have effective controls to ensure that products destined for export to the United States were produced under conditions equivalent to those which FSIS requires in domestic establishments.

Ten major concerns resulted from this audit:

- ? HACCP implementation was found to be deficient in 16 of the 18 establishments whose records were audited.
- ? SSOP implementation deficiencies were identified in eight of the 18 establishments whose records were audited.
- ? 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.
- ? Alternate 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 International Policy Division's Equivalence Branch in advance for equivalence determination.
- ? Some field inspection personnel in positions of responsibility for U.S.-listed establishments had not had formal HACCP training.

Eleven establishments were audited; two of these were unacceptable. The deficiencies encountered during the on-site establishment audits, in those establishments that were found to be acceptable, were adequately addressed to the auditor's satisfaction.

Dr. Gary D. Bolstad  
International Audit Staff Officer

---

### **ATTACHMENTS**

- A. Data collection instrument for SSOPs
- B. Data collection instrument for HACCP programs
- C. Data collection instrument for *E. coli* testing
- D. Data collection instrument for *Salmonella* testing
- E. Laboratory audit form
- F. Individual Foreign Establishment Audit Forms
- G. Written Foreign Country's Response to the Draft Final Audit Report

### Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1. Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Frequency addressed	6. Responsible indiv. identified	7. Documentation done daily	8. Dated and signed
02-502-01	?	?	?	?	?	?	?	?
24-336-04	?	?	?	Inadeq*	?	?	Inadeq.*	?
29-097-01	?	?	?	?	?	?	?	?
40-088-03	?	?	?	?	?	?	?	?
40-282-02	?	?	?	?	?	?	?*	?
46-102-04	?	?	?	?	?	?	?*	?
46-128-02	?	?	?	?	?	?	?*	?
67-447-05	?	?	?	?	?	?	?	?
67-482-21	?	?	?	?	?	?	?*	?
85-109-01	?	?	?	?	?	?	?	?
87-085-03	?	?	?	?	?	?	?	?

24-336-04 – Cleaning/disinfection of product-contact surfaces (hanging racks for carcasses) did not follow the non-specific written plan, which had one statement that all rooms and equipment are cleaned and disinfected. Also, one single number was entered in a form to indicate the pre-operational sanitation findings. An “X” entered in a block was the only indication of “cleaning and disinfection” during operations, but there was no indication of what was cleaned or disinfected.

46-102-04 – Records of pre-operational and operational findings did not reflect conditions observed during the audit.

46-128-02, 67-482-21 – Problems noted before the start of operations were documented, but routine operational sanitation activities, findings, and corrective actions were not.

40-282-02, 67-482-21 – Corrective actions were routinely documented, but preventive measures were not.

*Attachment A-2*

Documentation was also audited from the following establishments that were not visited on-site:

Est. #	1. Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Frequency addressed	6. Responsible indiv. identified	7. Documentation done daily	8. Dated and signed
19-031-02	?	?	?	?	?	?	?*	?
24-520-05	?	?	?	?	?	?	?	?
29-027-01	?	?	?	?	?	?	?	?
29-097-20	?	?	?	?	?	?	?	?
29-225-01	?	?	?	?	?	?	?	?
32-147-23	?	?	?	?	?	?	?*	?
47-157-03	?	?	?	?	?	?	?*	?

32-147-23 There was daily documentation of pre-operational sanitation activities, but it was quite superficial and did not include preventive measures; also some entries did not contain adequate descriptions of the deficiencies. Documentation of operational sanitation activities was very superficial.

19-031-02, 47-157-03 There was daily documentation of both pre-operational and operational sanitation activities, but it did not include preventive measures.

## Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment has conducted a hazard analysis that includes food safety hazards likely to occur.
3. The analysis includes the intended use of or the consumers of the finished product(s).
4. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
5. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
6. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
7. The plan describes corrective actions taken when a critical limit is exceeded.
8. The HACCP plan was validated using multiple monitoring results.
9. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
10. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
11. The HACCP plan is dated and signed by a responsible establishment official.
12. The establishment is performing routine pre-shipment document reviews.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Hazard analysis conducted	3. Use & users included	4. Plan for each hazard	5. CCPs for all hazards	6. Monitoring is specified	7. Corrective actions are described	8. Plan validated	9. Adequate verification procedures	10. Adequate documentation	11. Dated and signed	12. Pre-shipment document review
02-502-01	?	?	?	?	?	?	?	?	?*	?	?	?
24-336-04	?	Inad.*	?	?	?	Inadeq.*	?	?	NO	NO	?	?*
29-097-01	?	?	?	?	?	?	?	?	?*	?	?	?
40-088-03	?	?	?	?	?	?	?	?	?	?	?	?
40-282-02	?	?	?	?	?	?	?	?	?*	?	?	NO
46-102-04	?	?	?	?	?	?	?	?	?*	?	?	NO
46-128-02	?	Inad.*	?	?	?	Inadeq.*	NO	?	?*	?	?	NO
67-447-05	?	?	?	?	?	?	?	?	?	?	?	?
67-482-21	?	?	?	?	?	?	?	?	?	?	?	NO
85-109-01	?	?	?	?	?	?	?	?	?*	?	?	?
87-085-03	?	?	?	?	?	?	?	?	?*	?	?	?*

02-502-01, 29-097-01, 40-282-02, 46-102-04, 46-128-02, 85-109-01 There was documentation of calibration but not of observation of the actual monitoring of the critical limits during production.

24-336-04 Neither physical nor chemical hazards were considered when developing the HACCP plan. Critical limits for contamination at evisceration were not monitored except for documentation of ruptured gut during the slaughter procedure. Many steps in the slaughter process had been identified as CCPs that did not fit the definition (e.g., bleeding, scalding, plucking, and flaming). Verification was not addressed in the written HACCP plan. There was no documentation of any verification procedures (including calibration). A pre-shipment document review form of sorts had been developed, but it was extremely superficial.

40-282-02, 46-102-04, 67-482-21, 87-085-03—Documentation of the meeting of critical limits was kept, but formal pre-shipment document review forms had not yet been developed; the Auditor explained the requirement in detail; the management officials gave assurances they would be developed before any U.S.-eligible products leave the establishments.

46-128-02 Chemical hazards were not considered when developing the HACCP plan. Several CCPs for cooler temperature were recorded continuously. No routine daily monitoring of the critical limits was included in the written plan or documented. Corrective actions taken, when critical limits for cooler temperatures were exceeded, were not documented.

87-085-03 Verification procedures were conducted, according to management officials, but they were not described in the HACCP plan and were not documented.

Documentation was also audited from the following establishments that were not visited on-site:

Est. #	1. Flow diagram	2. Hazard analysis conducted	3. Use & users included	4. Plan for each hazard	5. CCPs for all hazards	6. Monitoring is specified	7. Corrections are described	8. Plan validated	9. Adequate verification procedures	10. Adequate documentation	11. Dated and signed	12. Pre-shipment .doc. review
19-031-02	?	?	?	?	?	?	?	?	?*	?	?	?
24-520-05	?	Inad.*	?	?	?	?	?	?	NO	?	?	NO
29-027-01	?	?	?	?	?	?	?	?	?*	?	?	?*
29-097-20	?	?	?	?	?	?	?	?	?*	?	?	?*
29-225-01	?	?	?	?	?	?	?	?	?*	?	?	?*
32-147-23	?	?	?	?	?	?	?	?	?*	?	?	NO
47-157-03	?	?*	?	?	?	?	?	?	?*	?	?	?

24-520-05 Neither physical nor chemical hazards were considered when developing the HACCP plan.

19-031-02, 29-027-01, 29-097-20, 29-225-01, 32-147-23 There was documentation of calibration but not of observation of the actual monitoring of the critical limits during production.

32-147-23 A formal pre-shipment document review form had not yet been developed, but the establishment had not exported any products to the U.S., although the management intended to begin in the foreseeable future. The manager gave assurances it would be developed before any products are produced for the U.S. The central authority DGAL representative gave assurances the establishment would be informed in writing of the need to correct these deficiencies within 30 days and that compliance would be ensured.

29-027-01, 29-097-20 A formal pre-shipment document review form had not yet been developed, but the establishment had not exported any products to the U.S., although the management intended to begin in the foreseeable future. The manager gave assurances it would be developed before any products are produced for the U.S.

29-225-01 A formal pre-shipment document review form had not yet been developed. The establishment had not exported any products to the U.S. yet this calendar year, and the manager gave assurances that it would be developed before any products are again produced for the U.S.

47-157-03 Both microbiological and physical hazards were part of the risk analysis. Chemical risks were also considered but were not part of the risk analysis documentation. There was documentation of calibration, but not of monitoring of the personnel recording the values at CCPs.

### Data Collection Instrument for Generic *E. coli* Testing

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written procedure for testing for generic *E. coli*.
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is/are being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

Est. #	1. Written procedure	2. Sampler designated	3. Sampling location given	4. Predominant species sampled	5. Sampling at the req'd freq.	6. Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
02-502-01	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
24-336-04	?	?	?	?	?	?	?	?	?	?
29-097-01	?	?	?	?	?	?	?	?	?	?
40-088-03	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
40-282-02	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
46-102-04	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
46-128-02	?	?	?	?	?	?	?	?	?	?
67-447-05	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
67-482-21	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
85-109-01	?	?	?	?	?	?	?	?	?	?
87-085-03	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

Documentation was also audited from the following establishments that were not visited on-site:

Est. #	1. Written procedure	2. Sampler designated	3. Sampling location given	4. Predominant species sampled	5. Sampling at the req'd freq.	6. Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
19-031-02	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
24-520-05	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
29-027-01	?	?	?	?	?	NO	?	?	?	?
29-225-01	?	?	?	?	?	NO	?	?	?	?
29-097-20	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
32-147-23	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
47-157-03	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

29-027-01, 29-225-01 Statistical process control methods had not been developed to evaluate the results of the E. coli testing, as required in establishments using the swab method of sampling: these establishments were using the method developed only for excision samples.

### Data Collection Instrument for *Salmonella* testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. *Salmonella* testing is being done in this establishment.
2. Carcasses are being sampled.
3. Ground product is being sampled.
4. The samples are being taken randomly.
5. The proper carcass site(s) and/or collection of proper product (carcass or ground) is/are being used for sampling.
6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

Est. #	1. Testing as required	2. Carcasses are sampled	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
02-502-01	NA	NA	NA	NA	NA	NA
24-336-04	NA*	NA	NA	NA	NA	NA
29-097-01	?	?	NA	?	?	NA
40-088-03	NA	NA	NA	NA	NA	NA
40-282-02	NA	NA	NA	NA	NA	NA
46-102-04	NA	NA	NA	NA	NA	NA
46-128-02	NA*	NA	NA	NA	NA	NA
67-447-05	NA	NA	NA	NA	NA	NA
67-482-21	NA	NA	NA	NA	NA	NA
85-109-01	NA*	NA	NA	NA	NA	NA
87-085-03	NA	NA	NA	NA	NA	NA

24-336-04, 46-128-02, 85-109-01 – *Salmonella* testing is not required for ducks and geese.

*Attachment D-2*

Documentation was also audited from the following establishments that were not visited on-site:

19-031-02	NA	NA	NA	NA	NA	NA
24-520-05	NA	NA	NA	NA	NA	NA
29-027-01	?	?	NA	?	?	NA
29-097-20	NA	NA	NA	NA	NA	NA
29-225-01	?	?	NA	?	?	NA
32-147-23	NA	NA	NA	NA	NA	NA
47-157-03	NA	NA	NA	NA	NA	NA

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS		REVIEW DATE 4/12/2002	NAME OF FOREIGN LABORATORY Laboratoire Departemental d'Analyses
<b>FOREIGN COUNTRY LABORATORY REVIEW</b>			
FOREIGN GOV'T AGENCY DGAL	CITY & COUNTRY Cahors, France	ADDRESS OF LABORATORY Regourd Sud - BP 295	
NAME OF REVIEWER Dr. Gary D. Bolstad	NAME OF FOREIGN OFFICIAL Dr. Maryse Flamme, Dr. Lilian Puech		

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

SIGNATURE OF REVIEWER

*GD Bolstad*

DATE

*4/12/02*

FOREIGN COUNTRY LABORATORY REVIEW (Comment Sheet)		REVIEW DATE 4/12/2002	NAME OF FOREIGN LABORATORY Laboratoire Departemental d'Analyses
FOREIGN GOV'T AGENCY DGAL		CITY & COUNTRY Cahors, France	ADDRESS OF LABORATORY Regourdud - BP 295
NAME OF REVIEWER Dr. Gary D. Bolstad		NAME OF FOREIGN OFFICIAL Dr. Maryse Flamme, Dr. Lilian Puech	
RESIDUE	ITEM	COMMENTS	
Both	07	<p>DGAL had officially informed FSIS that the FSIS regulatory requirements for generic E. coli had been adopted. However, in this microbiology laboratory an alternate method, AFNOR (Association Francaise de Normalisation) V-08-053, was being used for field E. coli samples. This alternate methodology had not been submitted to the International Policy Division's Equivalence Branch in advance for an equivalence determination before it was used for U.S.-eligible product. The DGAL and laboratory officials were informed that, until this has been done, the AOAC method must be used.</p> <p>Likewise, DGAL had officially informed FSIS that the ISO-6579 method was being used for Salmonella. However, "a simplified version of" this method (AFNOR V-08-052) was being used. Again, any alternate methodology must be submitted to the Policy Branch in advance for an equivalence determination before it may be used for U.S.-eligible product; this was not done. The DGAL and laboratory officials were informed that, until this has been done, the unsimplified ISO-6579 method must be used.</p>	

U.S. DEPARTMENT OF AGRICULTURE  
 FOOD SAFETY AND INSPECTION SERVICE  
 INTERNATIONAL PROGRAMS

REVIEW DATE

4/18/2002

NAME OF FOREIGN LABORATORY

Laboratoire Départemental d'Analyses

**FOREIGN COUNTRY LABORATORY REVIEW**

FOREIGN GOV'T AGENCY  
 Public Laboratory

CITY & COUNTRY  
 Vannes, France

ADDRESS OF LABORATORY  
 6, Avenue Edgar Degas

NAME OF REVIEWER  
 Dr. Gary D. Bolstad

NAME OF FOREIGN OFFICIAL  
 Dr. Herve Knockaert (Dept. Director), Dr. Lillian Puech

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

SIGNATURE OF REVIEWER

*Dr. Gary D. Bolstad*

DATE

4/18/02

FOREIGN COUNTRY LABORATORY REVIEW (Comment Sheet)		REVIEW DATE 4/18/2002	NAME OF FOREIGN LABORATORY Laboratoire Départemental d'Analyses
FOREIGN GOV'T AGENCY Public Laboratory		CITY & COUNTRY Vannes, France	ADDRESS OF LABORATORY 6, Avenue Edgar Degas
NAME OF REVIEWER Dr. Gary D. Bolstad		NAME OF FOREIGN OFFICIAL Dr. Herve Knockaert (Dept. Director), Dr. Llian Pucch	
RESIDUE	ITEM	COMMENTS	
All	03	Turnaround times met the requirements of the European Commission, and were usually in the range of two months for heavy metals, and between two and four months for the other classes of compounds. If any targeted samples were analyzed, e.g., for injection site lesions, the analyses were completed within 24-72 hours.	
CAP,OC OP,PCB	14	The check sample program met the requirements of the European Commission; the laboratory was accredited by the French Accreditation Committee and (except for the chromatography section) also under ISO-17025. Inter-laboratory check samples for organochlorines, organophosphates, PCBs, and heavy metals were provided annually by the French Agency for Food Safety AFFSA and the Interprofessional Bureau for Analytical Studies (BIPEA). Inter-laboratory check samples for chloramphenicol were expected to be provided in the near future.	
OC,OP, PCB	16	The chromatography section was not yet accredited under ISO-17025 and consequently written corrective action programs for organochlorines, organophosphates, and PCBs, had not yet been developed, but this was expected to be completed by the end of 2002.	

### Foreign Establishment Audit Checklist

1 ESTABLISHMENT NAME AND LOCATION Ets. Aromont.	2 AUDIT DATE 4/24/2002	3 ESTABLISHMENT NO 02-502-01	4 NAME OF COUNTRY France
French officials: Dr. Maryse Flamme, Dr. George Guichon, Ms. Dominique Wersinger	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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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	X
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		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/AQU/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

### Foreign Establishment Audit Checklist

1 ESTABLISHMENT NAME AND LOCATION Ets. Rougie Bizac International, Brive French officials: Dr. Maryse Flamme	2 AUDIT DATE 4/11/2002	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 type="checkbox"/> ON-SITE AUDIT <input checked="" 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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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		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/Laboratories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan		46. Sanitary Operations	
19. Verification and validation of HACCP plan	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		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/AQU/Park Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

United States Department of Agriculture  
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION C.A.T.; Prats-de-Carlux.  French officials: Dr. Maryse Flamme, Dr. Y. Lobjoit, Dr. B. Rouzier	2. AUDIT DATE 4-11-2002	3. ESTABLISHMENT NO. 24-336-04	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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.	X	37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	X	38. Establishment Grounds and Pest Control	X
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	X
14. Developed and implemented a written HACCP plan.	X	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	X
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.	X	47. Employee Hygiene	X
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	X
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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	X
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

## 60. Observation of the Establishment

Est. 24-336-04 - France

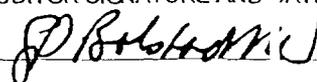
- 10 Cleaning/disinfection of product-contact surfaces (hanging racks for carcasses) did not follow the written plan, which had one statement that all rooms and equipment are to be cleaned and disinfected.
- 12 Documentation of both pre-operational and operational sanitation activities, findings, and corrective actions was inadequate. This documentation did not reflect the sanitary conditions observed during the audit.
- 15 Neither physical nor chemical hazards had been considered when developing the HACCP plan.
- 16 Documentation of the meeting of critical limits was kept, but a formal pre-shipment document review form had not yet been developed; the Auditor explained the requirement in detail; the management officials gave assurances it would be developed before any products are produced for the U.S.
- 19 No verification procedures were included in the written HACCP plan. Calibration of instruments was documented but not observation of persons recording critical limits or verifying their entries.
- 38 Many old cobwebs were present in the employees' changing rooms and in the window area directly above the main hand-wash station for employees at one entrance to the establishment. No corrective actions were taken.
- 39 (A) Bleeding was performed in an area that was open to the outside environment on two sides. (B) The conveyor to the de-feathering area passed through a large opening that was only half covered with swinging doors; the other half was completely open to the outside environment. (C) There were no effective walls between the de-feathering area and the evisceration/post-mortem inspection area.
- 40 European Commission Directives require 540 Lux (49 foot-candles) of light at post-mortem inspection stations. The light available at post-mortem inspection in this establishment was measured during the audit as only 220 Lux (20 foot-candles). No corrective actions were taken.
- 44 (A) At the main entrance to the establishment, the roll of hand towels was stored on an insanitary window shelf with obvious cobwebs, together with a coumarin-containing bait station. No corrective actions were taken. (B) Employees' work clothes were stored in direct contact with a fieldstone wall. Many cobwebs were observed, and general housekeeping was very poor. (C) The hand soap dispenser available to workers entering the evisceration room from the stunning/bleeding area was non-functional.
- 45 Racks for hanging freshly-slaughtered ducks that had apparently passed pre-operational sanitation inspection were observed with obvious residues from previous production. These were reported to be routinely "cleaned and sanitized" at a sister plant, and were only rinsed with (not hot) water at this plant before use. Corrective actions were ordered.
- 46 Several doors to the outside from exposed-product production areas were left open during operations. Corrective actions were ineffective.
- 50 The Veterinarian-In-Charge was reported to have made daily visits to the establishment, but there was no documentation of these routine visits unless he had problems to document.
- 55 Post-mortem inspection was performed by a DGAL employee from a distance of approximately 6 feet from the inspection surfaces.
- 57 The requirement for monthly supervisory reviews had been misunderstood until recently: supervisory visits had been done only once per year. The central French officials were now fully aware of the requirement; however, the veterinary health official who performed the supervisory visits had not been informed of the need for monthly supervisory reviews when U.S.-eligible product is produced. The Auditor carefully explained the requirement.

The DGAL officials determined that this establishment failed to meet basic U.S. requirements (the FSIS Auditor was in complete agreement) and voluntarily removed it from the list of plants eligible to produce products for the U.S., effective as of the start of operations on the day of the audit.

61. NAME OF AUDITOR

Gary D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE



4/11/02

### Foreign Establishment Audit Checklist

1 ESTABLISHMENT NAME AND LOCATION Coop. Perigord Quercy, Sarlat-la-Caneda; French officials: Dr. Maryse Flamme	2 AUDIT DATE 4/11/2002	3 ESTABLISHMENT NO 24-520-05	4 NAME OF COUNTRY France
	5 NAME OF AUDITOR(S) Dr. Gary D. Bolstad		6 TYPE OF AUDIT <input type="checkbox"/> ON-SITE AUDIT <input checked="" 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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of		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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan		46. Sanitary Operations	
19. Verification and validation of HACCP plan	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan		<b>Part F - Inspection Requirements</b>	
22. Records documenting the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Est. 24-520-05 - France

15 Neither physical nor chemical hazards were considered when developing the HACCP plan.

19 No verification procedures were written into the HACCP plan and none were carried out.

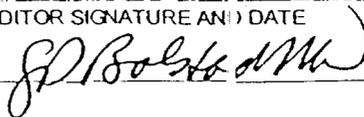
22 A pre-shipment document review procedure and form had not been developed.

Note: The DGAL officials suspended this establishment's eligibility to produce products eligible for U.S. export and issued the equivalent of a Letter of Intended Enforcement requiring prompt development and implementation of the missing elements of the HACCP system before U.S.-eligibility would be reinstated.

61. NAME OF AUDITOR

Gary D. Bolstad DVM

62. AUDITOR SIGNATURE AND DATE



4/11/02

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION  
Ets. Socopa, Chateaucneuf-du-Faou

2. AUDIT DATE  
4/19/2002

3. ESTABLISHMENT NO  
29-027-01

4. NAME OF COUNTRY  
France

French officials: Dr. Henri Peleton-Granier,  
Dr. Pierre Le Seac'h

5. NAME OF AUDITOR(S)  
Dr. Gary D. Bolstad

6. TYPE OF AUDIT  
 ON-SITE AUDIT  DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements		Audit Results	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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>			<b>Part E Other Requirements</b>	
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 Ground and Pest Control	
13. Daily records document item 10, 11 and 12 above			39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>			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 Sewag	
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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>			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.			<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.			49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>			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/AQU/Pork Skins/Moisture)			54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>			55. Post Mortem Inspection	
27. Written Procedures			<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis			56. European Community Directives	
29. Records			57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>			58.	
30. Corrective Actions			59.	
31. Reassessment				
32. Written Assurance				

60. Observation of the Establishment

Est. 29-027-01 - France

- 19 There was documentation of calibration but not of observation of the actual monitoring of the critical limits during production.
- 22 A formal pre-shipment document review form had not yet been developed, but the establishment had not exported any products to the U.S., although the management intended to begin in the foreseeable future. The manager gave assurances it would be developed before any products are produced for the U.S.
- 27 Statistical process control methods had not been developed to evaluate the results of the E. coli testing, as required in establishments using the swab method of sampling: this establishment was using the method developed only for excision samples.

61. NAME OF AUDITOR  
Gary D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE

*(Signature)*

4/19/02

Foreign Establishment Audit Checklist

1 ESTABLISHMENT NAME AND LOCATION Louis Gad, Lampaul Guimiliau French officials: Dr. Maryse Flamme, Dr. Eric David, Dr. Gaille Evain	2 AUDIT DATE 4/22/2002	3 ESTABLISHMENT NO. 29-097-01	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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E Other Requirements</b>	
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 Ground and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	X
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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

## 60. Observation of the Establishment

F-6b

Est. 29-097-01 - France

19 There was documentation of calibration but not of observation of the actual monitoring of the critical limits during production.

39a/56 Clear fluid was leaking from an overhead pipe into cartons with liners that had been prepared in readiness to receive meat for packaging, before the start of operations (the problem was identified by the FSIS Auditor). DGAL officials rejected the cartons and liners and ordered the line not to be used until the problem was resolved. Condensation had been identified as a problem during the previous FSIS audit, but in a different area. *Reference: E.C. Directive 64/433, Annex I, Chapter III, 3*

39b/56 Maintenance and cleaning of over-product structures had been neglected, to varying degrees, in many areas of the establishment: buildups of rust, particularly on rails and rail-changing solenoid switches. Several meat scraps were also observed adhered to over-product structures. The meat scraps were removed immediately, and DGAL ordered prompt implementation of an improved maintenance schedule and increased monitoring during pre-operational sanitation inspections. *Reference: E.C. Directive 64/433, Annex I, Chapter III, 3*

40 The European Commission requires 540 Lux, or 49 foot-candles (fc) of light at inspection stations. The Auditor measured light intensities of 330 Lux (30 fc) at mandibular lymph nodes at the post-mortem inspection station and at the level of forelegs and heads at the inspection station for the retained-carcass rail, and of only 110 Lux (10 fc) in thoracic and abdominal cavities at the retained-carcass rail. The management officials gave assurances additional lighting would be provided promptly.

45 - 56 An independent check of equipment was performed by DGAL after the establishment had concluded pre-operational sanitation inspection. Many pieces of product-contact equipment were observed that had not been adequately cleaned. The DGAL official ordered re-cleaning of all such equipment before operations were allowed to commence. *Reference: E.C. Directive 64/433, Annex I, Chapter III, 3 (c)*

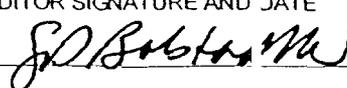
46 - 56 Neck flaps of split swine carcasses were observed to contact workers' boots and standing platforms on the slaughter line. DGAL immediately ordered the establishment to provide a worker to trim those that were too long and would be cross-contaminated and also ordered the neck flaps from the day's previous production to be removed and condemned. Note: cross-contamination had been identified on the slaughter floor during the previous FSIS audit (this had been corrected at that location). *Reference: E.C. Directive 64/433, Annex I, Chapter III, 5*

Note: This establishment had been evaluated as acceptable/re-review during the previous FSIS audit on 5/15/2001. Five of the seven deficiencies identified during the previous FSIS audit had been adequately addressed and corrected. Following the audit, the DGAL officials gave assurances that they would enforce measures (the equivalent of a Notice of Intended Enforcement) to require that the above deficiencies would be corrected in short order, before any product would be eligible for the U.S. market, and would monitor the continued effectiveness of those measures. (This establishment had not exported any products to the U.S. since 1998.)

61. NAME OF AUDITOR

Gary D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE



4/22/02

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Société Bretonne de Salaisons, Landivisiau Cedex. French officials: Dr. Gaelle Evain, Dr. Bernard Cam	2. AUDIT DATE 4/19/2002	3. ESTABLISHMENT NO. 29-097-20	4. NAME OF COUNTRY France
5. NAME OF AUDITOR(S) Dr. Gary D. Bolstad		6. TYPE OF AUDIT <input type="checkbox"/> ON-SITE AUDIT <input checked="" 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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E Other Requirements</b>	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Est. 29-097-20 - France

- 19 There was documentation of calibration but not of observation of the actual monitoring of the critical limits during production.
  
- 22 A formal pre-shipment document review form had not yet been developed, but the establishment had not exported any products to the U.S., although the management intended to begin in the foreseeable future. The manager gave assurances it would be developed before any products are produced for the U.S.

61. NAME OF AUDITOR

Gary D. Bolstad DVM

62. AUDITOR SIGNATURE AND DATE

*[Handwritten Signature]*

4/19/02

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Ets. Henaff, Pouldreuzic	2. AUDIT DATE 4/19/2002	3. ESTABLISHMENT NO. 29-225-01	4. NAME OF COUNTRY France
French official: Dr. Dominique Malo	5. NAME OF AUDITOR(S) Dr. Gary D. Bolstad	6. TYPE OF AUDIT <input type="checkbox"/> ON-SITE AUDIT <input checked="" 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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures	X	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

## 60. Observation of the Establishment

Est. 29-225-01 - France

- 19 There was documentation of calibration but not of observation of the actual monitoring of the critical limits during production.
- 22 A formal pre-shipment document review form had not yet been developed. The establishment had not exported any products to the U.S. yet this calendar year, and the manager gave assurances that it would be developed before any products are again produced for the U.S.
- 27 Statistical process control methods had not been developed to evaluate the results of the E. coli testing, as required in establishments using the swab method of sampling; this establishment was using the method developed only for excision samples.

61. NAME OF AUDITOR

Gary D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE



4/19/02

Foreign Establishment Audit Checklist

1 ESTABLISHMENT NAME AND LOCATION Ets. Comtesse du Barry; Gimont French officials: Emanuelle Soubeyran	2 AUDIT DATE 4/9/2002	3 ESTABLISHMENT NO 32-147-23	4 NAME OF COUNTRY France
	5 NAME OF AUDITOR(S) Dr. Gary D. Bolstad		6 TYPE OF AUDIT <input type="checkbox"/> ON-SITE AUDIT <input checked="" 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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>			<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of			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 Ground and Pest Control	
13. Daily records document item 10, 11 and 12 above.		X	39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>			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			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/Laboratories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>			45. Equipment and Utensils	
18. Monitoring of HACCP plan			46. Sanitary Operations	
19. Verification and validation of HACCP plan		X	47. Employee Hygiene	
20. Corrective action written in HACCP plan			48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan			<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		X	49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>			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/AQU/Park Skins/Moisture)			54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>			55. Post Mortem Inspection	
27. Written Procedures			<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis			56. European Community Directives	
29. Records			57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>			58.	
30. Corrective Actions			59.	
31. Reassessment				
32. Written Assurance				

60. Observation of the Establishment

Est. 32-147-23 - France

- 13 There was daily documentation of pre-operational sanitation activities, but it was quite superficial and did not include preventive measures; also some entries did not contain adequate descriptions of the deficiencies. Documentation of operational sanitation activities was very superficial. DGAL officials ordered correction.
  
- 19 There was documentation of calibration but not of observation of the actual monitoring of the critical limits during production. DGAL officials ordered correction.
  
- 22 Pre-shipment document review had not been implemented. DGAL officials ordered correction.

61. NAME OF AUDITOR

Gary D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE

*G.D. Bolstad, DVM*

4/9/02

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Roger Junca, Dax	2. AUDIT DATE 4-9-2002	3. ESTABLISHMENT NO 40-088-03	NAME OF COUNTRY France
DGAL Officials: Dr. Emanuelle Souberain, Dr. Pierre Parriaud, Dr. Marie Donguy	5. NAME OF AUDITOR(S) Dr. Gary D. Bolstad	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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

00. Observation of the Establishment

F-10b

Est. 40-088-03 - France

39 (A) Ceiling tiles had come loose directly above an exposed-product work table. It was scheduled for prompt repair. (B) A considerable gap some eight inches tall was present between the main carton storage area and a large, adjacent unused area above the ceiling of work rooms below. Establishment management agreed to close the gap.

Note: All deficiencies identified during the previous FSIS audit in May 2001 had been adequately addressed and corrected.

61. NAME OF AUDITOR  
Gary D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE

*G.D. Bolstad, DVM*

4/9/02

**Foreign Establishment Audit Checklist**

1. ESTABLISHMENT NAME AND LOCATION Ets. Castaing, Saint-Sever.	2. AUDIT DATE 4-10-2002	3. ESTABLISHMENT NO. 40-282-02	4. NAME OF COUNTRY France
DGAL Officials: Dr. Emanuelle Souberain, Dr. Pierre Parriaud, Dr. Michel Castets	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	X
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	X
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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.	X	43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Laboratories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	X
<b>Part C - Economic / Wholesomeness</b>		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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

## 60. Observation of the Establishment

F-11b

Est. 40-282-02 - France

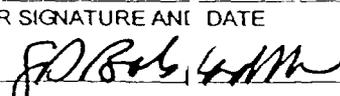
- 13 Corrective actions regarding daily sanitation activities were routinely documented, but preventive measures were not. Management officials agreed to fulfill this requirement.
- 16 A formal pre-shipment document review form had not yet been developed; the Auditor explained the requirement in detail. The manager gave assurances it would be developed before any products are produced for the U.S.
- 19 There was documentation of calibration but not of observation of the actual monitoring of the critical limits during production or the accuracy of the records. The Auditor explained the requirement; the management officials gave assurances they would correct the deficiency.
- 35/56 Several unmarked chemicals were found. They were labeled promptly. *Reference: E.C. Council Directive 64/433, Chapter III, 6*
- 39/56 (A) Maintenance of over-product equipment had been neglected in several areas. Management officials scheduled prompt cleaning and improved maintenance. (B) Several aluminum product trays with broken edges were observed. DGAL officials ordered them to be removed and either repaired or replaced. *Reference: E.C. Council Directive 64/433, Chapter III, 3 (c)*
- 45/56 Cleaned product-contact equipment was stored in metal racks that were not subjected to routine cleaning: rust, old product residues and other material had been allowed to collect on the racks. The DGAL officials ordered all the racks and equipment stored in them to be removed and subjected to thorough cleaning. *Reference: E.C. Council Directive 64/433, Chapter III, 3 (c)*

The Director of the *Département* stated that he would make a return visit to this establishment within a week to verify that corrective actions and preventive measures had been effective regarding the deficiencies identified during this audit.

61. NAME OF AUDITOR

Gary D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE



4/10/02

**Foreign Establishment Audit Checklist**

1. ESTABLISHMENT NAME AND LOCATION Société Nouvelle Larnaudie, Figeac	2. AUDIT DATE 4/12/2002	3. ESTABLISHMENT NO. 46-102-04	4. NAME OF COUNTRY France
French officials: Dr. Maryse Flamme, Dr. Cécile Kermin, Dr. Michele Rames	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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	X
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	X
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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.	X	43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.	X	44. Dressing Rooms/Laboratories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

F-12b

Est. 46-102-04 - France

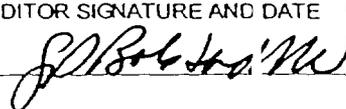
- 13 Records of pre-operational and operational findings did not reflect conditions observed during the audit. There were only about six entries during the course of the year indicating a piece of equipment that needed re-cleaning.
- 16 Documentation of the meeting of critical limits was kept, but a formal pre-shipment document review form had not yet been developed; the Auditor explained the requirement in detail; the management officials gave assurances it would be developed before any products are produced for the U.S.
- 17 The HACCP document had not been signed and dated. This was corrected immediately.
- 19 No verification procedures were included in the written HACCP plan. Calibration of instruments was documented but not observation of persons recording critical limits or verifying their entries.
- 36 Incubation of U.S.-eligible product had been performed for only seven days. The Auditor informed the management officials that U.S.-eligible products must be incubated for ten days.
- 39 Maintenance of overhead structures (ducts, pipes, insulation, ceilings) had been grossly neglected in the dry storage area where empty cans and many other materials were stored. Many old cobwebs were observed. Puddles of leaked liquid was found on several large cartons of empty cans; these were condemned by DGAL.
- 39/45 Maintenance and cleaning of all four canning machines had been neglected. Rust, flaking paint, grease, and old product residues were observed. The DGAL official leading the audit ordered production to be stopped until they had all been cleaned.

NOTE: The eligibility of this establishment to produce products eligible for export to the U.S. had been suspended by DGAL for having stored (non-U.S.-eligible) products in a non-approved cold store. Following this day's audit, the DGAL officials decided to continue the establishment's suspension regarding U.S.-export eligibility until such time as the management could demonstrate that all the above deficiencies had been adequately addressed and fully corrected. The DGAL officials furthermore stated that they would invoke the equivalent of a Notice of Intended Enforcement relating to the deficiencies.

61. NAME OF AUDITOR

Gary D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE



4/12/02

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Capel la Quercynoise, Gramat	2. AUDIT DATE 4/15/2002	3. ESTABLISHMENT NO. 46-128-02	4. NAME OF COUNTRY France
French officials: Dr. Maryse Flamme, Dr. Francoise Garapin	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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	X
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	X
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.	X	47. Employee Hygiene	X
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		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/AQU/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

F-13b

Est. 46-128-02 - France

- 13 Problems noted during operations were documented, but routine operational sanitation activities, findings—and, also for pre-operational sanitation—corrective actions, and preventive measures were not.
- 15 Chemical hazards were not considered when the HACCP plan was developed.
- 19 Verification procedures were not addressed in the written HACCP plan. There was documentation of calibration of thermometers, but no documentation of observation of the actual monitoring of the critical limits during production.
- 22 Corrective actions taken, when critical limits for cooler temperatures were exceeded, were not documented. No routine daily monitoring of the critical limits was included in the written plan or documented. (Several CCPs for cooler temperature were recorded continuously.) A pre-shipment document review had not been developed and conducted.
- 38 (A) Several dozen rodent droppings were found in the carton-storage and -preparation area. The management officials reported that the contracted pest control inspector seldom examined all the bait stations, and that the inspector did examine the bait station in this room but did not look at other areas of the room. The establishment individual responsible for pest control was reported to accompany the contracted inspector, but made no independent checks. (B) Old cobwebs were observed in the male and female locker rooms and in the chemical storage room.
- 39 (A) Maintenance and cleaning of over-product structures had been neglected on the ice machine (rust) in one packaging room and on the control box (buildup of old product residues) for the packaging machine in another room. No corrective actions were taken in the former; the latter was cleaned promptly.
- 40 Light at the post-mortem inspection station was inadequate. The European Commission Directives require 540 Lux (49 foot-candles). The intensity of the available light was measured as 220 Lux (20 foot-candles). No corrective actions were taken.
- 44 In both the male and female locker rooms, white work coveralls were found to have been stored in lockers reserved for street clothes. In one locker, street shoes were found on top of the white work coveralls. The DGAL official ordered the coveralls to be removed for cleaning.
- 45 A pre-operational sanitation check was performed by the Veterinarian-In-Charge after the responsible establishment worker had finished his pre-operational sanitation inspection. Many inadequately-cleaned items of product-contact equipment were observed, including edible-product trays, over-product structures, and the plastic cones on which duck carcasses were placed for cutting. All were ordered to be re-cleaned. Edible product trays that had been re-cleaned still had meat scraps from the previous day's production and were ordered by the Veterinarian-In-Charge to be cleaned yet again.
- 46 (A) Knife sterilizers were not at the required temperature when cutting operations started. European Commission Directives require a water temperature of 82°C (180°F); half the sterilizers were measured at 76.7°C (80°F) and the other half at 60°C (140°F). Also, the temperature of the water in the sterilizers at the sticking/bleeding station was 51.7°C (125°F). The cutting line was allowed to continue for ten minutes before it was stopped, and ducks continued to be hung for more than 15 minutes after the problem in that area was identified. (B) There was inadequate separation of clean product contact equipment from pallets. Also, clean product trays and a cleaned cutting board were stored on the floor. The Veterinarian-In-Charge ordered them to be re-cleaned.
- 47 (A) Edible product workers in the foie gras (duck liver) packaging room were wearing cloth vests that were not routinely cleaned outside their white protective coveralls; the vests were contacting carton liners, packaging trays, and product-contact equipment. The Veterinarian-In-Charge ordered the vests to be worn *under* the protective coveralls. (B) Edible-product workers were observed to handle pallets on the floor and continue to handle edible-product containers without washing their hands.
- 57 Supervisory reviews had been conducted only twice annually. The last supervisory review had been in August 2001.

The Veterinarian-In-Charge determined that the sanitary conditions and lack of effective corrective actions observed during the audit were unacceptable, and the FSIS Auditor was in full agreement with this decision. Consequently, this establishment was removed from the list of establishments certified as eligible to export to the United States as of the start of operations on the day of this audit.

61. NAME OF AUDITOR

Gary D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE

*Gary D. Bolstad, DVM*

4/15/02

**Foreign Establishment Audit Checklist**

1. ESTABLISHMENT NAME AND LOCATION Fruite d'Aquitaine Internat., S.A.; Marmande. French officials: Dr. Maryse Flamme	2. AUDIT DATE 4/11/2002	3. ESTABLISHMENT NO 47-157-03	4. NAME OF COUNTRY France
	5. NAME OF AUDITOR(S) Dr. Gary D. Bolstad		6. TYPE OF AUDIT <input type="checkbox"/> ON-SITE AUDIT <input checked="" 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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>			<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of			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 Ground and Pest Control	
13. Daily records document item 10, 11 and 12 above.		X	39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>			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		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>			45. Equipment and Utensils	
18. Monitoring of HACCP plan			46. Sanitary Operations	
19. Verification and validation of HACCP plan		X	47. Employee Hygiene	
20. Corrective action written in HACCP plan			48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan			<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.			49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>			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/AQU/Pork Skins/Moisture)			54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>			55. Post Mortem Inspection	
27. Written Procedures			<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis			56. European Community Directives	
29. Records			57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>			58.	
30. Corrective Actions			59.	
31. Reassessment				
32. Written Assurance				

60. Observation of the Establishment

Est. 47-157-03 - France

- 13 There was daily documentation of both pre-operational and operational sanitation activities, but it did not include preventive measures. DGAL ordered correction.
- 13 Both microbiological and physical hazards were part of the risk analysis. Chemical risks were also considered but were not part of the risk analysis documentation. DGAL ordered correction.
- 19 There was documentation of calibration, but not of monitoring of the personnel recording the values at CCPs. DGAL ordered correction.

61. NAME OF AUDITOR

Gary D. Bolstad DVM

62. AUDITOR SIGNATURE AND DATE

*G.D. Bolstad DVM*

4/11/02

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Feyel Artzner, Schiltigheim (Strasbourg)	2. AUDIT DATE 4/8/2002	3. ESTABLISHMENT NO. 67-447-05	4. NAME OF COUNTRY France
French officials: Dr. L. Repiquet-Bailleul, Dr. Vincent Spony	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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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/Laundries	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

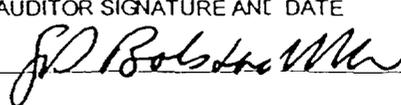
F-15b

Est. 67-447-05 - France

46-56 Heavy condensation was present on a large portion of the ceiling of a freezer containing uncovered frozen smoked duck breasts, many of which had ice visible on the exposed surfaces. The DGAL personnel ordered the top layer to be discarded and microbiological testing done on the rest of the product. The management officials stated that this was an unusual problem that had not been observed before. *Reference: E.C. Council Directive 64/433, Chapter III, 3*

61. NAME OF AUDITOR

62. AUDITOR SIGNATURE AND DATE



4/8/02

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Georges Bruck, Strasbourg.	2. AUDIT DATE 4/5/2002	3. ESTABLISHMENT NO. 67-482-21	4. NAME OF COUNTRY France
French officials: Dr. Emanuelle Souberain, Dr. Vincent Spony	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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	X
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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.	X	43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

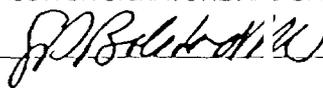
## 60. Observation of the Establishment

Est. 67-482-21 - France

- 13 (A) Problems noted during operations were documented, but routine operational sanitation activities were not. The management representative agreed to initiate the additional documentation. (B) Documentation of corrective actions for both pre-operational and operational sanitation problems did not include preventive measures. The management representative agreed to initiate the additional documentation.
- 16 Documentation of the meeting of critical limits was kept, but a formal pre-shipment document review form had not yet been developed; the Auditor explained the requirement in detail; the management officials gave assurances it would be developed before any products are produced for the U.S.
- 39 (A) Maintenance of overhead structures had been neglected in a few areas of a cooler: flaking paint and discolorations were in evidence. (B) Exposed insulation was observed over an exposed-product working table, though not directly over the area where product was being processed. The management representative agreed to correct these problems promptly. (C) The old wooden floor in the room where cartons and empty cans were stored was grossly deteriorated in one area, in the immediate vicinity of the steam boiler. DGAL ordered removal of cartons and cans from the area, repair of the floor, and construction of a barrier around the old equipment.
- 46 Cleaning chemicals were stored under insanitary conditions. DGAL ordered prompt correction.

61. NAME OF AUDITOR  
Gary D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE



4/5/02

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Rougé Bizac International, Les Herbiers	2. AUDIT DATE 4/17/2002	3. ESTABLISHMENT NO 85-109-01	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	

French officials: Dr. Paul Menecier, Dr. Rabah Bellahsene

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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>			<b>Part E Other Requirements</b>	
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 Ground and Pest Control	
13. Daily records document item 10, 11 and 12 above.			39. Establishment Construction/Maintenance	X
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>			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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>			45. Equipment and Utensils	
18. Monitoring of HACCP plan.			46. Sanitary Operations	
19. Verification and validation of HACCP plan.	X		47. Employee Hygiene	
20. Corrective action written in HACCP plan.			48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.			<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>			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	
<b>Part D - Sampling Generic E. coli Testing</b>			55. Post Mortem Inspection	
27. Written Procedures			<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis			56. European Community Directives	
29. Records			57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>			58.	
30. Corrective Actions			59.	
31. Reassessment				
32. Written Assurance				

## 60. Observation of the Establishment

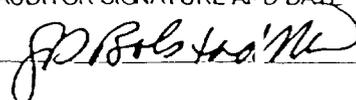
Est. 85-109-01 - France

- 19 There was documentation of calibration but not of observation of the actual monitoring of the critical limits during production.
- 22 Documentation of the meeting of critical limits was kept, but formal re-shipment document review forms had not yet been developed; the Auditor explained the requirement in detail; the management officials gave assurances they would be developed before any U.S.-eligible products leave the establishments.
- 39 (A) There was inadequate ventilation in the old de-feathering area, resulting in severe condensation problems on many of the over-product structures. DGAL had identified the problem and major improvements had been scheduled for the near future. (B) Many of the over-product pipes in the first carcass cooler had a great deal of exposed plumber's sealant fiber; DGAL ordered covering of the problem areas until the problem could be addressed adequately on the weekend.

61. NAME OF AUDITOR

Gary D. Bolstad DVM

62. AUDITOR SIGNATURE AND DATE



4/17/02

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Madrange, Limoges French officials: Dr. Emanuelle Soubeyran, Dr. Christine LeMao	2. AUDIT DATE 4/16/2002	3. ESTABLISHMENT NO 87-085-03	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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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/Laboratories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

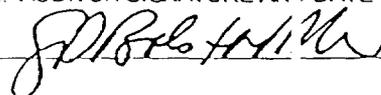
## 60. Observation of the Establishment

Est. 87-085-03 - France

- 13 Problems noted during operations were documented, but routine operational sanitation activities, findings, (and also for pre-operational sanitation) corrective actions, and preventive measures were not.
- 19 Verification procedures were conducted, but they were not documented and were not specifically mentioned in the HACCP plan.
- 22 Documentation of the meeting of critical limits was kept, but formal pre-shipment document review forms had not yet been developed; the Auditor explained the requirement in detail; the management officials gave assurances they would be developed before any U.S.-eligible products leave the establishments.
- 45 - 56 Approximately 10% of the wheeled stainless steel combo bins and half of the large plastic combo bins were cracked and in need of repair or replacement. Replacement bins had been ordered, but several seriously deteriorated containers were in use for exposed edible product. They were rejected by DGAL. *Reference: E.C. Council Directive 64/433, Annex I, Chapter III, 3 (c)*
- 46 - 56 Ham molds that had been cleaned and were ready for use were stored in a large, unclean and deteriorated plastic combo bin. DGAL ordered the molds to be re-cleaned and rejected the bin for use for this purpose. *Reference: E.C. Council Directive 64/433, Annex I, Chapter III, 3 (c)*

61. NAME OF AUDITOR  
Gary D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE



4/16/02

<PICTURE>

Liberty • Equality • Fraternity

.....  
French Republic

Direction générale de l'alimentation (General Directorate of Food)  
.....

<ON THE LEFT>

<LOGO>

Ministère de l'agriculture  
de l'alimentation

de la pêche

et des affaires rurales

(French Department of Agriculture, Food, Fisheries and Rural Affairs)

<ON THE RIGHT>

Sally STRATMOEN

Chief, Equivalence Section

International Policy Staff

Office of Policy, Program

Development and Evaluation

Paris, on June 11, 2002

Mission de Coordination Sanitaire Internationale (International Health Coordination Mission)

Sous-Direction de la Sécurité Sanitaire des Aliments (Under-Directorate of Health Safety of Foods)

Bureau des Accords Multilatéraux Sanitaires et Phytosanitaires (Bureau of Sanitary and Phytosanitary Reciprocal Agreements)

Bureau des Établissements de production et de Transformation (Bureau of Production and Processing Plants)

File Supervised by Catherine ROGY and Emmanuelle SOUBEYRAN

Extension: 8486 / 8109

Reference No.: USA / FSIS02 - 05

**Re:** Follow-up to the Mission of Mr. Bolstad (FSIS) in France

Dear Director,

I have the pleasure of informing you of the various actions undertaken by the Ministère de l'agriculture, de l'alimentation, de la pêche et des affaires rurales (French Department of Agriculture, Food, Fisheries and Rural Affairs), in response to the mission in France of Dr. Bolstad during the last month of April:

- The new list of establishments approved for export to the USA has been sent by way of a May 7, 2002 Information Notice to the directorates of the veterinary services in the départements (appendix 1);
- An information notice concerning the various points brought up by Dr. Bolstad was sent on May 13, 2002 to the directors of the veterinary services in the départements (appendix 2).

Moreover, my administrative services have questioned the Direction générale de la concurrence de la consommation et de la répression de fraudes (DGCCRF, or General Directorate of Competition in Consumption

and of Suppression of Fraud) of the Ministère de l'économie et des finances (French Department of the Economy and of Finances) in order to get a copy of the product composition analysis program, and in particular the identification of the species, according to the wish expressed by Dr. Bostad (the DGCCRF is the relevant department for this type of testing).

251, rue de Vaugirard - 75732 PARIS CEDEX 15 - FRANCE

The administrative services of the DGCCRF in the départements are taking samples during the year, as the need arises, in the following cases:

- When there is doubt after a test of the ingredients was performed in the company,
- When the labeling information such as "produit halal" ("halal product") implies the absence of a certain animal species or when the label information implies the use of meat from a single animal species [ex: steak de cheval (horse meat steak), etc.],
- To check the accuracy of the list of ingredients that is written on the labeling of the finished good.

Those analyses were performed using immunologic methods (Elisa or Ouchterlony) that are used to look for some specific antigens of a given animal species. In 2001, 400 such analyses were performed, with a percentage of detected defects under 10%. You will find attached a summary report of the analyses that were performed, giving in each case the product that was analyzed and the techniques that were used (Appendix 3).

With regard to the defects that were discovered at the level of the facilities that were inspected, the directorates of the veterinary services in the départements have taken a certain number of measures, that are described in detail below.

Establishment	Number	Decision	Follow-ups
CAT	24 336 04	Loss of accreditation	Mail was sent to the professional Mail was sent to the U.S. authorities Removal from the list of USDA approved establishments
CAPEL	46 128 02	Loss of accreditation	Mail was sent to the professional Mail was sent to the U.S. authorities Removal from the list of USDA approved establishments
LARNAUDIE	46 10204	Suspension maintained	Mail was sent to the professional asking for corrective actions to be taken
COOP PERIGORD QUERCY	24 520 05	Temporary suspension of production for the USA	Mail was sent to the professional asking for corrective actions to be taken and information to be given to USDA approved clients
GAD	29 097 01	Temporary suspension of production for the USA	Mail was sent to the professional asking for corrective actions to be taken and information to be given to USDA approved clients
AROMONT	02 502 01	Temporary suspension of production for the USA  Suspension was lifted on 05/07/02	Mail was sent to the professional asking for a partial suspension and for corrective actions to be taken  Visit of veterinary services took place and concluded that the requested corrective actions had been implemented
GEORGE BRÜCK	67 482 21	Acceptable	Mail was sent to the professional asking for corrective actions to be taken
FEYEL ARTZNER	67 447 05	Acceptable	Mail was sent to the professional asking for corrective actions to be taken
JUNCA	40 088 03	Acceptable	Mail was sent to the professional asking for corrective actions to be taken

COMTESSE DU BARRY	32 147 23	Acceptable	Mail was sent to the professional asking for corrective actions to be taken
CASTAING	40 282 02	Acceptable	Mail was sent to the professional asking for corrective actions to be taken  During visits on 04/12/02 and 04/15/02 the DSV concluded that corrective actions had been implemented, in particular in the specific scullery zone
FRUIT D'AQUITAINE	47 157 043	Acceptable	Mail was sent to the professional asking for corrective actions to be taken
RBI	19 031 02	Acceptable	Mail was sent to the professional asking for corrective actions to be taken
CHARCUTERIE DE LA VALOINE	87 085 03	Acceptable	Mail was sent to the professional asking for corrective actions to be taken During a visit on 04/22 '02 the DSV concluded that corrective actions had been implemented, in particular the installation of the missing dry sink
RBI	85 109 01	Acceptable	Mail was sent to the professional asking for corrective actions to be taken
SBS	29 097 20	Acceptable	Mail was sent to the professional asking for corrective actions to be taken
HENAFF	29 225 01	Acceptable	Mail was sent to the professional asking for corrective actions to be taken
SOCOPA	29 027 01	Acceptable	Mail was sent to the professional asking for corrective actions to be taken

Finally, the analytical labs have been reminded that the only techniques or methods that can be used are the reference analytical techniques required by the USDA, or else the methods standardized within the framework of the national observation plans, and approved by the American authorities.

We would be glad to take part in the near future in a conference call in order to discuss the follow-up to this American inspection mission, before or after the final project report has been received, if you'd agree with this and according to your wishes.

I will be sure to send you every piece of additional useful information concerning this file. Sincerely yours,

The Assistant General Director  
C.V.O.  
<SIGNATURE>  
Isabelle CHMITELIN

CC: Commission (Mr. Checchi-Lang)  
Embassy of the United States of America in France

Liberty • Equality • Fraternity

.....  
FRENCH REPUBLIC

<ON THE LEFT>

<LOGO>

MINISTÈRE

DE L'AGRICULTURE

ET DE LA PÊCHE

(French Department of Agriculture and of Fisheries)

-----  
<IN THE MIDDLE>

**Direction Générale**

**de l'Alimentation (General Directorate of Food)**

<ON THE RIGHT>

From the Chief Administrative Officer of the General Directorate of Food

To

The Prefects

*For the Directors of Veterinary Services*

<ON THE LEFT>

**sous-direction de la sécurité sanitaire des Aliments (Under-D irectorate of Health Safety of Foods)**

**Bureau des Établissements de Transformation (Bureau of Processing Plants)**

**Our Reference Number: Ic dsv usa 2002**

**File Supervised by: E. SOUBEYRAN <UNREADABLE> • 0710**

**Extension: 81 - 09**

**Re: Export of fresh meat and of meat-based products to the U.S.A.**

**Date: May 13, 2002**

An American expert, Dr. Bolstad, led in France, from April 3, 2001 to April 29, 2001, an inspection mission of the French establishments approved for export of fresh meat and meat based products to the United States of America. During this mission, 11 French establishments were subjected to an on-site inspection, and 7 establishments were subjected to a documentary audit. Moreover, the laboratory of the département of the Lot (46) (for the microbiological analysis part of the lab), and the laboratory of the département of the Morbihan (56) (for the residue testing part of the lab) were inspected.

In general, the findings of this mission were not very satisfactory.

Two establishments have lost their accreditation. Three establishments have stopped their production, partially or totally, while waiting for the implementation of corrective measures. The

suspension of one of the establishments had been ordered before the visit of the expert, and it was maintained.

However, the trust of the American authorities in the French administrative testing services has been reiterated.

The loss of accreditation has been announced to the American authorities by the DGAL. The reinstatement of the accreditation can only take place after the American authorities have given their opinion of the file sent to them, and after a possible audit by an American expert. Dr. Bolstad has specified that the visit by an American expert for the accreditation of an establishment taken off the list during an audit was possible before next year's audit.

A suspension is a national procedure that does not need to be officially announced to the American authorities. The establishment in which the non compliance was observed has a certain time period during which they can implement the corrective measures. The suspension is lifted as soon as the corrective measures are effective.

I have the pleasure to inform you below of the various points that have been brought up by this expert during the mission.

Lc dsv usa 2002

.....  
*251, rue de Vaugirard 75732 PARIS CEDEX 15 - FRANCE*

*Tel.: Switchboard +011 01 49 55 49 55 or Direct Line +011 01 49 5. + Extension Number - Fax:  
+011 01 49 55 56 80*

## A. Notes concerning the USDA approved establishments

### A.1 Main hygiene problems noted during the audit

The main problems that were noted and led to the loss of accreditation were:

Inadequacy of the premises (1), lack of hygiene of the employees (2) and of the cleaning of the equipment (2), inadequacy of the documentation (2), signs of the presence of pests (1), problems concerning animal welfare (1), insufficient light intensity at the level of the post mortem inspection station (2), lack of responsiveness of the professionals.

The main hygiene problems noted in the 11 audited facilities were as follows:

Inadequate cleaning of the equipment on which the raw material is handled (6 out of 11)  
Lack of hygiene of the employees (washing of hands, reusing a knife after it fell on the ground etc.) (4 out of 11)  
Unsuited pest management: presence of insects and/or of tracks from rats (3 out of 11)  
Inadequate cleanliness of the premises and of the equipment before the start of production (3 out of 11)  
Presence of condensation (2 out of 11)  
Cleanliness of the clothing of the employees  
Inadequacy of the storage conditions of the finished goods and of the packaging and packaging (2 out of 11)

### A.1 SSOP Plan - HACCP Plan

The SSOP and HACCP Plans have been considered lacking for most of the establishments:

#### **SSOP Plan:**

A document labeled « S.S.O.P - Plan for the General Hygiene of the Premises and of the Processes » has to be made available, separately from the H.A.C.C.P. Plan. It has to include all the elements covered by the American regulations, namely at least the maintenance of the premises and of the equipment before and after the operations.

The SSOP Plan of the tested establishment has been considered lacking for 8 out of 18 audited establishments (6 out of 18 in 2001). The following main problems were noted:

1. The lack of a testing procedure with the recording of the results during production
2. The lack of precision in the treatment of the problems that were noted

1. The testing procedures, before and after production, need to be written up. The tests before production **as well as the tests during production have to be recorded.**

The testing during production has to focus, for example, on:

- The cleanliness of the clothing of the employees,
- The presence of soap in the vicinity of the dry sink,
- The use of the dry sink by the employees,
- The temperature of the water of the knife sterilizers, etc...

2. Every problem that is noted during those controls need to be recorded and documented in the following way:

- Description of the non compliance
- Notification of the person in charge of the follow-up of the hygiene plan in the zone in question
- Description of the corrective measures that have been implemented
- Description of the precautionary measures that have been implemented (ex.: call to order of the involved person, resensitization of the employees during the staff meeting of the...)

**HACCCP Plan:** Inadequate for 16 out of 18 of the audited establishments (8 out of 18 in 2001) . The main problems that were noted within the framework of the HACCP Plan are as follows:

1. The physical and chemical dangers were not taken into account (4 out of 18)
2. The lack of a checking procedure of the effective enforcement of the HACCP Plan
3. The lack of Preshipment Review: a document written up by the professional, attesting that the CCP critical limits have been respected.
4. Confusion between the CCP and the CP, leading to the determination of a number of CCP that is too high and doesn't satisfy the exact definition of the CCP.
5. Results were not properly recorded

1. If chemical and physical dangers are not taken into account in the HACCP Plan, this violation will be considered severe enough by the American authorities, and USDA accreditation will not be given, or will be taken away.

2. The periodic checking of the proper enforcement of the HACCP plan consists of:

- The implementation of a testing procedure, by someone from the company, for the persons that are in charge of observing the CCP. The testing of the person in charge of recording the CCP allows one to ensure that the observation of the CCP is done according to the terms, and with the frequencies, that are defined in the HACCP Plan, and that the recorded data is exact and precise. The frequency of this testing is left up to the professional, according to his analysis of the dangers. **It has to be recorded.**

- The implementation of a calibration plan for the equipment

3. Before the departure of a lot that is intended either directly for the United States, or else for an establishment that processes raw material, the manager of the establishment has to certify that the CCP critical limits have been respected. In all of the audited establishments, this testing was actually carried out but no formal attestation had been written up. You will find in the appendix a sample for this attestation.

4. Like each year, this expert has noted that many companies suffered from a confusion between C.C.P. and C.P., leading to a number of C.C.P. that was too high.

A CCP has to be:

- Measurable,
- Its observation has to enable the immediate implementation of corrective measures,
- The implementation of preventive measures has to be possible in the establishment.

Organoleptic criterions, that are non measurable, or the results of microbiological analyses that do not allow the immediate implementation of corrective measures, do not constitute CCP. Similarly, the testing of the receipt temperature for which no preventive measure can be implemented in the establishment itself is not a CCP, even if it's something that needs to be tested.

A manufacturing diagram has to be made available in the H.A.C.C.P. document itself. The C.C.P. need to be clearly individually distinguished with all their parameters. For this reason, I remind you that for each defined C.C.P., the frequency of testing, target values, corrective measures or a cross-reference to the non compliance management procedure, and the reference of the recording document have to be established.

5. The modification of a recorded value cannot be done by simply altering the old value. The wrong value has to be crossed out in a way that it can stay visible, and the new value should be put on the next line. The person that did the modification has to initial the modification.

For your information and that of the professionals involved, I remind you that various Internet sites contain information on the American regulations, or examples of H.A.C.C.P. Plans. Included among these are the following Web sites:

- <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html> (allows one to read Title 9 containing the American regulations on fresh meat and on meat based products, and especially the concepts of H.A.C.C.P. (Part 417) and of S.S.O.P. (Part 416);
- <http://www.fsis.usda.gov/oa/haccp/imphaccp.htm> (Web site of the F.S.I.S., where you'll find the developments on H.A.C.C.P.)

## **A.2: Other Notes:**

### **Rat extermination - disinsectisation:**

A testing procedure of the service provider company that does pest management has to be implemented. It is necessary that someone from the company regularly accompanies the outside professionals during their visits.

### **Identification of the cleaning and disinfecting products:**

Every container full of cleaning or disinfecting products has to be correctly identified.

### **Storage of the raw material and of the finished goods:**

The storage of the raw material and of the finished goods of USDA approved establishments cannot be done in a non USDA approved warehouse. You will be careful that the storage indeed takes place in a USA approved slaughtering, cutting or processing facility, or in a USDA approved establishment.

**B. Notes regarding the inspection services:**

**1. HACCP method training:**

The American expert has noted that not all the inspectors and supervisors had been HACCP method trained. You will make sure that all the inspectors of your administrative services that are assigned to the follow-up of the companies processing, storing or marketing the animal or animal origin goods have followed a HACCP method training course.

**2. Inspection of the USDA approved facilities:**

***Inspection visits on the day of production for the USA***

An inspector has to visit the facility on the day of production for the United States.

***Supervision visits***

The frequency of the supervision visits that need to be made by the supervising veterinarian of the inspector in charge of the facility has to be adapted to the production of the establishments for the USA:

- If the establishment doesn't produce for the USA, this visit can be done annually as long as the visit is complete and includes, in particular, the visit of the establishment as well as the documentary testing of the HACCP and SSOP Plans.

- When the establishment produces for the USA, a supervision visit has to take place, if possible, each month of production. This visit doesn't then need to be necessarily complete, but all the testing points need to be reviewed during the year,

In order to fulfill this condition, you will ask the professionals to inform you sufficiently in advance of their production program for the USA.

To conclude, I remind you of the importance I attach to the American appraisal missions and to their impact on the general credibility of the administrative services at an international level.

Consequently, please remind the professionals of their obligations from the point of view of USDA accreditation, and to ensure their strict enforcement in USDA approved establishments.

**Finally, I remind you that there is good cause to suspend or cancel the exportation accreditation to the USA for any facility that doesn't respect the American regulations, and this is the case even before the definition of the inspection program of the new mission, that should take place next year.**

For the Assistant Director  
of the Sécurité Sanitaire des Aliments (Health Safety of Foods)

The Assistant

<SIGNATURE>

Olivier FAUGERE [Translator's Note: Not sure]

## PRESHIPMENT REVIEW \*

I, undersigned, "name" "job", after having examined the documents of record concerning the production of the lot "number of lot" "designation of product", attest that the CCP critical limits have been respected and that, if need be, corrective actions have been taken. In particular, the implementation of those corrective actions can lead to a decision-making process that is specific to the marketing of this lot.

*\* This attestation must be signed by a manager of the company (quality control manager, director, etc...) that hasn't produced the records himself. It needs to be drawn up for each separate lot produced for the USA, that is being sent either directly to the USA or to a UDSA approved cutting or processing facility.*